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# (12) United States Patent

# Michelson

## (54) SPINAL FUSION IMPLANT HAVING DEPLOYABLE BONE ENGAGING PROJECTIONS

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# (57) ABSTRACT

An interbody spinal fusion implant for implantation at least in part within and across the generally restored height of a disc space between two adjacent vertebral bodies of a human spine having an external housing and a substantially hollow internal rotatable member having bone engaging projections that are deployable through the housing to penetrably engage the adjacent vertebral bodies.

## 212 Claims, 9 Drawing Sheets































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## SPINAL FUSION IMPLANT HAVING DEPLOYABLE BONE ENGAGING PROJECTIONS

#### BACKGROUND

Push-in spinal fusion implants (allowing for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant) having upper and lower surfaces adapted for placement by linear insertion within a disc space <sup>10</sup> and in contact with the adjacent vertebral bodies are known in the related art. Such a push-in spinal fusion implant was invented by Michelson and is disclosed in U.S. Pat. No. 5,776,199, filed Jun. 28, 1988, which is hereby incorporated by reference. Push-in spinal fusion implants offer the advantage of being easily positioned in the implantation space and of having the ability to have varying height to width ratios.

Lordotic or tapered, push-in spinal fusion implants are also known in the art. By way of example, Michelson has invented such implants as disclosed in U.S. Pat. No. 5,609, 635, filed Jun. 7, 1995, which is hereby incorporated by reference. Lordotic or tapered, spinal fusion implants may more easily restore or enhance spinal lordosis.

Spinal fusion implants having projections that can be 25 deployed after the implant has been inserted into the disc space are also known in the related art. An example of a spinal fusion implant having deployable projections was invented by Michelson and also is disclosed in U.S. Pat. No. 5,776,199 previously incorporated by reference herein. Other examples of implants having deployable projections include, but are not limited to, U.S. Pat. No. 6,179,873 to Zientek and International Publication No. WO 01/01894 A1 to Bolger et al. Examples of spinal fusion implants having rotatable elements for fixing the implant to the vertebrae 35 include U.S. Pat. No. 6,210,442 to Wing et al., U.S. Pat. No. 6,090,143 to Meriwether et al., and U.S. Pat. No. 5,888,228 to Knothe et al.

None of the related art implants have a rotatable internal member with bone engaging projections that are retracted 40 within the interior of the implant to permit the implant to be inserted into the disc space and then deployed to extend through the exterior of the implant to penetrably engage the adjacent vertebral bodies, while permitting bone growth from adjacent vertebral body to adjacent vertebral body 45 through the interior of the implant and the interior of the internal rotatable member substantially unimpeded by the internal rotatable member and bone engaging projections.

There exists a need for a spinal fusion implant providing for all of the aforementioned features in combination.

### SUMMARY OF THE INVENTION

In accordance with the present invention, as embodied and broadly described herein, there is provided a spinal fusion implant for implantation at least in part within and 55 across the generally restored height of a disc space between two adjacent vertebral bodies of a human spine having an external housing with a substantially hollow internal rotatable member having bone engaging projections that are in a retracted position within the interior of the housing to permit 60 the assembled implant to be inserted into the disc space. The internal rotatable member may be inserted into the housing prior to insertion of the implant into the disc space, or alternatively, the housing may be inserted into the disc space and the internal rotatable member can be subsequently 65 inserted into the housing. The implant is preferably inserted into the disc space by linear insertion without substantial

rotation of the implant. Alternatively, the implant be can be rotated at least in part generally less than 180 degrees during its implantation into the disc space and is not screwed into the disc space. After insertion, the internal rotatable member is rotated to a deployed position so that the bone engaging projections extend through the exterior of the housing to penetrably engage the adjacent vertebral bodies to resist expulsion of the implant from the disc space, to gain access to the more vascular bone of the vertebral bodies further from the bone surfaces adjacent the disc space, to stabilize the adjacent vertebral bodies relative to the implant, and to stabilize the vertebral bodies relative to each other. The spinal implant is configured to permit bone growth from adjacent vertebral body to adjacent vertebral body through the housing and through the interior of the internal rotatable member preferably substantially unimpeded by further internal mechanisms.

