



US006770078B2

(12) **United States Patent**
Bonutti

(10) **Patent No.:** **US 6,770,078 B2**
(45) **Date of Patent:** **Aug. 3, 2004**

(54) **MOVABLE KNEE IMPLANT AND METHODS THEREFOR**

- (76) Inventor: **Peter M. Bonutti**, 15167 N. Cardinal Dr., Effingham, IL (US) 62401
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 159 days.

(21) Appl. No.: **09/976,396**

(22) Filed: **Oct. 11, 2001**

(65) **Prior Publication Data**

US 2002/0052606 A1 May 2, 2002

Related U.S. Application Data

- (63) Continuation-in-part of application No. 09/941,185, filed on Aug. 28, 2001, and a continuation-in-part of application No. 09/566,070, filed on May 5, 2000, now Pat. No. 6,575,982, and a continuation-in-part of application No. 09/737,380, filed on Dec. 15, 2000, now Pat. No. 6,503,267, and a continuation-in-part of application No. 09/815,405, filed on Mar. 22, 2001, now abandoned, and a continuation-in-part of application No. 09/569,020, filed on May 11, 2000, now Pat. No. 6,423,063, and a continuation-in-part of application No. 09/483,676, filed on Jan. 14, 2000, now Pat. No. 6,468,289, and a continuation-in-part of application No. 09/602,743, filed on Jun. 23, 2000, now Pat. No. 6,361,565, and a continuation-in-part of application No. 09/526,949, filed on Mar. 16, 2000, now Pat. No. 6,620,181, and a continuation-in-part of application No. 09/789,621, filed on Feb. 21, 2001, now Pat. No. 6,635,073.

- (51) **Int. Cl.⁷** **A61B 17/56**
- (52) **U.S. Cl.** **606/88; 623/20.14; 623/20.29**
- (58) **Field of Search** **623/14.12, 20.14, 623/20.17, 20.28, 20.29, 20.3, 20.33; 606/88, 53; 128/898**

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,229,006 A 1/1966 Nohl
3,624,747 A 11/1971 McKnight
3,807,393 A 4/1974 McDonald

(List continued on next page.)

OTHER PUBLICATIONS

John T. Andronico, MD, Peter M. Bonutti, MD, et al. *The Series 7000 Total Knee System Surgical Protocol*. Pasport Anterior Referencing Instrumentation Osteonics, pp. 1-45, Publication date unknown.

Aaron A. Hofmann, MD and Kenneth A. Gustke, MD. *Sulzer Orthopedics Natural-Knee II System Surgical Technique*. SulzerMedica, pp.1-47, Copyright 1998.

Professor Pier Giorgio Marchetti, Professor D. Jorge Ball-ester Soleda, Dr. Roberto Binazzi. *Restoration™ T3 Femoral Component Using the Command® Instrument System* Revision Surgical Technique Stryker Howmedica Osteonics, pp. 1-16, Publication date unknown.

Robert H. Bell, M.D., Peter M. Bonutti, M.D. et al. *Solar Total Shoulder System*, Surgical Protocol Stryker Osteonics, pp. 1-24.

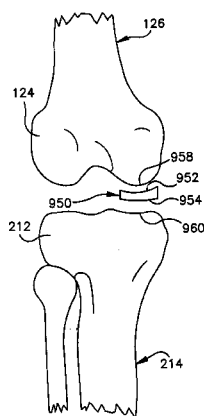
Primary Examiner—David O. Reip

(74) *Attorney, Agent, or Firm*—Fleit Kain Gibbons Gutman Bongini & Bianco; Paul D. Bianco; Martin Fleit

(57) **ABSTRACT**

An improved method of performing surgery on a joint in a patient's body, such as a knee, includes making an incision in a knee portion of one leg while a lower portion of the one leg is extending downward from an upper portion of the one leg and while a foot connected with the lower portion of the one leg is below a support surface on which the patient is disposed. The incision is relatively short, for example, between seven and thirteen centimeters. A patella may be offset from its normal position with an inner side of the patella facing inward during cutting of a bone with a cutting tool. During cutting of the bone, one or more guide members having opposite ends which are spaced apart by a distance less than the width of an implant may be utilized to guide movement of a cutting tool.

19 Claims, 25 Drawing Sheets



U.S. PATENT DOCUMENTS

3,811,449	A	5/1974	Gravlee	5,368,599	A	11/1994	Hirsch
3,903,549	A	9/1975	Deyerle	5,379,133	A	1/1995	Kirk
3,911,923	A	10/1975	Yoon	5,395,401	A	3/1995	Bahler
3,920,022	A	11/1975	Pastor	D358,647	S	5/1995	Cohen et al.
3,967,625	A	7/1976	Yoon	5,425,745	A	6/1995	Green
3,989,049	A	11/1976	Yoon	5,445,639	A	8/1995	Kuslich
3,991,426	A	11/1976	Flom	5,454,365	A	10/1995	Bonutti
3,994,287	A	11/1976	Turp	5,454,815	A	10/1995	Geisser
4,053,953	A	10/1977	Flom	5,456,268	A	10/1995	Bonutti
4,085,466	A *	4/1978	Goodfellow et al.	5,456,720	A	10/1995	Schultz
4,085,743	A	4/1978	Yoon	5,472,415	A	12/1995	King
4,103,680	A	8/1978	Yoon	5,484,095	A	1/1996	Green
4,224,696	A	9/1980	Murray et al.	5,497,933	A	3/1996	DeFonzo
4,298,992	A	11/1981	Burstein et al.	5,514,139	A	5/1996	Goldstein
4,299,224	A	11/1981	Noiles	5,514,153	A	5/1996	Bonutti
4,311,145	A	1/1982	Esty	5,522,897	A	6/1996	King
4,344,193	A *	8/1982	Kenny	5,540,695	A	7/1996	Levy
4,373,709	A	2/1983	Whitt	5,549,683	A	8/1996	Bonutti
4,374,523	A	2/1983	Yoon	5,554,169	A	9/1996	Green et al.
4,385,404	A	5/1983	Sully	5,569,163	A	10/1996	Francis
4,509,518	A	4/1985	McGarry	5,570,700	A	11/1996	Vogeler
4,545,375	A	10/1985	Cline	5,593,448	A	1/1997	Dong
4,619,391	A	10/1986	Sharkany	5,597,379	A	1/1997	Haines
4,624,254	A	11/1986	McGarry	5,609,603	A	3/1997	Linden
4,641,648	A	2/1987	Shapiro	5,609,644	A	3/1997	Ashby et al.
4,662,372	A	5/1987	Sharkany	5,624,463	A	4/1997	Stone
4,682,598	A	7/1987	Beraha	5,632,745	A	5/1997	Schwartz
4,685,460	A	8/1987	Thornton	5,643,272	A	7/1997	Haines
4,817,602	A	4/1989	Beraha	5,649,946	A	7/1997	Bramlet
4,936,852	A	6/1990	Kent	5,662,710	A	9/1997	Bonutti
4,961,954	A	10/1990	Goldberg	5,667,069	A	9/1997	Williams
4,964,865	A	10/1990	Burkhead	5,667,520	A	9/1997	Bonutti
4,985,038	A	1/1991	Lyell	5,702,447	A	12/1997	Walch
5,032,132	A	7/1991	Matsen	5,702,475	A	12/1997	Zahedi
5,060,678	A	10/1991	Bauman	5,707,350	A	1/1998	Krause
5,098,437	A	3/1992	Kashuba	5,712,543	A	1/1998	Sjostrom
5,100,689	A	3/1992	Goldberg	5,718,708	A	2/1998	Webb
5,108,441	A	4/1992	McDowell	5,723,331	A	3/1998	Tubo
5,111,987	A	5/1992	Moeinzadeh	5,755,731	A	5/1998	Grinberg
5,123,906	A	6/1992	Kelman	5,755,791	A	5/1998	Whitson
5,152,744	A	10/1992	Krause	5,755,803	A	5/1998	Haines
5,152,778	A	10/1992	Bales	5,769,899	A	6/1998	Schwartz
5,163,949	A	11/1992	Bonutti	5,810,827	A	9/1998	Haines
5,170,800	A	12/1992	Smith	5,817,109	A	10/1998	McGarry
5,171,243	A	12/1992	Kashuba	5,846,931	A	12/1998	Hattersley
5,174,300	A	12/1992	Bales	5,866,415	A	2/1999	Villeneuve
5,176,702	A	1/1993	Bales	5,871,493	A	2/1999	Sjostrom
5,178,622	A	1/1993	Lehner	5,879,354	A	3/1999	Haines
5,183,053	A	2/1993	Yeh	5,888,219	A	3/1999	Bonutti
5,183,464	A	2/1993	Dubrul et al.	5,899,914	A	5/1999	Zirps
5,186,178	A	2/1993	Yeh	5,913,874	A	6/1999	Berns et al.
5,197,968	A	3/1993	Clement	5,916,269	A	6/1999	Serbousek et al.
5,197,971	A	3/1993	Bonutti	5,921,990	A	7/1999	Webb
5,197,987	A	3/1993	Koch	5,961,499	A	10/1999	Bonutti
5,207,692	A	5/1993	Kraus	5,997,566	A	12/1999	Tobin
5,217,463	A	6/1993	Mikhail	6,012,456	A	1/2000	Schuerch
5,226,915	A *	7/1993	Bertin	6,013,103	A	1/2000	Kaufman et al.
5,228,459	A	7/1993	Caspari	6,015,419	A	1/2000	Strome
5,258,004	A	11/1993	Bales	6,022,350	A	2/2000	Ganem
5,269,785	A	12/1993	Bonutti	6,056,754	A	5/2000	Haines
5,273,524	A	12/1993	Fox	6,059,817	A	5/2000	Bonutti
5,275,166	A	1/1994	Vaitekunas	6,077,287	A	6/2000	Taylor
5,282,866	A	2/1994	Cohen et al.	6,086,593	A	7/2000	Bonutti
5,285,773	A	2/1994	Bonutti	6,090,122	A	7/2000	Sjostrom
5,293,878	A	3/1994	Bales	6,099,531	A	8/2000	Bonutti
5,295,994	A	3/1994	Bonutti	6,099,532	A	8/2000	Florea
5,320,611	A	6/1994	Bonutti et al.	6,171,340	B1	1/2001	McDowell
5,322,505	A	6/1994	Krause	6,174,314	B1	1/2001	Waddell
5,348,541	A	9/1994	Lyell	6,174,321	B1	1/2001	Webb
5,358,530	A	10/1994	Hodorek	6,187,023	B1	2/2001	Bonutti
				6,195,168	B1	2/2001	De Lega

US 6,770,078 B2

Page 3

6,197,064 B1	3/2001	Haines et al.	6,338,737 B1	1/2002	Toledano
6,206,927 B1	3/2001	Fell et al.	6,358,266 B1	3/2002	Bonutti
6,214,051 B1	4/2001	Badorf	6,391,040 B1	5/2002	Christoudias
6,228,121 B1	5/2001	Khalili	6,406,495 B1	6/2002	Schoch
6,258,127 B1	7/2001	Schmotzer	6,409,722 B1	6/2002	Hoey
6,277,136 B1	8/2001	Bonutti	6,431,743 B1	8/2002	Mizutani
6,280,476 B1	8/2001	Metzger et al.	D462,767 S	9/2002	Meyer
6,290,703 B1	9/2001	Ganem	2001/0034554 A1	10/2001	Pappas
6,299,645 B1	10/2001	Ogden	2001/0037155 A1	11/2001	Merchant
6,306,172 B1	10/2001	O'Neil et al.	2002/0029038 A1	3/2002	Haines
6,325,806 B1	12/2001	Fox			
6,328,572 B1	12/2001	Higashida			
6,338,730 B1	1/2002	Bonutti et al.			

* cited by examiner

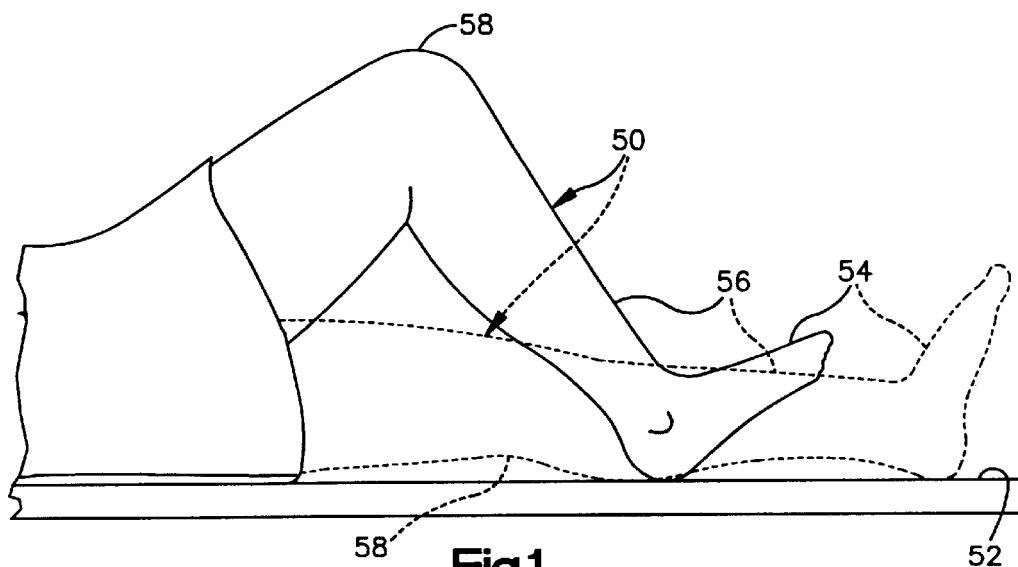


Fig.1
(PRIOR ART)

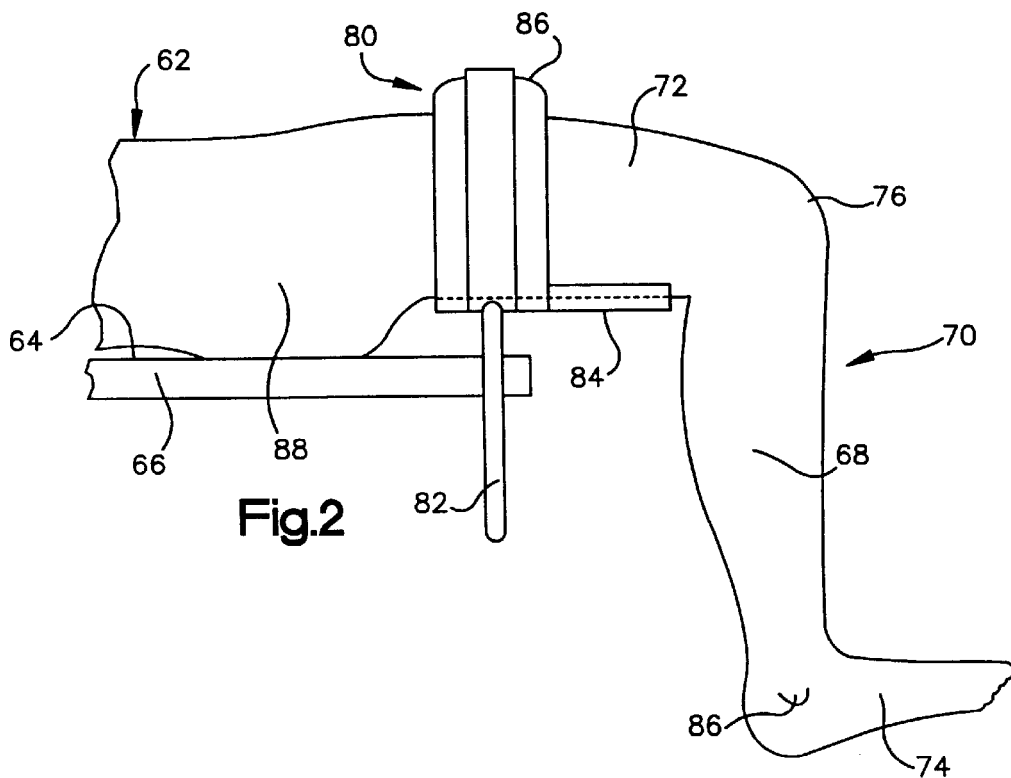
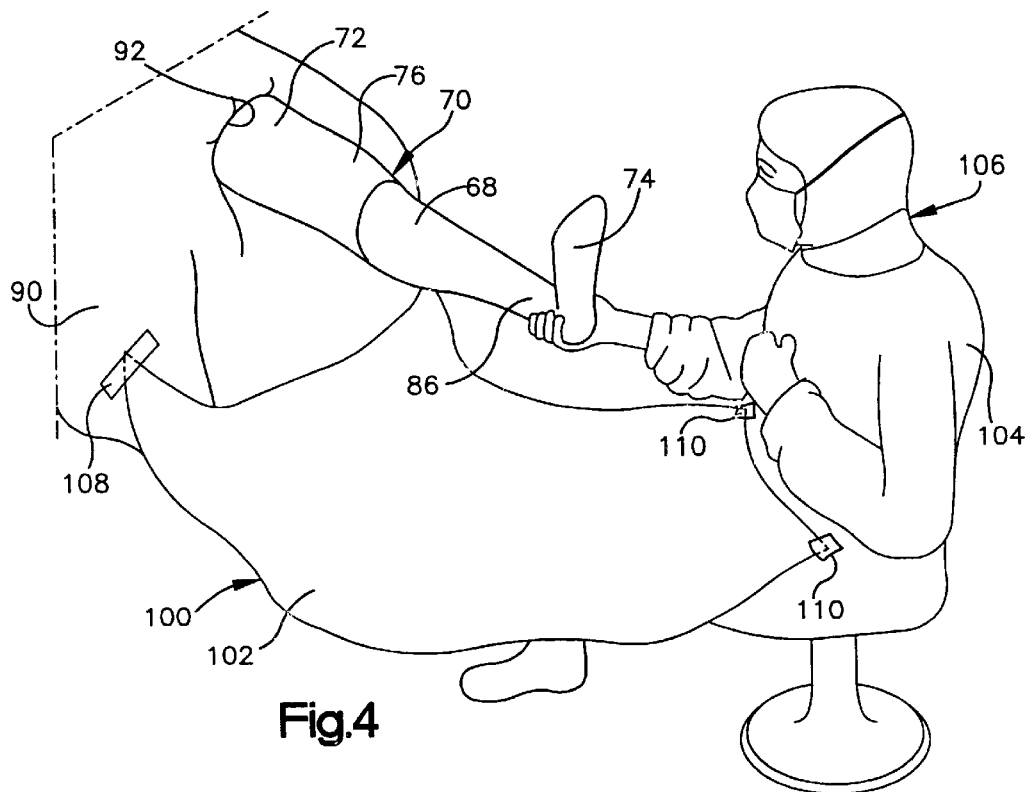
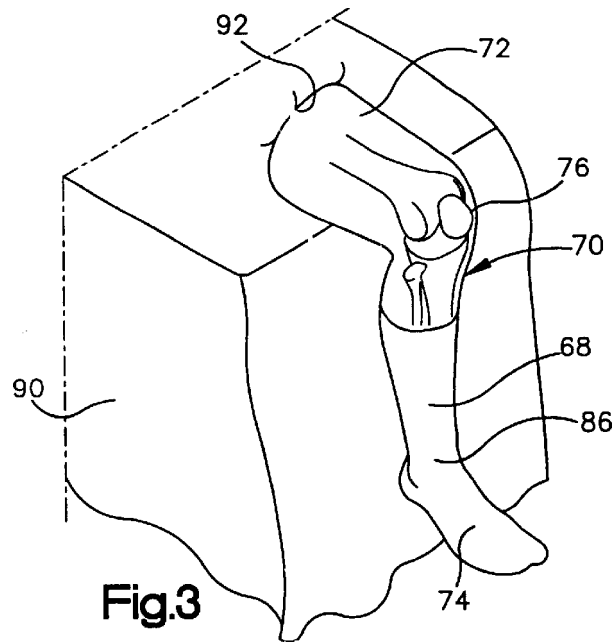


Fig.2



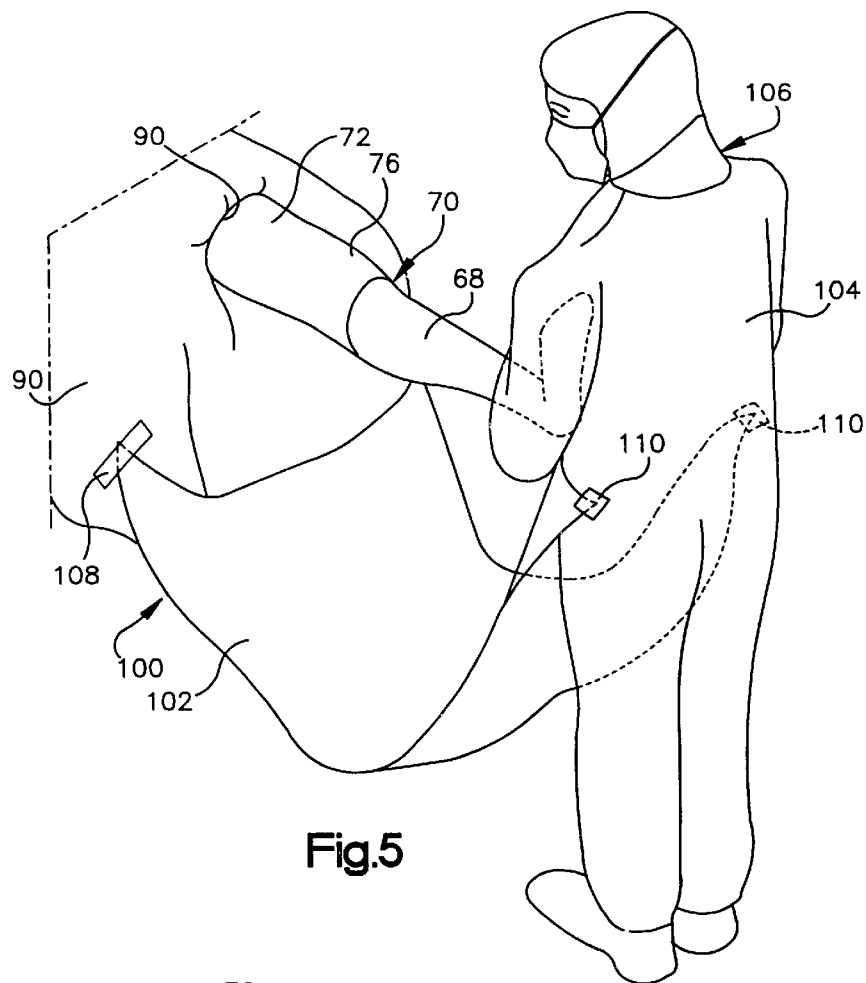


Fig.5

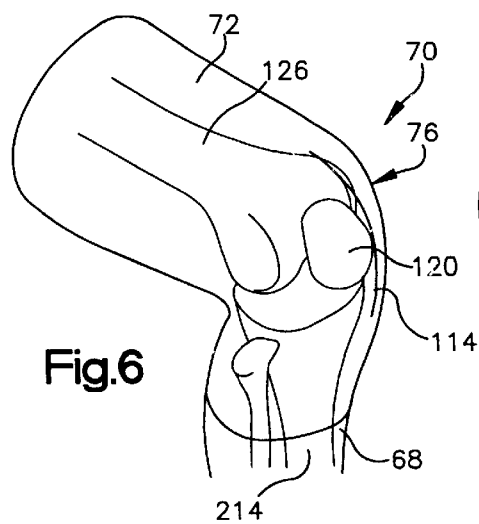


Fig.6

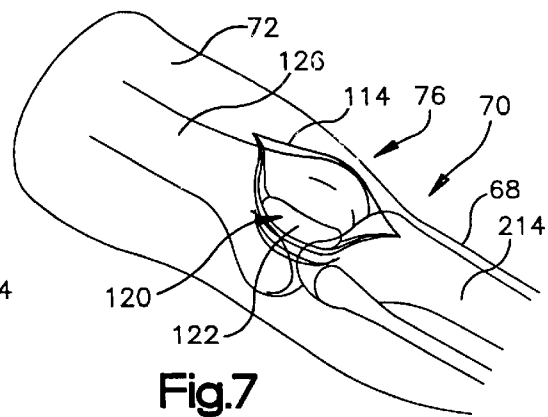
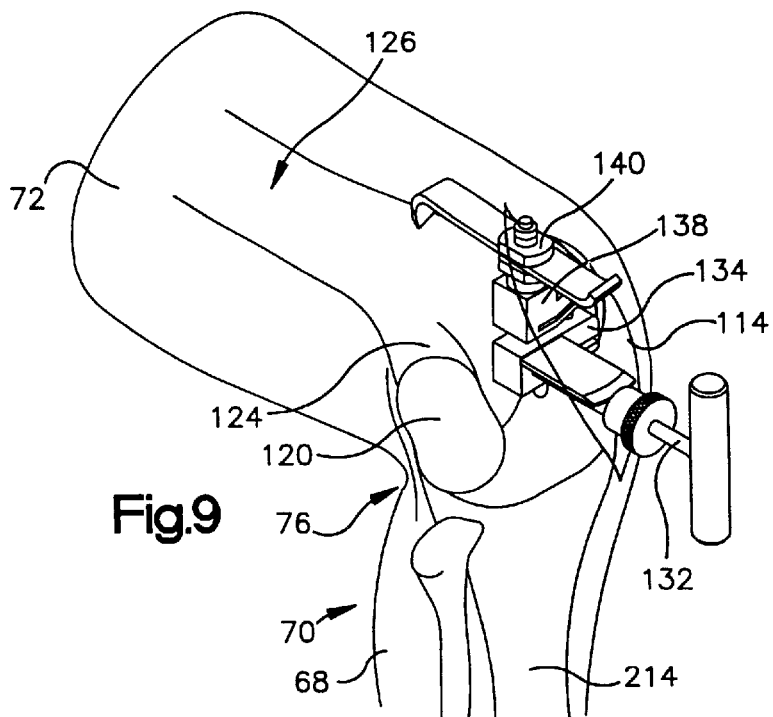
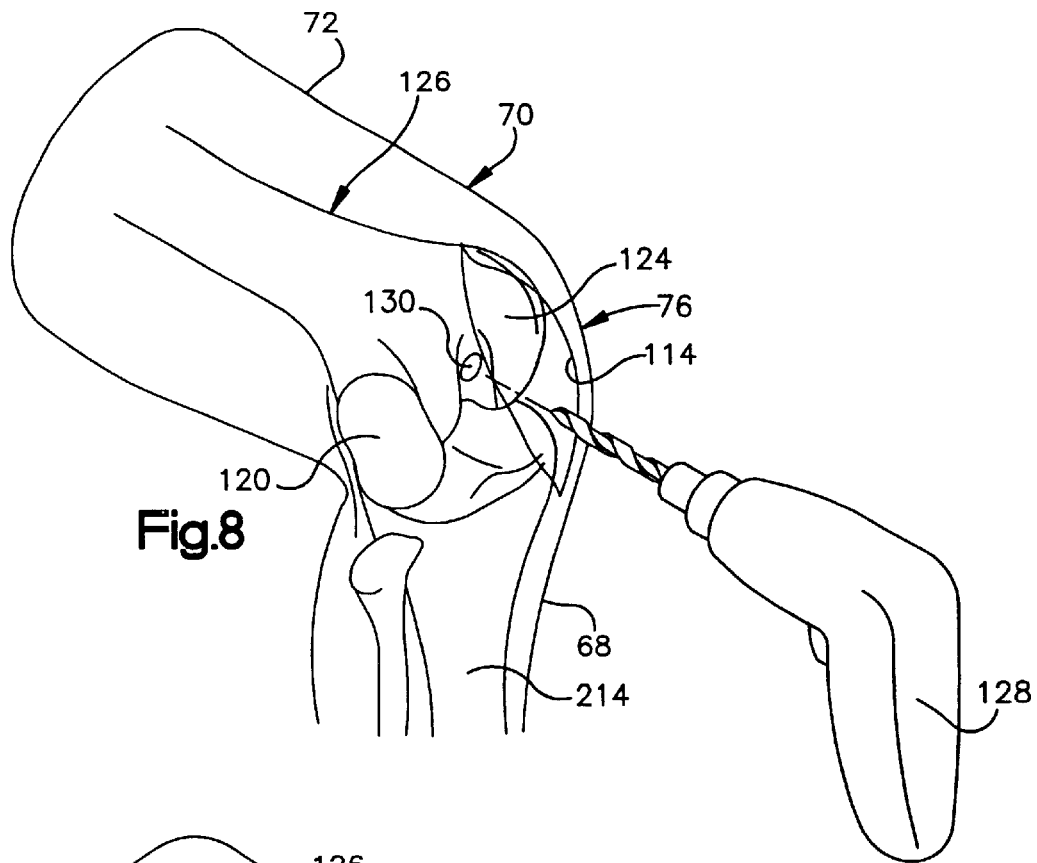
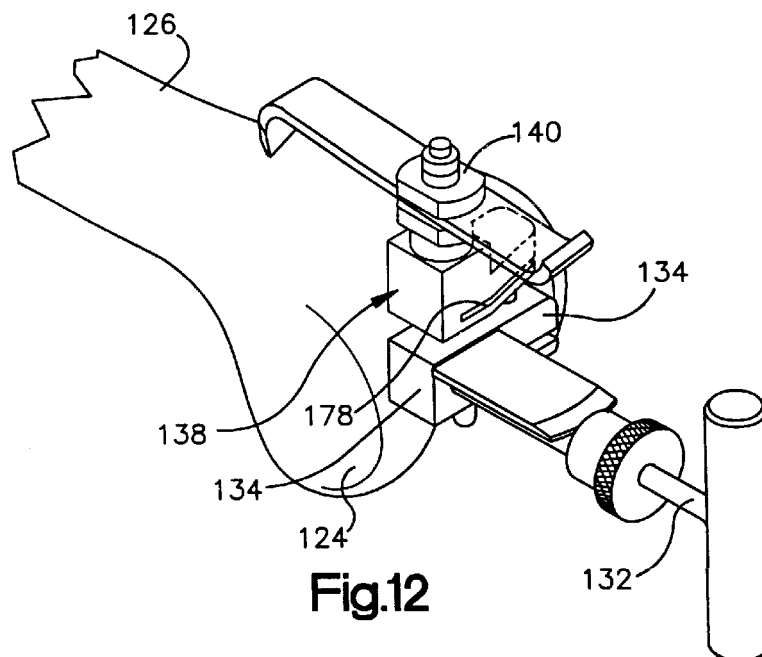
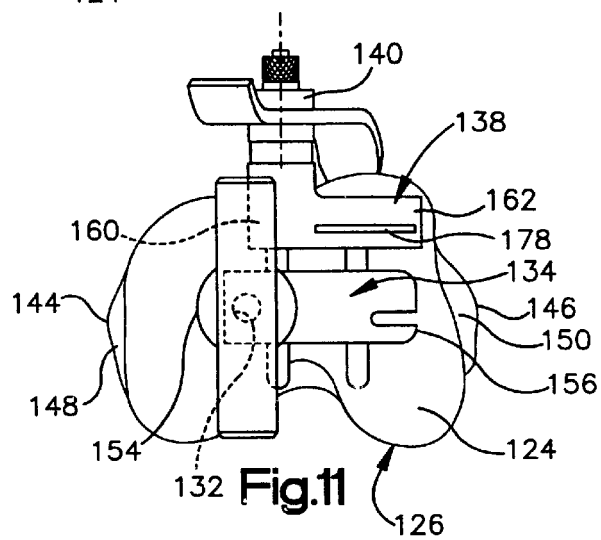
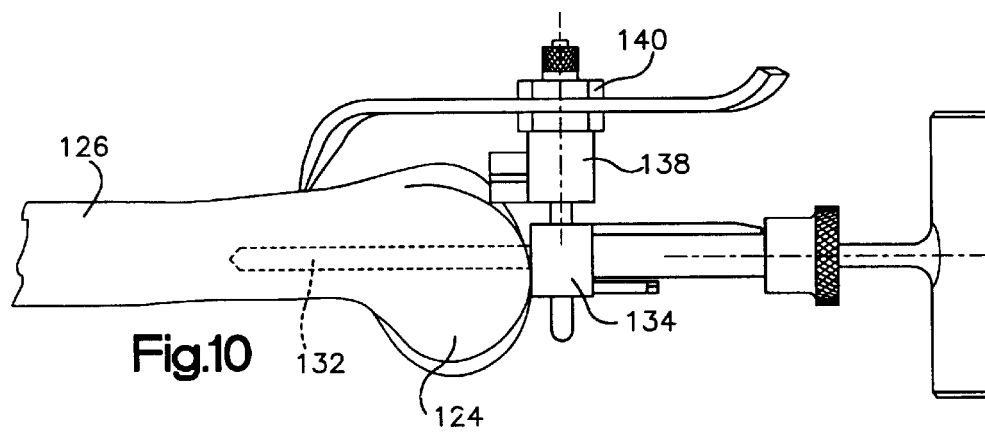
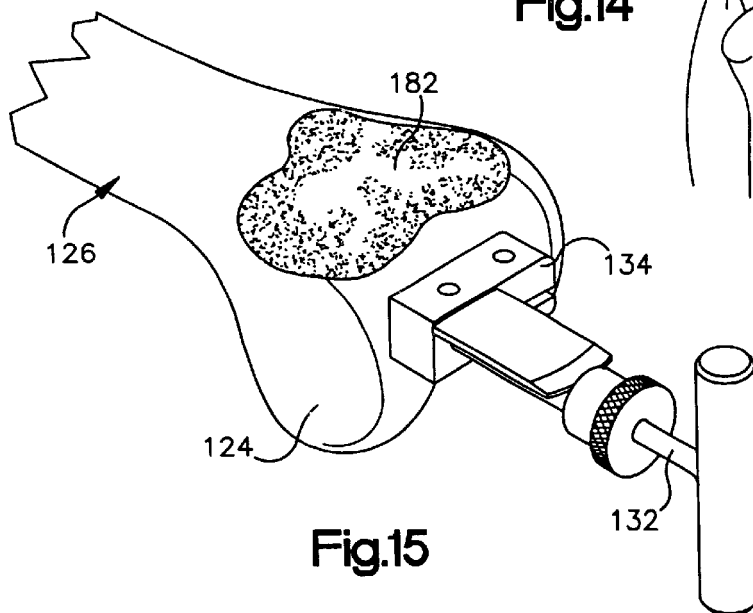
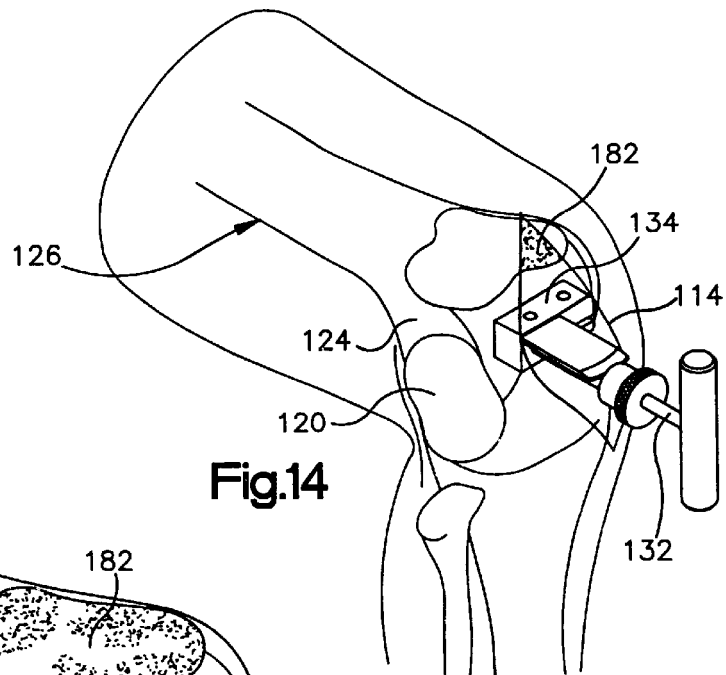
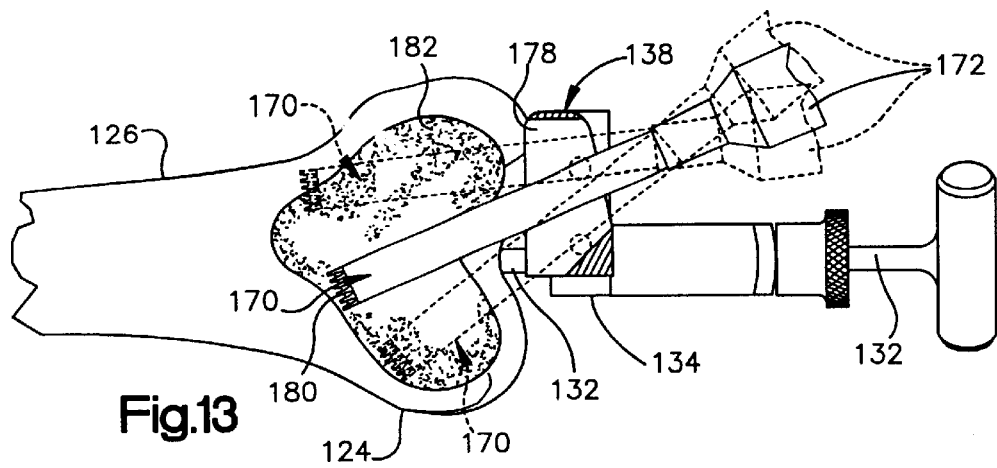
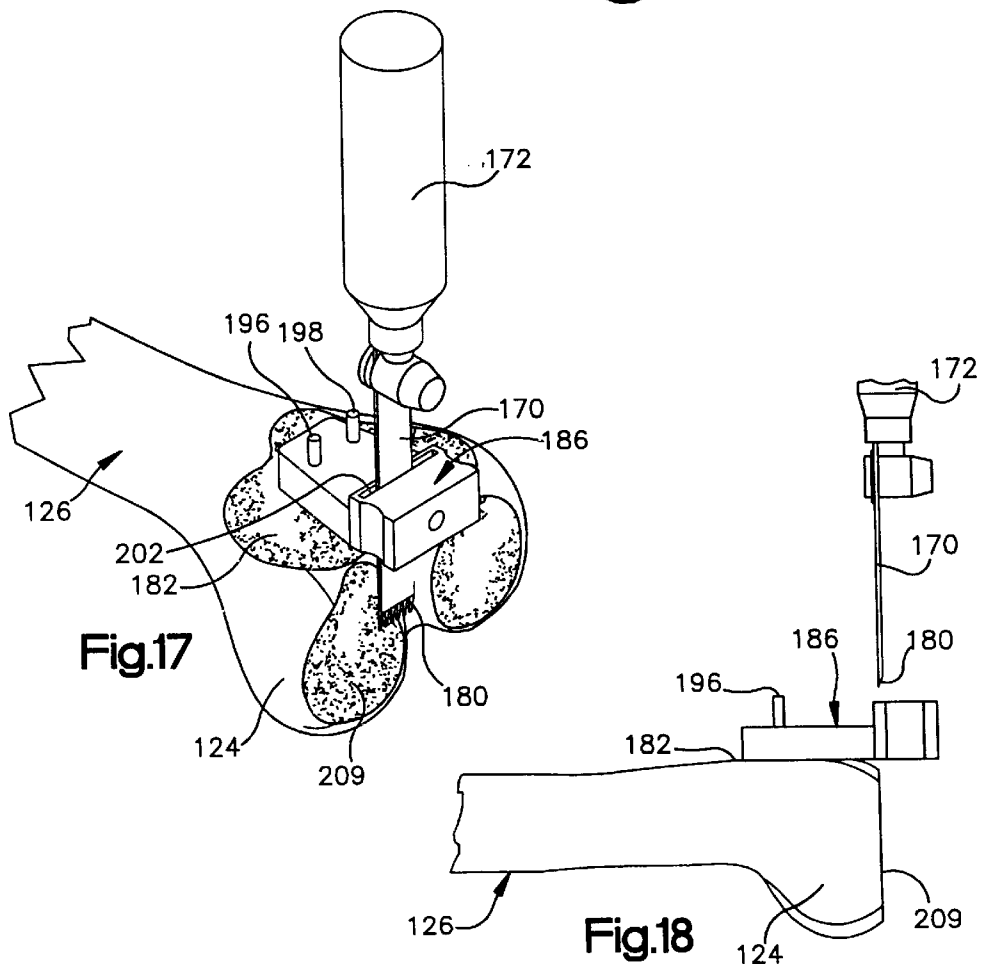
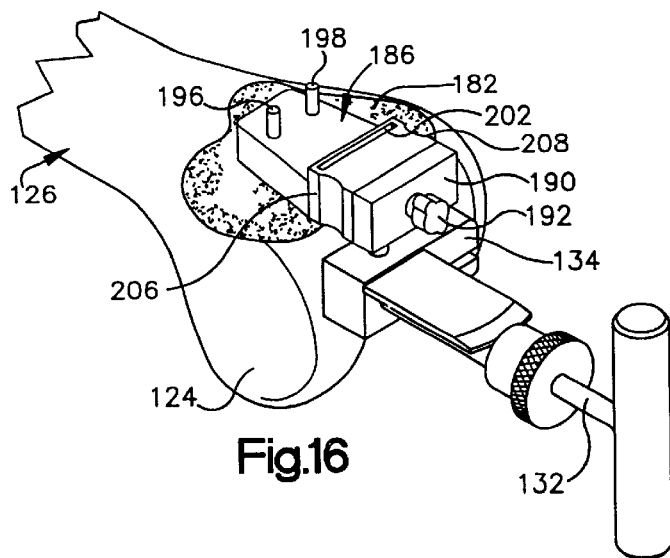


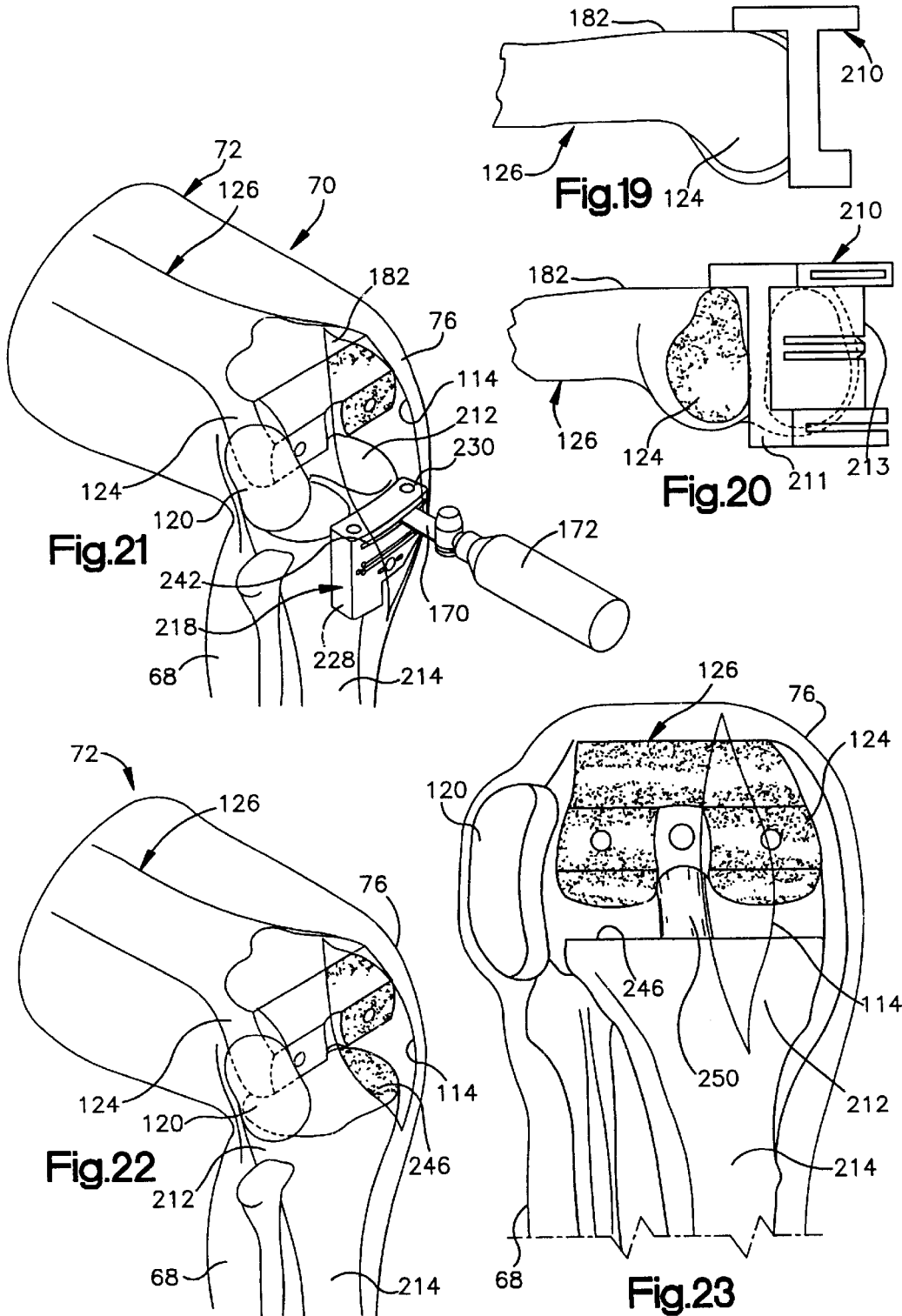
Fig.7

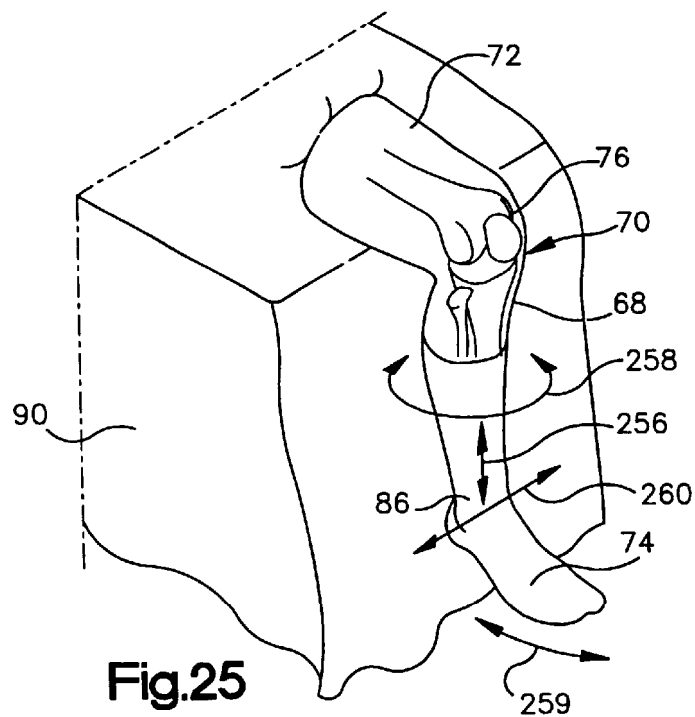
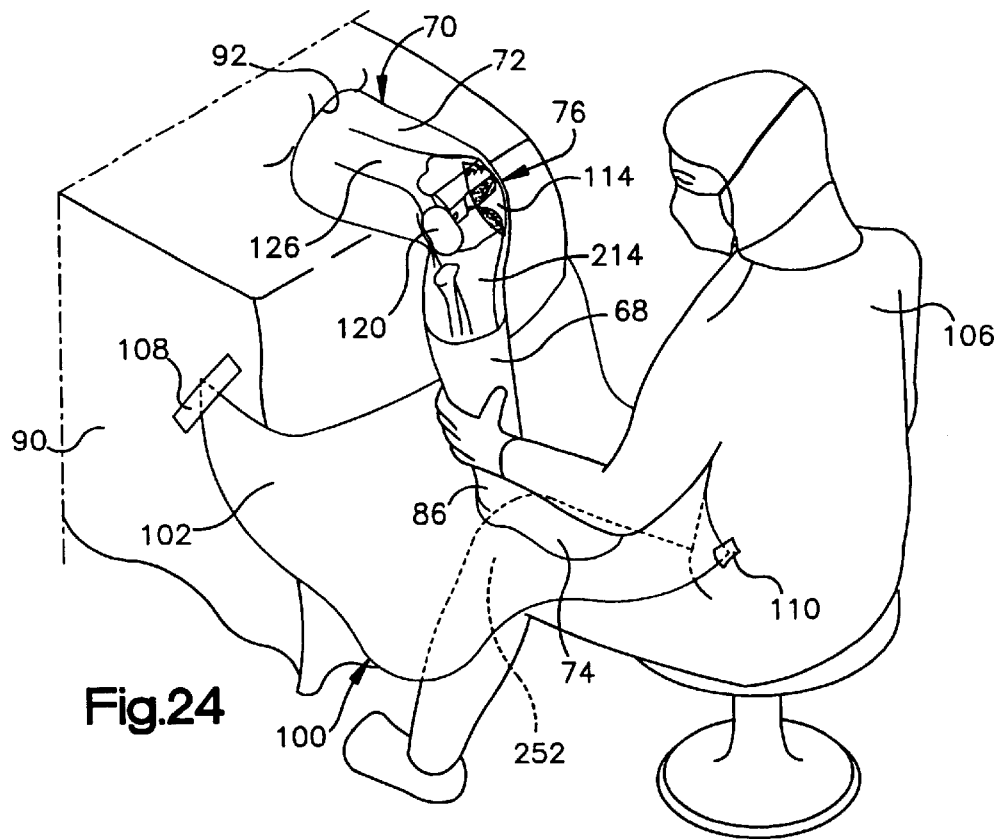