In one embodiment, the spinal implant of the present invention has an external housing having a hollow interior and a substantially hollow rotatable member therein. The implant and each of the hollow components, that is the housing and the internal rotatable member, are adapted to hold fusion promoting substances, such as but not limited to bone. The housing preferably has relatively thin walls, openings, and except for the openings preferably a relatively smooth exterior. The rotatable member has an open interior configured to hold bone growth promoting material and at least one aperture therethrough in communication with the open interior to permit for the growth of bone therethrough. The rotatable member preferably, but not necessarily, has a generally cylindrical or frusto-conical configuration, is preferably thin-walled, and is preferably in contact with the external housing, but is free to rotate therein sufficient for its intended purpose. The rotatable member has bone engaging projections adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating the rotatable member. The rotatable member is adapted to rotate within the hollow interior of the implant between a retracted position and a deployed position. The bone engaging projections extend through at least some of the openings in the upper and lower surfaces of the implant so as to penetrate the vertebral bodies adjacent the disc space to be fused deep to the adjacent superficial endplate surfaces when deployed.

In a preferred embodiment, the bone engaging projections have a blade-like configuration oriented transverse to the longitudinal axis of the rotatable member with a leading edge and a trailing edge angled relative to each other to form an apex adapted to penetrate the bone of a vertebral body. The bone engaging projections are preferably oriented on opposite sides of the rotational member and may, but need not, be diametrically opposite one another. The bone engaging projections may be arranged such that at least the apexes of two opposite bone engaging projections are on opposite sides of a mid-line passing therethrough. Such an overcenter arrangement of the bone engaging projections creates a more stable configuration of the implant when the bone engaging projections are fully deployed. Greater energy is required to de-rotate the rotatable member with opposed bone engaging projections in an over-center arrangement as the apex of each bone engaging projection has to be moved through the mid-line to move from a deployed to a retracted position.

The spinal implants of the present invention may have upper and lower surfaces that are generally parallel or angled relative to one another. The spinal implants of the present invention may have a cross-section transverse to the longitudinal axis of the implant that is generally square,

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rectangular, or any other configuration suitable for its intended purpose. The spinal implants of the present invention may have the width equal to the height, the width greater than the height, or the width less than the height. The spinal implants of the present invention may have more than one rotatable member with bone engaging projections. The rotatable member can have a generally cylindrical configuration, a generally frusto-conical configuration, or any other configuration suitable for the intended purpose.

The present invention is also directed to an implant 10 inserter instrument adapted to insert the spinal implant into an implantation site and deploy the bone engaging projections. The inserter instrument is configured to cooperatively engage the trailing end of the implant to rotate the rotatable member to deploy the bone engaging projections. The 15 present invention is also directed to the methods for inserting and deploying a spinal implant in accordance with the present invention.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a rear perspective view of a lumbar segment of <sup>20</sup> a spine with the dural sac retracted to the left showing a prepared recipient implantation site with a guard for providing guided access to the disc space and an embodiment of an inserter instrument and an embodiment of an implant in accordance with the present invention attached thereto <sup>25</sup> approaching the disc space between the adjacent vertebral bodies.

FIG. 2 is a fragmented side elevation view of the inserter instrument and implant of FIG. 1.

FIG. **3** is a cross sectional view of the implant of FIG. **1** taken along line **3—3** of FIG. **2**.

FIG. 4 is an exploded perspective view of the trailing end of the implant of FIG. 1 and the rotatable member having deployable bone engaging projections.

FIG. 5 is a partial perspective view of the leading end of the implant and the inserter instrument of FIG. 1 shown with bone engaging projections in a deployed position.

FIG. 6 is an exploded perspective view of the leading end of implant of FIG. 1.

FIG. 7 is a cross sectional end view of another embodiment of an implant with the bone engaging projections in a retracted position in accordance with the present invention.