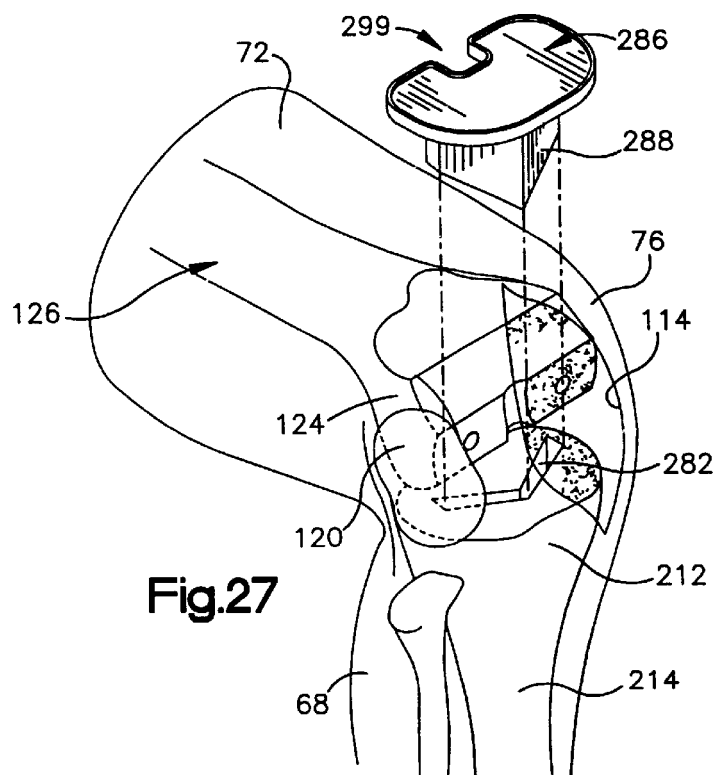
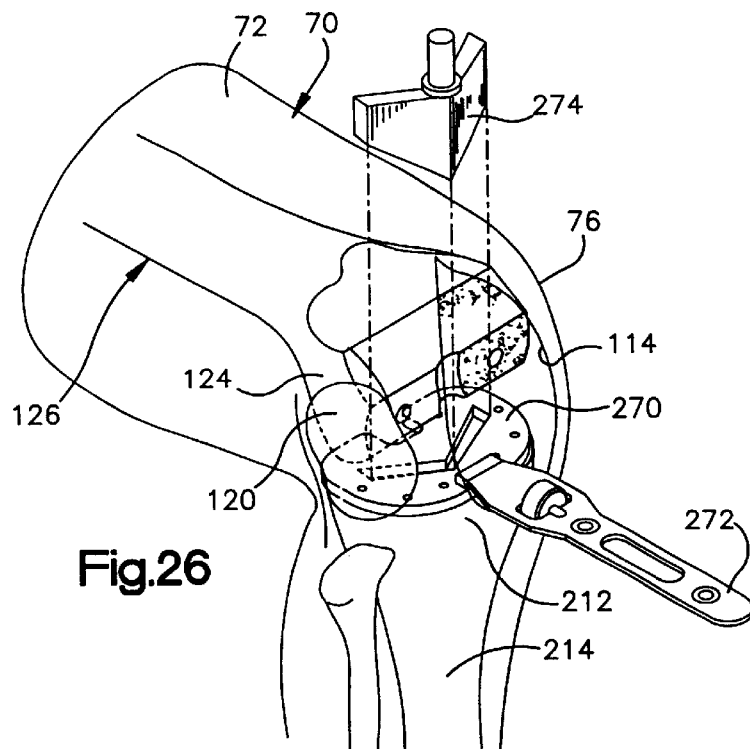


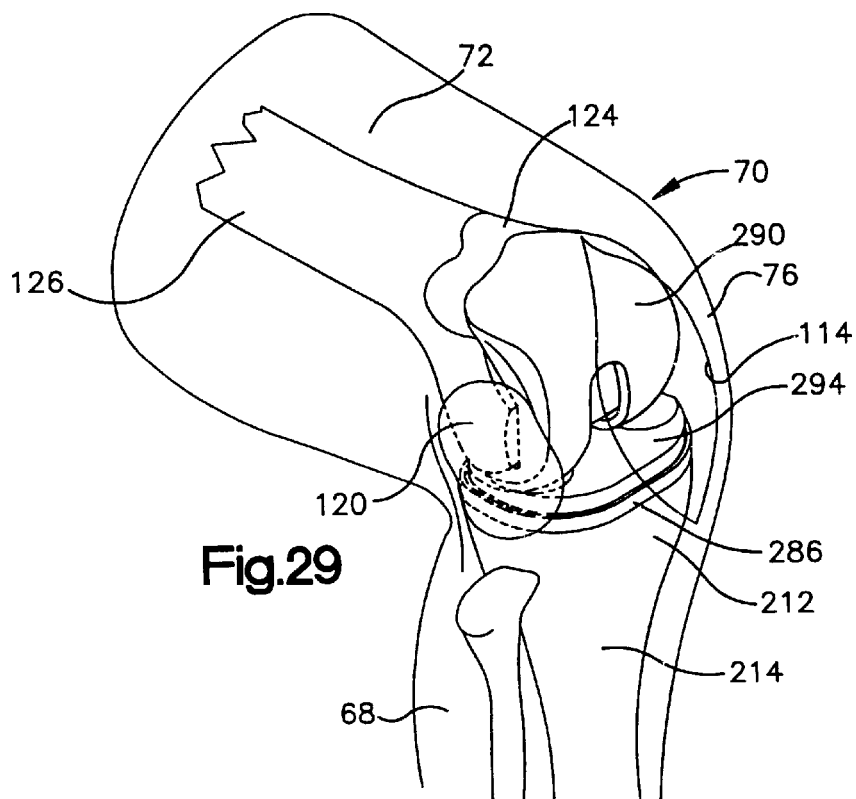
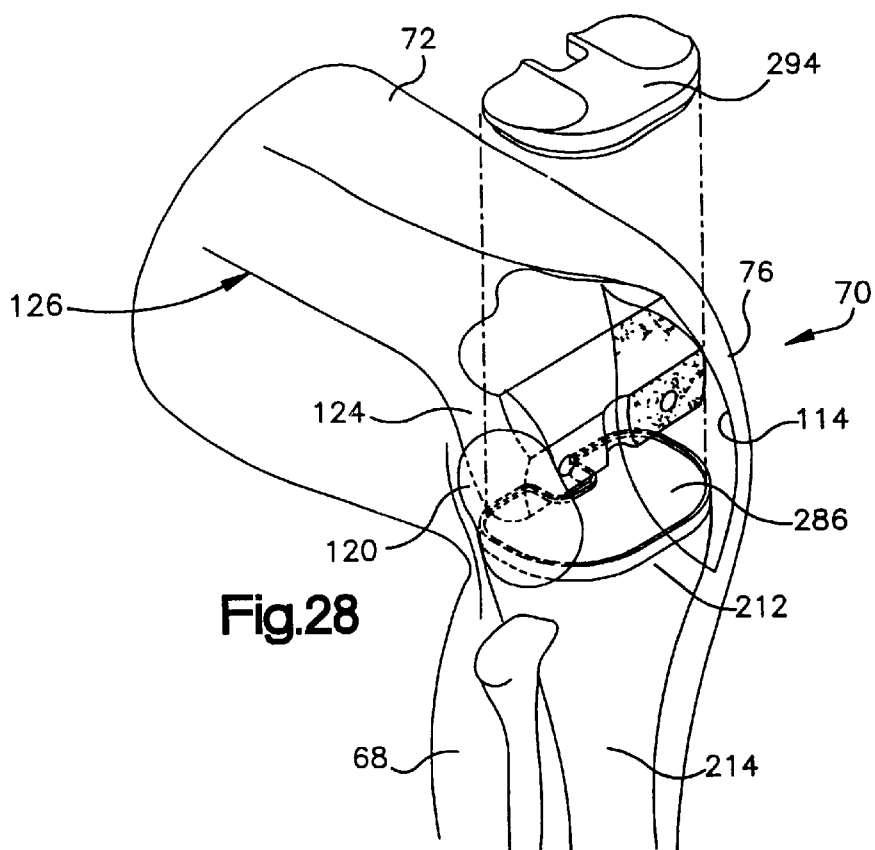


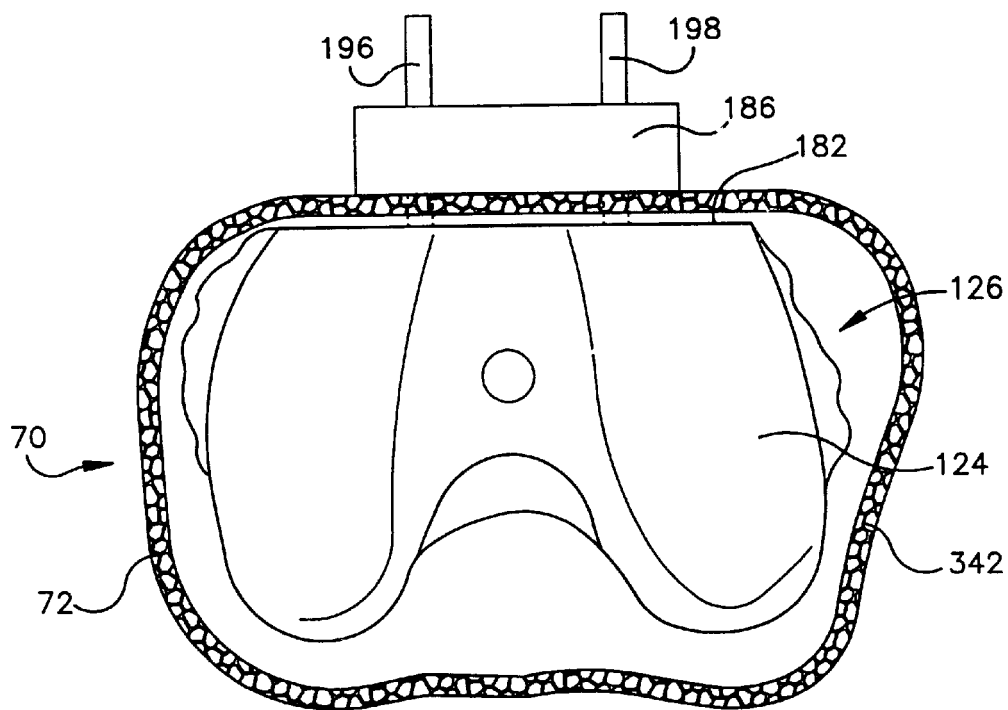
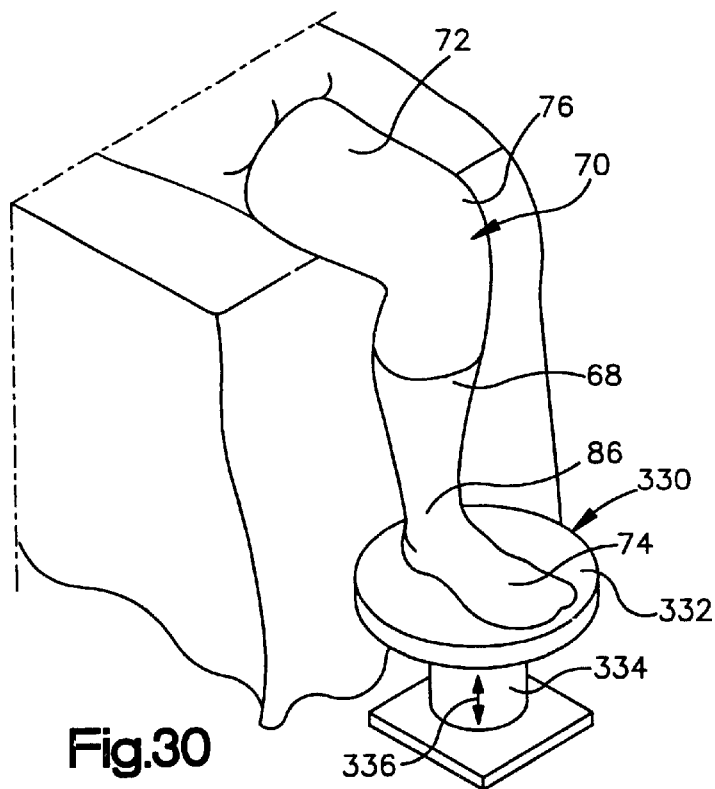


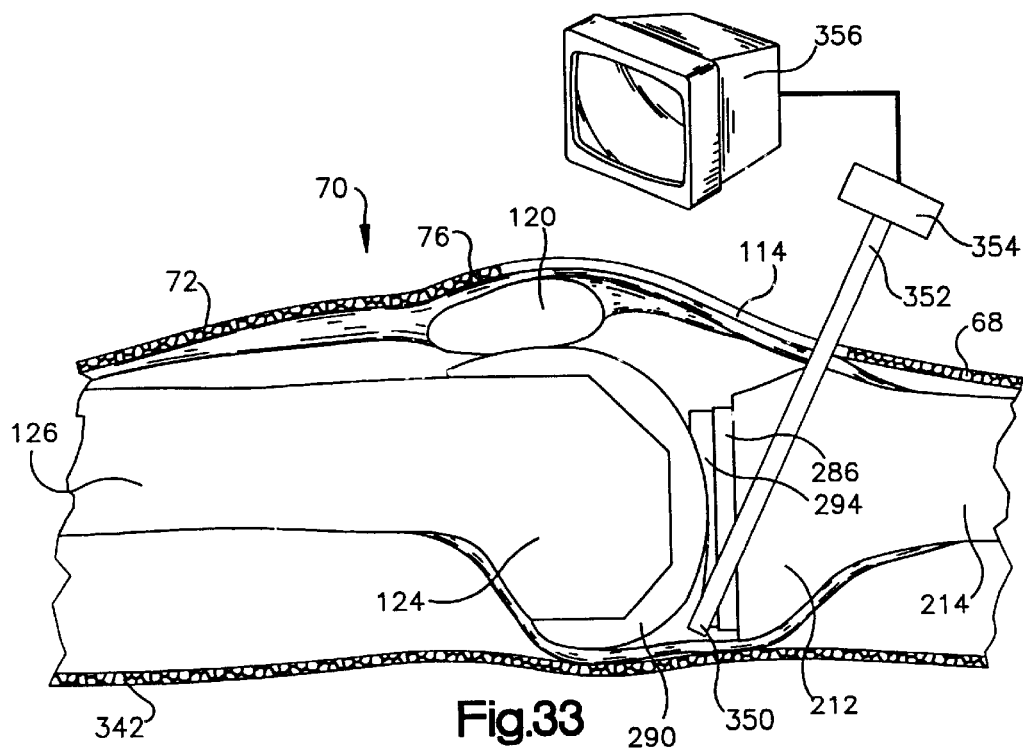
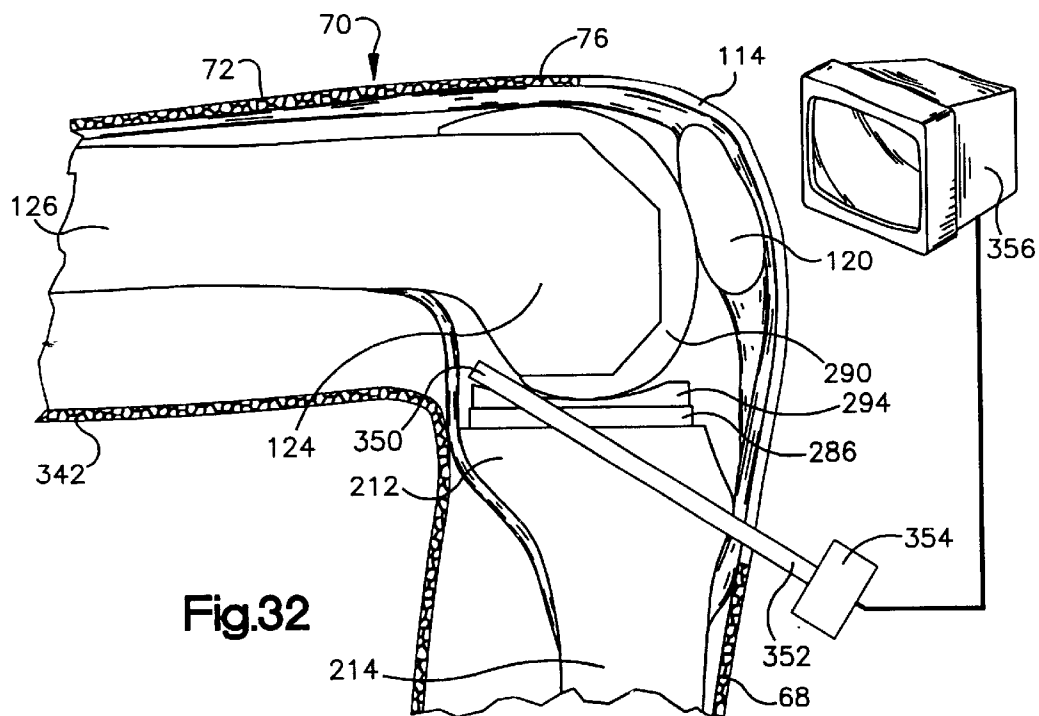


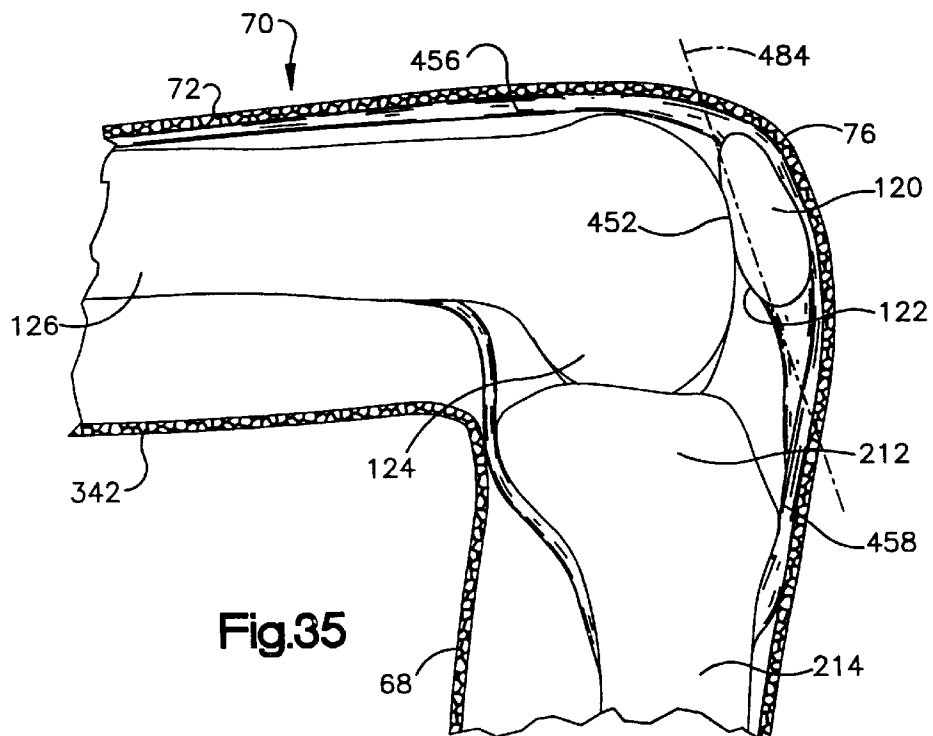
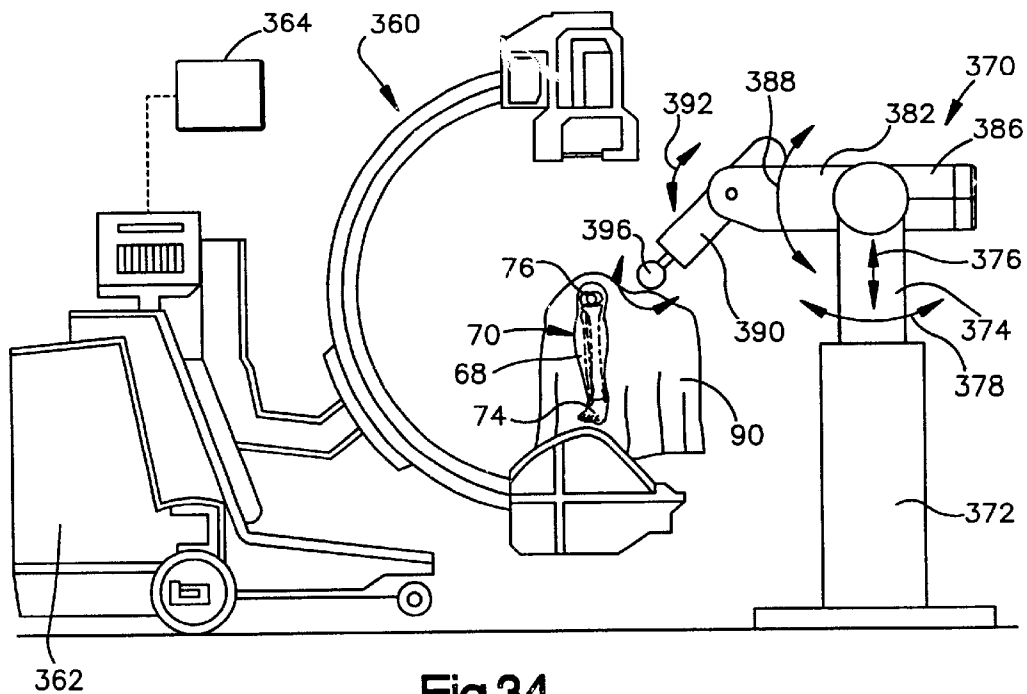


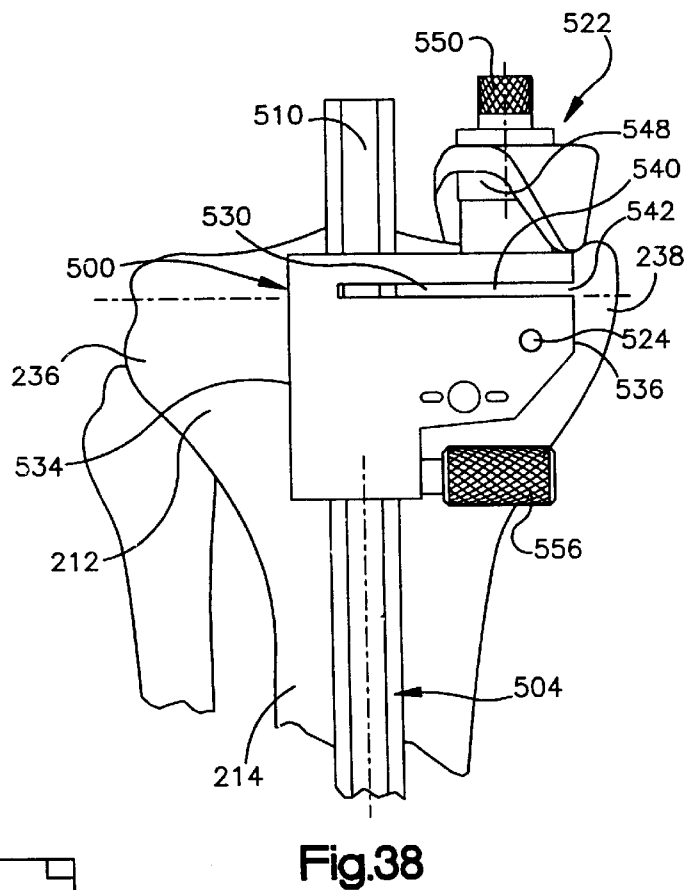
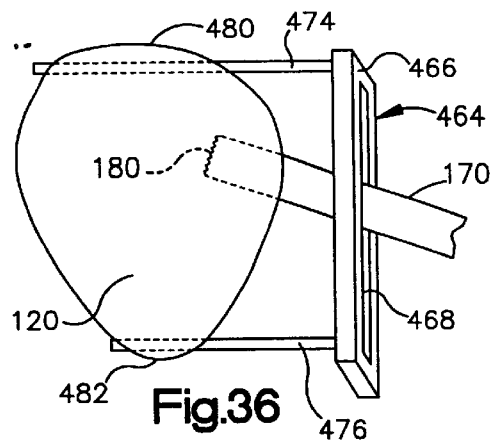
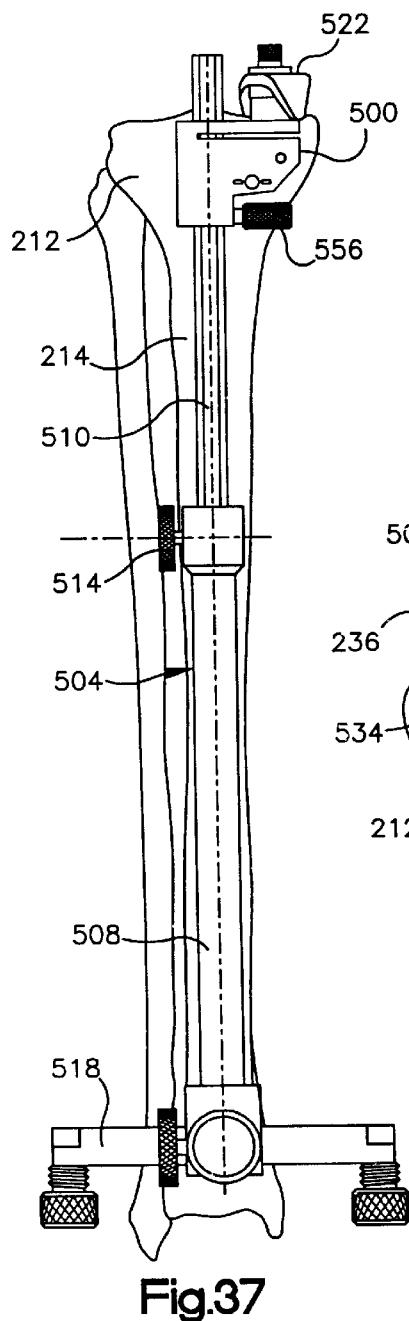












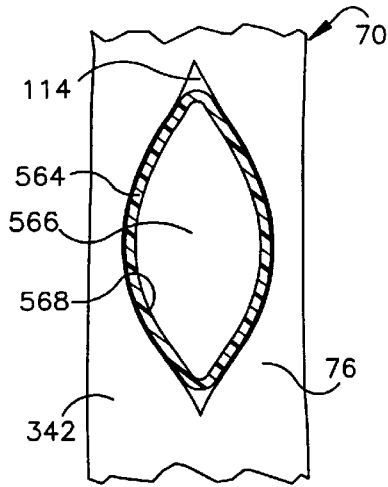


Fig.39

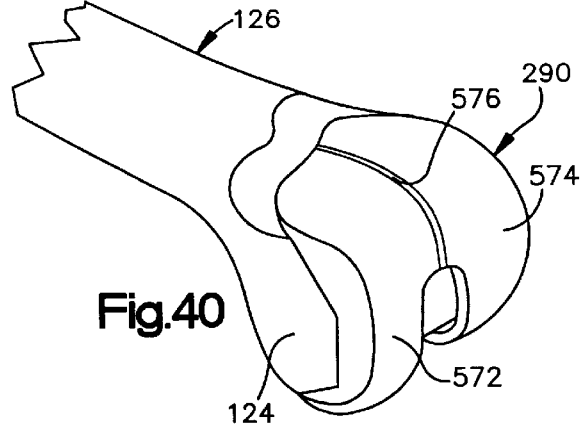


Fig.40

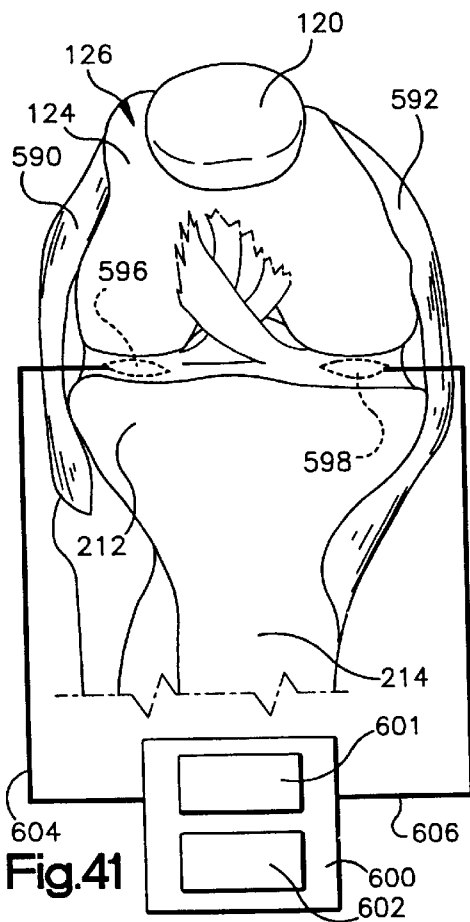


Fig.41

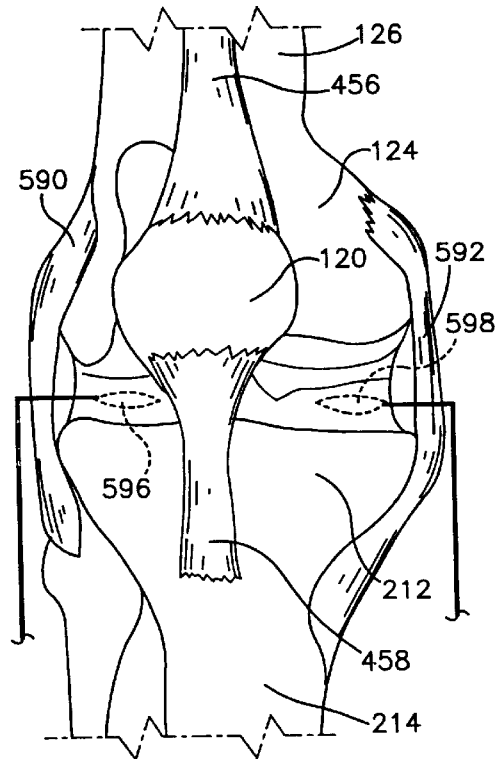
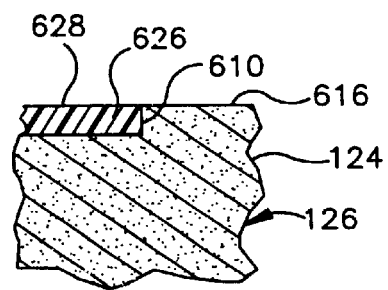
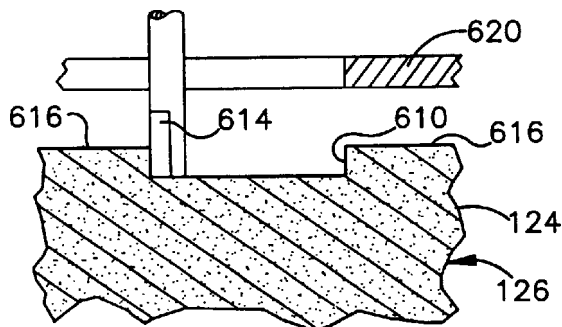
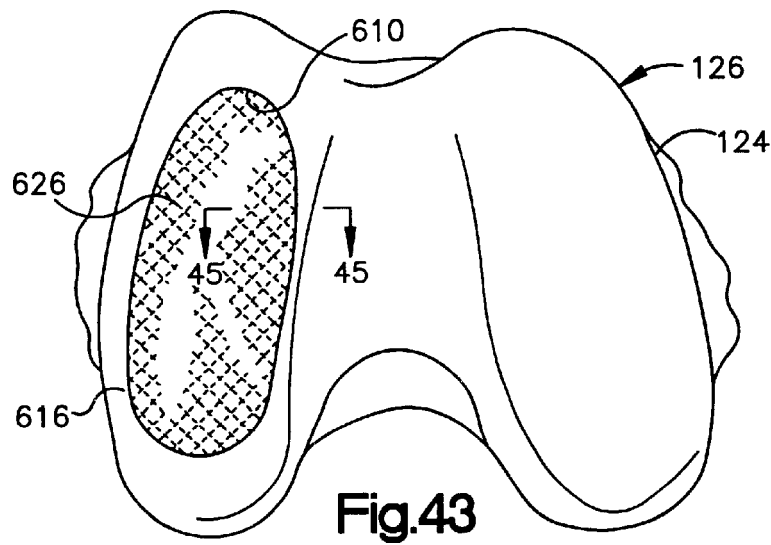


Fig.42



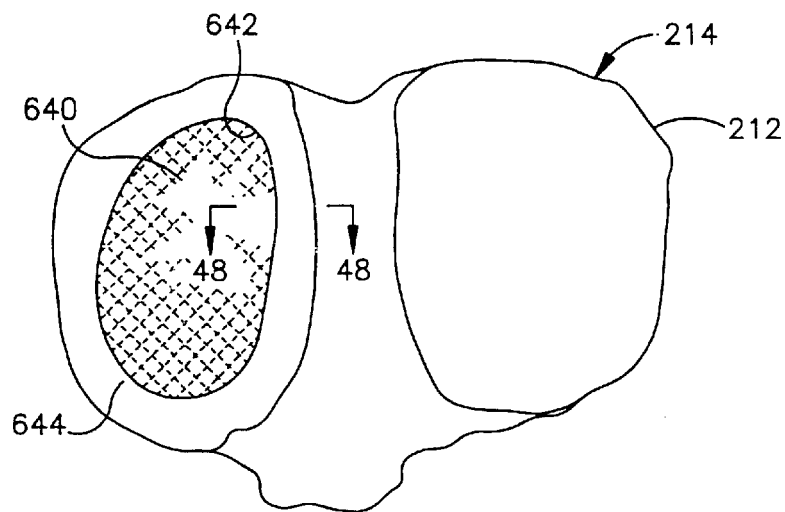


Fig.46

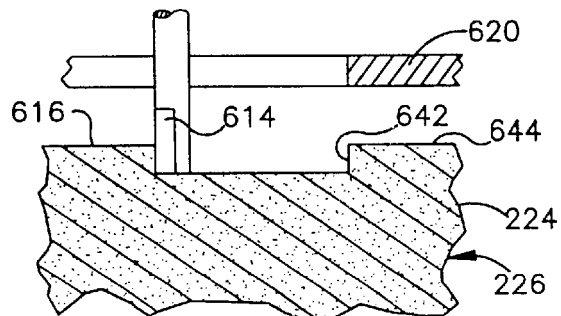


Fig.47

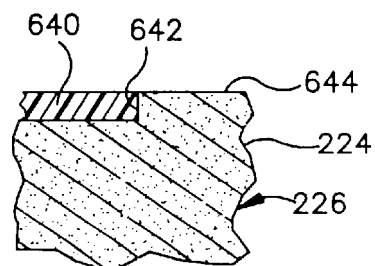


Fig.48

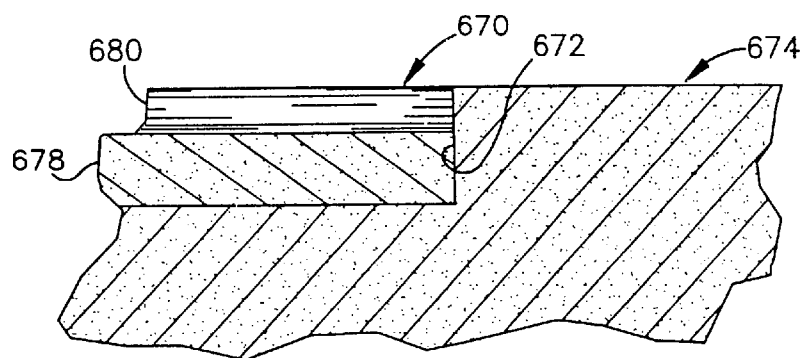
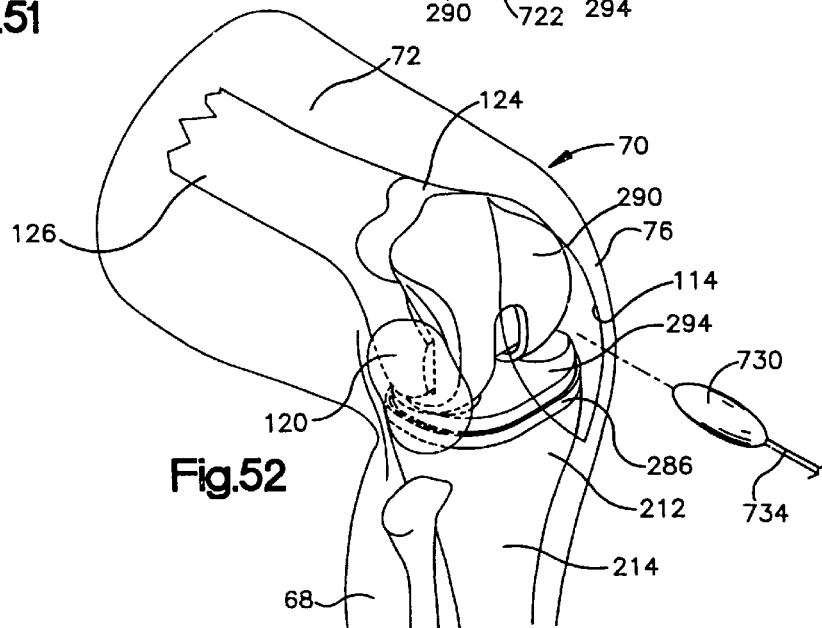
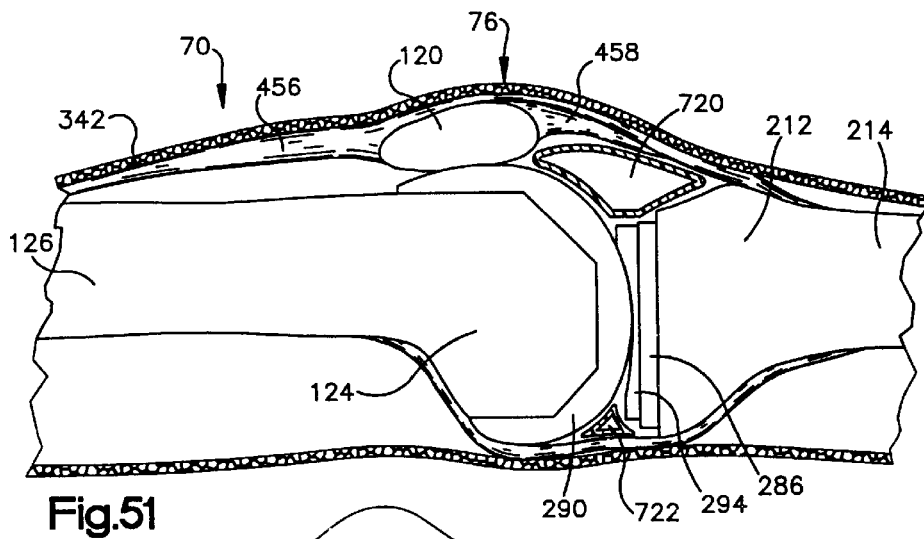
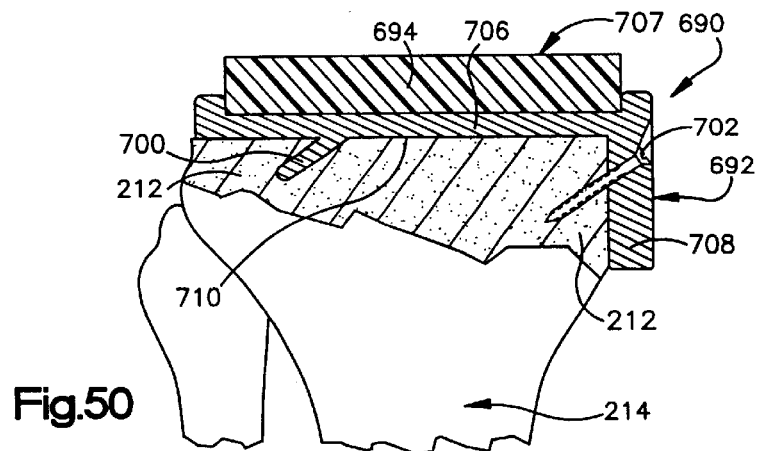