FIG. 8 is a cross sectional side view of the implant of FIG. 7 taken along line 8—8 of FIG. 7.

FIG. 9 is a cross sectional end view of the implant of FIG. 7 with the bone engaging projections in a deployed position.

FIG. **10** is a cross sectional top view of another embodiment of an implant in accordance with the present invention.

FIG. 11 is a cross sectional trailing end view of the implant of FIG. 10 with the bone engaging projections in a retracted position.

FIG. 12 is a cross sectional end view of the implant of FIG. 10 with bone engaging projections in a deployed  $_{55}$  position.

FIG. 13 is a front perspective view of another embodiment of an implant in accordance with the present invention with the bone engaging projections in a retracted position.

FIG. 14A is a cross sectional view along line 14-14 of  $_{60}$  FIG. 13.

FIG. 14B is a cross sectional view similar to FIG. 14A of an alternative embodiment of an implant in accordance with the present invention.

FIG. 15 is a cross sectional view along line 14-4 of FIG. 65 13 with the bone engaging projections in a deployed position.

FIG. 16 is a front perspective view of another embodiment of an implant in accordance with the present invention with the bone engaging projections in a retracted position.

FIG. 17 is a cross sectional view along line  $17\mathaccml{--}17$  of FIG. 16.

FIG. 18 is a cross sectional view along line 17—17 of FIG. 16 with the bone engaging projections in a deployed position.

FIG. 19 is a fragmented cross sectional view along line 19–19 of FIG. 18.

FIG. **20** is an enlarged fragmentary view of a rotatable member and a bone engaging projection of another preferred embodiment of an implant in accordance with the present invention.

FIG. 21 is an enlarged fragmentary view of a rotatable member and a bone engaging projection of yet another preferred embodiment of an implant in accordance with the present invention.

FIG. 22 is a front perspective view of another preferred embodiment of an implant in accordance with the present invention with the bone engaging projections in a retracted position.

FIG. **23** is an exploded side elevation view of the implant of FIG. **22**.

FIG. 24 is a top plan view in partial cross section of another preferred embodiment of an implant in accordance with the present invention with the bone engaging projections in a retracted position.

FIG. 25 a partial cross sectional end view along line 24—24 of FIG. 25 with the bone engaging projections in a retracted position shown in solid line and in a deployed position shown in hidden line.

## DETAILED DESCRIPTION OF THE DRAWINGS

Reference will now be made in detail to the present preferred embodiments (exemplary embodiments) of the invention, examples of which are illustrated in the accom-40 panying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

FIGS. 1-6 show a preferred embodiment of a spinal implant 100 and a preferred embodiment of an implant 45 inserter 200 in accordance with the present invention. Implant 100 has an external housing 101 with a leading end 102 for insertion first into the disc space between two adjacent vertebral bodies of the human spine, a trailing end 104 opposite leading end 102, an upper surface 106, a lower surface 108, and sides 110, 112 between upper and lower surfaces 106, 108. Leading end 102 may be tapered to facilitate insertion of implant 100 into the disc space. Housing 101 of implant 100 preferably has at least a portion along its longitudinal axis L that has a generally square cross section transverse to the longitudinal axis L. It is appreciated that housing 101 can have a generally rectangular cross section or other cross-sectional configuration suitable for its intended purpose. Housing 101 preferably has a hollow interior 114 configured to hold bone growth promoting material. In this embodiment, upper and lower surfaces 106, 108 are preferably at least in part non-arcuate. Upper and lower surfaces 106, 108, of housing 101 preferably each have at least one opening **116** in communication with hollow interior 114 and adapted to permit the growth of bone from adjacent vertebral body to adjacent vertebral body through housing 101. Upper and lower surfaces 106, 108 further preferably have a plurality of openings 118 configured to

permit the passage therethrough of bone engaging projections 132 described below from hollow interior 114 to the exterior of housing 101. Sides 110, 112 of implant 100 can also have openings 116.