Fig.49



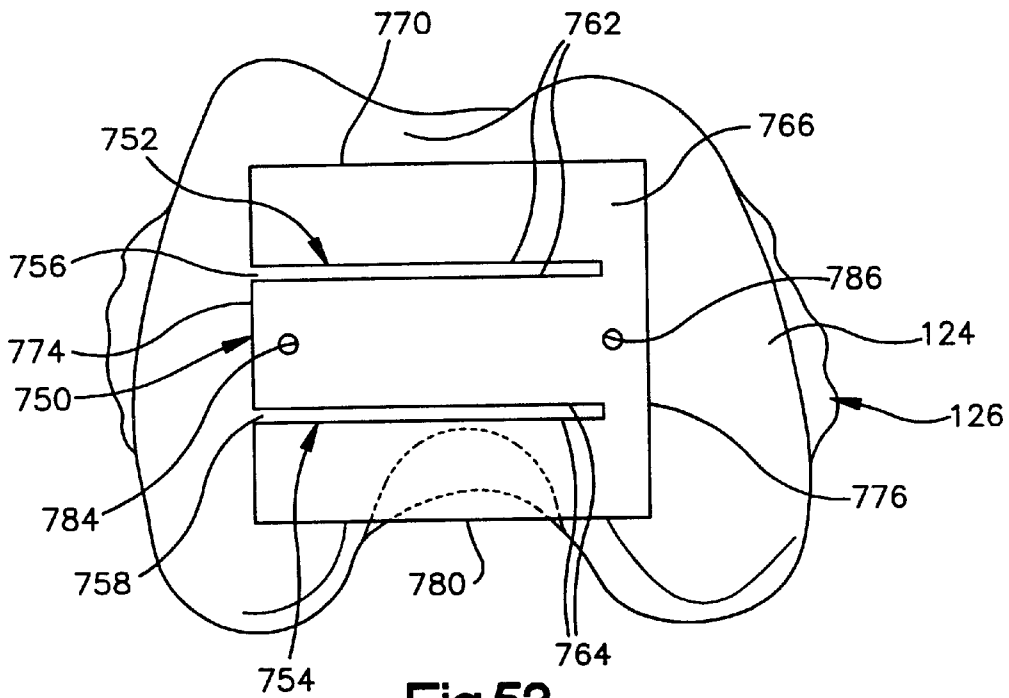


Fig.53

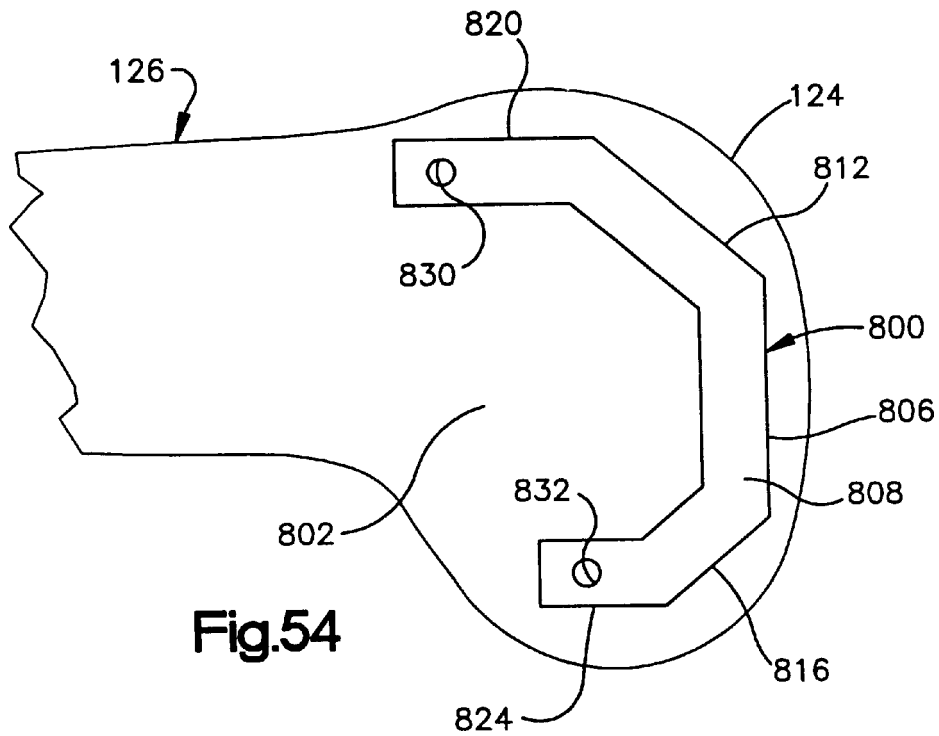


Fig.54

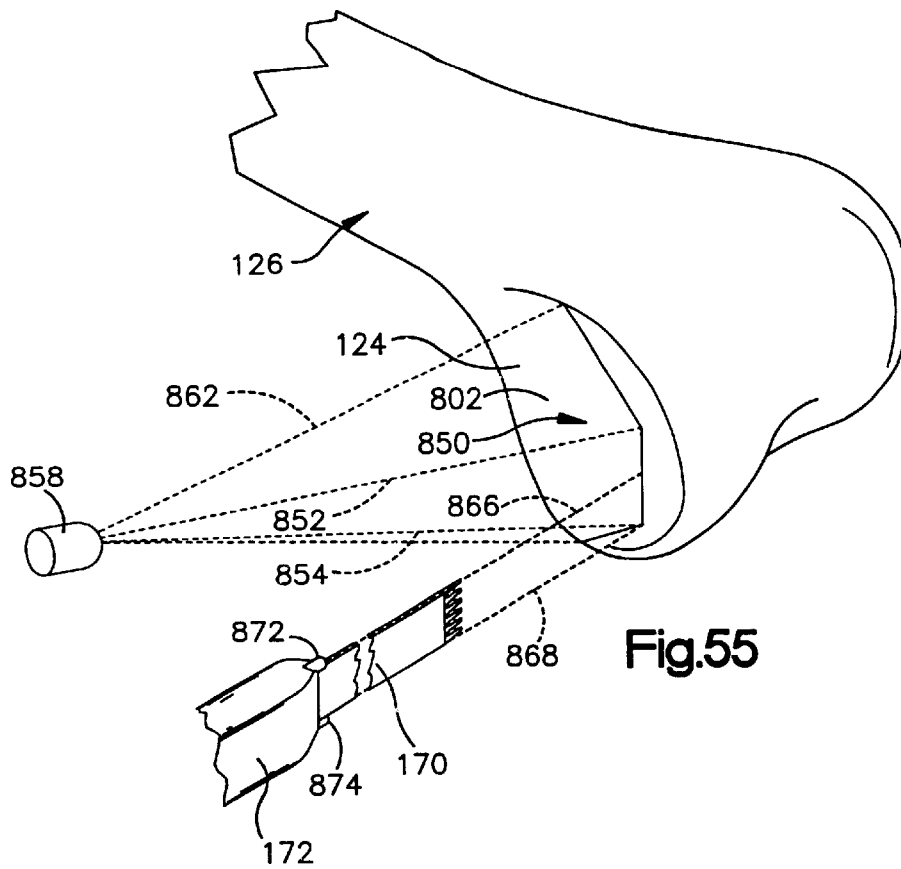


Fig.55

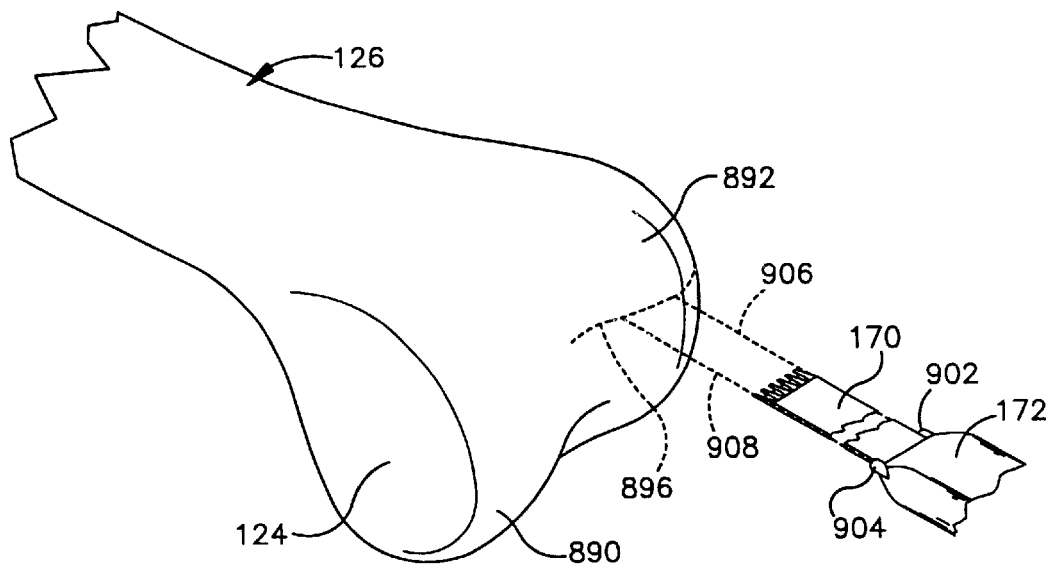


Fig.56

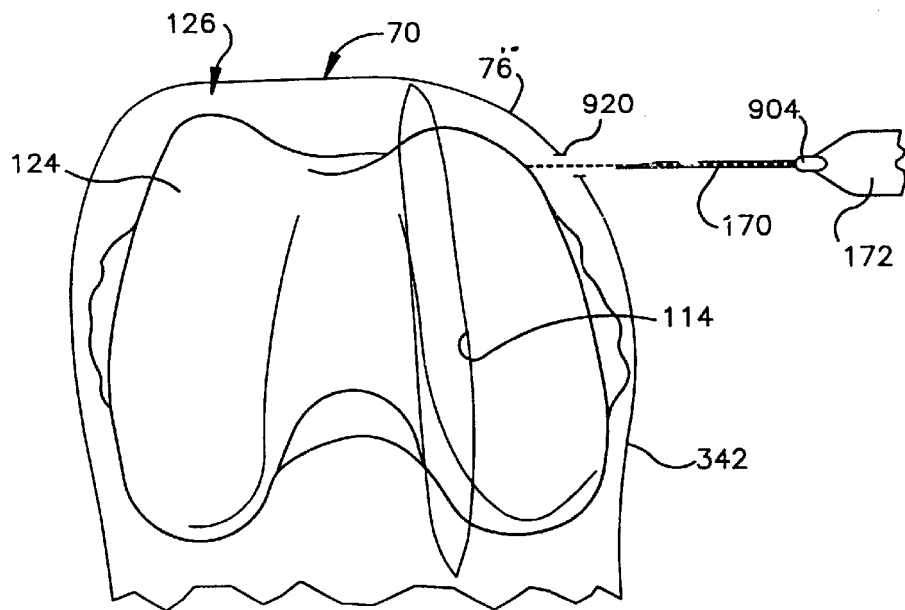


Fig.57

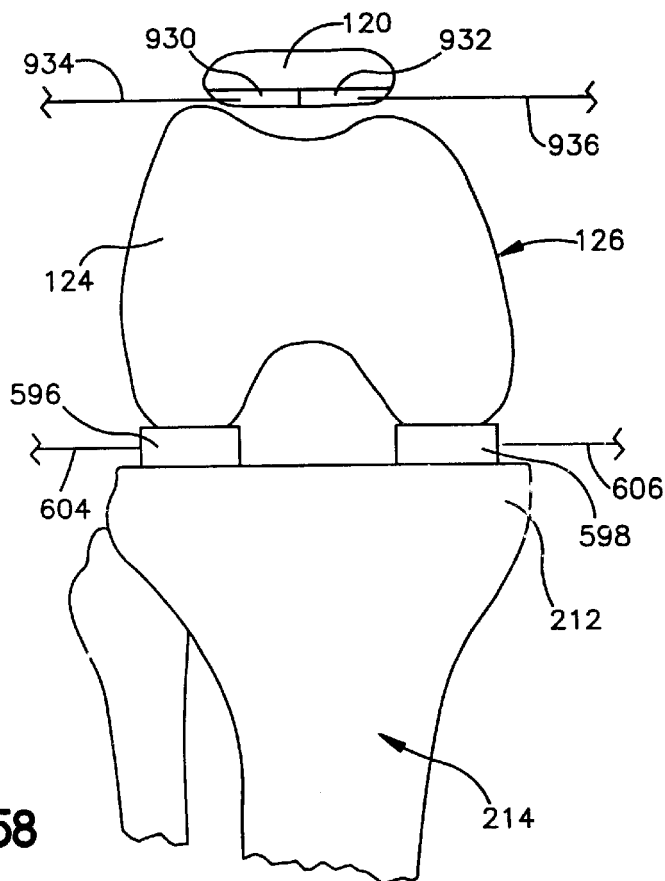


Fig.58

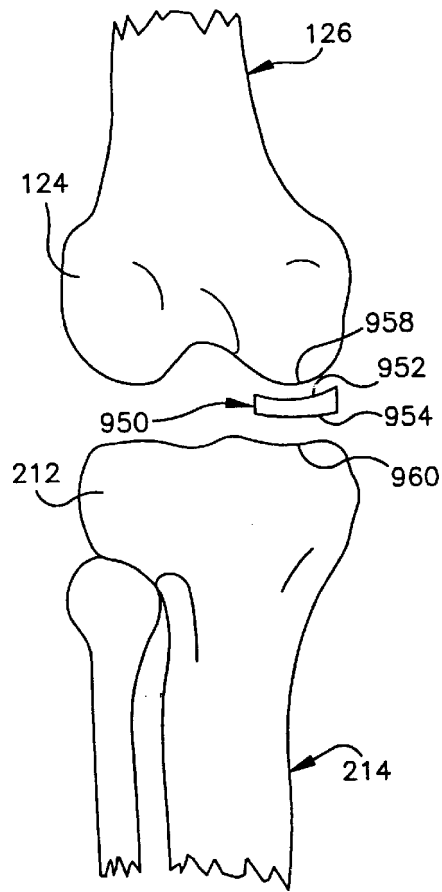


Fig.59

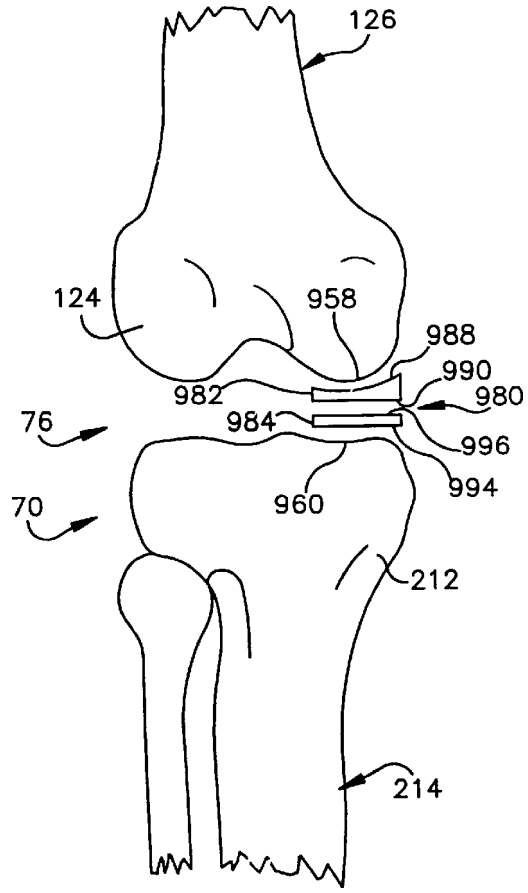


Fig.61

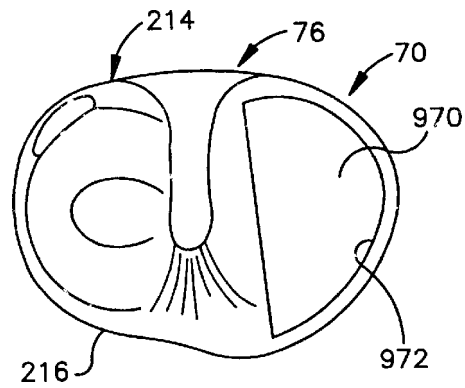


Fig.60

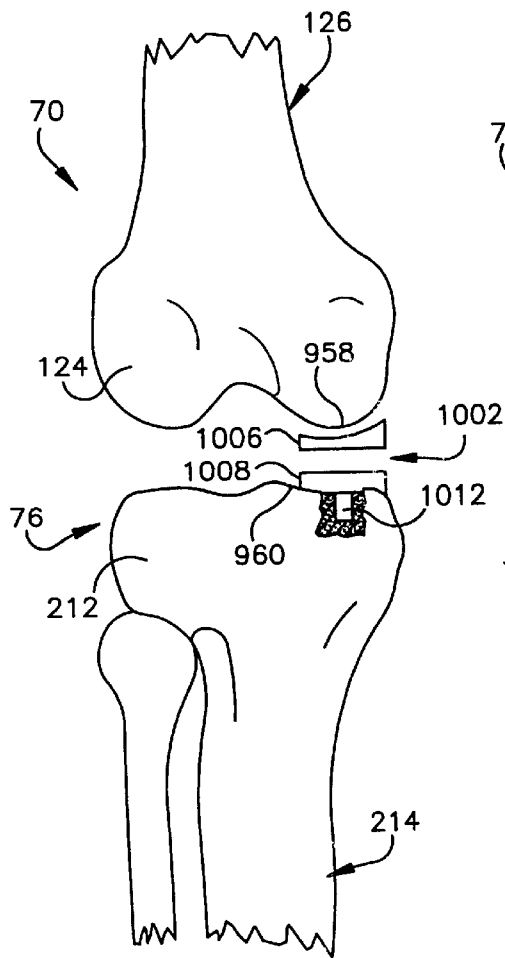


Fig.62

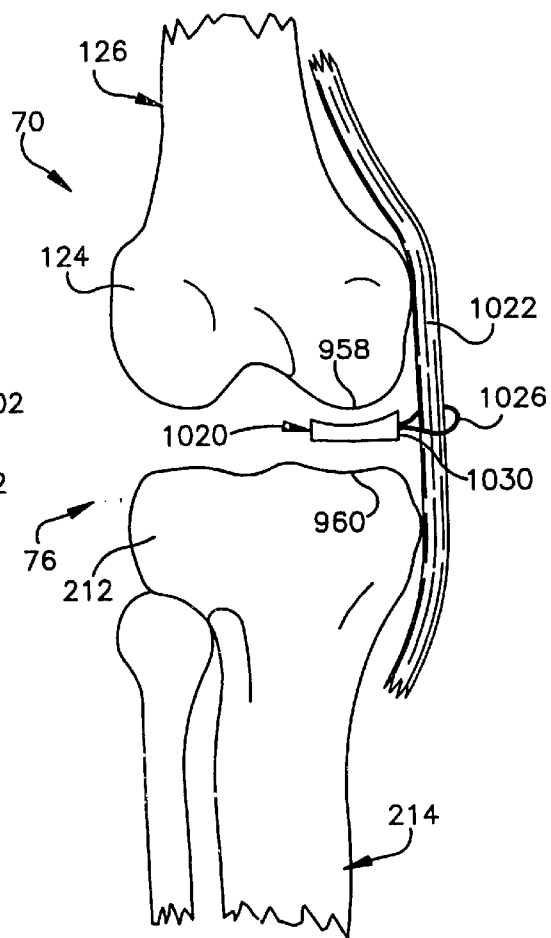
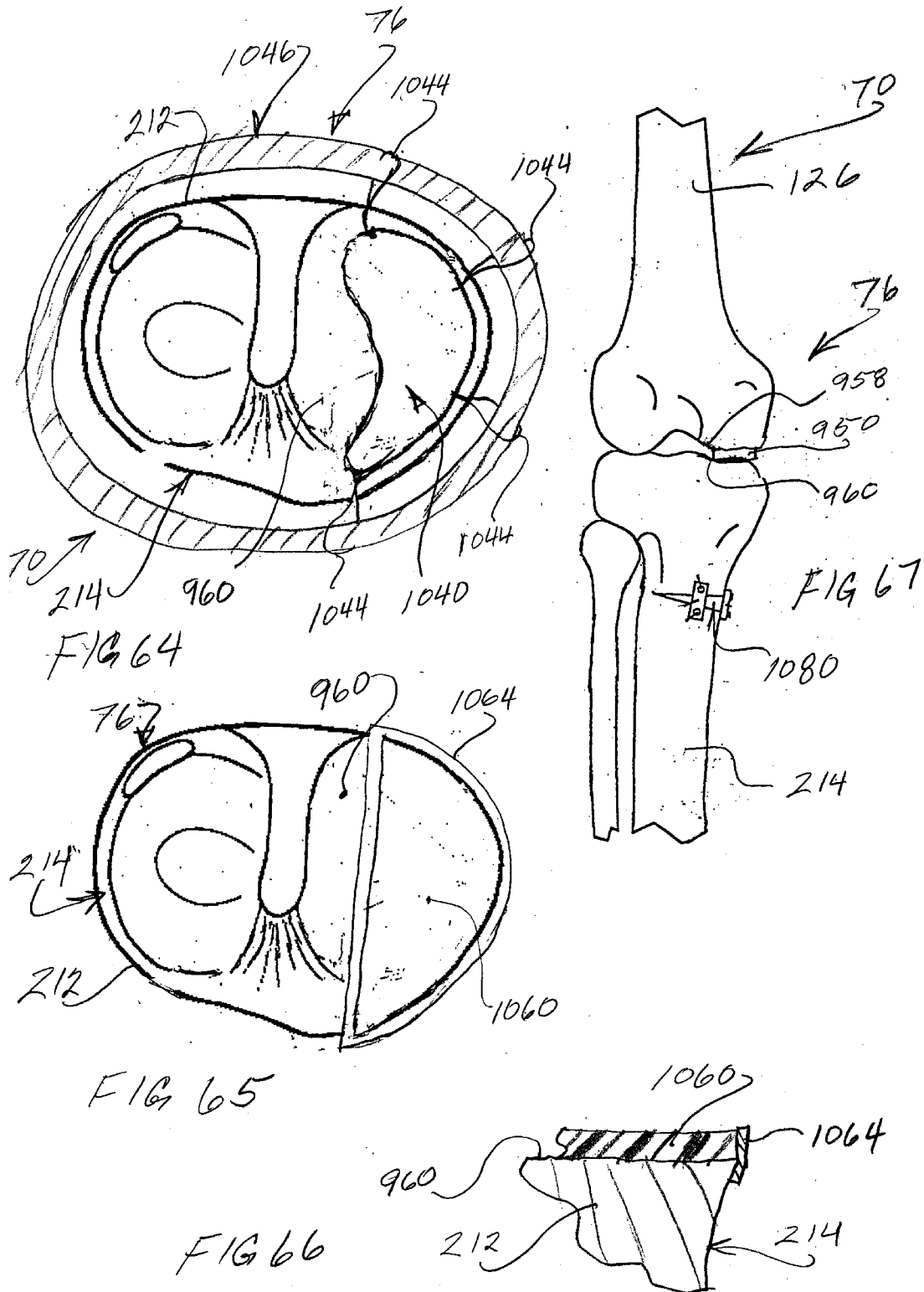


Fig.63



MOVABLE KNEE IMPLANT AND METHODS THEREFOR

RELATED APPLICATIONS

This applications is a continuation-in-part of U.S. patent application Ser. No. 09/941,185 filed Aug. 28, 2001. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/566,070 filed May 5, 2000, now U.S. Pat. No. 6,575,982. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/737,380 filed Dec. 15, 2000, now U.S. Pat. No. 6,503,267. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/815,405 filed Mar. 22, 2000, now abandoned. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/569,020 filed May 11, 2000, now U.S. Pat. No. 6,423,063. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/483,676 filed Jan. 14, 2000, now U.S. Pat. No. 6,468,289. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/602,743 filed Jun. 23, 2000, now U.S. Pat. No. 6,361,565. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/526,949 filed on Mar. 16, 2000, now U.S. Pat. No. 6,620,181. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/789,621 filed Feb. 21, 2001, now U.S. Pat. No. 6,635,073.

BACKGROUND OF THE INVENTION

The present invention relates to a new and improved method of performing surgery. The surgery may be of any desired type. The surgery may be performed on joints in a patient's body. The surgery may be performed on any desired joint in a patient's body. Regardless of the type of surgery to be performed, a limited incision may advantageously be utilized.

This specification relates to limited incision partial or total knee joint replacements and revisions and is the result of a continuation of work which was previously performed in conjunction with the subject matter of U.S. Pat. No. 5,514,143. This specification also contains subject matter which relates to U.S. Pat. Nos. 5,163,949; 5,269,785; 5,549,683; 5,662,710; 5,667,520; 5,961,499; 6,059,817; and 6,099,531. Although this specification refers to knee joints, it should be understood that the subject matter of this application is also applicable to joints in many different portions of a patient's body, for example a shoulder, spine, arm, hand, hip or foot of a patient.

During a total or partial knee replacement or revision, an incision is made in a knee portion of a leg of the patient to obtain access to the knee joint. The incision is relatively long to enable instrumentation, such as a femoral alignment guide, anterior resection guide, distal resection guide, femoral cutting guide, and femoral anterior, posterior and chamfer resection guide to be positioned relative to a distal end portion of the femur. In addition, the incision must be relatively large to enable a tibial resection guide to be positioned relative to the proximal end portion of the tibia.

With known procedures of total or partial knee replacement, the incision in the knee portion of the patient is made with the leg of the patient extended (straight) while the patient is lying on his or her back. At this time, the extended leg of the patient is disposed along and rests on a patient support surface. After the incision has been made in the knee portion of the leg of the patient, the leg is flexed and a foot connected with the leg moves along the patient support surface. The knee portion of the flexed leg of the

patient is disposed above the patient support surface. This results in the soft tissue in the knee being compressed against the back of the knee joint. This makes it very difficult to access posterior or soft tissue to remove bone spurs (ostified), meniscus, posterior capsule, ligaments in the back of the joint, and/or any residual soft tissue or connective tissue that is blocking further flexion.

After the incision has been made and while the leg is flexed with the foot above the patient support surface, the surgeon can not view arteries, nerves and veins which are sitting just posterior to the knee capsule. Therefore, a surgeon may be very reluctant, or at least very careful, of inserting instruments into the back of the knee joint to remove tissue. This may result in osteophytes, bone spurs and similar types of posterior soft tissue being left in place.

With known techniques, the patella is commonly everted from its normal position. When the patella is everted, the inner side of the patella is exposed and faces outward away from end portions of the femur and tibia. The outer side of the everted patella faces inward toward the end portions of the femur and the tibia. Moving the everted patella to one side of end portions of the femur and tibia tends to increase the size of the incision which must be made in the knee portion of the patient's leg.

After implants have been positioned in the knee portion of the patient's leg, it is common to check for flexion and extension balancing of ligaments by flexing and extending the knee portion with the foot above the support surface. If the ligaments are too tight medially or laterally, they can be released to obtain the desired tension. However, the checking of ligament balance by flexing and extending the leg of the patient, ignores rotational balancing of ligaments. Since the femoral implant is movable relative to the tibial implant, the stability of the knee joint is dependent upon balancing of the ligaments in flexion, extension, and rotation.

SUMMARY OF THE INVENTION

The present invention relates to a new and improved method and apparatus for use in performing any desired type of surgery on a joint in a patient's body. The joint may advantageously be a knee joint. However, the method and apparatus may be used in association with surgery on other joints in a patient's body. There are many different features of the present invention which may be used either together or separately in association with many different types of surgery. Although features of the present invention may be used with many different surgical procedures, the invention is described herein in conjunction with surgery on a joint in a patient's body.

One of the features of the present invention relates to the making of a limited incision. The limited incision may be in any desired portion of a patient's body. For example, the limited incision may be in a knee portion of a leg of a patient. The limited incision may be made while a lower portion of the leg of the patient is extending downward from the upper portion of the leg of the patient. At this time, a foot connected with the lower portion of the leg of the patient may be below a surface on which the patient is supported. The limited incision may be made while the lower portion of the leg of the patient is suspended from the upper portion of the leg or while the lower portion of the leg and/or the foot of the patient are held by a support device. After the incision has been made, any one of many surgical procedures may be undertaken.

It is believed that in certain circumstances, it may be desired to have a main incision of limited length and a

3

secondary incision of even smaller length. The secondary incision may be a portal or stab wound. A cutting tool may be moved through the secondary incision. An implant may be moved through the main incision.

Once the incision has been made, a patella in a knee portion of the patient may be offset to one side of its normal position. When the patella is offset, an inner side of the patella faces inward toward the end portions of a femur and tibia.

Although any one of many known surgical procedures may be undertaken through the limited incision, down sized instrumentation for use in the making of cuts in a femur and/or tibia may be moved through or part way through the incision. The down sized instrumentation may be smaller than implants to be positioned in the knee portion of the patient. The down sized instrumentation may have opposite ends which are spaced apart by a distance which is less than the distance between lateral and medial epicondyles on a femur or tibia in the leg of the patient.

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool.

It is contemplated that at least some, if not all, cuts on a bone may be made using light directed onto the bone as a guide. The light directed onto the bone may be in the form of a three dimensional image. The light directed onto the bone may be a beam along which a cutting tool is moved into engagement with the bone.

There are several different orders in which cuts may be made on bones in the knee portion of the leg of the patient. It is believed that it may be advantageous to make the patellar and tibial cuts before making the femoral cuts.

There are many different reasons to check ligament balancing in a knee portion of the leg of a patient. Ligament balancing may be checked while the knee portion of the leg of the patient is flexed and the foot of the patient is below the support surface on which the patient is disposed. Flexion and extension balancing of ligaments may be checked by varying the extent of flexion of the knee portion of the leg of the patient. In addition, rotational stability of the ligaments may be checked by rotating the lower portion of the leg of the patient about its central axis. Balancing of ligaments may also be checked by moving the foot of the patient sideways, rotating the lower portion of the leg of the patient, and/or moving the foot anteriorly or posteriorly.

It is believed that it may be advantageous to utilize an endoscope or a similar apparatus to examine portions of the patient's body which are spaced from the incision. It is also contemplated that images of the knee portion of the patient's leg may be obtained by using any one of many known image generating devices other than an endoscope. The images may be obtained while the patient's leg is stationary or in motion. The images may be obtained to assist a surgeon in conducting any desired type of surgery.

Balancing of the ligaments in the knee portion of a patient's leg may be facilitated by the positioning of one or more transducers between tendons, ligaments, and/or bones in the knee portion. One transducer may be positioned relative to a medial side of a knee joint. Another transducer may be positioned relative to a lateral side of the knee joint. During bending of the knee joint, the output from the transducers will vary as a function of variations in tension forces in the ligaments. This enables the tension forces in

4

ligaments in opposite sides of the knee portion to be compared to facilitate balancing of the ligaments.

Patellar tracking may be checked by the positioning of one or more transducers between the patella and the distal end portion of the femur. If desired, one transducer may be placed between a medial portion of the patella and the distal end portion of the femur. A second transducer may be placed between a lateral portion of the patella and the distal end portion of the femur. Output signals from a transducer will vary as a function of variations in force transmitted between the patella and femur during bending of the leg.

The articular surface on the patella may be repaired. The defective original articular surface on the patella may be removed by cutting the patella while an inner side of the patella faces toward a distal end portion of a femur. The step of cutting the patella may be performed while the patella is disposed in situ and is urged toward the distal end portion of the femur by connective tissue. An implant may then be positioned on the patella.

It is contemplated that the size of the incision in the knee or other portion of the patient may be minimized by conducting surgery through a cannula. The cannula may be expandable. To facilitate moving of an implant through the cannula, the implant may be formed in two or more portions. The portions of the implant may be interconnected when the portions of the implant have been positioned in the patient's body. Although the implants disclosed herein are associated with a patient's knee, it should be understood that the implants may be positioned at any desired location in a patient's body.

An implant may be positioned in a recess formed in a bone in a patient. The implant may contain biological resurfacing and/or bone growth promoting materials. The implant may contain mesenchymal cells and/or tissue inductive factors. Alternatively, the implant may be formed of one or more materials which do not enable bone to grow into the implant.

In accordance with one of the features of the present invention, body tissue may be moved or stretched by a device which is expandable. The expandable device may be biodegradable so that it can be left in a patient's body. The expandable device may be expanded to move and/or stretch body tissue and increase a range of motion of a joint. The expandable device may be used to stretch body tissue in which an incision is to be made.

An improved drape system is provided to maintain a sterile field between a surgeon and a patient during movement of the surgeon relative to the patient. The improved drape system includes a drape which extends between the surgeon and a drape for the patient. During surgery on a knee portion of a leg of a patient, the drape system extends beneath a foot portion of the leg of a patient. It is contemplated that the drape system will be utilized during many different types of operations other than surgery on a leg of a patient.

An implant may be movable relative to both a femur and a tibia in a leg of a patient during bending of the leg. The implant may include a single member which is disposed between and engaged by end portions of both the femur and tibia. Alternatively, the implant may include a plurality of members which are disposed in engagement with each other. If desired, one of the members of the plurality of members may be secured to a bone and engaged by a member which is not secured to a bone. The implant may be secured to soft tissue in the knee portion of the patient's leg.

There are many different features to the present invention. It is contemplated that these features may be used together

or separately. It is also contemplated that the features may be utilized in association with joints in a patient's body other than a knee joint. For example, features of the present invention may be used in association with surgery on vertebral joints or glenoid joints. However, it is believed that many of the features may be advantageously utilized together during the performance of surgery on a patient's knee. However, the invention should not be limited to any particular combination of features or to surgery on any particular joint in a patient's body. It is contemplated that features of the present invention will be used in association with surgery which is not performed on a joint in a patient's body.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the invention will become more apparent upon a consideration of the following description taken in connection with the accompanying drawings wherein:

FIG. 1 is a schematic illustration depicting extended and flexed positions of a patient's leg during performance of knee surgery in a known manner;

FIG. 2 is a schematic illustration depicting the manner in which a leg support is used to support an upper portion of a leg of a patient above a support surface on which the patient is disposed in a supine orientation during performance of knee surgery;

FIG. 3 is a schematic illustration depicting the patient's leg after a portion of a drape system has been positioned over the patient, the leg being shown in a flexed condition with the foot below the patient support surface and with an upper portion of the leg supported by the leg support of FIG. 2;

FIG. 4 is a schematic illustration of the patient's leg of FIGS. 2 and 3 in an extended condition and of the drape system which extends between a surgeon and the patient;

FIG. 5 is a schematic illustration depicting the manner in which the drape system of FIG. 4 maintains a sterile field during movement of the surgeon relative to the patient;

FIG. 6 is a schematic illustration depicting the manner in which an incision is made in the knee portion of the leg of the patient when the leg is in the position illustrated in FIGS. 2 and 3;

FIG. 7 is a schematic illustration depicting the manner in which the incision is expanded and a patella is everted with the leg of the patient extended;

FIG. 8 is a schematic illustration depicting the manner in which a drill is utilized to form a passage in a femur in the upper portion of the leg of the patient with the leg in the position illustrated in FIGS. 2 and 3 and the patella offset from its normal position;

FIG. 9 is a schematic illustration of the positioning of a femoral alignment guide in the hole formed by the drill of FIG. 8 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 10 is a schematic illustration depicting the position of an anterior resection guide and a stylus relative to the femoral alignment guide of FIG. 9 before an anterior femur cut has been made with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 11 is a schematic illustration, taken generally along the line 11—11 of FIG. 10, further illustrating the relationship of the anterior resection guide and stylus to the distal end portion of the femur;

FIG. 12 is a schematic illustration further illustrating the relationship of the anterior resection guide and stylus to the distal end portion of the femur;

FIG. 13 is a schematic illustration depicting the manner in which a cutting tool is moved along a guide surface on the anterior resection guide during making of an anterior femur cut with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 14 is a schematic illustration depicting the relationship of the femoral alignment guide to the femur after making of the anterior femur cut of FIG. 13, the anterior resection guide and stylus being removed from the femoral alignment guide, and the leg of the patient being in the position illustrated in FIGS. 2 and 3;

FIG. 15 is a schematic illustration of the anterior femur cut and femoral alignment guide of FIG. 14;

FIG. 16 is a schematic illustration depicting the manner in which the femoral alignment guide is utilized to position a distal resection guide relative to the distal end portion of the femur after making of the anterior femur cut and with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 17 is a schematic illustration depicting the manner in which a distal femur cut is made with a cutting tool after the femoral alignment guide has been removed, the leg of the patient being in the position illustrated in FIGS. 2 and 3;

FIG. 18 is a schematic illustration depicting the relationship of the cutting tool and distal resection guide of FIG. 17 to the femur;

FIG. 19 is a schematic illustration depicting the manner in which a femoral cutting guide is positioned on the distal end portion of the femur with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 20 is a schematic illustration further depicting the relationship of the femoral cutting guide to the distal end portion of the femur;

FIG. 21 is a schematic illustration depicting the relationship of a tibial resection guide to the proximal end portion of a tibia in the lower portion of the patient's leg after making the femoral cuts and with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 22 is a schematic illustration of the distal end portion of the femur and the proximal end portion of the tibia after making the femoral and tibial cuts with the leg of the patient in the position illustrated in FIGS. 2 and 3 and the patella offset to one side of the incision;

FIG. 23 is a schematic illustration further depicting the femoral and tibial cuts of FIG. 22;

FIG. 24 is a schematic illustration depicting the manner in which force is applied against the bottom of the patient's foot by a surgeon's knee with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 25 is a schematic illustration depicting the various directions in which the lower portion of the patient's leg can be moved relative to the upper portion of the patient's leg to expose portions of the bone at the incision in the knee portion of the patient's leg and to check ligament balancing;

FIG. 26 is a schematic illustration depicting the manner in which a tibial punch is positioned relative to a tibial base plate with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 27 is a schematic illustration depicting completed preparation of the tibia for a tibial tray implant with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 28 is a schematic illustration depicting positioning of a tibial bearing insert in the tibial tray of FIG. 27 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 29 is a schematic illustration depicting femoral and tibial implants with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 30 is a schematic illustration of an apparatus which may be utilized to move the lower portion of a patient's leg relative to the upper portion of a patient's leg when the patient's leg is in the position illustrated in FIGS. 2 and 3;

FIG. 31 is a schematic illustration depicting the manner in which a distal resection guide is connected with a patient's femur by pins which extend through the guide and through skin in the upper portion of the patient's leg into the femur with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 32 is a schematic illustration depicting the manner in which an endoscope may be inserted through an incision in a patient's knee to inspect portions of the patient's knee which are remote from the incision with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 33 is a schematic illustration similar to FIG. 32, depicting the manner in which the endoscope may be inserted through the incision in the patient's knee with the leg of the patient extended;

FIG. 34 is a schematic illustration depicting the manner in which an imaging apparatus may be utilized to generate images of a portion of the patient's leg and the manner in which a robot may be utilized to position cutting tools or other devices relative to the patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 35 is a schematic illustration depicting the relationship of a cut line to a patella in a knee of the leg of the patient with the leg in the position illustrated in FIGS. 2 and 3 and with the patella in the normal position;

FIG. 36 is a schematic illustration depicting the manner in which a cutting tool is moved relative to a guide member to cut the patella of FIG. 35 while the patella is disposed in situ;

FIG. 37 is a schematic illustration depicting the manner in which a tibial alignment shaft and a tibial resection guide are positioned relative to a tibia in a lower portion of a leg of the patient with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 38 is an enlarged fragmentary view of a portion of FIG. 37 and illustrating the construction of the tibial resection guide;

FIG. 39 is a schematic illustration depicting the relationship between an expandable cannula and an incision in the knee portion of one leg of the patient with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 40 is a schematic illustration depicting the relationship between two separate portions of an implant which are interconnected within the patient's body;

FIG. 41 is a schematic illustration depicting the relationship of transducers to a flexed knee joint of a patient when the leg of the patient is in the position illustrated in FIGS. 2 and 3;

FIG. 42 is a schematic illustration, generally similar to FIG. 41, illustrating the relationship of the transducers to the knee joint when the leg of the patient is extended;

FIG. 43 is a schematic illustration of a distal end portion of a femur in a leg of a patient with the leg in the position illustrated in FIGS. 2 and 3 and illustrating the relationship of an implant to a recess in the end portion of the femur;

FIG. 44 is a schematic sectional view depicting the manner in which a cutting tool is used to form a recess in the end portion of the femur of FIG. 43 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 45 is a schematic sectional view, taken generally along the line 45—45 of FIG. 43 further illustrating the relationship of the implant to the recess;

FIG. 46 is a schematic end view of a proximal end portion of a tibia in a leg of a patient, with the leg in the position illustrated in FIGS. 2 and 3, illustrating the relationship of an implant to a recess in the end portion of the tibia;

FIG. 47 is a schematic sectional view depicting the manner in which a cutting tool is used to form the recess in the end portion of the tibia of FIG. 46;

FIG. 48 is a schematic sectional view, taken generally along the line 48—48 of FIG. 46, further illustrating the relationship of the implant to the recess;

FIG. 49 is a schematic sectional view illustrating the relationship of another implant to a recess in a bone in a patient's body;

FIG. 50 is a schematic illustration depicting the relationship between a tibial implant and a tibia in the leg of the patient;

FIG. 51 is a schematic illustration depicting the relationship of expandable devices to the knee portion of a patient's leg;

FIG. 52 is a schematic illustration depicting the manner in which an expandable device may be positioned relative to a knee portion of a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 53 is a schematic illustration depicting the manner in which a femoral cutting guide may be mounted on a distal end of a femur in a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 54 is a schematic illustration of the manner in which a femoral cutting guide may be mounted on a side surface of a femur in a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 55 is a schematic illustration depicting the manner in which light is directed onto a distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 56 is a schematic illustration depicting the manner in which light is used to guide movement of a cutting tool relative to a distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 57 is a schematic illustration depicting the manner in which a cutting tool is moved relative to a secondary incision with a knee portion of a patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 58 is schematic illustration depicting the relationship of transducers to a patella and distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 59 is a schematic illustration depicting the relationship between a movable implant, a distal end portion of a femur, and a proximal end portion of a tibia in a knee portion of a leg of a patient;

FIG. 60 is a plan view of a proximal end portion of a tibia depicting the manner in which an implant may be inlaid into a tibia;

FIG. 61 is a schematic illustration, generally similar to FIG. 59, depicting the relationship between a movable implant formed by a plurality of members, a distal end portion of a femur, and a proximal end portion of a tibia in a knee portion of a leg of a patient;

FIG. 62 is a schematic illustration, generally similar to FIGS. 59 and 61, depicting the relationship between an

implant formed by a movable member and a fixed member, a distal end portion of a femur, and a proximal end portion of a tibia in a knee portion of a leg of a patient;

FIG. 63 is a schematic illustration, generally similar to FIG. 59, depicting the manner in which an implant is connected with a ligament in a knee portion of a patient's leg;

FIG. 64 is a schematic illustration, generally similar to FIG. 60, depicting the manner in which an implant is connected with a joint capsule in a knee portion of a patient's leg;

FIG. 65 is a schematic illustration, generally similar to FIG. 60, depicting the manner in which a retainer holds moldable implant material in place on a proximal end portion of a tibia in the knee portion of a leg of the patient;

FIG. 66 is a fragmentary sectional view, taken generally along the line 66—66 of FIG. 65 further illustrating the manner in which the retainer holds moldable implant material; and,

FIG. 67 is a schematic illustration depicting the manner in which an implant is provided in a knee portion of a leg of a patient to correct defects in a joint and in which an osteotomy wedge is provided to correct defects in bone alignment.

DESCRIPTION OF SPECIFIC PREFERRED EMBODIMENTS OF THE INVENTION

Known Method of Performing Surgery on a Patient's Knee

During the performance of surgery using known methods, a patient is supported on an operating table or other support surface 52 (FIG. 1). When a leg 50 of the patient is in the extended position illustrated in dashed lines in FIG. 1, a foot 54 connected with a lower portion 56 of the leg 50 is disposed above the support surface 52. During an operation on a knee portion 58 of the leg 50, the knee portion is raised and lowered relative to the support surface as the leg 50 is flexed and extended. However, the foot 54 is always disposed above the support surface 54 and may be supported by the support surface throughout the operation.

During this known operating procedure, an incision is made in the knee portion 58 of the leg 50 when the leg is in the extended position illustrated in dashed lines in FIG. 1. At this time, the foot 54 of the patient may rest on the support surface 52 or be disposed in a foot support located above the support surface. Once an incision has been formed in the knee portion 58, the leg 50 may be flexed or bent to the position illustrated in solid lines in FIG. 1.

As the knee portion 58 is bent, the leg 50 is flexed and compresses the soft tissue of the knee portion 58 against the back of the knee joint. This makes it very difficult to access the posterior of the knee portion 58 to remove bone spurs (ostified), the meniscus, the posterior capsule, and/or any residual soft tissue or bone that is blocking further flexion. The catching or pinching of soft tissue in the posterior aspect of the knee portion 58 may prevent further flexion and limits the range of motion. In addition, arteries, nerves and veins are sitting just posterior of the knee joint.

Due to the lack of access to the posterior of the knee portion 58, a surgeon may be very reluctant or, at least, very careful about inserting instruments blindly into the back of the knee joint to remove tissue. This may result in osteophytes, bone spurs and similar types of posterior soft tissue will be left in place.

Cuts are made on a femur and tibia with the leg 50 in the bent or flexed condition, illustrated in FIG. 1. This results in the distal end portion of the femur and the proximal end portion of the tibia in the leg 50 being pressed together

adjacent to the cuts. This interferes with ligament balancing. The relatively large incision which is necessary to accommodate known instrumentation systems increases time required for the patient to recover from the operation.

Preparation for Operation

It is contemplated that various features and/or combinations of features of the present invention will be utilized during surgery on different portions of a patient's body, such as a head, trunk or limbs of a patient. Although at least some of the features of the present invention are believed particularly advantageous when utilized in association with surgery on any one of the many joints in a patient's body, it is believed that the various features and/or combination of the features of the present invention are particularly advantageous when utilized in conjunction with surgery on a knee portion of a leg of a patient. It should be understood that the various features of the present invention may be use separately or in any desired combination of features.

Surgery on the knee portion of the patient may relate to any one of many different aspects of the knee portion, such as ligaments, tendons, articular surfaces, and/or total or partial knee replacements or revisions. Although the disclosure herein frequently refers to one particular type of knee operation, that is, a total knee replacement, features of the invention may be utilized with any desired type of surgery. It is believed that it will be apparent to a person having a knowledge of knee surgery how various features of the invention may be utilized with either a full or partial knee replacement. Therefore, there has been only minimal mention herein of how the features of the invention are applicable to partial knee replacements.

When knee surgery is to be performed in accordance with one of the features of the present invention, the patient 62 (FIG. 2) is disposed on a support surface 64 of an operating table 66. If desired, a patient support surface 64 other than an operating table could be used to support the patient. A lower portion 68 of a leg 70 extends downward from an upper portion 72 of the leg 70. A foot 74 connected with the lower portion 68 of the leg 70 is disposed below the support surface 64. The leg 70 is flexed so that a knee portion 76 of the leg is bent.

In accordance with another of the features of the present invention, the upper portion 72 of the leg 70 is supported above the support surface 64 by a leg support 80 (FIG. 2). The leg support 80 includes a stand or base section 82 which is connected with the operating table 66. The leg support 80 includes a base 84 which is connected with an upper end portion of the stand 82. The base 84 is engaged by and supports the upper portion 72 of the leg 70.

A generally annular thigh holder 86 extends around the upper portion 72 of the leg 70 of the patient and is connected with the base 84 and stand 82. The base 84 has a portion which extends along the posterior side of the upper portion 72 of the leg 70 of the patient. The base 84 supports the upper portion 72 of the leg 70 above and spaced from the support surface 64. However, the upper portion 72 of the leg 70 could be disposed in engagement with the support surface 64 if desired.

The leg support 80 supports the leg 70 of the patient with a hip 88 of the patient hyperflexed at an angle of twenty to thirty degrees throughout the operation on the knee portion 76. The leg support 80 may have a known commercial construction or may have a construction similar to that disclosed in U.S. Pat. Nos. 4,373,709 or 6,012,456. If desired, a tourniquet may be combined with the leg support 80 in a manner similar to that provided in known leg supports or in a manner similar to that disclosed in U.S. Pat. No. 4,457,302.

11

In accordance with another feature of the invention, the lower portion **68** (FIG. **3**) of the leg **70** is suspended from the upper portion **72** of the leg. This enables the foot **74** and ankle portion **86** of the leg **70** of the patient to be freely moved in any direction or a combination of directions. Thus, the foot **74** and ankle portion **86** of the leg **70** of the patient can be moved anteriorly or upward (as viewed in FIG. **3**) to decrease the extent of flexion of the knee portion **72** or even to extend or straighten the leg **70**.

Alternatively, the foot **74** and ankle portion **86** may be moved posteriorly toward the operating table **66**, from the position illustrated in FIG. **3**, to hyperflex the knee portion **72** of the leg of a patient. The foot **74** may be moved sidewardly, that is in either a lateral or medial direction. In addition, the foot **74** may be rotated about the longitudinal central axis of the lower portion **68** of the leg **70**.

It is contemplated that the foot **74** and ankle portion **86** may be simultaneously moved in a plurality of the directions previously mentioned. If desired, the upper portion **72** of the leg **70** of the patient may be supported on a separate section of the operating table **66**, in a manner similar to the disclosure in U.S. Pat. No. 5,007,912.

After a drape **90** has been positioned over the patient **62** and the operating table **66**, in the manner illustrated in FIG. **3**, the leg **70** extends out of the drape. The drape **90** may be connected with the leg support **80** and have an opening **92** (FIGS. **3** and **4**) through which the leg of the patient extends. This enables the leg **70** of a patient to be moved between the extended position illustrated in FIG. **4** and a hyperflexed position in which the foot **74** is disposed posteriorly from the position illustrated in FIG. **3**.

When the leg **70** is in a hyperflexed condition, the included angle between the upper and lower portions **72** and **68** of the leg **70** is less than ninety degrees. The leg **70** may be flexed from the extended position of FIG. **4** to a hyperflexed position by manually moving the foot **74** and an ankle portion **96** of the leg **70** relative to the operating table **66** (FIG. **2**) while the upper portion **72** of the leg is held by the leg support **80**. When the leg **70** is hyperflexed, a portion of the foot **74** may be disposed beneath the operating table **66** (FIG. **2**).

An improved drapery system **100** (FIG. **4**) includes the drape **90** and a drape **102** connected with a gown **104** on a surgeon **106**. The illustrated drape **102** is formed separately from the drape **90** and gown **104**. However, the drape **102** may be integrally formed as one piece with the drape **90**. Alternatively, the drape **102** may be integrally formed as one piece with the gown **104**.

In the embodiment illustrated in FIG. **4**, the drape **102** is formed separately from the gown **104** and the drape **90**. The drape **102** is connected to the drape **90** by suitable clamps **108**. The drape **102** is connected with the waist of the surgeon **106** by clamps **110** to the gown **104**. Rather than utilizing clamps **108** to interconnect the drapes **90** and **102**, the drapes could be interconnected by Velcro, ties, or other known devices. Of course, similar devices could be utilized to connect the drape **102** with the gown **104** of the surgeon **106**.

The improved drapery system **100** maintains a sterile field between the leg **70** and the surgeon **106** during movement of the surgeon relative to the patient **62**. Thus, when the surgeon is in a seated position (FIG. **4**) the drapery system **100** provides a sterile field which extends from the surgeon to the space beneath and adjacent to the leg **70**. When the surgeon stands (FIG. **5**) the drapery system **100** continues to maintain a sterile field between the surgeon and the patient. This enables the surgeon **106** to move the leg **70** of a patient

12

during an operation without contaminating the sterile field. The draping system **100** enables the sterile field to be maintained when the patient's leg is moved between the extended position of FIGS. **4** and **5** and a hyperflexed position in which the foot **74** of the patient is disposed beneath the operating table **66**.

During movement of the surgeon **106** relative to the patient, for example, between the seated position of FIG. **4** and the standing position of FIG. **5**, the drape **102** moves with the surgeon and maintains a sterile field. Thus, when the surgeon **106** moves toward and away from the patient, the end portion of the drape **102** connected with the surgeon also moves toward and away from the patient. As the surgeon moves toward the patient, a portion of the drape **102** between the surgeon **106** and patient is lowered. As the surgeon moves away from the patient, the portion of the drape **102** between the surgeon and patient is raised. The foot **74** connected with the leg **70** of the patient is always above the drape **102** during movement of the surgeon **106**.

Although the drapery system **100** has been illustrated in FIGS. **3-5** in association with a patient's leg **70**, the drapery system may be used in association with surgery on any desired portion of a patient's body. For example, the drapery system **100** could be used to maintain a sterile field between a surgeon and patient during surgery on a trunk portion of a patient's body. Alternatively, the drapery system **100** could be used to maintain a sterile field during surgery on a head or arm portion of a patient's body.

Incision

In accordance with another feature of the present invention, a limited incision **114** (FIG. **6**) is formed in the knee portion **76** of the leg **70**. The incision **114** is made just medial to the patella **120**. However, the incision **114** could be disposed laterally of the patella **120**. Although the length of the incision **114** may vary depending upon the circumstances, the incision **114** will usually have a length of between about seven (7) and about thirteen (13) centimeters. However, even smaller incisions may be made when circumstances permit.

The incision is made when the knee portion **76** of the leg is flexed and the lower portion **68** of the leg extends downward from the upper portion **72** of the leg in the manner illustrated in FIGS. **2** and **3**. At this time, the upper portion **72** of the leg **70** is supported above the support surface **64** by the leg support **80** (FIG. **2**). The lower portion **68** of the leg **70** is suspended from the upper portion **72** of the leg (FIGS. **2** and **3**).

When the knee portion **76** of the leg **70** is flexed so that the lower portion **68** of the leg is suspended at an angle of approximately ninety degrees relative to the upper portion **72** (FIGS. **2** and **3**), the incision **114** (FIG. **6**) may have a length of approximately ten (10) centimeters. When the leg **70** is straightened from the flexed condition of FIGS. **2** and **3** to the extended condition of FIGS. **4** and **5**, the length of the incision **114** may decrease by between ten and thirty percent. Thus, in one specific instance, an incision **114** had a length of approximately eleven (11) centimeters when the leg **70** was in the flexed condition of FIGS. **2**, **3** and **6** and a length of slightly less than ten (10) centimeters when the leg was in the extended condition of FIG. **5**. By making the incision **114** with the leg in a flexed condition (FIGS. **2**, **3**, and **6**) and operating on the leg **70** with the leg in a flexed condition, the overall length of the incision can be reduced from the length of incisions which have previously been made in the leg when it is in the extended condition.

It is preferred to have the incision **114** located adjacent to the medial edge of the patella **120**, in the manner illustrated

13

schematically in FIG. 6. However, the incision 114 could be located adjacent to the lateral edge of the patella 120 if desired. Alternatively, the incision 114 could be disposed midway between lateral and medial edges of the patella 120.

Although it is desired to minimize the length of the incision 114, it is contemplated that the incision may have a length of approximately twice the length of the patella. It may be desired to have the incision 114 extend from a proximal end of the tibia in the leg 70 to the epicondylar notch on the distal end portion of the femur in the leg 70. The length and location of the incision 114 may vary depending on the size of the implants to be positioned in the knee portion 76 and the location at which the implants are to be positioned. It is believed that it may be desired to have the incision 114 be smaller than the implants even though the implants must move through the incision. The viscoelastic nature of the body tissue and mobility of the incision 114 enables the implants to be larger than the incision and still move through the incision.

A straight incision 114 has been illustrated in FIG. 6. However, the incision 114 could have a different configuration if desired. For example, the incision 114 could have an L-shaped configuration. The incision 114 could be skewed at an acute angle to a longitudinal central axis of the patella 120. If desired, the incision 114 could have a configuration matching the configuration of either the lateral or medial edge of the patella 120.

Immediately after the incision 114 is formed, the leg 70 may be moved from the flexed condition of FIGS. 2 and 3 to the extended condition of FIG. 5. While the leg 70 is in the extended condition, the incision 114 (FIG. 7) is elastically expanded using suitable retractors. The retractors apply force against the viscoelastic body tissue of the knee portion 76. The retractors have a construction similar to that disclosed in U.S. Pat. No. 5,308,349. Alternatively, a pneumatic retractor, such as is disclosed in U.S. patent application Ser. No. 09/526,949 filed on Mar. 16, 2000 by Peter M. Bonutti may be utilized to expand the incision.

After the incision 114 has been elastically expanded, a patella 120 and tissue on the lateral side of the incision may be everted in a manner illustrated in FIG. 7. Thus, the patella 120 is moved from the normal orientation of FIG. 6 to the everted or flipped orientation of FIG. 7 while the leg 70 of the patient is in the extended orientation of FIG. 7. At this time, the inner side 122 of the patella 120 is facing outward away from other bones in the knee portion 76. The outer side of the everted patella 120 is facing inward toward other bones in the knee portion 76. This enables the inner side 122 of the patella 120 to be examined.

In order to enable a relatively small incision 114 to be used for operating on bones in the knee portion 76 of the leg 70 of the patient, the patella 120 is returned back to its normal position with the inner side 122 of the patella facing inward and the outer side of the patella facing outward. As this occurs, the opening at the incision 114 contracts. The retractors are then utilized to apply force against opposite sides of the incision 114. As this occurs, the viscoelastic body tissue is extended, the opening at the incision 114 is again expanded, and the patella 120 is pushed to the lateral side of the knee portion 76. This moves the patella 120 to a location offset to one side of the incision 114 in a manner illustrated in FIG. 8. The leg 70 is then flexed to the orientation shown in FIGS. 2 and 3.

If desired, the foregoing step of inverting the patella 120 may be omitted. The patella 120 may be left in orientations in which the inner side 122 of the patella faces inward throughout the operation. If this is done, the inner side 122

14

of the patella 120 may be inspected by tilting the patella from its normal orientation and/or using viewing devices, such as an endoscope. Regardless of how the inner side 122 of the patella 120 is inspected, moving the patella to the offset position of FIG. 8, with the inner side 122 facing inward, facilitates utilization of an incision 114 having a limited length. It is contemplated that many different surgical procedures could be conducted on the knee portion 76 with the patella 120 in the offset position of FIG. 8.

Femoral Procedure

Expansion of the incision 114 with the known retractors exposes a distal end portion 124 (FIG. 8) of a femur 126 in the upper portion 72 of the leg 70. The incision 114 is movable relative to the distal end portion 124 of the femur 126 to maximize exposure of the femur through the limited length of the incision. The femur 126 is then cut to receive an implant. Although either intramedullary or extramedullary instrumentation can be utilized, intramedullary instrumentation is used during cutting of the femur 126. Therefore, a drill 128 is utilized to access the intramedullary canal or marrow cavity in the femur 126.

The drill 128 is utilized to form a hole 130 in the center of the intercondylar notch in the distal end portion 124 of the femur 126 in a known manner. The drill 128 is used to form the hole 130 while the leg 70 is in the orientation illustrated in FIGS. 2 and 3. The patella 120 is in the offset position illustrated in FIG. 8. At this time, the inner side 122 (FIG. 7) of the patella faces toward the femur 126.

An epicondylar reference guide (not shown) engages the hole in the distal end portion 124 of the femur 126 to enable a line parallel to an epicondylar axis peaks of the medial and lateral condyles to be inscribed on the distal end portion 124 of the femur 126. At this time, the leg 70 is in the orientation illustrated in FIGS. 2, 3, 8 and 9. A shaft 132 (FIGS. 9, 10, 11 and 12) of a femoral alignment guide 134 is then inserted into the intermedullary opening 130.

The femoral alignment guide 134 is then aligned with the epicondylar line which extends parallel to the epicondylar axis through the peaks of the lateral and medial condyles on the distal end portion 124 of the femur 126. The femoral alignment guide 134 is utilized to support an anterior resection guide 138 and stylus 140 (FIGS. 10, 11 and 12) on the distal end portion 124 of the femur 126 in the upper portion 72 of the leg 70 of the patient. Although only the femur 126 is illustrated in FIGS. 10, 11 and 12, it should be understood that the leg 70 is in the orientation illustrated in FIGS. 2 and 3. The upper portion 72 of the leg 70 is supported by the leg support 80.

In accordance with one of the features of the present invention, the instrumentation is down sized to enable the size of the incision 114 (FIG. 9) to be minimized. The downsized instrumentation has a transverse dimension which is smaller than a transverse dimension of an implant to be placed in the knee portion 76 (FIG. 9). Thus, the femoral alignment guide 134 and anterior resection guide 138 have transverse dimensions, perpendicular to a longitudinal central axis of the femur 126, which are smaller than transverse dimensions of a femoral implant 290, tibial bearing insert 294, and a tibial tray 286 (FIG. 29) in a direction perpendicular to the longitudinal central axis of the femur 126 (FIG. 9).

The instrumentation extends from a center portion of the femur 126 toward one side of the femur (FIG. 11). In the particular operation illustrated schematically in FIGS. 7-12, the incision 114 is offset to the medial side of the patella 120. Therefore, the instrumentation is offset to the medial side of the femur 126. However, if the incision 114 is offset to the

15

lateral side of the patella 120, the instrumentation would be offset to the lateral side of the femur 126. If the incision 114 was centrally disposed relative to the femur 126, the instrumentation would be centrally disposed relative to the femur. Thus, the instrumentation is in general alignment with the incision 114 and extends only part way across the distal end portion 124 of the femur 126.

The femoral alignment guide 134 (FIGS. 10, 11 and 12) and anterior resection guide 138 have opposite ends which are spaced apart by distance which is less than a distance between epicondyles 148 and 150 on the distal end portion 124 of the femur 126. The distance between opposite ends 154 and 156 of the femoral alignment guide 134 is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 of the lateral and medial epicondyles 148 and 150. Similarly, a distance between an end 160 and an opposite end 162 of the anterior resection guide 138 is less than two thirds ($\frac{2}{3}$) of the distance between the tips 144 and 146 of the lateral and medial epicondyles 148 and 150.

The distance between opposite ends of a known femoral alignment guide and the distance between opposite ends of a known anterior resection guide are approximately the same as or greater than the distance between the tips 144 and 146 of the lateral and medial condyles 148 and 150. The distance between opposite ends of the known femoral alignment guide and the distance between opposite ends of the known anterior resection guide are greater than the transverse dimensions of the femoral and tibial implants 286, 290 and 294 (FIG. 29). This known anterior resection guide and femoral alignment guide are commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. under the designation "Scorpio" (trademark) Single Axis Total Knee System.

The incision 114 must be large enough to enable the femoral alignment guide 134 and the anterior resection guide 138 to pass through the incision. By reducing the size of the femoral alignment guide 134 and anterior resection guide 138, the size of the incision 114 can be reduced. Of course, reducing the size of the incision 114 reduces damage to body tissue of the patient 62. The femoral alignment guide 134 and the anterior resection guide 138 may be larger than the incision 114. This is because the incision 114 can be resiliently stretched and/or moved relative to the femur 126 to enable the femoral alignment guide 134 and anterior resection guide 138 to move through the incision.

The distance between opposite ends 154 and 156 of the femoral alignment guide 134 is less than the distance which a femoral implant extends across the distal end portion 124 of the femur 126. Similarly, the distance between opposite ends 160 and 162 of the anterior resection guide 138 is less than the distance which the femoral implant extends across the distal end portion 124 of the femur 126. The femoral alignment guide 134 and the anterior resection guide 138 both extend medially from a center portion of the femur 126. However, if the incision 114 was offset laterally of the patella 120, the femoral alignment guide 134 and the anterior resection guide 138 would extend laterally from the center portion of the femur 126. Similarly, if the incision 114 was centered relative to the patella 120, the femoral alignment guide 134 and anterior resection guide 138 would be centered relative to the femur 126.

Positioning of the femoral alignment guide 134 and anterior resection guide 138 on the distal end portion 124 of the femur 126 is facilitated by distracting the knee joint under the influence of the weight of the lower portion 68 of the patient's leg and the foot 74. Thus, when the femoral alignment guide 134 and anterior resection guide 138 are

16

positioned on the distal end portion 124 of the femur 126, the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg. At this time, the foot 74 is below the level of the support surface 64 (FIG. 2) on which the patient is disposed in a supine orientation. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2).

By distracting the knee joint under the influence of the weight of the lower portion 68 of the leg of the patient, the distal end portion 124 of the femur 126 is exposed through the relatively small incision 114 (FIG. 9). Exposure of the distal end portion 124 of the femur 126 at the limited incision 114 is promoted by moving the lower portion 68 of the leg 70 and the incision relative to the femur. In addition, exposure of the distal end portion 124 of the femur 126 is promoted by having the patella 120 offset to the lateral side of its normal position. The inner side 122 of the patella 120 faces inward toward the distal end portion 124 of the femur 126 so that the skin on the knee portion 76 is not excessively stretched by everting the patella.

In accordance with another feature of the present invention, the instrumentation is at least partially positioned between the distal end portion 124 of the femur 126 and body tissue of the knee portion 76 (FIG. 9). To enable the size of the incision 114 to be minimized, the instrumentation is moved laterally of the incision so that a portion of the instrumentation moves between the knee capsule and the end portion 124 of the femur 126. This results in a portion of the instrumentation being exposed at the incision 114 and a laterally extending portion of the instrumentation being concealed by body tissue. For example, the end 154 (FIG. 11) of the femoral alignment guide 134 and/or the end 160 of the anterior resection guide 138 are overlaid by body tissue adjacent to the lateral edge portion of the incision 114. The body tissue which overlies portions of the instrumentation may include skin, the knee capsule, and connective and soft tissues.

When the femoral alignment guide 134 and anterior resection guide 138 are connected with the femur 126, central axis of the femoral alignment guide and anterior resection guide are medially offset from the central axis of the femur. Thus, the central axis of the femur 216 extends through a lateral portion, that is, left portion as viewed in FIG. 11, of the femoral alignment guide 134. The anterior resection guide 138 is almost entirely offset to the right (as viewed in FIG. 11) of the central axis of the femur 126. The incision 114 is disposed along a medial edge, that is, a right edge as viewed in FIG. 6, of the patella 120 when the patella is in its normal or initial position.

By having both the incision 114 and the instrumentation medially offset relative to the femur 126, the central portion of the instrumentation is exposed at the incision. Thus, the medial edge of the incision overlaps the medial end 156 of the femoral alignment guide 134 and the medial end 162 of the anterior resection guide 138. Similarly, the lateral edge of the incision 114 overlaps the lateral end 154 of the femoral alignment guide 134 and the lateral end 160 of the anterior resection guide 138.

In view of the foregoing, it can be seen that the leg 70 (FIG. 3) of the patient 62 (FIG. 2) is maintained in the position illustrated in FIGS. 2 and 3 with the foot 74 of the patient below the support surface 64 upon which the patient is supported in a supine position during forming of the incision 114 in the knee portion 76 of the leg 70. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2). In addition, the leg of the patient is maintained in the position

17

illustrated in FIGS. 2 and 3 during connection of the femoral alignment guide 134 and anterior resection guide 138 with the distal end portion 124 of the femur 126.

Once the femoral alignment guide 134 and anterior resection guide 138 have been mounted on the distal end portion 124 of the femur 126, an anterior cut is made in the manner illustrated in FIG. 13. During the anterior cut, a blade 170 of a saw 172 is utilized to make a cut across anterior portions of the lateral and medial condyles. The saw blade 170 is moved along guide surface 178 (FIGS. 11 and 12) on the anterior resection guide 138.

The guide surface 178 extends only part way across of the end portion 124 of the femur 126 (FIGS. 11 and 13). The guide surface 178 does not extend across the lateral portion of the end portion 124 of the femur 126. This at least partially results from the fact that the incision 114 (FIG. 6) is offset in a medial direction from the center of the knee portion 76. The incision 114 extends along the medial edge portion of the patella 120 when the patella is in its normal, that is, initial, position. In addition, the large majority of the anterior resection guide 138 extends medially from the central axis of the shaft 132 of the femoral alignment guide 134 (FIG. 11). By having the anterior resection guide disposed in an overlying relationship with the medial portion of the end portion 124 of the femur 126 (FIGS. 11 and 13), the size of the incision 114 can be reduced.

When anterior portions of the lateral and medial condyles 148 and 150 (FIGS. 10, 11 and 12) on the distal end portion 124 of the femur 126 are to be cut with the saw 172, the blade 170 is pivoted sideways (FIG. 13) so that the cutting end of the blade has an arcuate component of movement. The cutting end of the blade 170 will move along a straight path during part of the movement of the blade along the guide surface 178. However, when the blade 170 reaches the ends of the guide surface 178, the saw 172 is pivoted to pivot the blade and move the cutting end of the blade along a path having an arcuate configuration. This results in a generally fan shaped cut which extends only part way across the anterior side of the lateral and medial condyles on the end portion 124 of the femur.

The saw blade may have teeth along opposite longitudinally extending edges. The saw blade 170 and saw 172 are of the oscillating type. However, a reciprocating type saw and blade may be utilized if desired.

Due to the limited length of the anterior resection guide 138, the saw blade 170 is moved along the guide surface 178 to only partially complete the anterior skim cut on the end portion 124 of the femur 126. The guide surface 178 is offset to the medial side of the central axis of femur 126 (FIG. 11). Therefore, the saw blade can only partially form the lateral portion of the anterior skim cut while the saw blade engages the guide surface 178. The anterior resection guide 138 is then disconnected from the femoral alignment guide 134 (FIGS. 14 and 15) and the anterior femur cut is completed.

During completion of the anterior femur (skim) cut, previously cut surfaces on the end portion 124 of the femur 126 are used to guide the saw blade 170 (FIG. 13). Thus, an initial portion of the anterior skim cut is made on the distal end portion 124 of the femur 126 while the saw blade 170 is moved along one or more guide surfaces on the anterior resection guide 138. After the anterior resection guide 138 has been disconnected from the femoral alignment guide 134, the saw blade 170 is positioned in engagement with the cut surfaces on the distal end portion 124 of the femur 126. This is accomplished by inserting the saw blade 170 into a slot or saw kerf formed in the distal end portion 124 of the femur during the initial portion of the anterior skim cut.

18

The saw blade 170 is then moved along the previously cut surfaces on the distal end portion of the femur 126 to guide the saw blade during completion of the anterior skim cut. Utilizing cut surfaces formed during an initial portion of the anterior skim cut to guide the saw blade 170 enables the size of the anterior resection guide 138 to be minimized. Although the illustrated saw blade 170 has teeth 180 at only one end, the saw blade could also have teeth along opposite longitudinally extending edges.

By utilizing the anterior resection guide 138 to guide movement of the saw blade 170 during only an initial portion of forming the anterior skim cut on the distal end portion 124 of the femur 126, the overall length of the anterior resection guide, that is, the distance between the ends 160 and 162 (FIG. 11) of the anterior resection guide can be limited to a distance which is less than the distance between the epicondyles 148 and 150. Specifically, the distance between the ends 160 and 162 of the anterior resection guide 138 is less than two thirds ($\frac{2}{3}$) of the distance between the tips 144 and 146 of lateral and medial epicondyles 148 and 150 on the distal end portion 124 of the femur 126. By limiting the length of the anterior resection guide 138, the size of the incision 114 can be minimized.

It is contemplated that the initial portion of the anterior skim cut could be made with a first cutting tool and the anterior skim cut completed with a second cutting tool. The initial portion of the anterior skim cut may be made with relatively small oscillating saw blade. The final portion of the anterior skim cut may be made with a larger reciprocating saw blade. Alternatively, a small milling cutter could be used to make the initial portion of the anterior skim cut. The final portion of the skim cut could be made with a relatively long milling cutter or saw blade. It may be desired to make the initial portion of the anterior skim cut with a chisel and to complete the anterior skim cut with either a saw blade or a milling cutter.

The illustrated anterior resection guide 138 has a slot which forms the guide surface 178. This results in the saw blade 170 being captured so that the saw blade is restrained against both up and down movement (as viewed in FIG. 11) relative to the anterior resection guide 138. However, in order to reduce the size of the anterior resection guide 138, the slot could be eliminated and the saw blade 170 moved along a flat outer side of the anterior resection guide.

During making of the anterior skim cut, with and without the anterior resection guide 138, body tissue (FIG. 9) overlies at least portions of the lateral and medial condyles being cut. This is due to the relatively short extent of the incision 114. Thus, the saw blade 170 and the portion of the femur 126 being cut by the saw blade are both at least partially enclosed by body tissue overlying the femur during making of the anterior skim cut. During making of the anterior skim cut, the incision 114 is moved relative to the femur 126 to provide clearance for the saw blade.

After the anterior portion of the lateral and medial epicondyles have been cut away and the anterior resection guide 138 removed, a flat anterior cut surface 182 (FIGS. 14 and 15) is disposed on the distal end portion 124 of the femur 126. The anterior skim cut is made on the distal end portion 124 of the femur 126 with the patella 120 offset to one side of the incision 118 (FIG. 14). The inner side of the patella 120 faces toward the distal end portion 124 of the femur 126 when the patella is in the offset position of FIGS. 9 and 14.

The flat anterior cut surface 182 (FIG. 15) extends parallel to the epicondylar axis. The maximum width of the anterior cut surface 182, as measured parallel to the epicondylar axis, is greater than the distance between opposite ends 154 and

156 (FIG. 11) of the femoral alignment guide 134. Similarly, the maximum width of the anterior cut surface 182 (FIG. 15), as measured parallel to the epicondylar axis, is greater than the distance between opposite ends 160 and 162 (FIG. 11) of the anterior resection guide 138. The anterior cut surface 182 is at least partially covered by body tissue which encloses the distal end portion of the femur 126 (FIG. 14).

During making of the anterior skim cut, the patient 62 (FIG. 2) is supported in a supine position on the support surface 64. The upper portion 72 of the leg 70 is disposed above the support surface on the leg support 80. The lower portion 68 of the leg 70 extends downward from the support surface 64. The foot 74 (FIG. 3) of the patient is disposed below the support surface.

Throughout the making of the anterior skim cut and the formation of the flat anterior cut surface 182 (FIGS. 14 and 15) on the distal end portion 124 of the femur 126, the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg in the manner illustrated in FIG. 3. This results in the knee portion 76 of the leg 70 being distracted by the combined weight of the lower portion 68 of the leg and the foot 74. At this time, the lower portion 68 of the leg 70 dangles from the upper portion 72 of the leg. If desired, a holder could be provided to engage either the foot 74 and/or the lower portion 68 of the leg 70 to maintain the foot 74 and lower portion 68 of the leg in a desired position relative to the support surface 64.

Once the anterior skim cut has been completed, a distal resection guide 186 is positioned relative to the flat anterior skim cut surface 182 (FIG. 16). To position the distal resection guide 186 relative to the cut surface 182, a resection guide stand 190 is mounted on the femoral alignment guide 134 in the manner illustrated in FIG. 16. The distal resection guide 186 is connected with the resection guide stand 190 by rotating a locking knob 192. The distal resection guide 186 and resection guide stand 190 may be magnetized to assure correct assembly. Since the femoral alignment guide 134 is medially offset relative to the distal end portion 124 of the femur 126, the distal resection guide 186 is also medially offset relative to the distal end portion of the femur.

When the distal resection guide 186 is to be connected with the resection guide stand 190, the distal resection guide is moved between the anterior skim cut surface 182 and body tissue overlying the anterior skim cut surface (FIG. 14). Thus, due to the limited extent of the incision 114, skin and other body tissues are disposed over the anterior skim cut surface 182. The distal resection guide 186 slides between the anterior skim cut surface 182 and the body tissue overlying the anterior skim cut surface. A lower (as viewed in FIGS. 16, 17 and 18) major side of the distal resection guide 186 engages the anterior skim cut surface 182. The opposite or upper (as viewed in FIGS. 16, 17 and 18) major side of the distal resection guide 186 is engaged by the body tissue overlying the anterior skim cut surface 182 (FIG. 14). The surgeon moves the incision 114 and/or the lower portion 68 of the leg 70 relative to the distal end portion of the femur 126 to facilitate movement of the distal resection guide 186 onto the anterior skim cut surface 182.

Once the distal resection guide 186 has been positioned in the desired location on the flat anterior cut surface 182, the distal resection guide 186 is secured in place with pins 196 and 198 (FIG. 16). At this time, body tissue overlies the portion of the distal resection guide 186 spaced from the distal end of the femur. The distal resection guide 186 is medially offset from a central portion of the femur 126 and is aligned with the incision 114. The incision 114 (FIG. 14)

is moved relative to the distal end portion 124 of the femur 216 to enable the pins 196 and 198 to be forced into the distal end portion of the femur.

The femoral alignment guide 134 and resection guide stand 190 are then separated from the distal end portion 124 of the femur 126 (FIGS. 17 and 18). As this is done, the resection guide stand 190 (FIG. 16) is separated from the distal resection guide 186. Separation of the resection guide stand 190 from the distal resection guide 186 is accomplished by rotating the knob 192 and moving the resection guide stand 190 upward (as viewed in FIG. 16) to disconnect the guide stand 190 from the femoral alignment guide 134. The intramedullary rod 132 and femoral alignment guide 134 are then removed from the femur 126. The distance between opposite ends 206 and 208 of the distal resection guide 186 is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 (FIG. 11) of the lateral and medial epicondyles 148 and 150.

The distal resection guide 186, like the anterior resection guide 138, is down sized to enable the distal resection guide to move into the knee portion 76 of the patient's leg 70 through a relatively small incision 114. To enable the distal resection guide 186 to move into the incision through a relatively small incision 114, opposite ends 206 and 208 (FIG. 16) of the distal resection guide 186 are spaced apart by a distance which is less than the distance between the lateral and medial epicondyles 148 and 150 (FIG. 11) on the distal end portion 124 of the femur 126. The distance between opposite ends 206 and 208 of the distal resection guide 186 is less than the distance which a femoral implant extends across the distal end portion 124 of the femur 126.

The distal resection guide 186 is offset medially relative to the distal end portion 124 of the femur 126. The incision 114 is also medially offset relative to the distal end portion 124 of the femur 126. This results in the central portion of the guide surface 202 being exposed through the incision 114. The lateral and medial edges of the incision 114 overlap opposite ends 206 and 208 of the distal resection guide 186. The incision 114 also overlaps the anterior side, that is, the upper side as viewed in FIG. 16, of the distal resection guide. During cutting with the saw blade 170 (FIGS. 17 and 18), the incision 114 is elastically expanded with suitable retractors.

During making of the distal femoral cut, the saw blade 170 moves along the guide surface 202 (FIG. 17) on the distal resection guide 186. The guide surface 202 on the down sized distal resection guide 186 has a length which is less than a transverse dimension of a cut to be made in the distal end portion 124 of the femur 126. The saw 172 may be pivoted, in a manner illustrated schematically in FIG. 13, adjacent to opposite ends of the guide surface 202. This moves the cutting end of the saw blade 170 along an arcuate path to form a generally fan shaped distal femoral cut. The saw 172 may be either a reciprocating or oscillating saw.

Due to the reduced size of the distal resection guide 186, the saw blade 170 (FIGS. 17 and 18) is ineffective to complete the distal femoral cut while the saw blade is in engagement with the guide surface 202 (FIGS. 16 and 17). Therefore, after an initial portion of the distal cut has been made by moving the saw blade 170 along the guide surface 202, the distal resection guide 186 is disconnected from the distal end portion 124 of the femur 126 and the distal femoral cut is completed.

During completion of the distal femoral cut, surfaces formed during the initial portion of the distal femoral cut are effective to guide the saw blade 170. The saw blade 170 (FIGS. 17 and 18) is moved into the saw kerf or slot formed

21

during the initial portion of the distal femoral cut. As the saw blade 170 extends the initial portion of the distal femoral cut, the saw blade slides along cut surfaces formed during the initial portion of the distal femoral cut. Thus, cut surfaces formed during movement of the saw blade 170 along the guide surface 202 are utilized to guide movement of the saw blade during completion of the distal femoral cut.

The initial portion of the distal femoral cut may be made with a first cutting tool and the final portion of the distal femoral cut may be made with a second cutting tool. For example, the initial portion of the distal femoral cut may be made with a relatively small oscillating saw blade which can be readily inserted through the incision 114 into engagement with the distal resection guide 186. The final portion of the distal femoral cut may be made with a larger saw blade which may be of the reciprocating type. It is contemplated that the initial and/or final portion of the distal femoral cut may be made with a milling cutter. It is also contemplated that a chisel may be used to make the initial and/or final portion of the distal femoral cut.

When the distal femoral cut is completed, a flat distal end surface 209 extends across the distal end of the femur 126 (FIG. 17). The distal end surface 209 extends perpendicular to the anterior cut surface 182. The maximum width of the distal end surface 209, as measured parallel to the anterior cut surface 182 and epicondylar axis, is greater than the distance between opposite ends 206 and 208 of the distal resection guide 186. The trochlear groove of the femur extends through the distal end surface 209.

The distal femoral cut is formed with the patella 120 (FIG. 14) offset to one side of the incision 114 and with the inner side 122 of the patella facing toward the distal end portion 124 of the femur 126. In addition, the leg 70 of the patient is in the orientation illustrated in FIGS. 2 and 3 with the foot 74 and lower portion 68 of the leg suspended from the upper portion 72 of the leg. The upper portion 72 of the leg is supported above the support surface 64 by the leg support 80.

A femoral cutting guide 210 (FIGS. 19 and 20) is then positioned on the distal end portion 124 of the femur 126 and utilized to make femoral anterior, posterior and chamfer cuts in a known manner. The femoral cutting guide 210 is connected with the distal end portion 124 of the femur 126 by two pins (not shown) in a known manner. The femoral cutting guide 210 is down sized so that it has opposite ends which are spaced apart by distance which is less than a distance between the lateral and medial epicondyles 148 and 150 (FIG. 11) on the distal end portion 124 of the femur 126. The femoral cutting guide 210 is offset in a medial direction from the center of the femur 126 (FIG. 20). The medially offset position of the femoral cutting guide 210 is the result of the medially offset position of the incision 114 (FIG. 6).

The initial portion of the femoral anterior, posterior and chamfer cuts are made by moving the saw blade 170 or other cutting tool along guide surfaces on the femoral cutting guide. Due to the relatively small size of the femoral cutting guide, the cuts cannot be completed while moving the saw blade 170 or other cutting tool along guide surfaces on the femoral cutting guide. Therefore, the femoral cutting guide 210 is separated from the distal end portion 124 of the femur 126 and the cuts are completed while guiding movement of the saw blade 170 or other cutting tool with cut surfaces formed during the making of the initial portions of the femoral anterior, posterior and chamfer cuts. When the femoral anterior, posterior and chamfer cuts are completed, the distal end portion 124 of the femur 126 will have the known configuration illustrated in FIGS. 22 and 23.

22

The femoral cutting guide 210 (FIGS. 19 and 20) may have the same construction as a femoral cutting guide which is commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. The femoral cutting guide may have the construction disclosed in U.S. Pat. Nos. 5,282,803 or 5,749,876. However, it is preferred to down size the known femoral cutting guides to have a distance between opposite ends which is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 (FIG. 11) of medial and lateral condyles 148 and 150 on the distal end portion 124 of the femur 126. This enables the femoral cutting guide 210 to move through the incision 114.

Since the femoral cutting guide 210 is down sized, initial portions of the femoral anterior, posterior and chamfer cuts are made while guiding a saw blade or other cutting tool with the femoral cutting guide. These cuts are subsequently completed utilizing previously cut surfaces to guide the saw blade 170. To complete a cut in this manner, the saw blade 170 or other cutting tool is moved along the previously cut surfaces to guide the saw blade as the cuts are extended.

During the making of the initial portions of the anterior, posterior and chamfer cuts with the femoral cutting guide 210 and the subsequent completion of the cuts without the femoral cutting guide, the knee portion 76 of the leg 70 of the patient is distracted by the weight of the lower portion 68 and foot 74 of the leg. Thus, the lower portion 68 and foot 74 of the leg 70 are suspended from the upper portion 72 of the leg in a manner illustrated in FIGS. 2 and 3 during the making of the femoral anterior, posterior and chamfer resections. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2).

By distracting the knee joint during the making of the femoral anterior, posterior and chamfer cuts, access to the distal end portion 124 of the femur 126 is promoted and the making of the cuts is facilitated. Access to the distal end portion 124 of the femur 126 is also promoted by moving the suspended lower portion 68 of the leg 70 relative to the distal end portion of the femur. The incision 114 may be moved relative to the distal end portion 124 of the femur 126 by applying force to body tissue adjacent to the incision.

Tibial Procedure

Since the knee portion 76 of the leg 70 is distracted, a proximal end portion 212 (FIG. 21) of a tibia 214 is separated from the distal end portion 124 of the femur 126. The foot 74 (FIG. 3) may be moved posteriorly to hyperflex the knee portion 76. This facilitates viewing of the proximal end portion 212 of the tibia 214 through the relatively small incision 114.

When the knee portion 76 (FIG. 2) is hyperflexed, the angle between the upper portion 72 and the lower portion 68 of the patient's leg 70 is less than ninety (90) degrees. At this time, the foot 74 is disposed posteriorly of the position illustrated in FIG. 2. This results in the proximal end portion 212 (FIG. 21) of the tibia 214 being moved anteriorly relative to the distal end portion 124 of the femur 126. The distal end portion 212 of the tibia 214 can then be viewed through limited incision 114. Even though the incision 114 has a relatively short length, it is possible to move the incision relative to the proximal end portion 212 of the tibia 214. Therefore, the entire or at least almost the entire, proximal end surface of the tibia 214 can be viewed through the incision 214.

It is contemplated that an external tibial alignment guide (not shown) will be utilized to align a tibial resection guide 218 (FIG. 21) with the proximal end portion 212 of the tibia 214. The tibial alignment guide has a known construction

and may be the same as is commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. Alternatively, the tibial alignment guide may have the construction disclosed in U.S. Pat. Nos. 5,578,039; or 5,282,803.

Once the tibial resection guide **218** (FIG. **21**) has been aligned with and secured to the proximal end portion **212** of the tibia **214**, the external tibial alignment guide (not shown) is disconnected from the tibial resection guide **218**. The tibial resection guide **218** is secured to the proximal end portion **212** of the tibia **214** by suitable pins.

In accordance with one of the features of the present invention, the tibial resection guide **218** is relatively small so that it can be moved through a relatively small incision **114** into engagement with the proximal end portion **212** of the tibia **214**. To facilitate moving of the tibial resection guide **218** through a relatively small incision **114**, the tibial resection guide **218** is smaller than implants **286** (FIG. **27**) and **294** (FIG. **28**) to be positioned on the proximal end portion **212** of the tibia **214**. The tibial resection guide **218** has a distance between opposite ends **228** and **230** (FIG. **21**) which is less than two thirds ($\frac{2}{3}$) of the distance between tips of lateral and medial epicondyles on the tibia **214**. Similarly, the distance between the ends **228** and **230** of the tibial resection guide **218** is less than two thirds ($\frac{2}{3}$) of the distance between tips **144** and **146** (FIG. **11**) of the lateral and medial condyles **148** and **150** on the femur **126**.

During positioning of the external tibial alignment guide and the tibial resection guide **218** (FIG. **21**) relative to the tibia **214** in the leg **70** of the patient, the leg **70** is supported in the manner illustrated in FIGS. **2** and **3**. Thus, the upper portion **72** (FIG. **2**) of the leg **70** is supported above the support surface **64** by the leg support **80**. The lower portion **68** of the leg **70** is suspended from the upper portion **72** of the leg. The foot **74** (FIG. **3**) connected with the lower portion **68** of the leg **70** is disposed below to support surface **64** (FIG. **2**).

During positioning of the tibial resection guide **218** on the proximal end portion **212** of the tibia **214**, the tibial resection guide is moved between the proximal end portion of the tibia and body tissue overlying the proximal end portion of the tibia. The tibial resection guide **218** is positioned relative to the proximal end portion **212** of the tibia **214** while the incision **114** is resiliently expanded. The incision **114** is expanded by applying force against opposite sides of the incision with suitable retractors. The retractors may have a construction similar to the construction disclosed in U.S. Pat. No. 5,308,349. Alternatively, a pneumatic retractor, such as is disclosed in U.S. patent application Ser. No. 09/526,949 filed Mar. 16, 2000 by Peter M. Bonutti may be used to expand the incision **114**.

The tibial resection guide **218** is slid inferiorly, that is, downward (as viewed in FIG. **21**) between the proximal end portion **212** of the tibia **214** and body tissue adjacent to the proximal end of the tibia. The tibial resection guide **218** is then connected to the proximal end portion **212** of the tibia **214** with suitable pins. Once the resection guide **218** has been connected with the tibia **214**, the force applied against opposite sides of the incision **114** by retractors is interrupted and the incision contracts. As this occurs, the body tissue moves over the lower (as viewed in FIG. **21**) portion of the tibial resection guide **218** to further enclose the tibial resection guide.

The tibial resection guide **218** is medially offset relative to the proximal end portion **212** of the tibia **214**. This is because the incision **114** is medially offset relative to the proximal end portion **212** of the tibia **214**. The incision **114**

extends from the proximal end portion **212** of the tibia **214** to the superior portion of the trochlear groove in the distal end portion **124** of the femur **126**. As was previously mentioned, the incision **114** and the instrumentation may be laterally offset relative to the femur **126** and the tibia **214**.

Once the tibial resection guide **218** (FIG. **21**) has been mounted on a proximal end portion **212** of the tibia **214**, a proximal tibial cut is made. The proximal tibial cut is made by moving the blade **170** of the saw **172** along a guide surface **242** on the tibial resection guide **218** (FIG. **21**). When the saw blade reaches an end portion of the tibial guide surface **242**, the saw **172** is pivoted to move the saw blade **170** in the manner illustrated schematically in FIG. **16**. This pivotal movement results in the cutting end portion of the saw blade **170** having an arcuate component of movement. This results in a generally fan shaped cut being formed in the proximal end portion **212** of the tibia **214**.

Due to the reduced size of the tibial resection guide **218** to facilitate movement of the tibial resection guide through the incision **114**, the saw **172** can only form an initial portion of the proximal tibial cut as the saw blade **170** moves along the guide surface **242** of the tibial resection guide **218**. To complete the proximal tibial resection cut, the tibial resection guide **218** is disconnected from the tibia **214**.

Once the tibial resection guide **218** has been separated from the tibia **214**, the saw blade **170** is inserted into the slit or kerf made by the saw blade during the initial portion of the proximal tibial cut. The cut surfaces which were formed during an initial portion of making the proximal tibial cut on the tibia **214** are then used to guide the saw blade **170** during completion of the proximal tibial cut. Thus, the saw blade **170** is moved along surfaces formed during the making of the initial portion of the proximal tibial cut to guide movement of the saw blade during completion of the proximal tibial cut.

It is contemplated that different cutting tools may be utilized to make the initial and final portions of the proximal tibial cut. Thus, the saw blade **170** used to make the initial portion of the tibial cut may be a relatively small oscillating blade and the saw blade used to make the final portion of the tibial cut may be a relatively long reciprocating blade. Alternatively, the initial and/or final portion of the tibial cut may be made with a milling cutter. If desired, a chisel could be utilized to make the initial portion of the tibial cut. The incision **114** may be expanded with suitable retractors during making of the tibial cut. The retractors may have any desired construction, including the construction disclosed in U.S. Pat. No. 5,308,349. Ligaments and other body tissue adjacent to the proximal end portion **212** of the tibia **214** may be shielded with suitable surgical instruments during making of the tibial cut.

Upon completion of the proximal tibial cut on the proximal end portion **212** of the tibia **214**, a flat proximal tibial cut surface **246** (FIG. **22**) is exposed on the proximal end portion **212** of the tibia **214** through the incision **114**. The flat cut surface **246** has a maximum width, as measured along an axis extending parallel to an axis extending through central axes of the collateral ligaments, which is greater than the distance between opposite ends **228** and **230** of the tibial resection guide **218**. The distal end portion **124** of the femur **126** is also exposed through the incision **118**.

In order to increase exposure of the proximal end portion **212** of the tibia **214** at the incision **218**, the foot **74** and lower portion **68** of the leg **70** (FIG. **24**) are moved posteriorly toward the operating table **66** (FIG. **2**) to hyperflex the knee portion **76** of the patient's leg **70** during the making of the proximal tibial cut. When the knee portion **76** of the leg **70**

25

is hyperflexed, the ankle **86** is moved from a position either extending through or anterior of a vertical plane extending perpendicular to a longitudinal central axis of the upper portion **72** of the patient's leg **70** to a position disposed posteriorly of the vertical plane. Thus, as viewed in FIGS. **2** and **24**, the ankle **86** is moved toward the left. As this occurs, an angle between a longitudinal central axis of the upper portion **72** of the patient's leg and the longitudinal central axis of the lower portion **68** of the patient's leg is decreased to an angle of less than ninety degrees.

Hyperflexing the patient's leg **70** moves the proximal end portion **212** (FIGS. **22** and **23**) of the tibia **214** anteriorly away from the distal end portion **124** of the femur **126**. At this time, the knee portion **76** of the patient's leg is distracted under the influence of the weight of the lower portion **68** of the patient's leg and the foot **74** connected with the lower portion of the patient's leg. If desired, a force pulling the lower portion of the patient's leg downward (as viewed in FIG. **3**) may be applied to the patient's leg to further increase the distraction of the knee portion **76** of the leg and the extent of exposure of the proximal end portion **212** of the tibia **214**.

By hyperflexing the knee portion **76** of the patient's leg **70** and applying a downward (as viewed in FIG. **3**) force against the lower portion **68** of the patient's leg, the proximal end portion **212** of the tibia **214** is delivered anteriorly that is, toward the surgeon **106** (FIG. **24**). Application of a downward force against the lower portion **68** of the patient's leg is effective to open the space between the proximal end portion **212** of the tibia **214** and the distal end portion **124** of the femur **126** to the maximum extent permitted by the tendons and ligaments, that is, fibrous connective tissue, interconnecting the femur and tibia.

This enables the posterior cruciate ligament **250** (FIG. **23**) to be checked. In addition, access is provided to the posterior side of the knee portion **76** of the leg **70**. The surgeon **106** (FIG. **24**) can manually feel the posterior portion of the knee joint. There is sufficient space between the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214** to enable the surgeon **106** to visually and tactilely check the posterior of the knee portion **76** of the patient's leg **70**.

Access to the posterior portion of the knee enables osteophytes, bone spurs and similar types of posterior soft tissue to be removed. This enables tissue which could block further flexion of the knee portion **76** to be removed. In addition, it is possible to check the collateral ligaments and other fibrous connective tissue associated with the knee.

At this time, the lower portion **68** of the leg **70** (FIGS. **23** and **24**) is suspended from the upper portion **72** of the leg. Therefore, the lower portion **68** of the leg **70** hangs from the upper portion **72**. The foot **74** may be supported on the surgeon's knee **252** (FIG. **24**). The foot **74** is free to move in any direction relative to the knee portion **76**. By raising or lowering his or her knee **252**, the surgeon **106** can move the tibia **214** relative to the femur **126** and vary the space between the distal end of the femur and the proximal end of the tibia.

By varying force indicated by arrows **256** (FIG. **25**), the vertical extent of space between the proximal end portion **212** of the tibia **214** and the distal end portion **124** of the femur **126** (FIGS. **22** and **23**) can be either increased or decreased. The force **256** is varied by raising and lowering the surgeon's knee **252**. Increasing the space between the proximal end portion **212** of the tibia **214** and the distal end portion **124** the femur **126** maximizes access to the posterior of the knee portion **76**.

26

By moving the lower portion **68** of the leg **70** upward, the ligaments and other connective tissue between the tibia **214** and femur **126** are relaxed. This enables the lower portion **68** of the leg **70** to be rotated about its longitudinal central axis, in a manner indicated by arrows **258** in FIG. **25**. Rotational movement of the lower portion **68** of the leg **70** about its central axis enables the surgeon to check the collateral ligaments and the resistance encountered to rotation of the lower portion **68** of the leg relative to the upper portion **72**.

In addition, the foot **74** can be pivoted in a clockwise direction (as viewed in FIG. **25**) about the knee portion **76**, in the manner indicated by arrow **259** in FIG. **25**, to increase the extent of flexion of the knee portion **76**. Alternatively, the foot **74** can be pivoted in a counterclockwise direction about the knee portion **76** to decrease the extent of flexion of the leg **70**.

The lower portion **68** of the leg **70** can also be moved sidewise, in the manner indicated by the arrow **260** in FIG. **25**. When the lower portion **68** of the leg **70** is moved in the manner indicated by the arrow **260**, the lower portion of the leg is moved along a path extending through lateral and medial surfaces of the foot **74** and the lower portion **68** of the leg **70**. This enables the ligaments and other fibrous connective tissue in the leg to be checked for a range of movement. Although the incision **114** has not been shown in FIG. **25**, it should be understood that the lower portion **68** of the leg **70** can be moved in the directions indicated by the arrows in FIG. **25** when the knee portion **76** is in the condition illustrated in FIGS. **22** and **23**.

The illustrated instrumentation is formed of a metal which enables the instrumentation to be sterilized and reused. For example, the instrumentation could be formed of stainless steel. However, known metal instruments are relatively heavy and bulky. This substantially increases transportation expense.

It is contemplated that it may be desired to use the instrumentation once and then dispose of the instrumentation. If this is done, the instrumentation may be partially or entirely formed of relatively inexpensive polymeric materials. Thus, the femoral resection guide **134**, anterior resection guide **138**, distal resection guide **186**, femoral cutting guide **210**, and/or tibial resection guide **218** could be formed of inexpensive polymeric materials. If this was done, the guides could be used once and disposed of without being sterilized. In addition, the polymeric guides would weigh substantially less than metal guides.

Implants

After the distal end portion **124** of the femur **126** has been prepared and the proximal end portion **212** of the tibia **214** is prepared to receive implants (FIGS. **22** and **23**) and prior to insertion of the implants, any necessary work on the patella **120** may be undertaken. During work on the patella, the leg **70** of the patient may be extended and the patella **120** is everted or flipped to the position illustrated in FIG. **7**. The inner side or articular surface **122** of the patella **120** faces outward and is exposed. Known surgical techniques are then utilized to cut the patella **120** and position an implant on the patella in a known manner. This may be accomplished utilizing any one of many known devices and procedures, such as the devices and procedures disclosed in U.S. Pat. Nos. 4,565,192; 5,520,692; 5,667,512; 5,716,360; and/or 6,159,246. If desired any necessary work on the patella **120** may be undertaken after the femoral and tibial implants have been installed.

Once the femoral and tibial cuts have been made and the patella repaired, femoral and tibial implants are installed in the knee portion of the leg **70**. Prior to permanently mount-

ing of the implants in the knee portion **76** of the leg **70**, trials are conducted, in a known manner, with provisional femoral and tibial implants. The provisional femoral and tibial implants are releasably positioned relative to the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**.

The provisional implants are intended to aid the surgeon **106** in assessment of the function and balance of the various ligaments. The trials enable the surgeon **106** to observe the relationship of the provisional femoral and tibial implants relative to each other during flexion and extension of the knee portion **76** of the leg **70**. The lower portion **68** of the leg **70** is suspended from the upper portion **72** of the leg (FIGS. **2** and **3**) during the trials with the provisional implants. Therefore, the lower portion of the leg **68** can be freely moved relative to the upper portion of the leg to check ligament balancing with the provisional implants. Since the lower portion of the leg **68** is suspended, it is possible to check for flexion and extension balancing of the ligaments and to check for rotational stability and rotational balancing of the ligaments during the trials with provisional implants. The lower portion **68** of the leg **70** can be moved with a combination of flexion or extension, rotation and sidewise movement.

The trials also enable the surgeon to check the manner in which the provisional implants interact with each other during flexion, extension, rotation, and sidewise movement. The manner in which the provisional femoral and tibial implants move relative to each other during combined bending and rotational movement of a patient's leg **70** enables a surgeon to check for the occurrence of excessive space or other undesirable situations between the provisional implants. During trials with provisional implants, the range of motion of the knee joint can be checked in both flexion/extension and rotation.

Utilizing known surgical techniques, it is very difficult, if not impossible, to check for both flexion/extension balancing, rotational balancing, and sidewise balancing during trials with provisional implants. With rotational balancing, the ligaments are balanced through multiple planes. When both flexion/extension and rotation are being checked, the surgeon can locate defects and improve the stability of the knee joint. The surgeon can assess the posterior cruciate ligament, collateral ligament balancing, and posterior capsule balancing. The surgeon can proceed with flexion/extension balancing of ligaments and rotational balancing of the ligaments. This enables the leg **70** to be examined throughout its range of motion during trials with provisional implants.

During an operation on the patient's leg **70**, the surgeon can apply upward force against the foot of the patient by resting the foot **74** on the surgeon's knee **252** (FIG. **23**) and raising the knee of the surgeon. Of course, when the foot **74** is to be lowered, the surgeon can lower the knee **252** upon which the foot **74** of the patient is resting. Alternatively, a pneumatic piston can be utilized to raise and lower the foot **74** of the patient.

Throughout the operation on the patient's knee **76**, the upper portion **72** of the patient's leg **70** is supported above the support surface **64** by the leg support **80**. This causes the hip of the patient to be hyperflexed by between 20 degrees and 40 degrees. Flexing of the hip by 20 degrees to 40 degrees improves rotational positioning and alignment. It also enhances the ability of the surgeon to hyperflex the knee portion **76** or to extend the knee portion during surgery. In addition, having the upper portion **72** of the patient's leg supported above the support surface **64** by the leg support **80**

improves suspension of the lower portion **68** of the leg from the upper portion **72** of the leg. It is believed that the combination of suspending the lower portion **68** of the leg **70** and having the upper portion **72** of the leg supported above the support surface **64** by the leg support **80** will enhance the ability of a surgeon to check ligament balancing in flexion/extension, and rotation during trials during which provisional femoral and tibial components are temporarily connected with the distal end portion **124** of the femur **126** and with the proximal end portion **212** of the tibia **214**.

During a portion of the trials, the patella **120** may be in the normal position relative to the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**. Therefore, during trials, it is possible to check tracking of the patella relative to the provisional femoral implant. This is done in order to prevent any possible interference of the patella **120** with the movement of the knee through its range of motion.

To install the trial femoral and tibial components, the proximal end portion **212** of the tibia **214** is prepared to receive the trial tibial implant. This is accomplished by positioning a tibial trial base plate **270** on the proximal end portion **212** of the tibia **214** (FIG. **26**). An alignment handle **272** is connected with the tibial trial base plate **270** to facilitate positioning of the tibial trial base plate relative to the proximal end portion **214** of the tibia.

The trial femoral implant (not shown) is then placed on the distal end portion **124** of the femur. This may be done in a known manner using a femoral impactor/extractor. A trial tibial bearing insert (not shown) is then mounted on the tibial trial base plate **270** in a known manner. Once this has been done, the trial provisional implants are used during conducting of trials with flexion/extension and rotational movements of the lower portion **68** of the patient's leg. When the trials are completed, the trial provisional implants are removed in a known manner.

After completion of the trials, the tibial trial base plate **270** is pinned to the proximal end portion **214** of the tibia. A tibial punch **274** (FIG. **26**) is positioned in a tibial punch tower (not shown) which is assembled onto the tibial trial base plate **270**. The tibial punch **274** is advanced relative to the tibial punch tower by impacting a mallet against the tibial punch. The foot **74** rests against the knee **252** of the surgeon during pounding of the tibial punch **274** into the tibia **214**. This results in the impaction forces being transmitted to the surgeon's knee **252** rather than to ligaments interconnecting the femur **126** and tibia **214**.

Once the tibial punch **274** has been advanced until it is fully seated on the base plate, the punch is removed. The tibial trial base plate **270** is then removed from the proximal end portion **214** of the tibia. Once the tibial trial base plate **270** has been removed, an opening **282** (FIG. **27**) formed in the proximal end portion **212** of the tibia **214** is exposed. The opening **282** has a configuration corresponding to the configuration of the tibial punch **274**.

A tibial tray **286** (FIG. **27**) forms a base portion of a tibial implant. The tibial tray **286** has a keel **288** with a configuration corresponding to the configuration of the tibial punch **274** (FIG. **26**) and the opening **282** (FIG. **27**) formed in the tibia **214**. The keel **288** (FIG. **27**) of the tibial tray **286** is covered with a suitable cement prior to being inserted into the opening **282**. If desired, the cement may be omitted.

A tibial component impactor/extractor may be used to insert the tibial tray **286** into the opening **282**. Once the tibial tray **286** has been mounted on the proximal end portion **212** (FIG. **28**) of the tibia **214**, a femoral component **290** (FIG. **29**) is mounted on the distal end portion **124** of the femur

126. A known femoral impactor/extractor may be used to position the femoral component 290 on the distal end portion of the femur. The femoral component 290 may be provided with or without an intramedullary stem. Cement may or may not be used in association with the femoral component 290. Once the femoral component 290 has been mounted on the distal end portion 124 of the femur 126, a tibial bearing insert 294 (FIGS. 28 and 29) is positioned in the tibial tray.

The femoral and tibial implants 286, 290, and 294 may have any one of many known constructions. For example, the femoral and tibial implants could have the construction of a knee replacement which is commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. under the designation of "Scorpio" (trademark) total knee. Rather than being a total replacement, the femoral and tibial implants could be for a partial knee replacement. Thus, the femoral and tibial implants 286, 290 and 294 could have a construction which is the same as is illustrated in U.S. Pat. No. 5,514,143. The femoral and tibial implants 286, 290 and 294 may be of either the cemented type or the cementless types.

Once the femoral component 290 has been positioned on the femur 126 and the tibial tray 286 and bearing insert 294 positioned on the tibia 214, ligament balancing is again conducted. The ligament balancing includes a check of stability of the joint in flexion, extension, and rotation. The ligament balancing check is performed with the lower portion 68 of the leg 70 suspended from the upper portion 72 of the leg. The upper portion 72 of the leg 70 is held above the support surface 64 (FIG. 2) by the leg support 80 during the ligament balancing.

Since the lower portion 68 of the leg 70 is suspended from the upper portion 72, in the manner illustrated in FIGS. 2, 3 and 25, the surgeon has a more natural feel of the true ligamentous structure. This is because tissues are not squashed or bunched in the back of the knee portion 76. Since the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg, the joint 76 is distracted without having the lower portion 68 of the leg jammed back against the upper portion 72 of the leg. With the leg suspended, a surgeon can view the tibial bearing insert 294 (FIG. 29) and the femoral component 290 to determine how the femoral and the tibial implants cooperate with each other and the ligaments, tendons, joint capsule and other tissues.

The knee portion 76 may be flexed and extended, by moving the lower portion of the leg 70 along the path indicated by arrow 259 in FIG. 25. In addition, the lower portion 68 of the leg 70 may be moved sideways, that is, laterally and/or medially, as indicated by arrow 260 in FIG. 25, to check for the occurrence of slight openings between the tibial bearing insert 294 (FIG. 29) and femoral component 290. The lower portion 68 of the leg can also be rotated about its longitudinal central axis, in the manner indicated by the arrow 258 in FIG. 25. By simultaneously applying a combination of rotational, sideward, and flexion or extension motion to the lower portion 68 of the leg 70, the surgeon can view the interaction between the tibial bearing insert 294 (FIG. 29) and femoral component 290 through the entire range of movement of the leg 70, including movement having rotational components.

By manually feeling resistance to flexion, rotational and/or sideward movement of the lower portion 68 of the patient's leg 70 (FIG. 25), the surgeon can check the balancing of ligaments and other tissues in the knee portion 76 of the leg. In addition, the surgeon can check the manner in which relative movement occurs between the tibial bear-

ing insert 294 and femoral component 290 (FIG. 29). If a check of the rotational alignment of the femoral and tibial implants indicates that they are misaligned, the surgeon can change the rotational positions of the implants. If the ligaments are too tight medially or laterally, the surgeon can release the ligaments to the extent necessary. Ligaments which are too loose can be tightened. Since the lower portion 68 of the leg 70 is suspended, the surgeon can feel the effects of any ligamentous imbalance and take corrective action.

A portion of the foregoing check of ligamentous balancing may be performed with the patella 120 offset to one side of the incision 114, in the manner illustrated in FIG. 29. This enables the surgeon to have a clear view of the tibial bearing insert 294 and femoral component 290 through the open incision 114. After conducting a complete check of the ligamentous balancing with the patella 120 offset to one side of its natural position, the patella can be moved back to its natural position.

When the patella 120 is moved back to its natural position, the incision 114 closes so that there is little or no exposure of the tibial bearing insert 294 and femoral component 290 to the view of the surgeon. However, the surgeon 106 can move the lower portion 68 of the leg 70 with flexion/extension motion, indicated by the arrow 259 in FIG. 25, and/or rotational motion, indicated by the arrows 258, or sideways motion indicated by arrows 260. During this motion of the lower portion 68 of the leg 70, the surgeon can check the manner in which the patella 120 interacts with the tibial and femoral implants and other tissues in the knee portion 76 of the patient's leg. By providing combinations of the foregoing rotational and flexion/extension motion of the lower portion of the leg 70, the manner in which the patella 120, with or without an implant thereon, tracks relative to the tibial and femoral implants can be readily checked.

In the foregoing description, the patella 120 was repaired after making the femoral and tibial cuts and before trials. However, it is contemplated that the patella 120 may be repaired after trials and after installation of the implants 286, 290 and 294. Of course, the patella 120 may not need to be repaired and will be maintained in its original condition.

It is contemplated that fluid operated devices may be utilized to release ligaments or other tissue. The fluid operated devices may be utilized to apply force to tissue to move tissue relative to a bone, to expand the tissue, or to lengthen the tissue. For example, a balloon or bladder may be placed between tissue at the posterior of the knee portion 76 prior to mounting of the implants 286, 290 and 294. The balloon may be inflated with gas or the bladder filled with liquid to move tissue relative to the distal end portion 124 of the femur 126 and relative to the proximal end portion 212 of the tibia 214. The balloon or bladder may be used to move tissue before or after making of the femoral and/or tibial cuts. The balloon or bladder may be used to move tissue before or after the trial implants are positioned in the knee portion 76. The balloon or bladder may be used to move tissue before or after the implants 286, 290 and 294 are positioned in the knee portion 76.

The balloon or bladder maybe formed of biodegradable or non-biodegradable material. If the balloon or bladder is formed of biodegradable material, it may be left in the knee portion during and after closing of the incision 114. Of course, the biodegradable balloon or bladder will eventually be absorbed by the patient's body.

It is contemplated that fluid operated retractors, expanders, and/or dissectors may be used to retract, expand or dissect body tissue. For example, retractors having a construction similar to any one of the constructions dis-

31

closed in U.S. Pat. No. 5,197,971 may be utilized to release tissue at locations spaced from the incision 114. When tissue is to be released at locations where there is limited accessibility from the incision 114, a device similar to any one of the devices disclosed in U.S. Pat. No. 5,295,994 may be utilized. It is believed that devices similar to those disclosed in U.S. patent application Ser. No. 09/526,949 filed Mar. 16, 2000 may be used in ways similar to those disclosed therein to move and/or release body tissue.

While the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg and while the upper portion of the leg is held above the support surface 64 by the leg support 80, the incision 114 in the knee portion 76 of the leg 70 is closed. Prior to closing of the incision 114, the incision is thoroughly drained. Tissues in the knee portion 78 are then interconnected using a suture or other suitable devices. The soft tissues are closed in a normal layered fashion.

Review

With the exception of the procedure on the patella 120 (FIG. 7), all of the foregoing procedures were performed with the leg 70 of the patient in the orientation illustrated in FIGS. 2, 3 and 25. Thus, with the exception of procedures on the patella 120, all of the foregoing procedures were conducted with the lower portion 68 of the leg 70 suspended from the upper portion 72 of the leg.

The incision 114 (FIG. 7) was made in the knee portion 76 of the leg 70 with the lower portion 68 of the leg suspended. Similarly, the incision 114 in the knee portion of the leg 70 was closed with the lower portion 68 of the leg suspended from the upper portion 72 of the leg. Thus, from the making of the incision 114 in the knee portion 76 of the leg 70 through the closing of the incision, the lower portion 68 of the leg is almost continuously extended downward from the upper portion 72 of the leg and the foot 74 was below the support surface 64. In addition, the upper portion 72 of the leg was supported above the support surface 64 by the leg support 80. Only during everting of the patella 120 (FIG. 7) and resecting of the patella to receive an implant was the leg 70 of the patient in an extended or straightened orientation. However, the leg 70 of the patient could be extended or straightened at any time the surgeon desires during the foregoing procedure.

Throughout the entire procedure, the drapery system 100 (FIGS. 4 and 5) maintained a sterile field between the surgeon 106 and the patient. As the surgeon moved between seated and standing positions and moved toward or away from the patient, the drape 102 would rise or fall. Thus, when the surgeon 106 moves from the seated position of FIG. 4 to the standing position of FIG. 5, the drape 102 tends to rise upward with the surgeon. Similarly, when the surgeon moves from the standing position of FIG. 5 back to the seated position of FIG. 4, the drape 102 tends to move downward. The drape 102 will tend to move upward as the surgeon moves away from the leg 70 of the patient and will tend to move downward as the surgeon moves toward the leg 70 of the patient. Although it is preferred to use the drapery system 100 illustrated in FIGS. 4 and 5, it is contemplated that a different drapery system could be utilized if desired.

It is believed that it will be particularly advantageous to utilize down sized instrumentation in performing the foregoing procedures on the knee portion 76 of the patient. The femoral alignment guide 134 (FIGS. 10-15), anterior resection guide 138 (FIGS. 10-13), resection guide stand 190 (FIG. 16), distal resection guide 186 (FIGS. 16-18), and tibial resection guide 218 (FIG. 21) all have sizes which are two thirds ($\frac{2}{3}$) of their normal sizes or smaller. However, the

32

various down sized instrumentation components of FIGS. 9-21 are utilized in their normal manner and have generally known constructions. Thus, the instrumentation of FIGS. 9-21, with the exception of being down sized, is generally similar to known instrumentation which is commercially available from Howmedica Osteonics Corp. of Rutherford, N.J. under the trademark "Scorpio" single access total knee system.

As was previously mentioned, it is contemplated that extramedullary and/or intramedullary instrumentation could be utilized if desired. Although it is believed that it may be preferred to use instrumentation which is anteriorly based, it is contemplated that posteriorly based instrumentation systems could be used if desired.

In the foregoing description, the saw 172 and blade 170 (FIG. 15) were utilized to make cuts in various bones in the knee portion 76 of the leg 70 of the patient. The saw 172 and blade 170 may be of either the oscillating or reciprocating type. However, it is contemplated that other known cutting instruments could be utilized. For example, a milling device could be utilized to form at least some of the cuts. Alternatively, a laser or ultrasonic cutter could be utilized in making some of the cuts. It is believed that it may be particularly advantageous to utilize a laser or ultrasonic cutter to initiate the formation of a cut and then to utilize a saw or other device to complete the cut.

It is contemplated that either extramedullary or intramedullary instrumentation having a construction which is different than the illustrated construction could be utilized. For example, the anterior resection guide 138 FIGS. 10, 11 and 12 has a guide surface 178 which is formed by a slot through which the saw blade extends. If desired, the guide surface 178 could be provided on an end face without providing for capturing or holding of the saw blade 170 in a slot.

The instrumentation may be entirely or partially formed of light weight polymeric materials which are relatively inexpensive. A femoral cutting guide 210 has a size which corresponds to the size of the specific femoral component 290 which is to be installed on the distal end portion 124 of a femur 126. An inexpensive femoral cutting guide 210, formed of polymeric material, may be packaged along with a femoral component 290 of the same size. After the femoral component 290 is installed, the femoral cutting guide 210 may be discarded. This would minimize investment in instrumentation and would tend to reduce the cost of handling and/or sterilizing cutting guides. The result would be a reduction in cost to the patient.

It is contemplated that the use of guide members, corresponding to the anterior resection guide 138 of FIG. 11, the distal resection guide 186 of FIG. 16, and the tibial resection guide 218 of FIG. 21 could be eliminated if desired. If this was done, positioning of a saw blade or other cutting device could be provided in a different manner. For example, light forming a three dimensional image could be projected onto the distal end portion 124 of the femur 126. The three dimensional image would have lines which would be visible on the surface of the end portion 124 of the femur 126. The saw cut would be formed along these lines. Alternatively, robot type devices having computer controls could be utilized to form the cuts without using guide members.

It is contemplated that computer navigation systems could be pinned onto the femur 126 and tibia 214 to provide cutting positions and to facilitate ligament balancing through relatively small incisions. The computer navigation system may utilize three or four separate registers which have optical feedback to a central unit. The computer navigation system may utilize electromagnetic or photo-optical feedback.

It is contemplated that various known structures could be utilized in association with the leg 70 of the patient during performing of one or more of the procedures described herein. For example, the apparatus disclosed in U.S. Pat. No. 5,514,143 could be connected with the leg 70 of the patient and used to control flexion and extension of the leg. Since the apparatus disclosed in U.S. Pat. No. 5,514,143 includes separate femoral and tibial sections, it is believed that this apparatus may be particularly well adapted for use with the leg of the patient in the orientation illustrated in FIGS. 2, 3 and 25. This apparatus does not interfere with distraction of the knee portion 76 and can accommodate flexion and extension of the leg 70 of the patient.

The foregoing description has primarily referred to a full knee replacement. However, it is contemplated that the apparatus and procedures disclosed herein may be utilized in association with a revision or partial knee replacement. For example, the method and apparatus disclosed herein could be utilized in association with a unicompartmental knee replacement of the type disclosed in the aforementioned U.S. Pat. No. 5,514,143. The method and apparatus disclosed herein could be utilized in association with a revision of a previously installed full or partial knee replacement. It is also contemplated that the procedures disclosed herein and apparatus similar to the apparatus disclosed herein may be utilized with many different types of joints. For example, the procedures and apparatus may be utilized in association with a joint in an arm, shoulder, spine or hip of a patient.

Support Assembly
In accordance with one of the features of the invention, a support assembly 330 (FIG. 30) is provided for the lower portion 68 of the leg 70 of the patient. Rather than support the foot 74 of the patient on the knee 252 of the surgeon (FIG. 24), as previously described herein, the support assembly 330 may be utilized. The support assembly 330 includes a flat surface 332 which engages the foot of the patient. A pneumatically actuated piston and cylinder assembly 334 is operable to raise and lower the foot 74 of the patient in the manner indicated schematically by an arrow 336 in FIG. 31.

When the knee portion 76 of the leg 70 is to be distracted, the piston and cylinder assembly is operated to lower the surface 332 and foot 74 of the patient. As this occurs, the weight is transferred from the foot 74 of the patient to the support surface decreases until the support surface 332 is below and spaced from the foot 74. Similarly, when the extent of distraction of the knee portion 76 is to be decreased, the piston and cylinder assembly 334 is operated to raise the support surface 332 and foot 74 of the patient.

By providing a flat support surface 332, the lower portion 68 of the leg of the patient may be rotated about its longitudinal central axis relative to the upper portion 72 of the leg of the patient when the support assembly 330 is being utilized to at least partially support the lower portion 68 of the leg of the patient. However, it is contemplated that a foot holder could be provided in place of the flat surface 332. The foot holder would have the advantage of being able to hold the foot 74 of the patient in a desired orientation relative to the upper portion 72 of the leg 70 of the patient. The foot holder could be constructed so as to have a pneumatically actuated drive to rotate the foot 74 about the longitudinal central axis of the leg 70 and/or lower portion 68 of the leg 70 of the patient.

The support surface 332 is raised and lowered by operation of the piston and cylinder assembly 334. Therefore, operation of the piston and cylinder assembly 334 is effective to move the lower portion 68 of the leg 70 of the patient

in the directions of the arrow 256 in FIG. 25. It is contemplated that a drive assembly could be connected with the support surface 332 to rotate the support surfaces about a vertical axis. The drive assembly may include a rack and pinion drive arrangement or a worm and wheel drive arrangement. By rotating the support surface 332 about a vertical axis relative to the piston and cylinder assembly 334, movement of the lower portion 68 of the leg 70 in the directions of the arrow 258 in FIG. 25 would be facilitated.

Percutaneous Instrumentation Mounting

In accordance with another feature of the invention, it is contemplated that the size of the incision 114 may be reduced by connecting one or more of the guide members with one or more bones through the skin of the patient. For example, the anterior resection guide 138 (FIGS. 10 and 11), distal resection guide 186 (FIG. 16), femoral cutting guide 210 (FIGS. 19 and 20), and/or tibial resection guide 218 (FIG. 21) could be mounted on the outside of the leg 70 and connected with bone in either the upper portion 72 or the lower portion 68 of the leg 70 of the patient. This would minimize or even eliminate the necessity of moving the guide through the incision 114 into engagement with the bone. It would also minimize or even eliminate the necessity of sizing the incision 114 so as to accommodate the guide.

For example, the distal resection guide 186 (FIGS. 16-18) is illustrated schematically in FIG. 31 as being mounted outside of the upper portion 72 of the leg 70 of the patient. The distal resection guide 186 is illustrated in FIG. 31 as being disposed in engagement with an outer surface of skin 342 which encloses the distal end portion 124 of the femur 126. The distal resection guide 186 is mounted directly outward of the flat anterior cut surface 182 formed on the distal end portion 124 of the femur 126. The skin 342 and other body tissue extends between the distal resection guide 186 and the distal end portion 124 of the femur 126.

The distal resection guide 186 is connected with the femur 126 by the pins 196 and 198. The pins 196 and 198 extend through the distal resection guide 186 and the skin 342 into the femur 126. The pins 196 and 198 extend through the flat anterior cut surface 182 into the femur 126 and hold the distal resection guide 186 against movement relative to the femur 126.

Although a distal resection guide 186 has been illustrated in FIG. 32, it is contemplated that an anterior resection guide, corresponding to the anterior resection guide 138 of FIG. 11 could be mounted in a similar manner. If this was to be done, the anterior resection guide 138 would have a generally L-shaped configuration with a body portion which would extend along the outer surface of the skin 342 (FIG. 32). Pins, corresponding to the pins 196 and 198 of FIG. 32, would extend through the relatively long body portion of the generally L-shaped anterior resection guide 138, through the skin 342 and into the femur 126.

The short leg of the L-shaped anterior resection guide 138 would be positioned adjacent to the distal end portion 124 of the femur 126. The short leg of the anterior resection guide would have a guide surface aligned with the distal end portion 124 of the femur 126 at a location corresponding to the location where the flat anterior cut surface 182 is to be formed. This guide surface could be of the slot or capture type illustrated in FIG. 14. Alternatively, the guide surface could be formed on a flat end face of the anterior resection guide. This would result in elimination of the slot commonly utilized to capture a saw blade or other cutting instrument. By having a portion of the anterior resection guide disposed outside of the incision 114 and connected with the femur 126 through the skin 342, the size of the incision 114 tends to be minimized.

35

In addition to the aforementioned guides associated with the femur 126, it is contemplated that a guide associated with the tibia 214 (FIG. 21) could be connected with the tibia by pins extending through the skin 342. For example, the tibial resection guide 218 could be placed in abutting engagement with skin which overlies the proximal end portion 212 of the tibia 214. Suitable pins would extend through the tibial resection guide 218 (FIG. 21) and through the skin 342 (FIG. 31) into engagement with the distal end portion 212 of the tibia. Although it may be preferred to provide a tibial guide surface 242 of the slot type illustrated in FIG. 22, it is contemplated that only a single guide surface could be provided on a flat end portion of the tibial resection guide if desired.

Inspection

It is contemplated that at various times during the performance of the foregoing procedures, it may be desired to inspect locations remote from the incision 114. Thus, it may be desired to visually ascertain the condition of soft tissue in the posterior of the knee portion 76. In addition, it may be desired to visually check the condition of the collateral ligaments or soft tissue adjacent to the ligaments. The inspections may be conducted before or after the making of femoral and tibial cuts, before or after trials, and/or before or after installation of the implants 286, 290 and 294.

In accordance with another feature of the invention, locations remote from the limited incision may be visually inspected. To inspect locations remote from the incision 114, a leading end portion 350 (FIG. 32) of an endoscope 352 is inserted through the incision 114 and moved to the posterior of the knee portion 76. A camera 354 transmits an image to a monitor 356. The surgeon 106 can then view images of the posterior of the knee portion 76 transmitted through the endoscope 352. The upper portion 72 of the leg 70 is supported by the leg support 80. The leg 70 is shown in FIG. 32 in the same position illustrated in FIGS. 2 and 3.

In order to provide the surgeon 106 with information as to how the femoral and tibial implants 286, 290 and 294 interact with tissues in the knee portion 76, the leg 70 of the patient may be bent between the flexed condition of FIG. 32 and the extended condition of FIG. 33. In addition, the lower portion 68 of the leg 70 may be rotated about its longitudinal central axis, in the manner indicated by the arrow 258 in FIG. 25. During bending of the knee portion 76, the surgeon views images of the posterior knee portion transmitted through the endoscope 352 to the monitor 356. This enables the surgeon to detect any present or potential interference of tissue in the knee portion 76 with the full range of motion of the knee portion. During relative movement between the femur 126 and tibia 214, the surgeon can view the manner in which the femoral and tibial implants interact with each other and the tissue in the joint capsule.

It is contemplated that the end portion 350 of the endoscope 352 will be moved so as to enable the surgeon 106 to view the collateral ligaments, particularly the ligament on the lateral side of the knee portion 76, during bending of the knee portion. Although the endoscope 352 is illustrated in FIGS. 32 and 33 as being utilized after the femoral and tibial implants 286, 290 and 294 have been connected with the femur 126 and tibia 214, it is contemplated that the endoscope will be utilized prior to cutting of the femur and tibia, after cutting of the femur and tibia and prior to trials, after trials, and/or during trials.

It is contemplated that the endoscope 352 may be inserted into the knee portion 76 of the patient at a location other than through the incision 114. Thus, if desired, a separate, very small portal or puncture type incision could be formed in the

36

knee portion 76 of the leg of the patient at a location adjacent to a location where it is desired to visually inspect the knee portion of the patient. Although it is believed that it will be desired to inspect the knee portion 76 of the patient while there is relative movement between the femur 126 and tibia 214, it should be understood that the endoscope 352 could be utilized to inspect the knee portion 76 while the femur 126 and tibia 214 are stationary relative to each other.

Although an endoscope 352 is illustrated in FIGS. 32 and 33, it is contemplated that other known devices could be utilized to inspect knee portion 76. Thus any desired fiber optic type instruments may be utilized to inspect the knee portion 76. For example any of the known instruments associated with arthroscopic surgery could be utilized to inspect the knee portion 76.

Generation of Images and Robotic Device

In accordance with another feature of the invention, during performance of surgery on a knee portion 76 of a patient's leg 70 (FIG. 34), a known C-arm fluoroscope 360 is utilized to generate images of the knee portion 76 of the leg 70 during movement of the lower portion 68 of the leg relative to the upper portion of the leg. Images are transmitted in any fashion from the C-arm fluoroscope 360 to a control unit 362. Video images are transmitted from the control unit 362 to a video screen 364 which is viewable by the surgeon 106 during surgery on the knee portion 76 of the leg 70. A continuous display of images is projected in rapid succession on the screen illustrating the knee portion 76 of the leg 70 when the lower portion 68 of the leg is in various positions relative to the upper portion of the leg.

Thus, during flexion and/or extension of the leg 70, video images are transmitted to the screen 364 to enable a surgeon to view images of the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 during bending of the knee portion. The video display of images may be undertaken prior to forming of the incision 114 to enable the surgeon to view the manner in which components of the knee portion 76 interact prior to surgery. After the incision 114 has been made, the images provided on the video screen 364 enable the surgeon to visually determine the relationship between the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 after the patella 120 has been moved to an offset position and prior to initiating any cuts on the bones in the patient's leg 70.

After cuts have been made on the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 in the manner previously explained, the lower portion 68 of the patient's leg can be moved relative to the upper portion 72 of the patient's leg. The images provided on the video screen 364 will enable a surgeon to better understand the relationship between the femur, tibia, and ligaments in the patient's leg during preliminary checking of ligament balancing after the distal end portion 124 of the femur 126 has been cut and after the proximal end portion 212 of the tibia 214 has been cut.

During trials when trial tibial and femoral components have been temporarily connected with the femur 126 and tibia 214, the images provided at the video screen 364 will enable the surgeon to better evaluate the interaction between the trial components and body tissue in the knee portion 76 of the patient's leg 70. Once the trials have been completed and the femoral and tibial implants 286, 290 and 294 positioned on the femur 126 and tibia 214, the images provided at the video screen 364 will enable the surgeon to evaluate the relationship between the femoral and tibial implants.

37

During ligamentous balancing, images provided at the video screen 364 will indicate to the surgeon whether or not there is any undesired relative movement between the femoral and tibial implants. It is contemplated that the images be transmitted from the control unit 362 to the video screen 364 during movement of the lower portion 68 of the patient's leg 70 in any one or a combination of the directions indicated by the arrows 256, 258, 259 and 260 in FIG. 25. Once the surgeon, with the assistance of images provided at the video screen 364, is satisfied that the femoral and tibial implants 286, 290 and 294 have been correctly positioned in the knee portion 76 of the patient's leg 70, the incision 114 is closed.

The general construction and mode of operation of the C-arm fluoroscope 360 (FIG. 34) and control unit 362 is the same as is disclosed in U.S. Pat. Nos. 5,099,859; 5,772,594; 6,118,845 and/or 6,198,794. However, it is contemplated that other known image generating devices could be utilized in place of the fluoroscope if desired. For example, an image generating device similar to a magnetic resonance imaging unit (MRI) could be utilized.

In accordance with still another feature of the invention, a robot 370 (FIG. 34) is provided to perform cutting and/or implant placement operations on the knee portion 76 in the leg 70 of a patient. The robot 370 includes a base 372. A support column 374 is moveable vertically relative to the base 372, in a manner indicated by arrows 376 in FIG. 34. In addition, the support column 374 is rotatable about coincident longitudinal central axes of the base 372 and support column in a manner indicated schematically by arrows 378 in FIG. 32. A main arm 382 is pivotally attached to an upper end portion of the support column 374. Motors and controls 386 are connected with the main arm 382. The main arm is pivotal relative to the support column 374 in the manner indicated by arrows 388 in FIG. 34.

A secondary arm 390 is pivotally mounted on an outer end portion of the main arm 382. The secondary arm 390 is pivotal relative to the main arm 382 in the manner indicated by arrows 392. A mounting section 396 is rotatable about a longitudinal central axis of the secondary arm 390 and has a mounting flange which is rotatable about an axis which extends perpendicular to the longitudinal central axis of the secondary arm 390.

It is contemplated that a cutting tool, such as the saw 172, may be mounted on the mounting section 396. Controls for the robot 370 effect movement of the saw relative to the distal end portion 124 of the femur 126 to form the anterior cut surface 182 on the femur and to form a distal end cut on the femur. In addition, the robot 370 moves the saw to form chamfer cuts on the distal end portion 124 of the femur 126.

The robot 370 may also be utilized to move the saw to make the cuts to form the proximal end portion 212 of the tibia 214. Thus, the robot may be utilized to form the proximal tibial cut surface 246 (FIG. 22).

By using the robot 370 to move the saw to form the cuts on the distal end portion 124 of the femur 126 and on the proximal end portion 212 of the tibia 214, the need for instrumentation, such as the femoral alignment guide 134 and anterior resection guide 138 of FIG. 11, the distal resection guide 186 of FIGS. 16 and 18, and the tibial resection guide 218, is eliminated. Controls for the robot 370 are connected with the C-arm fluoroscope 360 to enable the position of the saw relative to the femur and tibia to be viewed by the surgeon during an operation.

The robot 370 may have any one of many different constructions. Specifically, it is contemplated that the robot 370 may have the same construction as is disclosed in U.S. Pat. No. 5,154,717. Alternatively, the robot 370 could have

38

the construction disclosed in U.S. patent application Ser. No. 09/789,621 filed Feb. 21, 2001 by Peter M. Bonutti. However, it should be understood that other known robots could be utilized if desired. For example, a robot similar to the known "Robo Doc"™ could be utilized.

It is contemplated that a computer navigation system may be used with the robot 370 to guide movement of a cutting tool, such as a saw or milling cutter, relative to the tibia and femur in the leg 70 of the patient. Two or more locating devices are connected with the distal end portion 124 of the femur 126. In addition, two or more locating devices are connected to the proximal end portion of the tibia 214. The locating devices cooperate with motors and computer controls 386 for the robot 370 to provide the robot with information as to the position of the mounting section 396 and cutting tool relative to the femur 126 and tibia 214.

The locating devices may be of the reflective or energy emitting type. For example, three reflectors may be pinned onto the distal end portion 124 of the femur 126. Similarly, three reflectors may be pinned onto the proximal end portion 212 of the tibia 214. Light transmitted from the robot 370 to the reflectors on the femur and tibia is reflected back to photo cells on the robot to enable the robot to determine the positions of the femur and tibia. Rather than using reflectors, energy emitting devices may be pinned onto the femur 126 and tibia 214. The energy emitting devices may emit either light or radio waves.

It should be understood that the robot 370 could have any one of many different constructions. It is also contemplated that the robot 370 could interact with a surgeon and patient in many different ways. For example, the robot could have a plurality of articulate arms which are controlled by the surgeon. Images provided by the fluoroscope 360 would enable the surgeon to control the articulate arms. Locating devices connected with the femur and tibia are visible to the surgeon in images provided by the fluoroscope 360. Computer controls which respond to the locating devices provide information to the surgeon about cutting tools and/or other instruments being moved by the articulate arms. The surgeon operated controls, the articulate arms, and the fluoroscope or other imaging device may cooperate in the manner disclosed in U.S. Pat. Nos. 6,063,095 and 6,102,850 if desired.

It is believed that it may be desired to use a hologram to provide a three-dimensional optical image of cuts to be made. The three-dimensional image would be projected onto the end portion 124 of the femur 126 and/or onto the end portion 212 of the tibia 214. The three-dimensional image may be lines indicating where the femur 126 and/or tibia 214 are to be cut.

The three dimensional image would allow a surgeon 106 to visually monitor operation of the robot 370 during the making of cuts. If there was even a small discrepancy, the surgeon 106 could interrupt operation of the robot and take corrective action. It is believed that the projecting of a three-dimensional image onto surfaces to be cut will be particularly advantageous when a robotic system which has surgeon operated articulate arms is utilized. The projection of a hologram generated three-dimensional image would enable a surgeon to visually determine whether or not a robotic system, similar to the system disclosed in U.S. Pat. No. 6,063,095 or 6,102,850, is being operated properly.

Patellar Resection

In the foregoing description, the patella 120 was everted or flipped from its normal position to a position in which an inner side 122 of the patella faces outward (FIG. 7). The patella 120 was then cut while it was in the everted position.

A patellar implant was then mounted on the patella 120 in a known manner. The patella 120 was then returned to its normal position with the inner side of the patella facing inward toward the distal end portion 124 of the femur 126. This is a well known manner of performing surgery on a patella to install a patellar implant.

In accordance with one of the features of the present invention, it is contemplated that the patella 120 will be cut and an implant positioned on the patella while the patella remains in a substantially normal position relative to the femur 126. When the patella 120 is in its normal position relative to the femur 126 (FIG. 35), an inner side 122 of the patella 120 is disposed adjacent to the distal end portion 124 of the femur 126. The patella 120 is urged toward the trochlear groove 452 in the distal end portion 124 of the femur 126 by the patellar tendon 456 and the patellar ligament 458. The patellar tendon 456 connects the patella 120 with the quadriceps femoris muscle. The patellar ligament 458 connects the patella 120 with the tibia 214. The patellar tendon 456 and patellar ligament 458 may be referred to as fibrous connective tissue.

While the patella 120 is in the normal position illustrated in FIG. 35, a guide assembly 464 (FIG. 36) is positioned relative to the patella. The guide assembly 464 includes a main section 466 (FIG. 36) with a slot 468 having guide surfaces along which a blade 170 of a saw 172 is moved. The main section 466 of the guide assembly 464 is positioned relative to the patella 120 by a pair of parallel arms 474 and 476.

The arm 474 extends through the medially offset incision 114 and under the superior aspect 480 of the in situ patella 120. The arm 476 extends through the incision 114 and under the inferior aspect 482 of the in situ patella 120. By positioning the arm 474 under the upper end portion 480 of the patella and the arm 476 under the lower end portion 482 of the patella 120, the guide surfaces in the slot 468 are accurately aligned with the patella 120 while the patella is in its normal position relative to the femur 126 and tibia 214 (FIG. 35).

While the in situ patella 120 is urged toward the distal end portion 124 of the femur 126 by the patellar tendon 456 and the patellar ligament 458 (fibrous connective tissue), the saw 170 or other cutting tool cuts along a plane 484 (FIG. 35) to form a flat surface on the inside of the patella 120. A relatively thin layer on which the inner side 122 of the patella is disposed, is then removed from the patella 120. A patellar prosthesis or implant is then mounted on the cut surface on the inside of the patella while the patella remains in its normal position. A suitable cement is utilized to connect the implant with the patella. In addition, one or more projections may be provided on the inside of the implant to interconnect the implant and the patella in a known manner.

If desired, the patella 120 may be repaired before making cuts on the femur 126 and tibia 214. Thus, immediately after making the incision 114, the patella 120 may be cut while it is disposed in its normal position. An implant may then be mounted on the patella 120. The surgically repaired patella 120 may then be moved to the offset position of FIG. 8. The femoral and tibial cuts may then be made in the manner previously explained in association with FIGS. 8–25 and the tibial and femoral implants 286, 290 and 294 mounted on the femur 126 and tibia 214 (FIGS. 27–29) while the previously repaired patella is in the offset position.

Extramedullary Tibial Instrumentation

When a tibial resection guide 500 (FIGS. 37 and 38) or the tibial resection guide 218 (FIG. 21) is to be positioned relative to the proximal end portion 212 of the tibia 214, an

external tibial alignment guide 504 (FIG. 37) may be used to position the tibial resection guide relative to the tibia 214. The external tibial alignment guide 504 is disposed outside of the patient's leg 70 and extends along the lower portion 68 of the patient's leg while the patient's leg is in the position illustrated in FIGS. 2, 3, and 25.

The external tibial alignment guide 504 (FIG. 37) includes a hollow distal shaft 508. A proximal shaft 510 is telescopically received in the distal shaft 508. When the proximal shaft 510 has been extended for a desired distance from the distal shaft 508, a vertical adjustment knob 514 is tightened to hold the proximal shaft 510 against movement relative to the distal shaft 508.

The foot or lower end portion of the hollow distal shaft 508 is connected with the mid-point between the palpable medial and lateral malleoli by a spring clamp 518. The spring clamp 518 is aligned with the second metatarsal and grips the outside of the ankle portion 86 (FIG. 25) of the patient's leg 70. The proximal shaft 510 (FIG. 37) of the external tibial alignment guide 504 is aligned with the medial third of the tibial tubercle. This results in the external tibial alignment guide 504 being positioned along the outside of the patient's leg with the longitudinal axis of the external tibial alignment guide 504 extending parallel to a longitudinal central axis of the tibia 214.

A stylus 522 (FIG. 38) is mounted on the tibial resection guide 500. The stylus 522 engages the proximal end portion 212 of the tibia to position the tibial resection guide 500 relative to the tibia. The tibial resection guide 500 is connected to the proximal end portion 212 of the tibia by a single pin 524 (FIG. 38) which extends through the tibial resection guide 500 into engagement with the proximal end portion 212 of the tibia 214. The external tibial alignment guide 504 and the stylus 522 cooperate with the tibial resection guide 500 and pin 524 to hold the tibial resection guide against rotation.

Although the tibial resection guide 500 has been shown in FIG. 38 as being connected directly to the proximal end portion 212 of the tibia 214, the tibial resection guide could be connected with proximal end portion 212 of the tibia 214 in different manner. Thus, in FIG. 38, the posterior facing side of the tibial resection guide 500 is disposed in abutting engagement with the proximal end portion 212 of the tibia 214. However, the posterior facing side of the tibial resection guide 500 could be positioned in engagement with skin which encloses the proximal end portion 212 of the tibia 214 in order to minimize the overall length of the incision 114. This would result in the pin 524 extending through the tibial resection guide and through the skin and other tissue overlying the proximal end portion 212 of the tibia 214 into engagement with the proximal end portion of the tibia. The manner in which the tibial resection guide would be mounted on the tibia, would be similar to that disclosed in FIG. 31 for the distal resection guide 186. However, the tibial resection guide 500 is secured in place by a single pin 524, by the external tibial alignment guide 504, and, to some extent at least, the stylus 522.

The tibial resection guide 500 is medially offset from the external tibial alignment guide 504. This is because the incision 114 (FIG. 6) is disposed adjacent to the medial edge portion of the patella 120. If desired, the incision 114 could be disposed adjacent to the lateral side of the patella 120. If this was done, the tibial resection guide 500 would be laterally offset from the external tibial alignment guide 504. Regardless of which direction the tibial resection guide 500 is offset, a portion of the tibial resection guide may be disposed beneath body tissue to minimize the size of the incision 114.

41

In accordance with a feature of the apparatus of FIGS. 37 and 38, the external tibial alignment guide 504 is maintained in position on the tibia 214 during cutting of the proximal end portion 212 of the tibia 214 in a manner similar to that illustrated in FIG. 21. Maintaining the tibial alignment guide 504 in place during cutting of the proximal end portion 212 of the tibia 214, enables the tibial alignment guide to be utilized to position the tibial resection guide 500 relative to the tibia 214. This enables the tibial resection guide 500 to be connected to the tibia 214 by only the single pin 524. In the past, a plurality of pins have been utilized to connect the tibial resection guide 500 with the tibia 214 in a manner similar to the disclosures in U.S. Pat. Nos. 5,234,433 and 5,643,272. It should be understood that the tibial alignment guide 504 and a tibial resection guide, similar to the tibial resection guide 500, may be utilized during performance of a partial knee replacement in the manner disclosed in the aforementioned U.S. Pat. No. 5,234,433.

Since, the external tibial alignment guide 504 is maintained in position during cutting of the tibia, the saw blade 170 or other cutting tool must be angled around the proximal shaft 510 of the external tibial alignment guide 504 as the proximal end portion 212 of the tibia 214 is cut. During movement of the saw blade 170 (FIGS. 13 and 21) along the guide surface 530 (FIG. 38), only an initial portion of the cut in the proximal end portion 212 of the tibia is made. This is because the proximal shaft 510 of the external tibial alignment guide 504 partially blocks the saw blade 170. In addition, the tibial resection guide 500 is down sized.

Opposite ends 534 and 536 of the tibial resection guide 500 are space apart by a distance less than two thirds ($\frac{2}{3}$) of the distance between tips of lateral and medial epicondyles 236 and 238 (FIG. 38) on the proximal end portion 212 of the tibia 214. Therefore, after an initial portion of the cut across the proximal end portion 212 of the tibia 214 has been made while moving the saw blade 170 along the guide surface 530, the tibial resection guide 500 and external tibial alignment guide 504 are disconnected from the tibia 214. The tibial cut is then completed.

During completion of the tibial cut, the guide surface 530 on the resection guide 500 is not in position to guide the saw blade 170. Therefore, cut surfaces formed during the making of the initial portions of the tibial cut are utilized to guide the saw blade. When the tibial cut is to be completed the saw blade 170 is inserted into a slot or kerf formed in the distal end portion 212 of the tibia 214 by the saw blade 170 as it moved along the guide surface 530 and made the initial portion of the tibial cut. During completion of the tibial cut, the cut surfaces which were formed on the proximal end portion 212 of the tibia 214 during the initial portion of the tibial cut are used to guide movement of the saw blade.

The tibial resection guide 218 of FIG. 21 has a guide surface 242 formed by a closed ended slot. The tibial resection guide 500 of FIG. 38 has a guide surface 530 formed by an open ended slot. Thus, the tibial resection guide 500 includes a slot 540 which has an open end 542. The open end 542 of the slot 540 facilitates movement of the saw blade 170 along the slot and angling of the saw blade relative to the slot to maximize the extent of the initial portion of the tibial cut. Thus, the extent of the tibial cut formed during movement of the saw blade along the guide surface 530 on the tibial resection guide 500 is maximized by forming the slot 540 with the open end 542 so that the saw blade can be angled at the open end 542 of the slot.

The tibial resection guide 500 may be used with a first cutting tool during making of the initial portion of the tibial cut. A second cutting tool may be used to complete the tibial

42

cut. For example, a relatively small blade 170 of an oscillating saw 172 may be used to make the initial portion of the tibial cut. A relatively long blade of a reciprocating saw may be used to complete the tibial cut. If desired, a chisel and/or milling cutter could be used to make the initial portion and/or final portion of the tibial cut.

It is contemplated that it may be desired to set the tibial resection guide 500 (FIG. 37) for any one of a plurality of different resection levels. Thus, the tibial resection guide 500 could be set to make a tibial cut at a distance of two millimeters from a location on the proximal end portion 212 of the tibia 214 which is engaged by the stylus 522. Alternatively, the tibial resection guide 500 could be utilized to make a cut at a distance of eight millimeters from the location where the stylus 522 engages the proximal end portion 212 of the tibia 214. Of course, the greater the distance at which the tibial cut is made from the location where the stylus 522 engages the proximal end portion 212 of the tibia 214, the greater will be the thickness of a layer of bone removed from the distal end portion 212 of the tibia 214.

To facilitate movement of the tibial resection guide 500 between various depths, the stylus 522 includes a drive assembly 548 (FIG. 38). The drive assembly 548 is actuated by rotating a knob 550 on the stylus. Rotation of the knob 550 through a predetermined distance, that is, one complete revolution, will cause the drive assembly 548 to move the tibial resection guide 500 for a predetermined distance along the proximal shaft 510 of the external tibial alignment guide 504. Thus, rotation of the knob 550 for one complete revolution in a clockwise direction, viewed from above, is effective to move the tibial resection guide 500 through a distance of two millimeters downwards along the proximal shaft 510 of the external tibial alignment guide. Of course, this would increase the depth of the tibial cut by a distance of two millimeters. Similarly, rotating the knob 550 through two complete revolutions is effective to actuate the drive assembly 548 to move the tibial resection guide 500 downward (as viewed in FIG. 39) along the proximal shaft 510 of the external tibial alignment guide 504 through a distance of four millimeters.

The drive assembly 548 includes an externally threaded member which is connected with the knob 550. An internally threaded member is connected with the tibial resection guide 500. The internally threaded member engages the externally threaded member and is held against axial and rotational movement relative to the tibial resection guide 500.

After the tibial resection guide 500 has been moved to a desired position relative to the proximal end portion 212 of the tibia 214, a locking knob 556 is rotated to actuate a lock screw to hold the tibial resection guide 500 against movement along the proximal shaft 510 of the external tibial alignment guide 504. The pin 524 is then inserted through the tibial resection guide 500 into the proximal end portion 212 of the tibia 214.

Rather than moving the tibial resection guide 500 along the proximal shaft 510 of the external alignment guide 504 under the influence of force transmitted from the knob 550 through the drive assembly 548 to the tibial resection guide, the drive assembly could be connected with the knob 556. For example, the knob 556 could be connected with a pinion gear of a rack and pinion drive arrangement. The rack portion of the drive arrangement could be mounted on the proximal shaft 510. If this was done, rotation of the knob 556 would cause the rack and pinion gear set to move the tibial resection guide along the proximal shaft 510 through a distance which is a function of the extent of rotation of the

knob **556**. The stylus **552** would be connected to the tibial resection guide **500** and would engage the proximal end of the tibia **214** to indicate when the tibial resection guide **500** had moved to a desired position relative to proximal end portion **212** of the tibia.

It is contemplated that the stylus **522** could be eliminated if desired. The tibial resection guide **500** could be positioned by sliding a thin member, such as a blade, beneath tissue overlying the proximal end portion **212** of the femur **214**. A reference surface on the tibial resection guide **500** would then be moved into engagement with the blade or other thin member. The reference surface may be disposed on the upper (as viewed in FIG. **38**) end of the tibial resection guide **500** or may be disposed in a slot in the tibial resection guide. The reference surface may also be utilized to guide movement of a saw or other cutting tool.

If desired a hook or sickle shaped locating member could be extended from the tibial resection guide **500** to position the tibial resection guide relative to the proximal end portion **212** of the tibia **214**. When the incision **114** and tibial resection guide **500** are medially offset relative to the tibia **214**, the locating member would extend along the medial side of the proximal end portion **212** of the tibia. This would enable the stylus **522** to be eliminated.

It is contemplated that retractors may be mounted on the proximal shaft **510** of the external tibial alignment guide **504**. The retractors engage opposite sides of the incision. The retractors are effective to expand the incision **114** and/or maintain the incision in a desired position relative to the proximal end portion **212** of the tibia **214**.

Cannula

In accordance with another feature of the invention, access to the interior of the knee portion **76** of the leg **70** may be obtained through a cannula **564** (FIG. **39**). The cannula **564** is inserted into the incision **114** while the patient's leg **70** is in the position shown in FIGS. **2**, **3** and **25**. The upper portion of the patient's leg is supported by the leg support **80**.

The incision **114** is formed with a relatively short length in the manner previously described herein. The cannula **564** has an initial size, illustrated in FIG. **39**, which stretches the viscoelastic material of tissues forming the knee portion **76** of the leg **70**. Therefore, initial insertion of the cannula **564** into the incision **114** is effective to expand the incision.

Compact cutting tools, similar to those utilized for arthroscopic, endoscopic, or fiber optic assisted surgery may be at least partially moved through a passage **566** (FIG. **39**) formed by an inner side **568** of the cannula **564**. The cutting tools may have a construction similar to the construction illustrated in U.S. Pat. Nos. 5,540,695 or 5,609,603. Alternatively, the cutting tools may have a construction similar to the construction disclosed in U.S. patent application Ser. No. 09/483,676 filed Jan. 14, 2000 by Peter M. Bonutti and having a disclosure which corresponds to U.S. Pat. No. 5,269,785.

The cannula **564** is advantageously expandable to further stretch the viscoelastic tissue of the knee portion **76**. Of course, expanding the cannula **564** increases the size of the passage **566** to enable a relatively large object to pass through the passage. Thus, the cannula **564** may be expanded to facilitate movement of the implants **286**, **290** and **294** through the cannula. The leg **70** is in the position shown in FIGS. **2**, **3** and **24** during expansion of the cannula and movement of objects through the passage **566**.

It is contemplated that the expandable cannula **564** may have many different known constructions. The illustrated cannula **564** is formed of elastomeric material and has the

same construction as is disclosed in U.S. patent application Ser. No. 08/470,142 filed Jun. 6, 1995 by Peter M. Bonutti, et al. and having a disclosure which corresponds to the disclosure in U.S. Pat. No. 5,961,499. It should be understood that the cannula **564** could have a different construction, for example, a construction similar to the constructions disclosed in U.S. Pat. Nos. 3,811,449 or 5,183,464.

The cannula **564** can be expanded in many different ways other than under the influence of force transmitted directly to the cannula from an object moving through the cannula. For example, the cannula may be expanded by force transmitted from an implant **286**, **290** and/or **294** to the cannula. The cannula **564** may be expanded by inserting tubular members into the cannula. Alternatively, fluid pressure could be used to expand the cannula **564** in the manner disclosed in the aforementioned Bonutti, et al. patent application Ser. No. 08/470,142 filed Jun. 6, 1995.

Rather than being expanded by inserting the expandable cannula **564** into the incision **114**, the incision may be expanded by utilizing pneumatic retractors. The pneumatic retractors may have a construction similar to the construction disclosed in U.S. Pat. No. 5,163,949. By utilizing the expandable cannula **564** or the expandable pneumatic retractors, force can be applied against opposite sides of the incision **114** to stretch the viscoelastic material disposed adjacent to opposite sides of the incision. This will result in the relatively small incision **114** being expanded to accommodate relatively large surgical instruments and/or implants.

Although a single incision **114** is illustrated in FIG. **39**, it is contemplated that a plurality of incisions could be provided. Thus, a small incision may be spaced from the incision **114** to enable a cutting tool to be moved into the knee portion **76** along a path which is spaced from and may be transverse to a path along which a cutting tool is moved through the incision **114**. A second cannula, which is smaller than the cannula **564**, may be utilized with the second incision.

Implant with Interconnectable Portions

In order to enable surgery on a knee portion **76** of a patient's leg **70** to be conducted through an incision **114** of relatively small size, the implant may advantageously be formed in two or more portions (FIG. **40**). The portions of the implant are sequentially moved through the incision **114** into engagement with the distal end portion **124** of the femur **126** and/or the proximal end portion **212** of the tibia **214**. It is believed that having the implant formed as two or more portions will facilitate movement of the implant through the cannula **564** (FIG. **39**).

As the portions of the implant are sequentially moved through the incision **114**, they are positioned in engagement with one or more of the bones, that is, the femur **126** and/or the tibia **214** in the leg **70** of a patient. After the plurality of portions of the implant have been moved through the incision **114** and positioned in engagement with the femur **126** and/or tibia **214**, the portions of the implant are interconnected to form a unitary implant. The portions of the implant are moved through the incision **114** and interconnected while the leg of the patient is in the position illustrated in FIGS. **2**, **3** and **25**.

It is contemplated that the portions of the implant may be interconnected, while they are disposed in the patient's body and in engagement with either the femur **126** and/or tibia **214**, in many different ways. For example, the portions of the implant may be bonded together to form a one piece implant. The portions of the implant may be bonded together by the application of energy in anyone of many different

forms to a joint between portions of the implant. For example, ultrasonic energy could be applied to the implant. Alternatively, heat could be directly applied to the implant. If desired, a laser could be utilized to effect bonding of separate portions of the implant together.

It is also contemplated that the separate portions of the implant could be mechanically interconnected. This could be done with a fastener which extends between portions of the implant. Alternatively, a retainer member such as a rod or bar could extend between portions of the implant. Regardless of how the portions of the implant are interconnected, the portions of the implant are interconnected after they have been moved into the patient's body.

In the embodiment of the invention illustrated in FIG. 40, the femoral component 290 of an implant is formed as two separate portions 572 and 574. The portion 572 of the implant 290 is moved through the incision 114 into engagement with the distal end portion 124 of the femur 126. Thereafter, the portion 574 of the implant 290 is moved through the incision 114 into engagement with the distal end portion 124 of the femur 126. After the two portions 572 and 574 of the femoral component 290 of the implant have been positioned in abutting engagement with the femur 126, the two portions of the implant are interconnected at a joint 576 between the two portions of the implant. If desired, the portions 572 and 574 of the femoral component 290 of the implant may be moved through the cannula 564 of FIG. 39.

The specific implant 290 illustrated in FIG. 40 has portions formed of a polymeric material which may be either a polymer or a co-polymer. The material of the two portions 572 and 574 of the implant 290 are heated at the joint 576 while the two portions of the implant are disposed in the patient's body in engagement with the femur 126. As this occurs, the material forming the two portions 572 and 574 of the implant 290 is heated to a temperature within its transition temperature range and becomes tacky without changing its overall configuration. The two portions 572 and 574 of the implant 290 may be heated by the direct or indirect application of heat. The indirect application of heat may include applying ultrasonic energy to the implant.

The heated material of the two portions 572 and 574 of the implant 290 are then pressed together at the joint 576 to form a bond between the two portions of the implant. As this occurs, there is a fusing of the material of the portion 572 of the implant 290 with the material 574 of the implant. This fusing together of the two portions 572 and 574 occur in the patient's body and results in the formation of a one-piece unitary implant 290.

Rather than being formed of a polymeric material, it is contemplated that the two portions 572 and 574 of the implant could be formed of metal and have a polymeric layer on a side of the metal toward the femur 126. This would result in the layer of polymeric material being disposed in engagement with the distal end portion 124 of the femur 126 and the metal forming the femoral component 290 facing toward the tibia 214 for engagement with the tibial bearing insert 294 (FIG. 32). With such a construction, the application of energy to the two portions 572 and 574 of the implant would result in a heating of the layer of polymeric material on the inside of the layer of metal. The heated polymeric materials on the two portions 572 and 574 bends bond together at the joint 576 in a manner previously described.

When the two portions 572 and 574 of the femoral implant 290 are to be interconnected by fusing together sections of polymeric material which form the portions 572 and 574 of the implant or sections of polymeric material which are disposed on layers of metal forming part of the

portions 572 and 574 of the implant 290 to be interconnected, it is contemplated that they may be interconnected in many different ways. One way in which polymeric material on the portions 572 and 574 of the femoral implant 290 may be interconnected is the same as is disclosed in U.S. patent application Ser. No. 09/737,380 filed Dec. 15, 2000 by Peter M. Bonutti, et al. This patent application contains a disclosure which corresponds to the disclosure in U.S. Pat. No. 6,059,817.

The two portions 572 and 574 of the implant 290 (FIG. 40) may be formed of only metal. If this is done, the two portions 572 and 574 of the implant may be mechanically interconnected. For example, a screw could extend from the portion 574 of the implant 290 to the portion 572 of the implant while the two implants are in engagement with the distal end portion 124 of the femur 126. Alternatively, a snap type joint 576 could be provided between the portions 572 and 574 of the implant. Although the two portions 572 and 574 of the implant 290 are positioned in engagement with the femur 126 and interconnected while the leg 70 of the patient is in the position illustrated in FIGS. 2, 3 and 25, the two portions of the implant could be positioned in engagement with the femur 126 while the leg 70 is straight (extended).

The implant 290 is connected with the femur 126. However, it is contemplated that a tibial implant could be formed as a plurality of separate portions which are interconnected when they are in the knee portion 76 of the patient's leg 70. It should be understood that the implant 290 could be formed of more than two portions. For example the implant could be formed with four separate portions which are interconnected in the patient's body. Although the implant 290 is to be used in a knee portion of a patient's body, it is contemplated that implants used at other portions of a patient's body could be interconnected in the patient's body.

In the embodiment of the invention illustrated in FIG. 40, the separate portions 572 and 574 of the implant 290 are positioned in engagement with the same bone, that is, femur 126 and interconnected. However, it is contemplated that one position of an implant could be positioned in engagement with a first bone and another portion of the implant positioned in engagement with a second bone. However, the two portions of the implant would be interconnected in the patient's body. The two portions of the implant may be interconnected after they have been positioned in engagement with bones in the patient's body. Alternatively, the two portions of the implant could be interconnected in the patient's body, before one or both portions of the implant have been positioned in engagement with a bone.

For example, a first component of an implant may be connected with a femur 126 in a patient's body. A second component may be connected with a tibia 214 in the patient's body. The two components are interconnected, in the patient's body, after they have been connected with the femur and tibia.

Transducer for Ligament Balancing

After the femoral component 290 and tibial components 286 and 294 of the implant had been positioned in the knee portion 76 of the patient's leg 70, the ligaments are balanced in flexion, extension, and rotation in the manner previously described. It should be understood that even though the implants have not been shown in FIGS. 41 and 42, ligament balancing may be undertaken before and/or after the implants been positioned in engagement with the femur 126 and tibia 214. However, it is contemplated that ligament balancing could be undertaken during surgical procedures

which do not require cutting of the femur 126 and tibia 214 and/or implants.

In accordance with one of the features of the invention, during ligament balancing, tension forces in fibrous connective tissue such as collateral ligaments 590 and 592 (FIGS. 41 and 42) are compared. If the forces in one of the ligaments 590 or 592 is excessive, the ligament in which the excessive force is present may be released. Similarly, if one of the ligaments is too loose, the ligament may be tightened.

In accordance with another one of the features of the invention, transducers are positioned between one or more bones in the knee portion 76 of the leg 70 of the patient. The transducers enable tension forces in ligaments 590 and 592 to be compared. The transducers may be used to determine the magnitude of the tension forces in the ligaments 590 and 592.

Thus, a first or lateral transducer 596 (FIGS. 41 and 42) is positioned between a lateral side of the distal end portion 124 of the femur 126 and a lateral side of the proximal end portion 212 of the tibia 214. Similarly, a second or medial transducer 598 is positioned between a medial side of the distal end portion 124 of the femur 126 and a medial side of the proximal end portion of the tibia 214. The transducers 596 and 598 are connected with a computer 600 (FIG. 41).

The computer 600 (FIG. 41) has a display area 601 at which the output from the lateral transducer 596 is displayed. Similarly, the computer 600 has a display area 602 at which the output from the medial transducer 598 is displayed. By comparing the outputs at the display areas 601 and 602, a surgeon can determine the relationship between the tension in the ligament 590 and the tension in the ligament 592. In addition, the surgeon can determine the magnitude of the tension in the ligaments 590 and 592.

It is contemplated that the leg 70 of the patient will be moved between the flexed condition of FIGS. 2, 3, 25 and 41 and an extended position or straight condition (FIGS. 4 and 42), while the output from the transducers 596 and 598 is viewed at the display areas 601 and 602 of the computer 600. This will provide the surgeon with a clear indication of the manner in which tension forces in the ligaments 590 and 592 varies during bending of the knee portion 76 of the leg 70 of a patient. If an image generating device, similar to the C-arm fluoroscope 360 of FIG. 34, is used in association with the transducers 596 and 598, the surgeon can see how components of the knee joint are interacting as the tension in the ligaments varies.

In addition to checking the tension in the ligaments 590 and 592 during movement of the leg 70 of the patient between flexed and extended conditions, it is contemplated that the tension in the ligaments 590 and 592 will be compared during the application of rotational forces to the lower portion 68 of the knee of the patient. Thus, forces tending to rotate the lower portion 68 of the leg of the patient in the direction of the arrow 258 in FIG. 25 are applied to the lower portion 68 of the leg 70. As these rotational forces are applied, the outputs from the transducers 596 and 598 (FIG. 41) are displayed for review by a surgeon to determine whether or not the ligaments 590 and 592 are rotationally balanced. The transducers 596 and 598 may be utilized to provide outputs corresponding to forces resulting from a combination of flexion/extension movement and rotational movement of the lower portion 68 of the patient's leg 70. It should be understood that the transducers 596 and 598 may be utilized throughout the entire ligament balancing process previously described herein in order to enable a surgeon to compare tension forces in the ligaments 590 and 592 throughout the ligament balancing process.

Although the transducers 596 and 598 have been illustrated schematically in FIGS. 41 and 42 as being associated with the end portions of the femur 126 and tibia 214, it should be understood that the transducers 596 and 598 could be associated with other joints if desired. For example, the transducers 596 and 598 could be positioned between vertebrae in a patient's spine. If this was done, the patient's spine could be bent in either anterior or lateral flexion and extension. The output at the display areas 601 and 602 would indicate the manner in which forces transmitted between the vertebrae vary during bending of the spine.

It is contemplated that the transducers 596 and 598 could have many different constructions. However, in the illustrated embodiment of the invention, the transducers 596 and 598 are pneumatic transducers. Thus, the lateral transducer 596 (FIG. 42) includes a container or bladder having a chamber which is filled with fluid. It is contemplated that the chamber could be filled with either a gas or a liquid. In the embodiment of the invention illustrated in FIGS. 41 and 42, the transducers 596 and 598 have the same construction and are of pneumatic type. Therefore, the chamber is filled with air. However, the chamber could be filled with a liquid, for example, saline solution, if desired.

The transducers 596 and 598 are disposed between the femur 126 and the tibia 214. Although it should be understood that the femoral implant 290 and tibial tray 286 and bearing 294 have not been illustrated in FIGS. 41 and 42, the implants may or may not be present when the transducers are positioned between the femur 126 and tibia 214. Depending upon the location of the transducers 596 and 598 they may or may not be disposed in engagement with a portion of either the femoral or tibial implant. With a partial knee replacement, one of the transducers 596 or 598, is disposed between femoral and tibial implants. The other transducer is disposed between surfaces on the femur 126 and the tibia 214.

A conductor 604 is provided to transmit an output signal from the lateral transducer 596 to the computer display 601 (FIG. 42). The conductor 604 could be constructed so as to conduct either fluid pressure from the transducer 596 to the computer 600 or to conduct an electrical signal from a fluid pressure transducer exposed to the fluid pressure in the transducer 596. The medial transducer 598 is connected with the display 602 by a conductor 606.

It is contemplated that the transducers 596 and 598 could have many different constructions including any one of the constructions disclosed in U.S. Pat. No. 5,667,520 or in U.S. patent application Ser. No. 09/483,676 filed Jan. 14, 2000 by Peter M. Bonutti and having a disclosure corresponding to the disclosure in U.S. Pat. No. 5,269,785. The transducers 596 and 598 may be formed of a material which is biodegradable or a material which is non-biodegradable.

Although the illustrated transducers 596 and 598 (FIGS. 41 and 42) are of the pneumatic type, it is contemplated that a different type of transducer could be utilized if desired. For example, the transducers 596 and 598 could be solid state devices, such as piezoelectric load cells. Alternatively, the transducers could include deformable members to which strain gauges are attached.

It should be understood that the transducers 596 and 598 could be used to measure and/or compare tension in the ligaments 590 and 592 immediately after making the incision 114. In addition or alternatively, the transducers 596 and 598 could be used to measure and/or compare tension in the ligaments 590 and 592 during trials with provisional components. Of course, the transducers 596 and 598 can be used to measure and/or compare tension in the ligaments after the implants 286, 290 and 294 have been mounted in the knee portion 76.

In the embodiment of this invention illustrated in FIGS. 41 and 42, the transducers 596 and 598 are disposed between end portions of the femur 216 and tibia 214. Therefore, the transducers 596 and 598 only indirectly respond to variations in tension in the collateral ligaments 590 and 592. It is contemplated that the transducers 596 and 598 could be positioned so as to directly respond to variations in the tension in the collateral ligaments 590 and 592.

For example, the transducer 596 could be positioned between the ligament 590 and lateral sides of the femur 126 and/or tibia 214. Similarly, the transducer 598 could be positioned between the ligament 592 and medial sides of the femur 126 and/or tibia 214.

It is contemplated that transducers, similar to the transducers 596 and 598, could be utilized to determine variations in tension in ligaments and/or tendons other than the ligaments 590 and 592. For example, transducers could be utilized to determine the tension in the patellar tendon 456 (FIG. 42) and/or the patellar ligament 458. If desired, transducers, similar to the transducers 596 and 598, could be positioned so as to respond to variations in tension in the posterior cruciate ligament 250 and/or the anterior cruciate ligament. It is contemplated that a plurality of transducers, similar to the transducers 596 and 598, maybe positioned so as to respond to variations in tension in various combinations of ligaments and/or tendons.

In addition to providing outputs which are a function of variations in tension in ligaments and/or tendons, the transducers 596 and 598 may be utilized to apply force against the femur 126 and tibia 214. When this is to be done, fluid under pressure is conducted to either or both of the transducers 596 and/or 598. An increase in fluid pressure conducted to the transducers 596 and 598 is effective to expand containers or bladders in the transducers.

The fluid pressure force applied against the transducers 596 and/or 598 is transmitted to the femur 126 and tibia 214. This force may be used to stretch the collateral ligaments 590 and 592 and/or other body tissue. If it is desired to stretch one of the ligaments 590 or 592 to a greater extent the other ligament, the fluid pressure transmitted to one of the transducers 596 or 598 would be greater than the fluid pressure transmitted to the other transducer. The force transmitted to the femur 126 and tibia 214 is indicated at the displays 61 and 601.

It is contemplated that the transducers 596 and 598 will be removed before the limited incision 114 is closed. However, if it is desired, the transducers 596 and 598 may be left in place and utilized after the incision 114 is closed. When this is to be done, the transducers 596 and 598 may advantageously be formed of biodegradable material. By leaving the transducers 596 and 598 in place after the incision 114 is closed, the tension in the ligaments 590 and 592 may be compared during therapy. If desired, one or both ligaments 596 and/or 598 could be conducting fluid pressure to one or both transducers 596 and/or 598 during therapy.

Inlaid Implant—Femur

In the embodiment of the invention illustrated in FIGS. 8–28, articular surfaces on the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 are cut away using a saw or other cutting tool. This results in areas on the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214, where articular surfaces were previously disposed, being cut to have a flat planar configuration. Thus, an anterior skim cut, a distal end cut, and chamfer cuts are made on the distal end portion 124 of the femur 126 while a proximal end cut is made on the proximal end portion 212 of the tibia 214. After

the cuts have been made, the femoral implant extends across or encloses the cuts on the distal end portion 124 of the femur 126 and the tibial implant extends across the cut on the tibial end portion 212 of the tibia 214.

It is contemplated that rather than enclosing the end portions of the femur and tibia with implants, the implants could be inlaid into the end portion of the femur and/or tibia. When an implant is to be inlaid into the distal end portion 124 of the femur 126 (FIG. 43), a recess 610 is formed in the distal end portion 124 of the femur 126. To form the recess 610, a cutting tool, such as a milling cutter 614 (FIG. 44), is utilized to cut away a defective portion of an articular surface on the distal end portion 124 of the femur 126. The milling cutter 614 is rotated about its longitudinal central axis and has cutting edges disposed in a cylindrical array about the periphery of the milling cutter. The extent of the defective portion of the articular surface determines the extent to which the milling cutter 614 cuts away the articular surface.

A guide 620 (FIG. 44) is provided for the milling cutter or other cutting tool. The guide 620 is effective to limit the extent of axial movement of the milling cutter 614 into the distal end portion 124 of the femur 126 to thereby limit the depth of the recess 610. The guide 620 limits side wise, that is, radial movement of the milling cutter 614 to an area corresponding to the desired configuration of the recess 610. This results in the recess 610 being formed with a uniform depth throughout the extent of the recess and with a desired configuration. The construction of the guide 620 in the manner in which it cooperates with the milling cutter 614 may be similar to that disclosed in U.S. Pat. No. 5,344,423; 5,769,855; and/or 5,860,981.

Once the recess 610 has been formed using the milling cutter 614 in the manner illustrated schematically in FIG. 44, an implant 626 (FIGS. 43 and 45) is positioned in the recess. The implant 626 fills the recess 610 and has an outer surface 628 (FIG. 45) which forms a continuation of the naturally occurring articular surface 616 formed by the distal end portion 124 of the femur 126. The outer surface 628 of the implant 626 replaces defective articular surface area removed by the milling cutter 614 from the distal end portion 124 of the femur 126.

The outer surface 628 on the implant 626 cooperates with an articular surface on a tibia 214 in the same general manner as the original articular surface area removed by the milling cutter 614. Of course, the outer surface 628 of the implant 626 is free of defects that made it necessary to replace the corresponding area on the articular surface 616 of the distal end portion 124 of the femur 126. The outer surface 628 of the implant 626 may engage an articular surface formed by the boney material of the tibia 214. Alternatively, the outer surface 628 of the implant 626 may engage the surface of an implant disposed on the tibia 214.

During recovery of the patient, the naturally occurring surface 616 on the femur 126 and the implant 626 may both be load bearing. By having the implant 626 surrounded by load bearing natural bone, the implant is held in place on the distal end portion 124 of the femur 26. In addition, the magnitude of the load which must be transmitted through the implant 626 is minimized.

The implant 626 could have any desired construction. Thus, the implant could be formed of a polymeric material or it could be formed of a metallic material. However, in accordance with one of the features of the invention, the implant 626 is formed of a material which promotes biological resurfacing and the growth of bone from the distal end portion 124 of the femur 126 into the implant to fill the

51

recess **610** with new bone growth. The implant **626** may also be at least partially formed of material which promotes the growth of cartilage or other tissue over the implant.

The implant **626** may be formed with a non-living three dimensional scaffold or framework structure on which bone growth promoting materials, such as bone morphogenetic proteins, are disposed. The three dimensional framework or platform on which the bone growth promoting materials are disposed may be formed of either a biodegradable or a non-biodegradable material. When the scaffold or framework structure is formed of a non-biodegradable material, the bone from the distal end portion **124** will grow through the scaffold so that the scaffold becomes embedded in new bone growth. The scaffold may be formed of a porous metal or ceramic material. When the scaffold is formed of a bio-degradable material, the scaffold will eventually degrade and be absorbed by body tissue.

The scaffold may be formed of a mesh or a felt-like material, or a porous material similar to coral. The scaffold forms a growth supporting matrix to support cellular migration from the boney material of the distal end portion **124** of the femur **126** into the implant **626**. If the scaffold or platform is made of a bio-degradable material, then the scaffold or platform degrades and disappears after a period of time. It is contemplated that the scaffold could be formed of a bio-degradable material such as polyglycolic acid or polylactic acid. If desired, the scaffold or framework could be formed of fibrous connective materials such as portions of ligaments, tendons and/or bones obtained from human and/or animal sources. The scaffold could be formed of collagen. The scaffold may be formed of submucosal tissue.

The scaffold holds bone growth inducing materials and may include bone fragments to which tri-calcium phosphate, an antibiotic, hydroxyapatite, allografts, autografts, and/or any other polymeric has been added. It is believed that it will be particularly advantageous to provide a bone growth morphogenetics protein in the implant **626** to promote the growth of bone into the implant. The scaffold may hold cultured and/or noncultured cells which promote biological resurfacing.

The matrix or scaffold for the implant **626** may contain tissue inductive factors and/or cells. The cells may be mesenchymal cells which are introduced into the scaffold in the operating room. Thus, the matrix or scaffold may be either biodegradable or non-biodegradable and may be constructed at a location remote from an operation. After the scaffold has been transported to the operating room the mesenchymal cells may be introduced into the scaffold.

It is contemplated that the matrix or scaffold for the implant **626** may contain stem cells and/or fetal cells. The stem cells and/or fetal cells may be introduced into either a biodegradable or non-biodegradable matrix or scaffold in the operating room. It is contemplated that tissue inductive factors may be provided in the matrix or scaffold along with any desired type of precursor cells.

The matrix or scaffold for the implant **626** may contain osteoinductive materials. The implant **626** may contain osteoblasts or osteoclasts. The implant **626** may also contain platelet matrix centrifuged from blood in a manner similar to that described in U.S. patent application Ser. No. 09/483, 676, filed Jan. 14, 2000 by Peter M. Bonutti.

The matrix or scaffold for the implant **626** may be formed of allograft bone or collagen. Cartilage may be used to form the scaffold or matrix. The scaffold or matrix for the implant **626** may have a layered construction with the layers being formed of different materials. Each of the layers of the scaffold or matrix forming the implant **626** may be impreg-

52

nated with a different material. For example, precursor cells may be provided in one layer and bone morphogenetic protein may be provided in another layer.

It is contemplated that submucosal tissue may be used to form the scaffold for one or more of the layers of the implant **626**. The submucosal tissue may be prepared in a manner similar to the manner disclosed in U.S. Pat. No. 5,755,791. The various layers of the implant **626** may be assembled in the operating room.

The implant **626** may be formed of multiple tissue fragments. Thus, a tissue press, similar to the tissue presses disclosed in U.S. patent application Ser. No. 09/602,743 filed Jun. 23, 2000, by Peter M. Bonutti and having a disclosure which corresponds to the disclosure in U.S. Pat. No. 5,662,710 may be utilized to shape the implant to a desired configuration.

The implant **626** may be formed to have any one of a plurality of different sizes and configurations. The implant may be shaped to the desired configuration at a location remote from an operating room and transported to the operating room. Alternatively, the implant **626** could be cut to the desired shape in the operating room.

By providing a substantial number of implants of different sizes in the operating room and/or by cutting an implant to obtain a desired configuration, it is possible for a surgeon to make a recess **610** to a shape which corresponds to a defective area on a portion of the femur **126**. An implant **626** having the configuration of the particular recess can then be provided. This enables the surgeon to remove a relatively small defective area of the bone forming the articular surface on the femur **126** and to minimize the size of the implant **626**.

It is believed that it will be desired to provide a series of implants of different sizes ranging from a relatively small size to a relatively large size. In addition, it is believed that it will be desired to provide a plurality of guides **620**. The guides **620** will have surfaces to guide movement of the milling cutter **614** or other cutting tool to form a recess **610** of a size corresponding to any one of the sizes of the implants in the series of implants. Thus, the plurality of guides **620** would be provided with each guide having guide surfaces corresponding to the configuration of an implant of a different size.

The scaffold or base of the implant **626** may be formed of a porous bio-degradable material. The porous bio-degradable material provides a matrix for demineralized bone, collagen, bone morphogenetic protein, growth factors, and autogenous bone marrow. In addition, progenitor cells, stem cells and/or fetal cells may be disposed on the scaffold. Some non-tissue-derived components may include coralline-based HA (ProOsteon), antibiotics, calcium sulfate, calcium and phosphorus oxide rich amorphous glass, anti-inflammatories, and bovine fibrillar collagen. The resulting material will have osteoinductive and osteoconductive qualities. Cortical cancellous bone chips which are freeze dried may be provided in the implant **626**. In addition, demineralized bone matrix may be provided in the implant **626**.

The implant **626** may be secured in the recess **610** with a suitable adhesive. There are many different known adhesives which may be used. Fibrin can be used as an adhesive, either in a natural state or after being compressed, to hold material together and to hold the implant **626** in the recess **610**.

It is contemplated that the patient's leg **70** may be in the position illustrated in FIGS. 2, 3 and 25 during forming of the recess **610** and positioning of the implant **626** in the recess. The upper portion **72** of the patient's leg **70** may be

53

supported above the support surface **64** by the leg support **80**. The limited incision **114** (FIG. **6**) may be formed in the knee portion **76** of the patient's leg. The patella **120** may be in the offset position of FIG. **8** during forming of the recess **610**.

The drapery system **100** of FIGS. **4** and **5** may advantageously be utilized to provide a sterile field. Although it may be desired to use a milling cutter as the cutting tool **614** (FIG. **44**), other known cutting tools could be used if desired. For example, a laser or ultrasonic cutting tool could be used to form the recess **610**.

Although it is believed that it will be preferred to have the patient's leg **70** in the position illustrated in FIGS. **2**, **3** and **25**, to support the patient's leg **70** with the leg support **80**, to offset the patella **120**, and to use the drapery system **100**, the implant **626** may be positioned in a patient's leg **70** without using any one or any combination of these features. Thus, the implant **626** could be positioned in a patient's leg **70** with the leg in the position shown in FIG. **1** with any known drapery system. The patella may be everted (FIG. **7**) rather than offset.

The foregoing description of the implant **626** has assumed that the implant is to be positioned in the femur **126** in a leg of a patient. However, the implant **626** could be positioned in any desired bone in a patient's body. The implant **626** could be positioned at a location remote from an articular surface of a bone. The implant **626** may be positioned on a bone in ways other than positioning the implant in a recess similar to the recess **610**.

Inlaid Implant—Tibia

The implant **626** is illustrated in FIG. **43** in association with a femur **126** in a patient's body. It is contemplated that a similar implant **640** (FIG. **46**) may be provided in the proximal end portion **212** of the tibia **214** in a leg **70** of the patient. The implant **640** is disposed in a recess **642**. The recess **642** may have any desired configuration. It is contemplated that the configuration of the recess **642** would be a function of the configuration of defective portions of the bone in the proximal end portion **212** of the tibia **214**.

The recess **642** is surrounded by an articular surface **644** of naturally occurring bone. Thus, the articular surface **644** is not defective and extends around the recess **642**. It should be understood that the extent of the articular surface **644** around the recess **642** could be substantially greater than is illustrated in FIG. **46** relative to the size of the implant **640**. This is because the implant **640** is sized and has a configuration which is a function of the size and configuration of an area which was previously defective bone on the proximal end portion **212** of the tibia **214**. The articular surface **644** is load bearing and functions to transmit forces between the tibia **214** and the femur **126** in the leg **70** of the patient.

The recess **642** is formed with the milling cutter **614** (FIG. **47**). A guide **620** is provided to control the depth to which the milling cutter **614** removes bone from the proximal end portion **212** of the tibia **214** in the manner previously explained in conjunction with femur **126** (FIGS. **43–45**). The guide **620** and milling cutter **614** are utilized to form the recess **642** in a manner which is similar to that disclosed in U.S. Pat. No. 5,908,424. Rather than being formed by the use of a milling cutter **614** and guide **620**, it is contemplated that the recess **642** in the proximal end portion **212** of the tibia **214** and/or the recess **610** in the distal end portion **124** of the femur **126** could be formed by a robot having a construction similar to the construction of the robot **370** of FIG. **33**.

The implant **640** (FIGS. **46** and **48**) may be formed of metal or a hard polymeric material. Alternatively, the

54

implant **626** may be of a layered construction with a layer of metal backed by polymeric material. The surface of the implant forms a portion of the overall articular surface on the proximal end portion **212** of the tibia **214**.

Of course, the articular surface area on the proximal end portion **212** of the tibia **214** cooperates with articular surface areas on the distal end portion **124** of the femur **126** (FIG. **43**). It is contemplated that the implant **626** in the femur **126** and the implant **640** in the tibia **214** (FIG. **46**) could be disposed in engagement with each other. Alternatively, the implant **626** in the distal end portion **124** of the femur **126** (FIG. **43**) could be engaged by a naturally occurring articular surface on the proximal end portion **212** of the tibia **214** (FIG. **46**). Similarly, the implant **640** in the proximal end portion **212** of the tibia **214** may engage a naturally occurring articular surface area on the distal end portion **124** of the femur **126**.

It is contemplated that it may be preferred that the implant **640** contain bone growth promoting materials and/or materials which promote biological resurfacing. These bone growth promoting materials would promote growth of bone from the proximal end portion **212** of the tibia **214** into the recess **642**. This would result in the recess **642** being filled with new bone growth. The biological resurfacing materials would promote the growth of naturally occurring tissues on the implant **640**.

The implant **640** may include a three dimensional scaffold or framework structure formed of either a biodegradable material or a non-biodegradable material. Osteoinductive and/or osteoconductive materials may be disposed on this framework or platform. The scaffold may be formed of cortical bone, cartilage submucosal tissue, or other materials.

The matrix or scaffold for the implant **640** has interstitial spaces which contain material which promotes the growth of bone from the proximal end portion **212** of the tibia **214** into the matrix or scaffold. The bone growth materials may include bone morphogenic protein, factors that stimulate migration of cells, anti-inflammatories and/or immuno suppressants. Collagen, fibrin, osteoinductive materials, progenitor cells, and/or tissue inductive factors may be disposed on the platform. The implant **640** may contain cortical cancellous bone chips or demineralized bone matrix. It may be preferred to form the outer surface of the implant **640** of materials which promote biological resurfacing.

When the implant **640** is formed with a biodegradable three dimensional scaffold or matrix, it is contemplated that there will be cellular migration and growth of bone from the proximal end portion **212** of the tibia **214** into the scaffold or matrix. The scaffold or matrix will then degrade and disappear as material of the scaffold or platform hydrolyzes. However, if the matrix or scaffold is made of a non-biodegradable material, it is contemplated that the scaffold will become embedded in the bone growth from the proximal end portion **212** of the tibia **214** into the recess **614**. The scaffold, whether biodegradable or non-biodegradable, may be impregnated with mesenchymal cells.

The implant **640** on the tibia has the same construction as the implant **626** on the femur. However, the implant **640** on the tibia could have a construction which is different than the construction of the implant **626** on the femur.

It is contemplated that the patient's leg will be in the position illustrated in FIGS. **2**, **3** and **25** during forming of the recess **642** and positioning of the implant **640** in the recess. The upper portion **72** of the patient's leg **70** will be supported above the support surface **64** by the leg support **80**. The limited incision **114** (FIG. **6**) will be formed in the

knee portion 76 of the patient's leg. The patella 120 will be in the offset position of FIG. 8 during forming of the recess 642. The drapery system of FIGS. 4 and 5 may advantageously be utilized to provide a sterile field. Although it may be desired to use a milling cutter as the cutting tool, other known cutting tools could be used if desired.

Layered Implant

A multi layered inlaid implant 670 for use in biological resurfacing is schematically illustrated in FIG. 49. The implant 670 is disposed in a recess 672 formed in a bone 674. The recess 672 is formed in the same manner as is illustrated in FIGS. 44 and 47 for forming the recess 610 and the recess 642. The recess 672 may be disposed in a defective portion of an articular surface on the distal end portion 124 of a femur 126, as illustrated in FIG. 43, or may be located at a defective portion of an articular surface on the proximal end portion 212 of a tibia 214 as illustrated in FIG. 46. However, it is contemplated that the implant 670 may be disposed in the bone 674 at many different locations. At least some of these locations would be spaced from an articular surface on the bone. The bone may be located in many different portions of a patient's body, for example, a shoulder, spine, arm, hand, hip or foot.

The implant 670 is formed by a plurality of layers. The specific implant 670 illustrated in FIG. 49 has a base layer 678 and an outer layer 680. It should be understood that more than two layers could be provided if desired. For example, an intermediate layer could be disposed between the base layer 678 and outer layer 680 if desired. Each of the layers 678 and 680 of the implant 670 could be formed with its own separate platform or scaffold made of biodegradable materials. Alternatively, a single biodegradable scaffold or matrix could extend between the two layers 678 and 680.

The inner or base layer 678 is disposed in engagement with the bone 674. The inner layer 678 may be formed of bone growth promoting materials which promote migration of bone cells from the bone 674 to the base layer 678. New bone growth into the base layer 678 will interconnect the base layer and the bone 674. The base layer 678 may contain cortical cancellous bone powder or chips and/or demineralized bone matrix, bone morphogenic protein, anti-inflammatories and/or immuno suppressants may be disposed in the base layer 678. An antibiotic, hydroxyapatite, tricalcium phosphate and/or polymers and copolymers may also be included in the base layer 678.

The outer layer 680 may be formed of cartilage. Embryonal cells, fetal cells, and/or stem cells may be provided in the outer layer 680. The outer layer 680 may be formed of submucosal tissue. The outer layer 680 promotes biological resurfacing of a portion of the bone 674 where the implant 670 is disposed.

It is contemplated that the recess 672 may be formed in the bone 674 at a location where there is a defect in an articular surface on the bone. However, it is also contemplated that the recess 672 in a position in a portion of the bone 674 where there is no articular surface.

It is contemplated that the patient's leg will be in the position illustrated in FIGS. 2, 3 and 25 during forming of the recess 672 and positioning of the implant 670 in the recess. The upper portion 72 of the patient's leg 70 will be supported above the support surface 64 by the leg support 80. The limited incision 114 (FIG. 6) will be formed in the knee portion 76 of the patient's leg. The patella 120 will be in the offset position of FIG. 8 during forming of the recess 672. The drapery system of FIGS. 4 and 5 may advantageously be utilized to provide a sterile field. Although it may be desired to use a milling cutter as the cutting tool, other known cutting tools could be used if desired.

Implant

An improved implant 690 is illustrated in FIG. 50. The implant 690 may be utilized in association with either a full or partial knee replacement. Alternatively, the implant 690 could be utilized in association with a repair of a glenoid joint, an elbow, an ankle, a spine or any desired joint in a patient's body. Implant 690 includes a base 692 and an articular layer 694. The base 692 has been illustrated in FIG. 50 as being connected with the proximal end portion 212 of a tibia 214. The implant 690 is intended for use in association with either a partial or full knee replacement. However, it should be understood that an implant having a construction corresponding to the construction of the implant 690 could be utilized in association with any desired joint in a patient's body.

The base 692 (FIG. 50) is connected with the tibia 214 by projection 700 and a fastener 702. The projection 700 has a generally cylindrical configuration and extends from a main section 706 of base 692. The projection 700 extends at an acute angle to the main section 706 in a direction away from the fastener 702. When the implant 690 is positioned on the proximal end portion 212 of the tibia 214, the implant is moved along a path which extends parallel to a longitudinal central axis of the projection 700. The path of movement of the implant 690 onto the proximal end portion 212 of the tibia 214 is indicated by an arrow 707 in FIG. 50. The arrow 707 is skewed at an acute angle to a longitudinal central axis of the tibia 214. This results in the projection 700 being forced into the bone of the proximal end portion 212 of the tibia 214. Deformation of the bone occurs adjacent to a leading end of the projection 700. There is no significant deformation of the adjacent to a longitudinally extending outer side surface of the generally cylindrical projection 700.

When the implant 690 is positioned on the proximal end portion 212 of the tibia 214, the implant is moved along a path which extends parallel to a longitudinal central axis of the projection 700. The path of movement of the implant 690 onto the proximal end portion 212 of the tibia 214 is indicated by an arrow 707 in FIG. 50. The arrow 707 is skewed at an acute angle to a longitudinal central axis of the tibia 214. This results in the projection 700 being forced into the bone of the distal end portion 212 of the tibia 214. Deformation of the bone occurs adjacent to a leading end of the projection 700. There is no significant deformation of the adjacent to a longitudinally extending outer side surface of the generally cylindrical projection 700.

As the implant 690 is moved into position on the proximal end portion 212 of the tibia 214, a downwardly extending flange 708 connected with the main section 706 moves into engagement with an outer side surface area on the tibia 214 as the main section 706 of the implant 690 moves into engagement with flat distal proximal end surface 710 on the tibia 214. Once the inner side of the main section 706 has been pressed firmly against the flat end surface 710 on the tibia 214 and the projection 700 is moved to the position illustrated in FIG. 50, the fastener 702 is inserted through the flange 708. The fastener 702 is a screw and engages the proximal end portion 212 of the tibia 214 to securely connect the implant 690 with the tibia. A longitudinal central axis of the fastener 702 extends generally parallel to a longitudinal central axis of the projection 700. Therefore, as the fastener 702 is tightened to press the flange 708 against the outer side of the tibia 214, the projection 700 is cammed or forced inward to press the main section 706 against the end surface 710 on the tibia.

It is contemplated that the base 692 of the implant 690 may be formed of metal. For example, the base 692 may be

57

formed of porous tantalum. Of course, the base **692** could be formed of a different material if desired. Thus, the base **692** could be formed of a polymer or copolymer if desired. The articular layer **694** is formed of a smooth polymeric material which engages in articular surface on a femur.

It is contemplated that the patient's leg will be in the position illustrated in FIGS. **2**, **3** and **25** during positioning of the implant **690** on the proximal end portion of the tibia **214**. The upper portion of the patient's leg **70** will be supported above the support surface **64** (FIG. **2**) by the leg support **80**. The limited incision **114** (FIG. **6**) will be formed in the knee portion **76** of the patient's leg **70**. The patella **120** will be in the offset position of FIG. **8** during positioning of the implant **690**. The drapery system **100** (FIGS. **4** and **5**) will provide a sterile field. The tibial resection guide **218** (FIG. **21**) may be used during forming of the flat end surface **710** on the tibia **214**.

Expandable Devices

In accordance with another feature of the invention, one or more expandable devices **720** and **722** (FIG. **51**) may be utilized to move, stretch, or separate body tissue. The expandable devices **720** and **722** may be utilized at any time during a full or partial knee replacement. Thus, the expandable devices **720** and **722** may be utilized to separate body tissue from the distal end portion **124** of a femur **214** before a femoral component or implant **290** is connected with the femur and before the tibial tray **286** and tibial bearing insert **294** are connected with the proximal end portion **212** of the tibia **214**.

The expandable devices **720** and **722** may be inserted into the knee portion **76** of the patient's leg **70** one or more days before either a partial or full knee replacement operation is to be undertaken. Before the surgery is initiated, the expandable device **720** may be expanded to stretch skin **342**, the joint capsule, and other tissue in the anterior of the knee portion **76**. The viscoelastic body tissue is resiliently stretched by the expandable device **720** in the general area where the limited incision **114** (FIG. **6**) is to be formed.

The incision **114** is subsequently made in the body tissue which has been resiliently stretched by the expandable device **720**. After the surgery on the patient's leg **70** has been completed, for example, after a full or partial knee replacement in accordance with FIGS. **8–29**, the incision **114** in the stretched tissue is closed. The body tissue which was previously resiliently stretched by the expandable device **720** can, after closing of the incision **114**, return to its normal or unstretched condition. As this occurs, the length of any scar resulting from the incision **114** decreases. By making the incision **114** in body tissue which has previously been resiliently stretched by the expandable device **720**, the overall effective length of the incision **114** is reduced.

The expandable devices **720** and **722** may be resilient balloons which are inflated by a gas, such as air, or resilient bladders which are expanded under the influence of a liquid, such as saline solution. The resilient expandable devices **720** and **722** may be formed of a biodegradable material or a non-biodegradable material. It is contemplated that if the expandable devices **720** and **722** are to be left in the patient's body, they may advantageously be formed of a biodegradable material. However, if it is contemplated that when the expandable devices are to be removed from the patient's body during or after surgery, the expandable devices may be formed of a non-biodegradable material.

Rather than being inserted into the knee portion **76** prior to formation of the incision **114**, the expandable devices **720** and **722** (FIG. **51**) may be inserted into the knee portion immediately after making the incision. The expandable

58

devices **720** and **722** may then be expanded to separate body tissue in the knee portion **76**. The expandable devices **720** and **722** are inserted into the knee portion **76** in a collapsed condition. The expandable devices are expanded after being inserted into the knee portion.

For example, the expandable device **720** may be resiliently expanded to stretch the patellar ligament **458** (FIG. **51**) and move the patella **120** away from the distal end portion **124** of the femur **126**. Alternatively, the expandable device **720** may be positioned between the femur **126** and the patellar tendon **456**. Expansion of the expandable device **720** would then result in movement of the patellar tendon **456** and patella **120** away from the distal end portion **124** of the femur **126**. Of course, if expandable devices were provided between the distal end portion **124** of the femur and both the patellar tendon **456** and patellar ligament **458**, the patella tendon and ligament would both be moved by expansion of the expandable devices. Positioning of the expandable device **720** between the patellar ligament and/or tendon facilitates subsequent movement of the patella **120** to offset position of FIG. **8**.

The expandable device **722** (FIG. **51**) is disposed in the posterior portion of the knee portion **76** of the leg **70**. Expansion of the expandable device **722** in the posterior portion of the patient's knee is effective to move the joint capsule and fibrous connective tissue away from the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**. The expandable device **722** may be expanded immediately after the incision **114** is formed to effect releases of body tissue from the distal end portion **124** of the femur **126** and/or the proximal end portion **212** of the tibia **214**.

Expansion of the expandable device **722** is effective to move arteries, nerves and veins in the posterior of the knee portion **76** away from the distal end portion **124** of the femur **126** and proximal end portion **212** of the tibia **214** prior to making of the femoral and/or tibial cuts (FIGS. **8–29**). If desired, the expandable device **722** may be maintained in the expanded condition during making of one or more of the femoral and/or tibial cuts. If desired, the expandable device **722** may be provided with a tough surface which would protect arteries, nerves and/or veins during the making of one or more of the femoral and tibial cuts.

It should be understood that the expandable device **722** may have a configuration which is different from the configuration illustrated in FIG. **51**. For example, the expandable device **722** may extend for a greater distance along the posterior of the femur **126** and tibia **214** if desired. Although the implants **286**, **290** and **294** have been illustrated in FIG. **51**, it should be understood that the expandable devices **720** and **722** may be used before and/or after installation of the implants. The expandable devices **720** and **722** may be positioned in the knee portion **76** of the patient's leg **70** with the leg in the flexed condition of FIGS. **2** and **3** or with the leg in the extended condition of FIG. **51**.

After the femoral component **290** and tibial tray **286** and tibial bearing insert **294** have been positioned in the knee portion **76** of the patient's leg **70**, the expandable devices **720** and **722** may be utilized to assist the surgeon during ligament balancing. The expandable devices **720** and **722** will also assist the surgeon in obtaining a full range of motion of the knee portion **76**. Thus, the expandable devices **720** and **722** may be expanded, under the influence of fluid pressure, to effect ligament releases or to move tissue out of an interfering relationship with relative movement between the femur **126** and tibia **214**.

The expandable devices **720** and **722** may be resiliently expanded under the influence of fluid pressure conducted

through conduits to the expandable devices, If the expandable devices **720** and **722** are inserted after the incision **114** is formed in the knee portion **76** of the patient's leg **70**, the conduits for conducting fluid to and from the expandable devices **720** and **722** may extend through the incision. However, if the expandable devices **720** and **722** are inserted prior to making of the incision **114**, the conduits for conducting fluid to and from the expandable devices may extend through small portals or stab wounds formed in the knee portion of the patient's leg. It should be understood that the conduits for conducting fluid to and from the expandable devices **720** and **722** may extend through small secondary incisions spaced from the main incision **114** even though the expandable devices **720** and **722** are positioned in the knee portion **76** after making the main incision.

The small portals or stab wounds which form secondary incisions are spaced from the location where the main incision **114** is formed. Thus, the conduit for conducting fluid to and from the expandable device **722** may extend through a portal or stab wound formed in the posterior portion of the knee portion **76** of the patient's leg **70**. Before they are expanded, the contracted expandable devices **720** and **722**, are very small and flexible. The contracted expandable devices **720** and **722** have an appearance similar to a collapsed balloon. The contracted expandable devices are easily moved through the small secondary incisions.

It is contemplated that the expandable devices **720** and **722** may be left in the knee portion **76** of a patient's leg **70** after the incision **114** has been closed. If this is done, the expandable devices **720** and **722** may be utilized to obtain a full range of motion of the patient's knee **76** during therapy and/or recovery of the patient after the incision has been closed. If the expandable devices **720** and **722** are formed of a non-biodegradable material, it may be desirable to remove the expandable devices after the incision **114** has been closed. If the expandable devices **720** and **722** are formed of a biodegradable material, they do not have to be removed after the incision has been closed. It is contemplated that the expandable devices **720** and **722** may be contracted by piercing the skin **342** and puncturing the expandable devices.

It is contemplated that it may be desired to form the expandable devices **720** and **722** of a biodegradable material which is absorbable by the patient's body. If this is done, the expandable devices **720** and **722** may be formed of polylactic acid, polylactic acid, or combinations of these materials. It is contemplated that the expandable devices **720** and **722** could be formed of materials which include hyaluronic acid, catgut material, gelatin, cellulose, nitrocellulose, collagen or other naturally occurring biodegradable materials. Although it is believed that it would be preferred to form the expandable devices **720** and **722** of biodegradable materials so that they can be left in the patient's body and hydrolyzed so as to be absorbed by the patient's body, it is contemplated that the expandable devices **720** and **722** could be made of a non-biodegradable material if desired. The resiliently expandable devices **720** and **722** may have any of the constructions disclosed in U.S. Pat. Nos. 5,163,949; 5,454,365 and 5,514,153. Of course, the resiliently expandable devices **720** and **722** could have a different construction if desired.

Obtaining Range of Motion

After the implants **286**, **290** and **294** have been positioned on the femur **126** and tibia **214** in the manner illustrated schematically in FIG. **52**, it is contemplated that the range of motion of the knee portion **76** will be checked. During the check of the range of motion of the knee portion **76**, it may

be found that the range is unduly limited due to interference between body tissue in the posterior of the knee portion **76** and the implants. The range of motion of the knee portion **76** may be limited by tightness of tendons, ligaments and/or other tissue in the knee portion **76**.

Although it is believed that the expandable devices **720** and **722** of FIG. **51** may be utilized to alleviate these conditions, it may be preferred to use an expandable device **730** (FIG. **52**) which is inserted between the tibial bearing insert **294** and the trochlear groove in the femur **126**. Thus, once the implants **286**, **290** and **294** have been positioned in the knee portion **76** of the patient's leg **70**, the expandable device **730** may be moved through the incision **114**. The expandable device **730** is then moved between the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**.

The expandable device **730** may be a balloon or bladder which is made of resilient material. When fluid pressure in the expandable device **730** is increased, the expandable device is expanded from a collapsed condition to an extended condition. The resilient material of the expandable device **730** may or may not be stretched when the expandable device **730** is expanded.

The expandable device **730** may be moved posteriorly of the implants **286**, **290** and **294** so as to engage tissue in the posterior portion of the patient's knee. Alternatively, the expandable device **730** may be positioned between the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**. It is contemplated that the patient's leg **70** will be in the position illustrated in FIGS. **2** and **3** with the patella **120** (FIG. **52**) offset when the expandable device **730** is positioned in the knee portion **76**.

When the expandable device **730** is moved to the posterior of the patient's knee portion **76**, expansion of the expandable device **730** applies pressure against tissue in the posterior portion of the patient's knee. This results in movement of body tissue away from the implants **286**, **290** and **294**. Assuming that body tissue in the posterior of the patient's knee portion **76** is interfering with the range of relative movement between the implants **286**, **290** and **294**, applying pressure against the body tissue in the posterior of knee portion will move the body tissue away from the implants to enable the range of motion to be increased.

Expansion of the expandable device **730** is effective to move and stretch body tissue, such as the joint capsule, ligaments, tendons, skin or other tissue associated with the posterior portion of the patient's knee. Space is established between the distal end portion **120** of the femur **126** and body tissue. Space is also established between the proximal end portion **212** of the tibia **214** and body tissue. Since the body tissue is moved and stretched by expansion of the expandable device **730**, a portion of the space tends to remain even though the viscoelastic body tissue retracts when fluid is conducted from the expandable device **730** and the size of the device decreases.

The expandable device **730** may be left in place in the posterior of the patient's knee portion **76** after the incision **114** is closed. A conduit **734** connected with the expandable device **730** would extend through the closed incision **114** to enable fluid to be conducted to and from the expandable device **730**. Therefore, after the incision **114** has been closed, the expandable device **730** can be expanded to increase the range of movement of the knee portion **76** of the patient's leg **70**. After fluid has been conducted from the expandable device through the conduit **734**, the size of the expandable device is reduced by exhausting fluid through the conduit. The reduced size of the expandable device

61

enables the conduit **734** to be pulled outward, away from the knee portion **76**, to pull the expandable device **730** through a very small opening in the closed incision.

If desired, the expandable device **730** could be formed of a biodegradable material and left in the posterior of the knee portion **76**. The conduit **734** could be formed of a non-biodegradable material and pulled from the opening in the incision after the expandable device **730** has at least started to degrade. Of course, the conduit **734** could also be biodegradable.

Rather than applying force against body tissue at the posterior of the knee portion **76**, the expandable device **734** may be utilized to apply force against the distal end portion **124** of the femur **126** and against the proximal end portion **212** of the tibia **214**. This force would tend to stretch or release ligaments or other fibrous connective tissue connected with the femur **126** and tibia **214**. This force would also stretch the joint capsule, collateral ligaments **590** and **592** (FIG. **41**), and other tissues around the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214**.

When this is to be done, the expandable device **730** (FIG. **52**) is moved to a position midway between posterior and anterior portions of the implants **286**, **290** and **294**. The expandable device **730** is then expanded under the influence of fluid pressure conducted through the conduit **734**. As the expandable device expands, it acts as a joint jack to apply force against the femur **126** and tibia **214**. This force will tend to stretch the collateral ligaments and other ligaments and tendons connected with the femur **126** and tibia **214**.

Once the expandable device **730** has been utilized to apply an upwardly directed force (as viewed in FIG. **52**) against the distal end portion **120** of the femur **126** and a downwardly directed force (as viewed in FIG. **52**) against the proximal end portion **212** of the tibia **214**, the expandable device **730** is contracted by conducting a flow of fluid from the expandable device through the conduit **734**. The surgeon can then check ligament balancing and/or the range of motion of the knee portion **76**. If the ligament balancing check and/or range of motion check indicates that it would be beneficial, the expandable device **730** can again be utilized to apply force against the femur **126** and tibia **214**. Fluid pressure would again connected through the conduit **734** to the expandable device **730**. Expansion and contraction of the expandable device **730** can be repeated as many times as necessary to obtain the desired ligament balancing and/or range of motion of the knee portion **76**.

In FIG. **52**, the leg **70** of the patient is in the position indicated in FIGS. **2**, **3** and **25**. However, the leg **70** of the patient could be moved from the flexed position of FIG. **52** to the extended condition of FIG. **51** with the expandable device in position between the distal end portion **120** of the femur **126** and the proximal end portion **212** of the tibia **214**. It should be understood that the expandable devices **720**, **722** and **730** of FIGS. **51** and **52** may be utilized with the leg **70** of the patient in either the extended orientation of FIG. **51** or the flexed orientation of FIG. **52**. The leg **70** of the patient may be maintained stationary after insertion of the expandable devices **720**, **722** and/or **730**. Alternatively, the patient's leg **70** may be moved in any one or a combination of the directions indicated by the arrows **256**, **258**, **259** and **260** in FIG. **25** after insertion of the expandable devices **720**, **722** and/or **730**.

Although a single expandable device **730** is illustrated in FIG. **52**, it should be understood that a plurality of expandable devices **730** could be inserted into the knee portion **76** of the patient's leg. A first one of the expandable devices **730**

62

may be inserted into the posterior of the knee portion **76**. A second expandable devices **730** may be positioned between the lateral portions of the femur **126** and tibia, that is, in a position similar to the position of the transducer **596** in FIG. **41**. A third expandable device **730** may be positioned between medial portions of the femur **126** and tibia **214**, that is, in a position similar to the position of the transducer **598** in FIG. **41**.

It is contemplated that different pressures may be conducted to the expandable devices in different positions in the knee portion **76**. For example, a relatively low fluid pressure may be conducted to the first expandable device **730** in the posterior of the knee portion **76** to move and/or stretch body tissue with a limited force. A relatively high fluid pressure may be conducted to the second and third expandable devices **730** disposed between the femur **126** and tibia **214** to effect relative movement between the femur and tibia.

If desired, a higher fluid pressure could be conducted to one of the expandable devices **730** disposed between the femur **126** and tibia **214** than the other expandable device. For example, a higher fluid pressure may be conducted to the second expandable device **730** disposed between lateral portions of the femur **126** and tibia **214** than to the third expandable device **730** disposed between the medial portions of the femur and tibia. Alternatively, a higher fluid pressure may be conducted to the third expandable device **730** disposed between medial portions of the femur **126** and tibia **214** than to the second expandable device **730** disposed between lateral portions of the femur **126** and tibia **214**.

When a plurality of expandable devices **730** are used, the expandable devices may be made of the same material or different materials. For example, the first expandable device **730** in the posterior of the knee portion may be formed of a biodegradable material. The second and third expandable devices **730**, located between the femur **126** and tibia **214**, may be formed of a non-biodegradable material. Alternatively, the expandable devices **730** may all be formed of the same biodegradable material as the expandable devices **720** and **722**.

It is contemplated that the expandable devices **720**, **722** and/or **730** of FIGS. **51** and **52** may be utilized in association with many different joints in a patient's body. For example, the expandable devices may be utilized in association with surgery on a glenoid joint. Alternatively, the expandable devices may be used in association with surgery on a patient's spine. During spinal surgery, the expandable devices **720**, **722** and/or **730** may be utilized to move one vertebra relative to an adjacent vertebra during replacement of an intervertebral disc between the vertebrae. If desired, the expandable devices **720**, **722** and **730** could be positioned between articular processes on vertebrae. When the expandable devices **720**, **722** and **730** are formed of a biodegradable material, they may be positioned relative to a patient's vertebral column during surgery and left in place after the surgery. This would allow at least partial healing after the surgery with the expandable devices being effective to transmit force between components of the patient's vertebral column.

The manner in which the expandable devices **720**, **722** and **730** may be utilized in association with any one of many joints in the patient's body is similar to that disclosed in U.S. patent application Ser. No. 09/526,949 filed on Mar. 16, 2000. The manner in which an expandable device similar to the expandable devices **720**, **722** and **730** may be placed within a shoulder joint is similar to the disclosure in the aforementioned application Ser. No. 09/526,949 of which this application is a continuation-in-part. The expandable

63

devices **720**, **722** and **730** may be utilized during carpal tunnel surgery in the manner disclosed in the aforementioned application Ser. No. 09/526,949. It is believed that it will be particularly advantageous to make the expandable devices **720**, **722** and **730** of biodegradable material so that they may be left in a patient's body at the end of the surgery.

As previously mentioned, the expandable devices **720**, **722** and **730** may be utilized during therapy after surgery to stretch body tissue in the knee portion **76** of the patient's leg **70** and/or to increase the range of motion of the knee portion. It is contemplated that an orthosis may be utilized to stretch tissue that limits joint movement. The orthosis may have a construction similar to the construction disclosed in U.S. Pat. No. 5,611,764. The orthosis may be utilized to affect static progressive stretching of tissue in the knee portion **76** of the patient's leg **70**. In addition, the orthosis may be utilized during progressive stress reduction. The orthosis may be utilized in conjunction with one or more expandable devices corresponding to the expandable devices **720**, **722** and **730** in the patient's knee portion. Alternatively, the orthosis may be utilized without providing expandable devices in the patient's knee portion.

It is contemplated that, during restoration of the range of motion of the knee portion **76**, a constant passive motion device may be connected with the patient's leg. The constant passive motion device may include one or more load or force limiting devices similar to those disclosed in U.S. Pat. No. 5,456,268. The constant passive motion device may have a construction similar to that illustrated in U.S. Pat. No. 5,285,773. Of course, the constant passive motion device may have a different construction if desired. It is contemplated that a pulsatile stocking may be utilized to reduce the possibility of blood clots while a constant passive motion machine is utilized to increase the range of motion of the knee portion of a patient's leg.

It is contemplated that a laminar spreader may be used in association with the knee portion **76** during ligament balancing and/or gap balancing with the implants **286**, **290** and **294**. Alternatively, a distraction device which is spring loaded may be utilized on a medial, lateral or both sides of the knee portion **56** rather than the expandable elements **720**, **722** and **730** to increase range of motion and/or provide a desired ligament balancing. Insol's technique may be utilized in establishing a desired range of motion of the knee portion **76** of the patient's leg **70**.

Surgical Procedure

In the foregoing description of a specific surgical procedure which may be utilized in association with a knee portion **76** of a patient's leg, the femoral and tibial cuts are made, the patella is repaired and implants are installed in the knee portion **76** of the leg **70**. However, it is contemplated that the various steps in this surgical operation may be performed in a different order if desired.

Immediately after the limited incision **114** (FIG. **6**) is made in the knee portion **76** in the manner previously explained, repair of the patella **120** may be undertaken. During repair of the patella **120**, the patient's leg **70** is in the position illustrated in FIGS. **2** and **3**. The patella **120** is cut in situ with the guide assembly **464** (FIG. **36**). After a flat surface has been cut along the plane **484** (FIG. **35**) to form a flat surface on the inside of the patella, a layer on which the inner side **122** of the patella is disposed is removed. This decreases the thickness of the patella.

After the patellar cut has been made, in the manner previously explained and before installation of the patellar implant, the tibial cut is undertaken. During the tibial cut, the patient's leg **70** is in the position illustrated in FIGS. **2** and

64

3. The proximal end portion **212** of the tibia **214** is cut, in the manner illustrated schematically in FIG. **21**.

While the tibial cut is being made, the patella **120** is offset from its normal position with the flat cut surface, previously formed on the inner side of the patella, facing toward the distal end portion **124** of the femur **126**. Since the patellar cut has already been made, the patella **120** is relatively thin and provides minimal stretching of the skin **342** and other tissues in the knee portion **76** when the patella is in the offset position of FIG. **21** during the making of the tibial cut.

After the tibial cut has been made, the femoral cuts are made. Making of the femoral cuts after making of the tibial cut and after making of the patellar cut maximizes the space which is available for the making of the femoral cuts. During the making of the femoral cuts, the patient's leg **70** is in the position illustrated in FIGS. **2** and **3**. After the tibial cut has been made, a layer is removed from the tibia and the cut surface **246** (FIGS. **22** and **23**) on the proximal end portion **212** of the tibia is spaced from the distal end portion **124** of the femur **126**. In addition, the patellar cut has been made so that the patella **120** is relatively thin and provides minimal interference. The femoral cuts are made in the manner previously explained in conjunction with FIGS. **8-20**.

After the femoral cuts have been made, the tibial tray **286** is positioned on the distal end portion **212** of the tibia **214** in the manner illustrated schematically in FIGS. **27** and **28**. After the tibial tray **286** has been positioned on the tibia **214**, the femoral implant **290** (FIG. **29**) is positioned on the distal end portion **124** of the femur **126**. After the femoral implant **290** has been positioned on the distal end portion **124** of the femur **126**, the tibial bearing insert **294** (FIG. **29**) is positioned on the tibial tray **286** in the manner previously explained.

Once the tibial and femoral implants **286**, **290** and **294** have been positioned, the patellar implant is mounted on the cut surface of the patella **120**. The patellar implant is positioned on the cut surface of the patella **120** while the patella is in the medially offset position illustrated in FIG. **29**. By applying force to the patella pulling it outward away from the distal end portion **124** of the femur **126**, a patellar implant can be moved between the patella **120** and the femoral implant **290** (FIG. **29**) and mounted on the patella **120**. When the patella **120** has been moved back to the normal or initial position illustrated in FIG. **6**, the implant on the patella is aligned with the distal end portion **124** of the femur **126**.

By making the patellar cut before making of the tibial cut and the femoral cuts, the available space for the tibial cut and femoral cuts is maximized. Maximization of the space for the tibial cut and femoral cuts and for the insertion of the femoral implant **290** and tibial implants **286** and **294** is maximized by mounting the patellar implant after the femoral and tibial implants have been mounted.

It should be understood that the foregoing procedure is performed with the patient's leg in the position illustrated in FIGS. **2**, **3** and **25**. Thus, the upper portion **72** of the patient's leg is supported above the support surface **64** by the leg support **80**. The lower portion **68** of the patient's leg is suspended from the upper portion **72** of the patient's leg. The foot **74** is disposed below the support surface **64**.

Femoral Cutting Guide

A femoral cutting guide **750** (FIG. **53**) has cutting guide slots **752** and **754** with open ends **756** and **758**. The guide slot **752** has parallel guide surfaces **762**. Similarly, the guide slot **754** has parallel guide surfaces **764**.

The guide surfaces **762** for the guide slot **752** are skewed at an acute angle of forty-five degrees to a major side surface

65

766 of the femoral cutting guide 750. Similarly, the guide surfaces 764 are skewed at an angle of forty-five degrees to the major side surface 756 of the femoral cutting guide 750. The guide surfaces 762 extend perpendicular to the guide surfaces 764. The guide surface 762 guide a saw blade during the making of an anterior chamfer resection on the distal end portion 124 of the femur 126. Similarly, the guide surfaces 764 guide a saw blade during the making of a posterior chamfer cut on the distal end portion 124 of the femur 126.

The femoral cutting guide 750 has an anterior guide surface 770 which guides movement of a saw blade during the making of an anterior resection on the distal end portion 124 of the femur 126. Anterior guide surface 770 extends across the femoral cutting guide 750 between the lateral end portion 774 and a medial end portion 776 of the femoral cutting guide 750. The anterior guide surface 750 extends perpendicular to the major side surface 766 of the femoral cutting guide 750.

A posterior guide surface 780 guides movement of a saw blade during the making of a posterior resection on the distal end portion 124 of the femur 126. The posterior guide surface 780 extends between the lateral end portion 774 and the medial end portion 776 of the femoral cutting guide 770. The posterior guide surface 780 extends perpendicular to the major side surface 766 and extends parallel to the anterior guide surface 770. The anterior guide surface 770 and the posterior guide surface 780 extend transverse to the guide surfaces 762 and 764 of the guide slots 752 and 754.

The femoral cutting guide 750 is disposed on the distal end of the femur 126. The femoral cutting guide 750 is connected with the distal end of the femur 126 by a pair of pins 784 and 786. The pins 784 and 786 have longitudinal central axes which extend perpendicular to the major side surface 766 of the femoral cutting guide 750 and extend generally parallel to a longitudinal central axis of the femur 126.

When the femoral cuts are to be made on the distal end portion 124 of the femur 126, the femoral cutting guide 750 is connected to the distal end of the femur. Initial portions of the various femoral cuts are then made by moving the saw blade along the guide surfaces 762, 764, 770 and 780 on the femoral cutting guide 750. Since the femoral cutting guide 750 extends only part way across the distal end portion 124 of the femur 126, the femoral cutting guide is disconnected from the femur and the femoral cuts are completed.

After the femoral cutting guide 750 has been disconnected from the femur 126, cut surfaces during formation of the initial portion of the anterior femoral cut are utilized to guide the saw blade during completion of the anterior femoral cut. Similarly, cut surfaces formed during the initial portion of the posterior femoral cut are utilized to guide the saw blade during completion of the posterior femoral cut. Cut surfaces formed during the making of anterior chamfer cut are utilized to guide the saw blade during completion of the anterior chamfer cut. Similarly, cut surfaces formed during making of the initial portion of the posterior chamfer cut are utilized to guide the saw blade during completion of the posterior chamfer cut.

The cutting tool which is used to form the femoral cuts, tibial cuts, and patellar cut may have any desired construction. Although a saw 172 and blade 170 have been disclosed herein as making the various cuts, many known types of cutting tools may be used if desired. For example, laser cutters, milling cutters, and/or ultrasonic cutters may be utilized. When one or more features of the present invention are utilized to perform knee joint revisions, an ultrasonic

66

cutter may advantageously be utilized to cut cement previously used in association with an implant.

Side Cutting Guide

Using the femoral cutting guide 210 of FIG. 19 or the femoral cutting guide 750 of FIG. 53, the femoral cuts are made by moving a saw blade from a distal end of the femur 126 toward a proximal end of the femur. However, it is contemplated that the femoral cuts could be made by moving a saw blade between opposite sides of the femur in a direction extending generally perpendicular to a longitudinal central axis of the femur. Thus, the saw blade is moved along a path which extends between lateral and medial surfaces on the distal end portion 124 of the femur 126.

A femoral cutting guide 800 is illustrated in FIG. 54 as being mounted on a lateral surface 802 of the femur 126. However, the femoral cutting guide 800 could be mounted on the medial surface of the femur 126 if desired. When the cutting guide 800 is mounted on the lateral surface 802 of the femur 126, the incision 114 (FIG. 6) is laterally offset. Similarly, when the cutting guide 800 is mounted on a medial surface of the femur 126, the incision 114 is medially offset.

The femoral cutting guide 800 has a distal guide surface 806. The distal guide surface 806 is disposed in a plane which extends perpendicular to a longitudinal central axis of the femur 126 and extends through the lateral and medial condyles. The distal guide surface 806 extends perpendicular to a major side surface 808 of the femoral cutting guide 800.

An anterior chamfer guide surface 812 extends between opposite major sides of the femoral cutting guide 800. The anterior chamfer guide surface 812 is disposed in a plane which extends at an acute angle of forty-five degrees to a plane containing the distal guide surface 806. The anterior chamfer guide surface 812 extends perpendicular to the major side surface 808 of the femoral cutting guide 800. Similarly, a posterior chamfer guide surface 816 extends between opposite major sides of the femoral cutting guide 800. The posterior chamfer guide surface 816 is disposed in a plane which extends at an acute angle of forty-five degrees to a plane containing the distal guide surface 806. The plane containing the posterior chamfer guide surface 816 extends perpendicular to the plane containing the anterior chamfer guide surface 812.

An anterior guide surface 820 is disposed on the femoral cutting guide 800. The anterior guide surface 820 extends between opposite major sides of the femoral cutting guide 800. The anterior guide surface 820 is disposed in a plane which extends perpendicular to a plane containing the distal guide surface 806. The plane containing the anterior guide surface 820 extends generally parallel to a longitudinal central axis of the femur 126.

Similarly, the femoral cutting guide 800 includes a posterior guide surface 824. The posterior guide surface 824 extends between opposite major sides of the femoral cutting guide 800. The posterior guide surface 824 is disposed in a plane which extends parallel to a plane containing the anterior guide surface 820 and perpendicular to a plane containing the distal guide surface 806.

The femoral guide 800 is formed of one piece of metal and has parallel opposite major side surfaces 808. The femoral cutting guide 800 is connected with the lateral side 802 of the distal end portion 124 of the femur 126 by a pair of pins 830 and 832. The lateral side 802 of the femur may be cut to form a flat surface which is abuttingly engaged by a major side surface of the femoral cutting guide 800.

When the femoral cuts are to be made, the lateral side of the femur is cut to form a flat side surface on which the

67

femoral cutting guide **800** is mounted by the pins **830** and **832**. A saw blade or other cutting tool is then moved from the lateral side to the medial side of the distal end portion **124** of the femur **126** while the saw blade or other cutting tool is guided by the distal guide surface **806** on the femoral cutting guide **800**. The distal guide surface **806** has an extent which is less than the extent of the distal end cut to be formed on the distal end portion **124** of the femur **126**. Therefore, after an initial portion of the distal end cut has been made utilizing the guide surface **806** to guide movement of a saw blade or other cutting tool, the cut surfaces are utilized to guide movement of the cutting tool during completion of the distal end cut.

Once the distal end cut has been completed, the saw blade or other cutting tool is moved from the lateral side of the femur **126** to the medial side of the femur along the anterior chamfer guide surface **812**. The cutting tool is then moved from the lateral side of the femur **126** to the medial side of the femur along the posterior chamfer guide surface **816**. Since the anterior chamfer guide surface **812** and posterior chamfer guide surface **816** have lengths which are less than the length of the anterior chamfer cut and posterior chamfer cut, only the initial portions of the chamfer cuts are made utilizing the guide surfaces **812** and **816** on the femoral cutting guide **800**. The cuts are completed by guiding movement of the saw blade or other cutting tool with the previously cut surfaces.

The anterior guide surface **820** is then utilized to guide movement of the saw blade during an initial portion of an anterior cut. During making of the anterior cut, the saw blade or other cutting tool is moved from the lateral side to the medial side of the distal end portion **124** of the femur **126**. Since the anterior guide surface **820** is smaller than the anterior cut, surfaces formed during making of an initial portion of the anterior cut are utilized to guide the saw blade or other cutting tool during a final portion of the anterior cut.

Similarly, the posterior guide surface **824** on the femoral cutting guide **800** is utilized to guide the saw blade or other cutting tool during making of a posterior cut. During the making of an initial portion of the posterior cut, the saw blade is moved along the posterior guide surface **824** from the lateral side **802** of the distal end portion **124** of the femur **126** to the medial side. The posterior guide surface **824** is shorter than the posterior cut. Therefore, cut surfaces formed during an initial portion of the posterior cut are utilized to guide the saw blade during completion of the posterior cut.

The femoral cutting guide **800** remains connected with the femur **126** during the initial portion of each of the femoral cuts and during completion of the femoral cuts. The femoral cutting guide **800** is not of the capture type. Therefore, a saw blade is free to move past the guide surfaces **806**, **812**, **816**, **820** and **824** during completion of the femoral cuts. If the guide surfaces **806**, **812**, **816**, **820** and **824** were formed by slots, the femoral cutting guide **800** would have to be disconnected from the femur before the femoral cuts could be completed.

The femoral cutting guide **800** has been illustrated in FIG. **54** as being mounted on the lateral side **802** of the femur **126**. However, it is contemplated that the femoral cutting guide could be mounted on the medial side of the femur if desired. The distal cuts, chamfer cuts, anterior cuts and posterior cuts were set forth as being performed in that order. However, there is no critical order as to the sequence of the cuts. It is contemplated that the cuts may be formed in any desired sequence.

During use of the femoral cutting guide **800**, the patient's leg **70** is in the orientation illustrated in FIGS. **2**, **3** and **25**.

68

The drapery system **100** was utilized to maintain a sterile field during the operation on the patient's leg.

Optical Systems

Rather than using the guide members illustrated in FIGS. **9-21**, it is contemplated that an optically created guide could be utilized. The optically created guide may be a three dimensional image created by projecting a hologram onto an end portion of a bone which is to be cut. For example, a hologram may be used in projecting a three dimensional image of any one of the guides **138** (FIG. **11**), **186** (FIG. **17**), **210** (FIG. **20**), and **218** (FIG. **21**) onto a femur **126** or tibia **214** in a patient's body. Alternatively, one or more beams of coherent or non-coherent light may be projected onto the bone which is to be cut to provide a two dimensional cutting guide.

Utilizing pre-operative templating based on images of one or more bones in a patient's body, for example, a distal end portion **124** (FIG. **55**) of a femur **126**, a hologram may be developed. The hologram is utilized with a projector **858** to create a three dimensional image **850**. The illustrated three dimensional image is of a pattern of cuts to be made on the distal end portion of the femur **126**. In FIG. **55**, the three dimensional image **850** is visible to the surgeon **106** and is utilized to replace the femoral cutting guide **800** of FIG. **54**. Rather than replacing the femoral cutting guide **800** with a pattern of cuts as shown in FIG. **55**, the three dimensional image **850** may be an image of the femoral cutting guide **800**.

Although a hologram may be used to produce the three dimensional image **850** which is visible to the surgeon **106**, the image may be created in other ways if desired. When the visible image **850** is to be projected onto a flat surface cut on the distal end portion **124** of the femur **126**, a two dimensional image may be utilized if desired. The two dimensional image **850** may be accurately projected on to the flat surface on the end portion **124** of the femur **126** utilizing either coherent or non-coherent light and known image projection techniques.

The three dimensional image **850** has visible light beams **852** and **854** which define opposite ends of a sight line for guidance of a saw **172** or other cutting tool. If desired, light may be projected with a plane of colored light which extends between the light beams **852** and **854**. The colored light plane extending between the light beams **852** and **854** is visible and provides a guide for alignment of a blade **170** in a desired spatial orientation relative to the side surface **802** on the femur **126**.

The surgeon **106** moves the saw blade **170** along the colored plane of light extending between the light beams **852** and **854**. The colored plane of light extending between the light beams **852** and **854** indicates to the surgeon the desired spatial orientation of the saw blade **170** during the making of a cut. A sensor connected with the saw **172** enables a computer connected with a source **858** of the image **850** to have the plane of light extend along each of the desired saw cuts during the making of the saw cut. Thus, during the making of the femoral cut which extends between the light beams **852** and **854**, a plane of colored light extends between the light beams. This enables the surgeon to determine when the saw blade is properly aligned with the side surface **802** of the femur **126**. When a different cut is to be made, for example, a cut between the light beam **852** and a light beam **862**, a plane of colored light extends between the light beams **852** and **862**. The plane of light is visible and indicates to the surgeon the desired spatial orientation of the blade **170** of the saw **172** relative to the femur **126**.

In addition, locating laser light beams **866** and **868** are projected from laser light sources **872** and **874** mounted on

the saw **172**. The locating laser light beams **866** and **868** are visible to the surgeon **106** and are of a different color than the plane of light extending between the light beams **852** and **854** of the image **850**. Therefore, a surgeon can visually determine when the locating laser light beams **866** and **868** are aligned with the plane of light extending between the light beams **852** and **854** of the image **850**.

When the locating laser light beams **866** and **868** are disposed in the plane of light extending between the light beams **852** and **854**, the saw blade **170** is accurately aligned with the portion of the femoral cut to be made between the light beams **852** and **854** of the image **850**. If the locating laser light beams **866** and **868** are not disposed in the plane of light extending between the light beams **852** and **854**, the saw blade **170** is not in alignment with the desired location for the femoral cut.

In addition to the visual indication provided by alignment of the locating laser light beams **866** and **868** with the plane of light between the light beams **852** and **854**, audible and/or visual signals may be provided to the surgeon indicating whether or not the locating laser light beams **866** and **868** are in alignment with the plane of colored light extending between the light beams **852** and **854**. For example, a green light may be illuminated when the locating laser light beams **866** and **868** are in the same plane as the light beams **852** and **854** of the image **850**. A red light may be illuminated when either or both of the locating laser light beams **866** and **868** are not located in the plane of colored light extending between the light beam **852** and the light beam **854**. In addition, a warning sound, that is, an alarm, may be sounded when either one of the locating laser light beams **866** or **868** is offset from the plane of colored light extending between the light beams **852** and **854**.

Once the femoral cut extending between the light beams **852** and **854** has been completed, the saw **172** and saw blade **170** are moved into alignment with a plane of colored light extending between the light beam **852** and **862**. A second femoral cut is then made in the same manner as previously described in conjunction with the light beams **852** and **854**. This process is repeated until the desired number of femoral cuts have been made.

In the embodiment illustrated in FIG. **55**, the image **850** is projected onto a side surface **802** of the femur **26**. If desired, a three dimensional image may be projected onto all sides of the distal end portion **124** of the femur **126**. If this is done, the image may advantageously be a three dimensional image formed by lines which define the cuts to be made. As the saw blade **170** moves along lines of the three dimensional image, the saw blade **170** is moved to orientations corresponding to the orientations of the saw blade when making the femoral cuts illustrated in FIGS. **12-23**. However, rather than using the cutting guides illustrated in FIGS. **12-23**, the three dimensional image, corresponding to the image **850** of FIG. **55**, is projected onto the entire distal end portion **124** of the femur **126**. Locating laser light beams would be projected from the saw **172** to indicate to a surgeon when a saw was in the desired orientation relative to light planes forming portions of the image projected onto the distal end **874**. This enables the saw blade **170** to be located relative to the distal end **874** of the femur **126** in the same manner as previously explained in conjunction with the side surface **802** of the femur.

As was previously mentioned, the three dimensional image **850** may be an image of anyone of the guides **138**, **186**, **210**, **500**, **750** or **800**. The saw blade **170** would be moved along the image of a guide surface on the three dimensional image of the guide. The locating laser light

beams **866** and **868** would indicate to the surgeon the orientation of the saw blade **170** relative to the three dimensional image of a guide surface on the three dimensional image of any one of the guides **138**, **186**, **210**, **218**, **500**, **750** or **800**. This would eliminate the heavy metal guides which have previously been used. When the size of any one of the three dimensional images of one of the guides **138**, **186**, **210**, **218**, **500**, **750** or **800** is to be changed, it is merely necessary to have a computer controlling the projection of the three dimensional image to change a hologram being used to project the image or to effect a change in optics through which the image is projected.

Once the femoral cuts have been completed, an optical measuring device, such as an interferometer, may scan the cuts to determine if they have the desired configuration. Scanning the cuts with an optical measuring device may be used to eliminate the necessity of performing trials with provisional components. Eliminating the necessity of utilizing provisional components substantially reduces the amount of equipment required during a partial or total knee replacement.

The cut surfaces on the distal end portion **124** of the femur **126** and the proximal end portion **212** of the tibia **214** are illustrated in FIGS. **22** and **23**. Rather than performing trials with provisional implants, the cut surfaces on the femur **126** and tibia **214** are measured using known optical measuring devices. A computer, connected with the optical measuring device, is utilized to compare the measurement of the cut surfaces on the femur **216** and the tibia **214** with desired measurements for the specific implants **286**, **290** and **294** to be mounted on the femur and tibia. The computer also compares optically determined orientations of the cut surfaces on the femur **126** and tibia **214** relative to desired orientations of the cut surfaces.

The optical measuring device may have any one of many known constructions. For example, the optical measuring device may have the construction illustrated in U.S. Pat. Nos. 6,185,315 or 6,195,168 if desired. If an optical measuring device or other measuring device indicates that the cut surfaces are incorrect, a computer connected with the source **858** (FIG. **55**) of the image **850** will change the hologram to correspond to a next smaller size of implant. When a surgeon determines that the femur **126** should be cut for the next smaller size implant, the surgeon manually enters data into the computer. In response to this data, the computer causes the projector **858** of the image **850** to project an image corresponding to a next smaller size image. The saw **172** is then utilized to cut the femur along the lines indicated by the next smaller size image. This will allow the next smaller size implant to be mounted on the femur.

It is contemplated that the projector **858** could have any desired construction. For example, the projector **858** could have a construction which is generally similar to the construction of apparatus disclosed in U.S. Pat. No. 6,211,976. It is contemplated that the laser light sources **872** and **874** could have a construction similar to the construction of devices disclosed in U.S. Pat. No. 5,425,355. The laser light sources **872** and **874** may have a construction which is similar to the construction of devices which are commercially available from Laserscope, Inc. of San Jose, Calif.

It is contemplated that the patient's leg **70** will be in the position illustrated in FIGS. **2** and **3** when either the two dimensional or the three dimensional image is projected onto the end portion **124** of the femur **126**. The relatively small incision **114** may be resiliently expanded and/or moved relative to the distal end portion **124** of the femur **126** to allow the image **850** to be sequentially projected onto

various areas on the distal end portion **124** of the femur **126**. A three dimensional image may be generated by any one of several known methods, including the method disclosed in U.S. Pat. No. 5,379,133.

It is contemplated that the three dimensional image **850** may be used with procedures other than cutting of one or more bones in a patient's leg **70**. For example, a three dimensional image of cuts to be made on a vertebra in a patient's back may be projected onto the vertebra. The three dimensional image may be used in surgery involving soft tissue in a patient's body. For example, the three dimensional image may be projected to a location in a patient's body where a vascular anastomosis or an intestinal anastomosis is to be undertaken. The three dimensional image may correspond to a pattern of stitches to be made between portions of soft body tissue. By projecting the three dimensional image into a patient's body at any desired location where surgery of any type is to be undertaken, a guide is provided in the patient's body to assist the surgeon.

The locating laser light beams **852** and **854** may be used with surgical instruments other than the saw **172**. For example, the locating laser light beams **852** and/or **854** could be utilized to indicate the position of a bovie, or a needle, or forceps relative to body tissue. The locating laser light beams may have an intensity which is sufficient to shine through body tissue and enable a surgeon on one side of body tissue to visually determine the position of a surgical instrument on the opposite side of the body tissue.

Unicompartmental Knee Replacement

The drawings associated with the foregoing description have illustrated a full knee replacement rather than a partial knee replacement. However, it is contemplated that the previously described features of the present invention may be utilized with either a partial knee replacement or a full knee replacement. A femur **126** is illustrated schematically in FIG. **56** and has a distal end portion **124** with a pair of condyles **890** and **892**. When a partial knee replacement is to be made, only one of the two condyles, that is the condyle **892**, is cut. A saw **172** having a blade **170** is used to cut the condyle **892** along a line indicated at **896** in FIG. **56**.

The saw **172** is provided with laser light sources **902** and **904**. The laser light sources **902** and **904** project visible locating laser light beams **906** and **908** which extend along opposite longitudinal edges of the saw blade **170**. The locating laser light beams **906** and **908** impinge against the condyle **892**. The locating light beams are of colored coherent light which is visible to a surgeon to indicate the orientation of the saw blade **170** relative to the condyle **892**.

It is contemplated that the saw **172** and blade **170** may be utilized in association with a guide member which is connected with the femur **126**. Alternatively, a two or three dimensional image, corresponding to the image **850** of FIG. **55**, may be projected onto the distal end portion of the femur **126**. Another alternative would be to make a line **896** on the condyle **892** with a marking instrument.

Rather than using a saw blade **170** to make the cut in the condyle **892**, it should be understood that a different type of cutting tool could be utilized if desired. For example, a milling cutter could be used to cut along a line **896** in FIG. **56**. If a full knee replacement, rather than a partial knee replacement, is desired, both condyles **890** and **892** may be cut with the saw **172** and blade **170** using the laser light sources **902** and **904** to indicate the position of the saw blade relative to the distal end portion **124** of the femur **126**. Once the femoral cuts have been made, an optical measuring device may be utilized to determine whether or not the cuts are of the proper size.

Multiple Incisions

A single incision **114** is illustrated in FIGS. **6-8** to provide access to the knee portion **76** of the patient's leg **70**. As has been previously explained herein, the length of the incision **114** is minimized. However, it is contemplated that the length of the incision **114** could be further reduced by providing one or more very small incisions **920** (FIG. **57**) in the knee portion **76** of a patient's leg **70** in association with the incision **114**. The incision **920** is a small stab wound which forms a portal through the skin **342**. The blade **170** of the saw **172** or other cutting tool may be moved through the small incision **920** to make one or more femoral cuts.

After the femoral cuts have been made through the small incision **920** and the larger or main incision **114**, femoral and/or tibial implants are moved through the main incision. By providing the small incision **920** in association with the larger main incision **114**, the overall length of the main incision may be minimized.

During making of the incisions **114** and **920**, the patient's leg **70** is in the position illustrated in FIGS. **2** and **3**. During making of the tibial and femoral cuts and insertion of the implants, the patient's leg **70** is also in the position illustrated in FIGS. **2** and **3**. If desired, one or more expandable devices, corresponding to the expandable devices of FIGS. **51** and **52**, may be inserted through one or more small incisions **920** and/or the main incision **114**.

In the embodiment of the invention illustrated in FIG. **57**, laser light sources **902** and **904** are connected with the saw **172** in the manner illustrated schematically in FIG. **56**. The laser light sources provide visible locating laser light beams, corresponding to the locating laser light beams **906** and **908** of FIG. **56**.

By using more than one incision, that is, the main incision **114** and one or more small incisions **920**, cutting tools can approach and move along the distal end portion **124** of the femur **126** from different directions. Thus, the saw blade **170** moves from the right to the left as viewed in FIG. **57**, that is, in a lateral direction, during making of a femoral cut. A cutting tool which moves through the incision **114** may move in a superior direction along the femur **126**, that is, from the distal end portion **124** of the femur **126** toward a proximal end portion of the femur. The cutting tools may be used to make cuts required for either a partial or full knee replacement.

Although it is preferred to make the incisions **114** and **920** and to cut the femur **126** with the leg **70** of the patient in the position illustrated in FIGS. **2** and **3**, it should be understood that the use of a plurality of incisions during the surgery with the leg in other positions may be desired. Although the foregoing description has been in conjunction with surgery on a knee portion of a leg **70** of a patient, it is contemplated that the surgery could be performed on a different portion of the patient if desired.

Patellar Tracking

A pair of transducers **596** and **598** are illustrated in FIGS. **41** and **42** to compare tension and collateral ligaments **590** and **592**. The manner in which the transducers **596** and **598** are positioned between the femur **126** and tibia **214** is illustrated schematically in FIG. **58**.

In accordance with another feature of the invention, a pair of patellar transducers **930** and **932** are disposed on an inner side of the patella **120**. The patellar transducers **930** and **932** are connected with a display, corresponding to the computer display areas **601** and **602** of FIG. **41**. The patellar transducers **930** and **932** are disposed between the distal end portion **124** of the femur **126** and the patella **120**.

The patellar transducers **930** and **932** have outputs which correspond to force transmitted between the patella **120** and

the femur 126. Thus, the output from the transducer 930 corresponds to the force transmitted between the lateral side of the patella 120 and a lateral side of a trochlear groove in the femur 126. Similarly, the output from the transducer 932 corresponds to the force transmitted between a medial side of the patella 120 and a medial side of the trochlear groove in the femur 126. By comparing the output from the patellar transducers 930 and 932 during relative movement between the femur 126 and tibia 214, variations in the force transmitted between the lateral and medial portions of the patella 120 can be compared. This enables a surgeon to determine when the patella is tracking properly relative to the femur 126.

The patellar transducers 930 and 932 are resiliently expandable containers which hold fluid. As the force transmitted between the patella 120 and the femur 126 increases, the pressure of the fluid in the patellar transducers 930 and 932 increases. It is contemplated that the containers 930 and 932 may hold either a gas or a liquid. Pressure signals corresponding to the pressure in the patellar transducers 930 and 932 are conducted through conductors 934 and 936 to a display, corresponding to the computer displays 601 and 602 of FIG. 41. The patellar transducers 930 and 932 may have any desired construction which enables them to measure the force transmitted between the patella 120 and the femur 126. Thus, the transducers 930 and 932 could be of the piezoelectric type or of a strain-gage type.

During checking of patellar tracking with the transducers 930 and 932, the upper portion 72 of the leg 70 of the patient is supported above the support surface 64 by the leg holder 80 (FIG. 2). The leg 70 is moved between the flexed condition of FIGS. 2 and 3 and the extended condition of FIG. 4. During movement of the leg 70 between the flexed and extended conditions, there is relative movement between the end portion 124 of the femur 126 and the patella 120 (FIG. 58). During relative movement between the femur 126 and patella 120, the output from the patellar transducers 930 and 932 indicates the manner in which force transmitted between the patella and femur varies. This enables a surgeon to detect any defects in tracking of the patella 120 relative to the femur 126.

The patellar transducers 930 and 932 are mounted on the patella 120 after the patellar implant has been mounted on the patella. This enables the patellar transducers 930 and 932 to be utilized to detect any irregularities in the manner in which the patellar implant cooperates with the femoral implant 290 (FIG. 29). However, it is contemplated that the patellar transducers may be mounted on the patella 120 before the patellar implant is mounted on the patella. When this is to be done, the transducers 930 and 932 may be mounted in a body having a size and configuration corresponding to the intended size and configuration of the patellar implant.

In the embodiment of FIG. 58, the patellar transducers 930 and 932 extend across the patella 120 between lateral and medial edges of the patella. However, it is contemplated that the transducers 930 and 932 may extend only part way across the patella. If desired, more than the two illustrated patellar transducers 930 and 932 may be provided on the patella 120.

The transducers 596 and 598 are utilized in combination with the patellar transducers 930 and 932 (FIG. 58). This enables the surgeon to determine the manner in which tension varies in the collateral ligaments 590 and 592 (FIGS. 41 and 42) with variations in force transmitted between the patella 120 (FIG. 58) and the femur 126. However, the patellar transducers 930 and 932 may be utilized without the transducers 596 and 598.

When it is determined that the patella 120 is not tracking properly, corrective action may be taken by increasing the fluid pressure in either or both of the patellar transducers 930 and 932. If the transducers 596 and 598 are utilized, the corrective action may include increasing the fluid pressure in either or both of the transducers 596 and 598. The transducers 596 and 598 and the patella transducers 930 and 932 are formed of resilient material which can be expanded under the influence of fluid pressure.

Although the patellar transducers 930 and 932 are utilized to measure force transmitted between lateral and medial portions of the patella 120 and the femur 126, the patellar transducers can be utilized to stretch or move body tissue in the same manner as the expandable devices 720, 722 and 730 (FIGS. 51 and 52). By increasing the fluid pressure conducted to the patellar transducer 930 (FIG. 58), the patellar transducer expands to stretch fibrous connective body tissue connected with the lateral side of the patella 120. Similarly, increasing the fluid pressure conducted to the patellar transducer 932 expands the patellar transducer 932 to stretch fibrous connective body tissue connected with the medial side of the patella 120. Increasing the fluid pressure conducted to both patellar transducers 930 and 932 is effective to expand both transducers and stretch fibrous connective body tissue with both sides of the patella 120.

The patellar transducers 930 and 932 may be formed of either a biodegradable material or a non-biodegradable material. When the patellar transducers 930 and 932 are to be left in the knee portion 76, the patellar transducers may be formed of a biodegradable material which is eventually absorbed by the patient's body. When the patellar transducers 930 and 932 are to be removed from the knee portion 76, the patella transducers may be formed of a non-biodegradable material. If the patellar transducers 930 and 932 are formed of a biodegradable material and are left in the knee portion 76 after closing of the incision 114, the patellar transducers may be expanded during therapy to stretch body tissue connected with the patella 120.

Movable Implant

The implant 690 of FIG. 50 is fixedly secured to the proximal end portion 212 of a tibia 214 by the projection 700 and fastener 702. In the embodiment of the invention illustrated in FIG. 59, a moveable implant 950 is provided between the distal end portion 124 of a femur 126 and a proximal end portion 212 of a tibia 214. In accordance with a feature of this embodiment of the invention, the implant 950 is freely moveable relative to both the femur 126 and the tibia 214.

The moveable implant 950 has a smooth upper (as viewed in FIG. 59) surface 952 which is engaged by a medial portion of the distal end portion 124 of the femur. Similarly, the moveable implant 950 has a smooth lower (as viewed in FIG. 59) surface 954 which is engaged by a medial portion of the proximal end portion 212 of the tibia 214. This smooth upper and lower end surfaces 952 and 954 compensate for defects in the existing surfaces on the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214. By providing the moveable implant 950 between the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214, pain which results from engagement of a surface 958 on the distal end portion 124 of the femur 126 with a surface 960 on the proximal end portion 212 of the tibia 214 is eliminated or at least substantially reduced.

During bending of the knee portion 76 of the patient's leg 70, the implant 950 may move relative to both the femur 126 and the tibia 214. The implant 950 can move in either a

75

lateral or medial direction relative to the femur 126 and tibia 214. In addition, the implant 950 can move in either a posterior or anterior direction relative to the femur 126 and tibia 214.

By having a three hundred and sixty degree (360°) range of movement relative to both the femur 126 and tibia 214, the moveable implant 950 accommodates relative movement between the femur and tibia with minimal pain. This is because relative movement will occur between the implant 950, femur 126 and tibia 214 at locations where frictional forces due to irregularities on the surfaces of the femur 126 and tibia 214 are minimal. In addition, the implant 950 can shift relative to the femur 126 and tibia 214 during bending of the knee portion 76 to accommodate irregularities in the existing surfaces 958 and 960 on the distal end portion 124 of the femur and the proximal end portion 212 of the tibia.

The range of movement of the implant 950 relative to the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 is limited by engagement of the moveable implant 950 with soft tissue in the knee portion 76 of the patient's leg 70. Therefore, even though the implant 950 can move relative to the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214, the implant is held against excessive movement relative to the femur and tibia by soft tissues associated with the femur and tibia.

For example, engagement of the implant 950 with cartilage or other soft tissue which is located at the peripheral aspect of the knee joint between the femur 126 and tibia 214 retains the implant 950 within a desired range of movement. The cartilage may be articular cartilage and/or fibrocartilage. The cartilage is engaged by peripheral surfaces on the moveable implant 952 and retains the implant in a desired position relative to the femur 126 and tibia 214. In addition, fibrous connective tissue extending between the femur 126 and tibia 214 limits movement of the implant 950 relative to the femur and tibia.

The joint capsule in the knee portion 76 of the patient's leg may be engaged by the periphery of the implant 950 to retain the implant in a desired position. By using cartilaginous, ligamentous, or other tissues to limit the range of movement of the moveable implant 950, the implant can freely shift relative to the femur 126 and tibia 214 through a limited range of movement during bending of the knee portion 76 of the patient's leg 70. If desired, growth of the tissues used to limit the range of movement of the implant may be promoted.

The moveable implant 950 is sized so as to fit the surfaces 958 and 960 on the distal end portion 124 and proximal end portion 212 of the femur 126 and tibia 214 (FIG. 59). The sizing is accomplished by imaging the knee portion 76 of the patient's leg. The moveable implant 950 may be one of a series of implants of different sizes. After the patient's knee portion 76 has been imaged, a moveable implant is selected from the series of moveable implants of different sizes. The size of the selected moveable implant closely approximates the size of the space between the surfaces 958 and 960 on the distal end portion 124 and proximal end portion 212 of the femur 126 and tibia 214.

Thus, for a relatively large individual, a moveable implant 950 having a relatively large size is selected from the series of moveable implants. Similarly, for an individual having a relatively small size, a moveable implant 950 having a relatively small size is selected from the series of moveable implants. The selected implant has a size which corresponds to the general size of the space between the surfaces 958 and 960.

76

As a result of imaging of the knee portion 76 of the patient's leg 70, the actual configurations of the existing surfaces 958 and 960 on the femur 126 and tibia 214 can be accommodated by shaping the upper surface 952 of the moveable implant 958 to have a configuration corresponding to the surface 958 on the femur 126. Similarly, the lower surface 954 on the moveable implant 950 can be shaped to have a configuration corresponding to the configuration of the surface 960 on the tibia 214. Of course, the configuration of the periphery of the moveable implant can be changed to correspond to the configuration of the periphery of the space between the surfaces 958 and 960 into which the moveable implant 950 is to be placed.

It is contemplated that the imaging of the knee portion 76 of the patient's leg 70 may be done preoperatively, on an out-patient basis. The moveable implant 950 may then be selected from the series of available moveable implants and shaped to have a configuration which corresponds to the configuration of the space between the surfaces 958 and 960. The implant 950, which has been shaped to conform to the space between the surfaces 958 and 960, may then be moved to an operating room for insertion into a patient during the surgical procedure. Alternatively, the imaging of the knee portion 76 and shaping of the moveable implant 950 to the desired configuration may be performed in the operating room as part of the surgical procedure.

When the moveable implant 950 is to be positioned in the knee portion 76 of the patient's leg 70, in the manner indicated schematically in FIG. 59, a limited incision is made in the knee portion of the patient's leg. The limited incision is made while the patient's leg 70 is supported in the position shown in FIGS. 2, 3 and 25. The upper portion of the patient's leg is supported by the leg support 80.

The incision may have a limited length, corresponding to the limited length of the incision 114 of FIG. 7 and be located adjacent to an edge of the patella 120. When the implant 950 is to be positioned adjacent to a medial portion of the femur 126 and a medial portion of the tibia 214, in the manner illustrated schematically in FIG. 59, the incision 114 would be located adjacent to a medial edge of the patella 120, in the manner illustrated in FIG. 6. However, it should be understood that if the implant 950 is to be located adjacent to a lateral portion of the femur 126 and a lateral portion of the tibia 214, the incision 114 could be formed adjacent to a lateral edge of the patella 120.

Once the limited incision 114 has been formed in the manner previously described in conjunction with FIGS. 6 and 7 herein, the patella 120 may be moved to the offset position of FIG. 8 with the inner side 122 of the patella facing inward to facilitate utilization of an incision 114 having a limited length. Once the limited incision 114 has been formed, locations in the knee portion 76 of the patient's leg 70 may be inspected utilizing an optical device similar to the endoscope 352 of FIGS. 32 and 33. It is believed that the surgeon will bend the leg 70 of the patient between the flexed condition of FIG. 32 and the extended condition of FIG. 33 and will rotate the lower portion of the leg about its longitudinal central axis, in the manner indicated by the arrow 258 in FIG. 25 prior to positioning of the implant 950 in the knee portion 76 of the leg 70. This will enable the surgeon to detect any present or potential interference between the implant 950 and tissue in the knee portion 76 of the patient's leg 70.

Once this has been done, the surgeon may or may not decide to cut tissue in the knee portion 76 of the patient's leg 70 before inserting the moveable implant 950. If the surgeon elects to cut tissue in the knee portion 76 before insertion of

the implant, this cutting will be relatively minor and will not involve the femoral and tibial cuts depicted in FIGS. 13–23 herein. This is because the moveable implant 950 is to be positioned between surfaces 958 and 960 which are in their existing condition. Of course, eliminating the major femoral and tibial cuts illustrated in FIGS. 13–23 herein will reduce the patient's post-operative recovery time. In addition, elimination of the major femoral and tibial cuts illustrated in FIGS. 13–23 enables the size of the incision 114 to be reduced.

Once the moveable implant 950 has been positioned between the existing surfaces 958 and 960 on the femur 126 and tibia 214, the patella 120 is moved from the offset position of FIG. 8 back to its normal position relative to the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214. While the lower portion of the leg 70 is suspended from the upper portion of the leg and while the upper portion of the leg is held above the support surface 64 by the leg support 80 (FIG. 2), the incision 114 is closed in a normal manner. Prior to closing of the incision, an imaging apparatus can be utilized to generate images of the knee portion 76 during bending of the leg 70 between the flexed and extended conditions of FIGS. 32 and 33.

Any known imaging apparatus may be utilized to image the knee portion 76 of the patient's leg 70. For example, the known C-arm fluoroscope 360 of FIG. 34 may be utilized to generate images of the knee portion 76 of the patient's leg 70. These images will enable the surgeon to determine the manner in which the implant 950 will move relative to the femur 126 and tibia 214 during bending of the patient's leg. Prior to closing of the incision 114, any corrective action which the surgeon may believe is necessary can be taken to make certain that the moveable implant 950 is in the desired relationship with the femur 126 and tibia 214.

Rather than forming the incision 114 in the manner illustrated schematically in FIG. 6, the incision may be formed with an even shorter length and a cannula, corresponding to the cannula 364 of FIG. 39, inserted into the incision. The implant 950 may be moved through the resiliently expandable cannula into the space between the existing surfaces 958 and 960 (FIG. 59) on the femur 126 and tibia 214. The cannula would stretch the viscoelastic material of tissues in which the very limited incision is formed to resiliently expand the extent of the incision 114 to enable the implant 950 to be moved through the incision even though the moveable implant 950 is larger than the incision.

The cannula 564 (FIG. 39) through which the implant 950 (FIG. 59) is moved into the space between the surfaces 958 and 960 is advantageously expandable to accommodate the implant 950. The cannula may have any one of the constructions previously described in conjunction with FIG. 39 herein. If desired, multiple incisions, corresponding to the incisions 114 and 920 of FIG. 57 may be utilized during positioning of the implant 950. An expandable cannula may be associated with either or both of the incisions. Fiberoptic devices, such as an endoscope or arthroscope, may be inserted through a very small incision, corresponding to the incision 920 of FIG. 57, to facilitate positioning of the implant 950. By utilizing an expandable cannula and/or arthroscopic and endoscopic surgical procedures, the size of the incision 114 through which the implant 950 is moved can be minimized.

The moveable implant 950 is flexible so that force transmitted between the femur 126 and tibia 214 deflects the moveable implant 950. This results in the moveable implant 950 being shaped by the surfaces 958 and 960 on the femur

126 and tibia 214. By shaping the upper surface 952 on the moveable implant 950 with the surface 958 on the femur 126, smooth sliding engagement is provided between the surface 958 on the femur 126 and the upper surface 952 on the moveable implant 950. Similarly, the lower surface 954 on the implant 950 is shaped by the surface 960 on the tibia 214. By shaping the lower surface 954 on the implant 950 with the surface 960 on the tibia 214, smooth sliding engagement is provided between the surface 960 on the tibia 214 and the lower surface 954 on the moveable implant 950 during bending of the knee portion 76.

Shaping of the surfaces 952 and 954 on the moveable implant 950 may be accomplished in any one of many different ways. For example, the implant 950 may be formed of a material which is resiliently deflected by the surfaces 958 and 960 on the femur 126 and tibia 214. This results in the upper surface 952 and lower surface 954 and the moveable implant 950 being resiliently deflected to have a configuration corresponding to the configuration of the portions of the surfaces 958 and 960 which are engaged by the moveable implant during bending of the knee portion 76. During bending of the knee portion 76, the moveable implant 950 shifts or moves relative to the surfaces 958 and 960 on the femur 126 and tibia 214. During this shifting movement, the configuration of the upper surface 952 and the lower surface 954 of the moveable implant 950 is resiliently changed by forces transmitted between the femur 126 and tibia 214 through the moveable implant 950.

Rather than having the moveable implant 950 resiliently deflected by force transmitted between the femur 126 and tibia 214, the moveable implant 950 may be plastically deformed by the force transmitted between the femur and the tibia. Thus, the surface 958 on the femur 126 may plastically deform the upper surface 952 on the moveable implant 950 so that it retains a configuration corresponding to the configuration of the surface 958 on the femur 126. Similarly, the surface 960 on the tibia 214 may be plastically deform the lower surface 954 on the moveable implant 950 so that it maintains a configuration corresponding to the configuration of the surface 960 on the tibia 214. By plastically deforming the material of the moveable implant 950 with the surfaces 958 and 960 on the femur 126 and tibia 214, smooth sliding engagement is obtained between the upper and lower surfaces 952 and 954 on the moveable implant 950 during bending of the knee portion 76.

Even though the upper and lower surfaces 952 and 954 on the moveable implant 950 are either elastically or plastically shaped by the force transmitted between the femur 126 or tibia 214, the moveable implant will, initially, be configured to have a shape corresponding to the existing space between the surfaces 958 and 960. It is contemplated that this will result in the surfaces 952 and 954 being spaced apart by different distances between different portions of the moveable implant 950.

For example, the distance between the upper surface 952 and lower surface 954 on the moveable implant 950 may be relatively large adjacent to a medial edge portion of the moveable implant 950. The distance between the upper and lower surfaces 952 and 954 on the moveable implant 950 may be relatively small adjacent to a lateral edge portion of the moveable implant. As was previously mentioned, it is contemplated that images be generated of the knee portion 76 to enable the shape of the existing space between the surfaces 958 and 960 to be determined and to enable the moveable implant 950 to be configured, outside of the patient's body, to a configuration which generally conforms to the configuration of the space between the surfaces 958

and 960. Once the moveable implant 950 has been initially shaped to a configuration corresponding to the configuration of the space between the surfaces 958 and 960, the implant is positioned between the surfaces.

It is contemplated that the moveable implant 950 may be relatively thin compared to the thickness of the moveable implant illustrated schematically in FIG. 59. This would result in the upper surface 952 of the moveable implant 950 being spaced apart from the lower surface 954 of the moveable implant by a relatively small distance. By forming the moveable implant 950 with a relatively small thickness, that is, the distance between the upper surface 952 and the lower surface 954, the implant will be relatively flexible. This enables the implant to be deflected by force transmitted between the surfaces 958 and 960 on the femur 126 and the tibia 214.

It is contemplated that a relatively flexible moveable implant 950 may be configured so as to readily fit into an existing space in the knee portion 76. This would result in a tendency for the moveable implant 950 to become seated on the proximal end portion 212 of the tibia 214. The moveable implant 950 would be seated on the proximal end portion 212 of the tibia 214 by force applied against the moveable implant by the surface 958 on the femur 126. The lower surface of the moveable implant would be permanently deflected to have a configuration corresponding to the configuration of the upper surface 960 in the tibia 214. The upper surface 952 of the moveable implant would have an overall configuration which may differ from the configuration of the surface 958 on the femur 126. However, even though the configuration of the upper surface 952 on the moveable implant 950 is different than the configuration on the surface 958 on the femur 126, there would be smooth sliding engagement between the surface 958 on the femur 126 and the upper surface 952 of the moveable implant 950. The result would be that there would be relatively little movement between the lower surface 954 of the moveable implant 950 and the surface 960 on the tibia 214 during bending of the knee portion 76. However, there would be a relatively large amount of movement between the upper surface 952 of the implant 950 and the surface 958 on the femur 126. Since the moveable implant 950 would be permanently deflected to have a configuration corresponding to the space between the existing surfaces 958 and 960 on the femur 126 and tibia 214, the existing surfaces 958 and 960 on the femur 126 and tibia 214 would cooperate with the moveable implant 950 without inducing pain in the knee portion 76 of the leg 70 of the patient.

It is contemplated that the moveable implant 950 may be formed of many different materials. For example, the moveable implant 950 may be formed of a biological material. For example, the moveable implant 950 may be formed of allograft or autograft or xenograft. Combinations of these graft materials may be utilized. These graft materials may be shaped in the manner disclosed in U.S. Pat. No. 5,888,219. The moveable implant 950 may be formed of the same materials as the implant 626 of FIGS. 43 and 45 if desired.

It is believed that it may be desired to form the moveable implant 950 of metal. For example, the moveable implant 950 could be formed of chromium, titanium, tantalum, zirconium or aluminum. The metal forming a moveable implant may or may not have a porous construction. The metal forming the moveable implant 950 would have a wettable surface which can be wetted by body fluids to provide lubricity. If the moveable implant 950 is formed of a porous metal, the metal may be impregnated with one or more polymeric materials which function as lubricants.

The moveable implant 950 may be formed of a ceramic material. The ceramic material of the moveable implant may have either a porous or non-porous construction. When the ceramic material of the moveable implant 950 has a porous construction, it is contemplated that the openings in the ceramic material will be filled with a lubricant to facilitate relative movement between the surfaces 958 and 960 on the femur 126 and tibia 214 and the surfaces 952 and 954 on the moveable implant 950.

When the moveable implant 950 is formed of a porous material, for example a porous metal or a porous ceramic, it is contemplated that the moveable implant could be impregnated with both a bone growth promoting material and a lubricant. For example, the portion of the porous moveable implant 950 adjacent to the upper surface 952 of the implant may be impregnated with a lubricant. The portion of the moveable implant 950 adjacent to the lower surface 954 may be impregnated with bone growth inductive materials.

With such a construction, the lower surface 954 of the moveable implant is configured to correspond to the configuration of the surface 960 on the tibia 214. Therefore, the moveable implant will tend to become seated on the proximal end portion 212 of the tibia 214. Once this has occurred, the bone growth promoting materials in the porous implant 950, adjacent to the lower surface 954 of the implant, will promote growth of bone into the moveable implant 950 to connect the moveable implant with the tibia 214. The lubricant in the porous material adjacent to the upper surface 952 of the moveable implant 950 will minimize friction with the surface 958 on the femur 126 so that there will be minimal tendencies for the moveable implant 950 to move relative to the tibia 214 once the moveable implant has become seated on the proximal end portion 212 of the tibia. Of course, this will facilitate the growth of bone between the surface 960 on the proximal end portion 212 of the tibia 214 and the moveable implant 950.

The moveable implant 950 may be formed of graft materials which have been shaped in the manner disclosed in U.S. Pat. No. 5,888,219. If desired, the moveable implant 950 may have a three dimensional scaffold or framework structure on which graft materials are disposed. The framework on which the graft materials are disposed may have sufficient flexibility to enable the moveable implant 950 to be flexed to correspond to the configuration of the surface 960 on the tibia 214 by force applied against the upper surface 952 of the moveable implant by the femur 126. The graft materials on the scaffold will be shaped by the surface 958 on the femur 126 to form the upper surface 952 of the implant with the configuration which corresponds to the configuration of the surface 958 on the femur.

It is contemplated that the moveable implant 950 may be formed of materials which degrade with the passage of time. Thus, after the implant 950 has been disposed in the knee portion 76 of a patient's leg 70 for a predetermined period of time, for example two years, it may be necessary to replace the moveable implant 950. Due to the limited incision required to enable the implant 950 to be positioned in the knee portion 76, it is a relatively simple operation to replace the moveable implant 950. The size of the incision and the trauma induced in the patient by replacing the moveable implant 950 may be minimized by the use of a cannula corresponding to the cannula 564 of FIG. 39. The cannula through which the implant 950 is moved into the knee portion 76 of the patient's leg may have a construction similar to the construction illustrated in U.S. Pat. Nos. 3,811,449; 5,183,464; and/or 5,961,499.

Seating of the moveable implant on the tibia 214 may be promoted by forming the moveable implant of a hydrophilic

81

material which absorbs body fluids and expands. When the implant **950** of hydrophilic material is positioned in the space between the surfaces **958** and **960** on the femur **126** and tibia **214**, the hydrophilic material of the implant will absorb body fluids and expand to fully occupy the space. This will result in the lower surface **954** of the moveable implant **950** being pressed firmly against the surface **960** on the tibia **214**. Similarly, the upper surface **952** on the moveable implant **950** will be pressed against the surface **958** on the femur **126** as the moveable implant absorbs body fluids and expands. This results in the moveable implant **950** expanding in such a manner as to change the configuration of the moveable implant to the configuration of the space between the surfaces **958** and **960** on the femur **126** and tibia **214**.

The hydrophilic material of the moveable implant **950** may be a polymeric material which is either a copolymer or a dipolymer. The hydrophilic material may contain petroyl-glupamic acid, carboxymethylcellulose, a collagen or polylactide. The hydrophilic material may be a ceramic that is found in hydroxyapatite composites with polyethylene, polylactide or polyhydroxybutyrate. Of course, the moveable implant **950** could be formed of other known hydrophilic materials which attract body liquid under the influence of molecular attraction and establishes molecular linkages with the body liquid. The hydrophilic material may be disposed on a frame work or base which is formed of a non-hydrophilic material such as a porous metal.

It should be understood that the patient's leg **70** is supported in a manner previously explained herein in conjunction with FIGS. **2** and **3**. The improved drape system **100** of FIGS. **4** and **5** may be utilized during surgery in which the moveable implant **950** is positioned in the knee portion **76** of the patient's leg **70**. The patient's leg **70** may be moved in the manner schematically by arrows in FIG. **25** to enable a surgeon to make certain that the moveable implant **950** cooperates with the femur **126** and tibia **214** in a desired manner. The articular surface **122** on the patella **120** may be repaired in the manner indicated schematically in FIGS. **35** and **36**, contemporaneously with positioning of the moveable implant **950** in the knee portion **76**. One or more expandable devices, similar to the expandable devices **720**, **722** and **730** of FIGS. **51** and **52** may be utilized to facilitate positioning of the moveable implant **950** in the knee portion **76** of a patient's leg **70**. It should be understood that any of the features previously described in conjunction with FIGS. **1-58** herein could be utilized, if desired, in association with the moveable implant **950**.

Moveable Inlay

In the embodiment of FIG. **59**, the moveable implant **950** is positioned in engagement with existing surfaces **958** and **960** on the femur **126** and tibia **214**. In the embodiment illustrated in FIG. **60**, a moveable implant **970** is positioned in a recess **972** formed in a medial portion of the proximal end portion **212** of the tibia **214**. The recess **972** may be relatively shallow and formed with a minimum or no cutting away of bone from the proximal end portion **212** of the tibia **214**. The recess may be formed by cutting away cartilage and/or other material disclosed on the proximal end portion **212** of the tibia **214**. Depending upon the condition of the proximal end portion **212** of the tibia **214**, the bone may or may not be cut away to form the recess **972**. Thus, the recess may be formed in tissues, such as fibrous tissues, associated with the end portion of the bone at the proximal end portion of the tibia **214**.

The moveable implant **970** may be held in position relative to the proximal end portion **212** of the tibia **214** by

82

engagement with the recess **972**. If this is done, tissue growth promoting materials and/or materials which promote biological resurfacing may be provided in the moveable implant **970**. These materials would promote the growth of tissue adjacent to the proximal end portion **212** of the tibia **214** into the moveable implant **970**. The biological resurfacing materials would promote the growth of naturally occurring tissues, which were not removed to form the recess **972**, into the moveable implant **970**. Thus, cartilage tissues located adjacent to the peripheral aspect of the proximal end portion **212** of the tibia **214** would grow into the moveable implant **970**.

It should be understood that the recess **972** may have a lower surface formed by the existing surface **960** of the tibia and side surfaces formed by fibrocartilage which extends around the periphery of the moveable implant **970**. It is believed that it will be desired to position the moveable implant **970** in the recess **972** without anchoring the moveable implant to the tibia **214**. However, if desired, an adhesive such as fibrin could be utilized to connect the moveable implant with the existing surface **960** on the proximal end portion **212** of the tibia. The moveable implant **970** may have any one of the constructions previously described in conjunction with the implant **640** of FIGS. **46** and **48** or the multi layered implant **670** of FIG. **49**.

Multi Component Moveable Implant

The moveable implant **950** of FIG. **59** is formed as one piece. In the embodiment of the invention illustrated in FIG. **61**, the moveable implant **980** is formed with a plurality of pieces. The moveable implant **980** is disposed between a medial portion of the distal end portion **124** of a femur **126** and a medial portion of the proximal end portion **212** of a tibia **214**. The moveable implant **960** is positioned between an existing surface **958** on the femur **126** and an existing surface **960** on the tibia **214**. The moveable implant **980** includes an upper section **982** and a lower section **984**. The upper section **982** has an upper surface **988** which engages the existing surface **958** on the distal end portion **124** of the femur **126**. The upper section **982** of the moveable implant **980** has a lower surface **990** which engages the lower section **984** of the moveable implant **980**.

The lower section **984** of the moveable implant **980** has a lower surface **994** which engages the existing surface **960** on the proximal end portion **212** of the tibia **214**. In addition, the lower section **984** of the implant **980** has an upper surface **986** which engages a lower surface **990** on the upper section **982** of the moveable implant **980**.

The surfaces on the moveable implant **980** which engage existing surfaces on the femur **126** or tibia **214** are shaped to conform to the configuration of the existing surfaces on the femur and the tibia. To enable the surfaces on the moveable implant to be shaped to conform to the configuration of existing surfaces on the femur **126** and tibia **214**, images of the femur and tibia are generated utilizing known imaging apparatus, such as an MRI, X-ray, or fluoroscope. These images are utilized to determine the configuration of the existing surface **958** on the femur **126** and the existing surface **960** on the tibia **214**. The upper surface **988** on the upper section **982** of the moveable implant **980** is then shaped to a configuration corresponding to the configuration of the existing surface **958** on the femur **126**. The lower surface **994** on the lower section **984** of the moveable implant **980** is shaped to a configuration corresponding to the configuration of the existing surface **960** on the tibia **214**. By shaping the upper and lower surfaces **988** and **994** on the implant **990** to conform to the shape of the existing surfaces **958** and **960** on the femur **126** and tibia **214**, the upper and

83

lower sections **982** and **984** tend to seat themselves on the femur **126** and tibia **214**. Thus, the upper surface **988** on the upper section **982** of the moveable implant **980** becomes seated against the existing surface **958** on the femur **126** under the influence of force transmitted between the existing surface **958** on the femur and the upper surface **988** on the upper section **982** of the moveable implant **980**. Similarly, the lower surface **994** on the lower section **984** of the implant **980** becomes seated against the existing surface **960** on the tibia **214** under the influence of force applied to the upper surface **996** on the lower section **984** of the moveable implant **980** by the upper section **982** of the moveable implant.

The lower surface **990** on the upper section **982** of the moveable implant **980** and the upper surface **996** on the lower section **984** of the moveable implant **980** are shaped to promote the desired articulation in the knee portion **76** of the leg **70**. Once the two sections **982** and **984** of the moveable implant **980** have been positioned between the existing surfaces **958** and **960** on the femur **126** and tibia **214**, relative movement occurs where the lower surface **990** on the upper section **982** of the moveable implant **980** engages the upper surface **996** on the lower section **984** of the moveable implant. This tends to minimize any pain or discomfort resulting from defects in the existing surfaces **958** and **960** on the femur **126** and tibia **214** during bending of the knee portion **76**.

The upper section **982** and lower section **984** may be formed of the same materials or any combination of the same materials as previously described in conjunction with the moveable implant **950** of FIG. **59**. Although the upper section **982** and lower section **984** of the moveable implant **980** are formed of the same material, it is contemplated that the upper section **982** could be formed of a material which is different than the material forming the lower section **984** of the moveable implant **980**.

The moveable implant **980** will be positioned in the space between the existing surfaces **958** and **960** on the femur **126** and tibia **214** in the manner previously discussed in conjunction with the embodiment of the invention illustrated in FIG. **59**. Thus, the patient's leg will be supported in the orientation illustrated in FIGS. **2** and **3** during the making of a limited incision along one side of the patella **120** in the manner illustrated in FIG. **6**. The patella **120** may then be offset to one side. Alternatively, the patella may remain in its initial position or be offset just slightly to provide sufficient space to insert the moveable implant **980**. It is contemplated that the knee portion **76** will be inspected utilizing fiberoptic devices similar to the endoscope **352** of FIGS. **32** and **33**. An expandable cannula corresponding to the cannula **364** of FIG. **39**, may be inserted into the incision and the endoscope and/or the moveable implant **980** inserted into the knee portion **76** through the expandable cannula.

Moveable Implant with Anchored Section

In the embodiment of the invention illustrated in FIG. **61**, the moveable implant **980** has upper and lower sections **982** and **984** which are moveable relative to each other and relative to the femur **126** and tibia **214**. The embodiment of the invention illustrated in FIG. **62**, a moveable implant **1002** has a section which is fixedly connected with a bone in the knee portion **76** of the patient. In the embodiment of the invention illustrated in FIG. **62**, the moveable implant **1002** includes an upper section **1006** and a lower section **1008**. The upper section **1006** of the implant **1002** is freely moveable relative to the femur **126**. The lower section **1008** of the moveable implant **1002** is anchored to the tibia **214**. Thus, the upper section **1006** of the moveable implant **1002**

84

is freely moveable relative to the existing surface **958** on a medial portion of the distal end portion **124** of the femur **126**. The upper section **1006** is also freely moveable relative to the tibia **214**. However, the lower section **1008** of the moveable implant **1002** is anchored to the tibia **214** by a keel or projecting section **1012**. The projecting section **1012** extends through the existing surface **960** on a medial portion of the proximal end portion **212** of the tibia **214**.

The upper section **1006** and lower section **1008** of the moveable implant **1002** are formed of the same material as previously discussed in conjunction with the moveable implant **950**. The upper and lower sections **1006** and **1008** of the moveable implant **1002** are positioned in the space between the existing surfaces **958** and **960** through a cannula which corresponds to the cannula **564** of FIG. **39**. The cannula extends into a limited incision and is resiliently expandable to stretch the viscoelastic body tissue in which the limited incision is formed to enable the moveable implant **1002** to be moved through the cannula into the space between the existing surfaces **958** and **960** on the femur **126** and tibia **214**.

Although the lower section **1008** of the moveable implant **1002** has been illustrated in FIG. **62** as being anchored to the tibia **214** and the upper section **1006** freely moveable relative to the femur **126**, this could be reversed if desired. Thus, the upper section **1006** of the moveable implant **1002** could be anchored to the femur **126**. If this was done, the lower section **1008** of the moveable implant **1002** would be freely moveable relative to the tibia **214**.

Securing Moveable Anchor

In the embodiment of the invention illustrated in FIG. **59**, the moveable implant **950** is freely moveable relative to the existing surfaces **958** and **960** on the femur **126** and tibia **214**. In the embodiment of the invention illustrated in FIG. **63**, a moveable implant **1020** is connected with the medial collateral ligament **1022**. Although the moveable implant **1020** is disposed between and is freely moveable relative to existing surfaces **958** and **960** on the femur **126** and the tibia **214**, the connection between the moveable implant **1020** and the medial collateral ligament **1022** limits the range of movement of the moveable implant **1020** relative to the existing surface **958** on a medial portion of the distal end portion **124** of the femur **126**. Similarly, the connection between the moveable implant **1020** and the medial collateral ligament **1022** limits the range of movement of the implant **1020** relative to the existing surface **960** on a medial portion of the proximal end portion **212** of the tibia **214**.

The moveable implant **1020** has the same construction as the moveable implant **950** of FIG. **59**. However, the moveable implant **1020** is provided with a small passage or opening which enables a suture **1026** to be used to interconnect the moveable implant **1020** and the ligament **1022**. The suture **1026** extends through the opening in the moveable implant **1020** and extends around the ligament **1022**. The suture **1026** holds the moveable implant **1020** in engagement with the ligament **1022**. This results in a side surface **1030** on the moveable implant **1020** being held in intimate apposition with the ligament **1022**. Due to engagement of the side surface **1030** on the moveable implant **1020** with the ligament **1022**, tissue can grow from the ligament into the moveable implant **1020** to further interconnect the ligament and the movable implant.

It is contemplated that the moveable implant **1020** will have a construction which promotes the in growth of tissue from the ligament **1022** into the implant. Thus, the moveable implant **1020** may have a porous scaffold on which tissue growth inductive factors are disposed. For example, the

85

moveable implant **1020** could be formed of porous tantalum. The porous tantalum scaffold could contain collagen, fibrin, progenitor cells and/or tissue inductive factors. Of course, other known materials which promote biological resurfacing could be provided on the porous metal scaffold of the moveable implant **1020** if desired.

Although one specific construction of the moveable implant **1020** has been described, it is contemplated that the moveable implant **1020** could have many different constructions. For example, the moveable implant **1020** could have any one of the constructions and be formed of any one or more of the materials previously described in conjunction with the moveable implant **950**.

It is contemplated that the patient's leg **70** may be in the position illustrated in FIGS. **2** and **3** during positioning of the moveable implant **1020** in the space between the existing surfaces **958** and **960** on the femur **126** and tibia **214**. The upper portion of the patient's leg **70** may be supported above the support surface **64** (FIG. **2**) by the leg support **80**. The drapery system **100** of FIGS. **4** and **5** may advantageously be utilized during positioning of the moveable implant **1020** to provide a sterile field.

Connection of Moveable Implant with Soft Tissue

In the embodiment of the invention illustrated in FIG. **59**, the moveable implant **950** is freely moveable relative to the existing surfaces **958** and **960** on the femur **126** and tibia **214**. In the embodiment of the invention illustrated in FIG. **63**, the moveable implant **1020** is connected with the ligament **1022** to limit the range of movement of the moveable implant **1020**. In the embodiment of the invention illustrated in FIG. **64**, a moveable implant **1040** is connected with soft tissue other than the ligament **1022** of FIG. **63**. Rather than being connected with the soft tissue by single suture **1026** in the manner illustrated in FIG. **63**, the moveable implant **1040** is connected with soft tissue in a plurality of locations by a plurality of sutures.

The moveable implant **1040** (FIG. **64**) has the same construction as the moveable implant **950** of FIG. **59**. The moveable implant **1040** is positioned between existing surfaces **958** and **960** (FIG. **59**) on a femur **126** and tibia **214** in the same manner as is illustrated schematically in FIG. **59** for the moveable implant **950**. The moveable implant **1040** is moved into position between the existing surfaces on a femur and a tibia in the same manner as previously explained in conjunction with the moveable implant **950** of FIG. **59**. Thus, the moveable implant **1040** of FIG. **64** is moved into a position between existing surfaces **958** and **960** on a femur and tibia through a limited incision and a resiliently expandable cannula corresponding to the cannula **564** of FIG. **39**.

In accordance with one of the features of this embodiment of the invention, a plurality of connections **1044** are provided between the periphery of the moveable implant **1040** and soft tissue **1046**. Although many different soft tissues in the knee portion **76** of a patient's leg may be connected with the moveable implant **1040** by connections **1044**, in the embodiment of the invention illustrated in FIG. **64**, the moveable implant **1040** is connected with the joint capsule in the knee portion **76** of the patient's leg **70**. The joint capsule extends around and encloses the knee joint. Therefore, the connections **1044** can be formed between the moveable implant **1040** and the soft tissue of the joint capsule **1046** at a plurality of locations in the manner illustrated in FIG. **64**.

By providing anterior and posterior connections **1044** with the soft tissue of the joint capsule **1046**, the moveable implant **1040** is held against excessive movement in either

86

a posterior or anterior direction. Similarly, the connections **1044** between the moveable implant **1040** and the medial portion of the soft tissue or joint capsule **1046** holds the moveable implant **1040** against excessive movement in either the medial or lateral direction. The connections **1040** may initially be formed by sutures.

Although the range of movement of the moveable implant **1040** relative to the femur **126** and tibia **214** (FIG. **59**) is limited by the connections **1044** (FIG. **64**), the moveable implant **1040** is freely moveable relative to the existing surfaces **958** and **960** (FIG. **59**) on the femur **126** and tibia **214** within the range of movement established by the connections **1044** with the soft tissue or joint capsule **1046**.

Tissue inductive growth factors are provided on the moveable implant **1040**. The tissue inductive growth factors promote a growth of the soft tissue onto the moveable implant **1040**. It is contemplated that the moveable implant **1040** will have a porous platform in which the tissue growth inductive factors are disposed. This will promote a growth of the soft tissue or joint capsule **1046** into the moveable implant **1040** to assist the sutures at the connections **1044** in interconnecting the moveable implant **1040** and the soft tissue or joint capsule **1046**.

Thus, the connections **1044** between the moveable implant **1040** and the soft tissue **1046** is initially established by sutures which extend between the moveable implant **1040** and the soft tissue or joint capsule **1046**. With the passage of time, tissue grows from the soft tissue or joint capsule **1046** into the periphery of the moveable implant **1040** to further interconnect the moveable implant **1040** and the soft tissue. The sutures which initially form the connections **1044**, hold the periphery of the moveable implant **1040** in engagement with the soft tissue **1046**. Due to the intimate apposition of the moveable implant **1040** with the soft tissue or joint capsule **1046** and the tissue growth promoting factors in the moveable implant **1040**, growth of the soft tissue or joint capsule **1046** into the periphery of the moveable implant **1040** is promoted.

Molded Implant

In the embodiment of the invention illustrated in FIGS. **65** and **66**, an implant **1060** is molded onto an existing surface **960** on the proximal end portion **212** of the tibia **214**. The implant **1060** is formed of bone cement which is held in place by a retainer or dam **1064** which extends around a medial portion of the proximal end portion **212** of the tibia **214**. The dam forms a compartment which is filled with the bone cement. As the bone cement hardens, the femur **126** (FIG. **59**) is moved relative to the tibia **214** to impart a desired configuration to the bone cement.

Once the bone cement has hardened, the retainer or dam **1064** may be removed. The bone cement then forms an implant which is disposed on the existing surface **960** of the tibia **214**. The bone cement is connected with existing surface **960** of the tibia **214** by adhesion between the implant **1060** and the existing surface **960** of the tibia **214**. It is contemplated that a releasing agent could be mixed with the bone cement which is used to form the implant **1060** so that the implant would not adhere to the existing surface **960** of the tibia **214**. This would result in the implant **1060** being freely moveable relative to both the tibia **214** and the femur **126** in the same manner as in which the moveable implant **950** is freely moveable relative to the femur **126** and tibia **214**.

Deformity Correction

The moveable implants of FIGS. **59–66** are utilized to affect a resurfacing of joint surfaces to minimize pain resulting from defective joint surfaces. The moveable

implants of FIGS. 59–66 are not particularly effective in correcting deformities in the femur 126 and/or tibia 214. Thus, the moveable implant 950 (FIG. 67) is positioned between the femur 126 and tibia 214 to compensate for defects in the existing surfaces 958 and 960 on the femur 126 and tibia 214. It is contemplated that other devices will have to be utilized to compensate for bone deformities. The devices which are utilized to compensate for bone deformities may be positioned in the femur 126 and/or tibia 214.

The devices which compensate for bone deformities may have a construction similar to the construction of any one of the devices disclosed in U.S. Pat. No. 6,086,593. Of course, other known devices could be utilized to correct bone deformities if desired.

One specific device which may be utilized to correct bone deformities is a wedge member 1080 (FIG. 67). The wedge member 1080 is formed of a relatively hard rigid material. The wedge member 1080 is capable of transmitting force between upper and lower portions of a bone, such as the tibia 214. The wedge member 1080 may be hollow and have a compartment which is filled with bone growth inductive material. The wedge member may be formed of a suitable rigid material, such as tantalum or stainless steel. Alternatively, the wedge member 1080 could be formed of a biodegradable material. It is contemplated that the wedge member 1080 may be formed of human bone.

When the wedge member 1080 is to be positioned in the tibia 214, a saw cut is made to form a slot at the location where the wedge member 1080 is to be installed. The saw cut and resulting slot extend only part way through the tibia 214. The wedge member 1080 is then moved into the slot. As the wedge member is forced into the slot, the wedge member pivots an upper portion of the tibia 214 in a counter-clockwise direction (as viewed in FIG. 67) relative to a lower portion of the tibia to correct a deformity in the tibia or to compensate for a deformity in the femur 126.

Although the wedge member 1080 has been illustrated in FIG. 67 as being installed in the tibia 214, it is contemplated that the wedge member could be installed in the femur 126 if desired. Although the wedge member 1080 has been illustrated in FIG. 67 as being installed in a medial portion of the tibia 214, the wedge member 1080 could be installed in a posterior, anterior or lateral portion of the tibia if desired. The wedge member 1080 has the same construction and cooperates with the femur in the same manner as is disclosed in the aforementioned U.S. Pat. No. 6,086,593.

It is contemplated that the patient's leg 70 will be in the position illustrated in FIGS. 2 and 3 during installation of any one of the implants illustrated in FIGS. 59–66. However, the implants could be positioned in the patient's leg with the patient's leg in a different orientation if desired. Thus, any one of the implants of FIGS. 59–66 could be placed in the patient's leg with the patient's leg in either the flexed or extended orientation illustrated in FIG. 1.

The foregoing description of the moveable implants of FIGS. 59–66 has been in conjunction with the knee portion 76 of a patient's leg 70. However, it is contemplated that the implants will be used in association with other joints in a patient's body. For example, any one of the implants of FIGS. 59–66 could be utilized in association with a glenoid joint. Alternatively, any one of the implants could be used in association with an ankle, wrist or elbow joint. It is contemplated that any one of the many different features of the present invention may be utilized separately or in association with the implants illustrated in FIGS. 59–66 and that the implants may be used in association with any desired joint in a patient's body.

Conclusion

In view of the foregoing description, it is apparent that the present invention relates to a new and improved method and apparatus for use in performing any desired type of surgery on a joint in a patient's body. The joint may advantageously be a joint in a knee portion 76 of a patient's leg 70. However, the method and apparatus may be used in association with surgery on other joints in a patient's body. There are many different features of the present invention which may be used either together or separately in association with many different types of surgery. Although features of the present invention may be used with many different surgical procedures, the invention is described herein in conjunction with surgery on a joint in a patient's body.

One of the features of the present invention relates to the making of a limited incision 114. The limited incision 114 may be in any desired portion of a patient's body. For example, the limited incision 114 may be in a knee portion 76 of a leg 70 of a patient. The limited incision 114 may be made while a lower portion 68 of the leg 70 of the patient is extending downward from the upper portion 72 of the leg of the patient. At this time, a foot 74 connected with the lower portion 68 of the leg of the patient may be below a surface 64 on which the patient is supported. The limited incision 114 may be made while the lower portion 68 of the leg 70 of the patient is suspended from the upper portion of the leg or while the lower portion of the leg and/or the foot 74 of the patient are held by a support device. After the incision 114 has been made, any one of many surgical procedures may be undertaken.

It is believed that in certain circumstances, it may be desired to have a main incision 114 of limited length and a secondary incision 920 of even smaller length. The secondary incision 920 may be a portal or stab wound. A cutting tool 170 may be moved through the secondary incision 920. An implant 286, 290 and/or 294 may be moved through the main incision 114.

Once the incision 114 has been made, a patella 120 in the knee portion 76 of the patient may be offset to one side of its normal position. When the patella 120 is offset, an inner side 122 of the patella faces inward toward the end portions 124 and 212 of a femur 126 and tibia 214.

Although any one of many known surgical procedures may be undertaken through the limited incision 114, down sized instrumentation 134, 138, 186, 210 and/or 218 for use in the making of cuts in a femur 126 and/or tibia 214 may be moved through or part way through the incision. The down sized instrumentation may be smaller than implants 286, 290 and/or 294 to be positioned in the knee portion 76 of the patient. The down sized instrumentation 286, 290 and/or 294 may have opposite ends which are spaced apart by a distance which is less than the distance between lateral and medial epicondyles on a femur or tibia in the leg of the patient.

It is contemplated that the down sized instrumentation 134, 138, 186, 210 and/or 218 may have cutting tool guide surfaces of reduced length. The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool.

It is contemplated that at least some, if not all, cuts on a bone may be made using light directed onto the bone as a guide. The light directed onto the bone may be in the form of a three dimensional image 850. The light directed onto the bone may be a beam 866 or 868 along which a cutting tool 170 is moved into engagement with the bone.

There are several different orders in which cuts may be made on bones in the knee portion of the leg of the patient. It is believed that it may be advantageous to make the patellar and tibial cuts before making the femoral cuts.

There are many different reasons to check ligament balancing in a knee portion 76 of the leg of a patient. Ligament balancing may be checked while the knee portion 76 of the leg 70 of the patient is flexed and the foot 74 of the patient is below the support surface 64 on which the patient is disposed. Flexion and extension balancing of ligaments may be checked by varying the extent of flexion of the knee portion 76 of the leg 70 of the patient. In addition, rotational stability of the ligaments may be checked by rotating the lower portion of the leg of the patient about its central axis. Balancing of ligaments may also be checked by moving the foot 74 of the patient sideways, rotating the lower portion 68 of the leg 70 of the patient, and/or moving the foot anteriorly or posteriorly.

It is believed that it may be advantageous to utilize an endoscope 352 or a similar apparatus to examine portions of the patient's body which are spaced from the incision 114. It is also contemplated that images of the knee portion of the patient's leg may be obtained by using any one of many known image generating devices other than an endoscope 352. The images may be obtained while the patient's leg 70 is stationary or in motion. The images may be obtained to assist a surgeon in conducting any desired type of surgery.

Balancing of the ligaments in the knee portion 76 of a patient's leg 70 may be facilitated by the positioning of one or more transducers 596 and/or 598 between tendons, ligaments, and/or bones in the knee portion. One transducer 598 may be positioned relative to a medial side of a knee joint. Another transducer 596 may be positioned relative to a lateral side of the knee joint. During bending of the knee joint, the output from the transducers 596 and 598 will vary as a function of variations in tension forces in the ligaments. This enables the tension forces in ligaments in opposite sides of the knee portion to be compared to facilitate balancing of the ligaments.

Patellar tracking may be checked by the positioning of one or more transducers 930 and/or 932 between the patella 120 and the distal end portion 124 of the femur 126. If desired, one transducer 932 may be placed between a medial portion of the patella 120 and the distal end portion 124 of the femur 126. A second transducer 930 may be placed between a lateral portion of the patella 120 and the distal end portion 124 of the femur 126. Output signals from a transducer 930 will vary as a function of variations in force transmitted between the patella 120 and femur 126 during bending of the leg.

The articular surface 122 on the patella 120 may be repaired. The defective original articular surface 122 on the patella 120 may be removed by cutting the patella while an inner side of the patella faces toward a distal end portion 124 of a femur 126. The step of cutting the patella may be performed while the patella is disposed in situ and is urged toward the distal end portion of the femur by connective tissue. An implant may then be positioned on the patella 120.

It is contemplated that the size of the incision 114 in the knee or other portion of the patient may be minimized by conducting surgery through a cannula 564. The cannula 564 may be expandable. To facilitate moving of an implant 286, 290 and/or 294 through the cannula 564, the implant may be formed in two or more portions 572 and 574. The portions of the implant 286, 290 and/or 294 may be interconnected when the portions of the implant have been positioned in the patient's body. Although the implants disclosed herein are

associated with a patient's knee, it should be understood that the implants may be positioned at any desired location in a patient's body.

An implant 626, 640 or 670 may be positioned in a recess 610, 642 or 672 formed in a bone 126 or 214 in a patient. The implant 626, 640 or 670 may contain biological resurfacing and/or bone growth promoting materials. The implant 626, 640 and/or 670 may contain mesenchymal cells and/or tissue inductive factors. Alternatively, the implant 626 or 640 may be formed of one or more materials which do not enable bone to grow into the implant.

In accordance with one of the features of the present invention, body tissue may be moved or stretched by a device 720, 722 and/or 730 which is expandable. The expandable device 720, 722 and/or 730 may be biodegradable so that it can be left in a patient's body. The expandable device 720, 722 and/or 730 may be expanded to move and/or stretch body tissue and increase a range of motion of a joint. The expandable device may be used to stretch body tissue in which an incision is to be made.

An improved drape system 100 is provided to maintain a sterile field between a surgeon 106 and a patient during movement of the surgeon relative to the patient. The improved drape system 100 includes a drape 102 which extends between the surgeon and a drape 90 for the patient. During surgery on a knee portion 76 of a leg 70 of a patient, the drape system 100 extends beneath the foot portion 74 of the leg 70 of a patient. It is contemplated that the drape system 100 will be utilized during many different types of operations other than surgery on a leg of a patient.

An implant 950, 970, 980, 1002, 1020, 1040 or 1060 may be movable relative to both a femur 126 and a tibia 214 in a leg of a patient during bending of the leg. The implant may include a single member (FIGS. 59, 60, 63, 64 and 65) which is disposed between and engage by end portions of the femur and tibia. Alternatively, the implant may include a plurality of members (FIGS. 61 and 62) which are disposed in engagement with each other. If desired one of the members of the plurality of members may be secured to a bone and engaged by a member which is not secured to a bone. The implant may be secured to soft tissue in the knee portion of the patient's leg (FIGS. 63 and 64).

There are many different features to the present invention. It is contemplated that these features may be used together or separately. It is also contemplated that the features may be utilized in association with joints in a patient's body other than a knee joint. For example, features of the present invention may be used in association with surgery on vertebral joints or glenoid joints. However, it is believed that many of the features may be advantageously utilized together during the performance of surgery on a patient's knee. However, the invention should not be limited to any particular combination of features or to surgery on any particular joint in a patient's body. It is contemplated that features of the present invention will be used in association with surgery which is not performed on a joint in a patient's body.

Having described the invention, the following is claimed:

1. A method of performing surgery on a patient's knee, said method comprising the steps of making an incision in a knee portion of one leg of a patient, moving an implant through the incision into the knee portion of the one leg of the patient, positioning the implant between a distal end portion of a femur and a proximal end portion of a tibia in the one leg of the patient, and allowing the implant to move relative to both the femur and tibia in the one leg of the patient during bending of the one leg of the patient, wherein the implant is made of a biodegradable material.

91

2. A method as set forth in claim 1 further including the step of deflecting the implant to change the implant's configuration after performing said step of positioning the implant between the distal end portion of the femur and the proximal end portion of the tibia.

3. A method as set forth in claim 2 wherein the implant is moveable in a 360° range of movement relative to both the femur and tibia.

4. A method as set forth in claim 2 wherein the implant has smooth upper and lower surfaces.

5. A method as set forth in claim 2 wherein engagement of the implant with soft tissue limits movement of the implant.

6. A method as set forth in claim 2 further including the steps of imaging the knee and determining the size of the implant based on the knee imaging.

7. A method as set forth in claim 2 wherein the implant is resiliently deflected.

8. A method as set forth in claim 1 further including the step of connecting the implant to soft body tissue in the knee portion of the patient's one leg to retain the implant against excessive movement relative to the femur and tibia in the one leg of the patient.

9. A method as set forth in claim 8 wherein said step of connecting the implant to soft body tissue in the knee portion of the one leg of the patient includes growing tissue into the implant.

10. A method as set forth in claim 8 wherein said step of connecting the implant to soft tissue in the knee portion of the one leg of the patient includes connecting the implant with a ligament in the knee portion of the one leg of the patient.

11. A method as set forth in claim 8 wherein said step of connecting the implant to soft tissue in the knee portion of the one leg of the patient includes connecting the implant with a joint capsule which is disposed in the knee portion of the one leg of the patient.

12. A method as set forth in claim 1, further comprising replacing the degraded implant after a predetermined time.

13. A method as set forth in claim 12, wherein replacing the degraded implant comprises:

making an incision in a knee portion of one leg of a patient;

92

moving a replacement implant through the incision into the knee portion of the one leg of the patient;

positioning the replacement implant between a distal end portion of a femur and a proximal end portion of a tibia in the one leg of the patient; and

allowing the replacement implant to move relative to both the femur and tibia in the one leg of the patient during bending of the one leg of the patient.

14. A method as set forth in claim 15 wherein the replacement implant is made of a material selected from the group consisting of a biological material, biodegradable material, metal, ceramic material, and porous material.

15. A method of performing surgery on a patient's knee, said method comprising the steps of:

making an incision in a knee portion of one leg of a patient;

moving an implant through the incision into the knee portion of the one leg of the patient;

positioning the implant between a distal end portion of a femur and a proximal end portion of a tibia in the one leg of the patient;

deflecting the implant to change the implant's configuration after positioning the implant between the distal end portion of the femur and the proximal end portion of the tibia; and

allowing the implant to move relative to both the femur and tibia in the one leg of the patient during bending of the one leg of the patient, wherein the implant is plastically deformed.

16. A method as set forth in claim 15 wherein the implant is moveable in a 360° range of movement relative to both the femur and tibia.

17. A method as set forth in claim 15 wherein the implant has smooth upper and lower surfaces.

18. A method as set forth in claim 15 wherein engagement of the implant with soft tissue limits movement of the implant.

19. A method as set forth in claim 15 further including imaging the knee and determining the size of the implant based on the knee imaging.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,770,078 B2
DATED : August 3, 2004
INVENTOR(S) : Peter M. Bonutti

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 91.

Line 29, replace "connecting the implant to soft tissue in to the knee portion"
with -- connecting the implant to soft tissue in the knee portion --

Signed and Sealed this

Twenty-sixth Day of October, 2004

A handwritten signature in black ink on a light gray dotted background. The signature reads "Jon W. Dudas" in a cursive, stylized script. The "J" is large and loops around the "on". The "W" is written with two distinct peaks. The "Dudas" part is also cursive, with the "D" being particularly large and looping.

JON W. DUDAS

Director of the United States Patent and Trademark Office