Implant 100 has an internal rotatable member 120 con- 5 figured to be preferably at least in part within hollow interior 114 of housing 101 and as shown in this embodiment is insertable within hollow interior 114 by the user. While in this embodiment, rotatable member 120 is shown entirely within hollow interior 114 of housing 101, it is appreciated 10 that the rotatable member need not be entirely within hollow interior 114. For example, the rotatable member may have an external flange that is at least in part outside of hollow interior 114. Rotatable member 120 is preferably substantially hollow and has a leading end 122, a trailing end 124, 15 an exterior surface 126, and an open interior 128. Trailing end 124 preferably is configured to cooperatively engage an instrument for rotating rotatable member 120 such as, for example, inserter 200 (described below). For example, the inner perimeter of trailing end 124 can be hex-shaped or  $_{20}$ have any other configuration suitable for cooperatively engaging an instrument for rotating rotatable member 120. Exterior surface 126 of rotatable member 120 preferably has at least one opening 130 that permits bone to grow therethrough. Preferably, at least one of openings 130 in rotatable 25 member 120 is configured to generally align with at least one of openings 116 in housing 101 to allow bone to grow from adjacent vertebral body to adjacent vertebral body though housing 101 and through rotatable member 120.

The upper and lower surfaces of rotatable member **120** <sub>30</sub> have at least one bone engaging projection **132** adapted to penetrably engage the bone of the adjacent vertebral bodies. Bone engaging projections **132** are preferably configured such that when rotatable member **120** is in a retracted position, implant **100** may be linearly inserted into the disc space, rotatable member **120** is moved to a deployed position so that bone engaging projections **132** penetrably engage the endplates of an adjacent vertebral body and prevent expulsion of implant **100** from the disc space.

In a preferred embodiment, bone engaging projections 132 have a blade-like configuration oriented transverse to the longitudinal axis of rotatable member 120 with a leading edge and a trailing edge angled relative to each other to form an apex adapted to penetrate the bone of a vertebral body. 45 The blade-like bone engaging projections 132 are preferably of appropriate thickness, shape and sharpness to penetrate the vertebral bodies adjacent the disc space to be fused deep to the adjacent superficial endplate surfaces when the implant is in the deployed position. Bone engaging projec- 50 tions 132 are preferably oriented on opposite sides of rotational member 120 and may, but need not, be diametrically opposite one another. Bone engaging projections 132 may be arranged such that at least the apexes of two opposite bone engaging projections 132 are on opposite sides of a 55 mid-line passing therethrough. Such an over-center arrangement of bone engaging projections 132 creates a more stable configuration of the implant when the bone engaging projections are fully deployed. Greater energy is required to de-rotate a rotatable member with opposed bone engaging 60 projections when in an over-center arrangement as the apex of each bone engaging projection has to be moved through the mid-line to move from a deployed to a retracted position.

As will be appreciated by those skilled in the art, bone engaging projections other than blades may be employed 65 that are suitable for the intended purpose. The number and orientation of the bone engaging projections along rotatable 6

member 120 may be varied without departing from the broad scope of the present invention. For example, at least two of the bone engaging projections may be arranged at an angle to the outer surface of rotatable member 120, the angle may be 90 degrees or an angle other than 90 degrees to enhance the resistance of implant 100 to expulsion from the disc space. As another example, bone engaging projections 132 may also be oriented parallel to one another along at least a portion of the longitudinal axis of implant 100.

As shown in FIG. 3, interior surface 134 of hollow interior 114 of housing 101 preferably forms a pair of opposed abutment surfaces 136. Abutment surfaces 136 are configured to support and permit rotatable member 120 to rotate within hollow interior 114 from a retracted to a deployed position to deploy bone engaging projections 132. The rotation of rotatable member 120 is limited when bone engaging projections 132 contact abutment surfaces 136. The rotation of rotatable member 120 can be limited to approximately 180 degrees or less about its axis of rotation so that it takes a half turn or less of the rotatable member to deploy the bone engaging projections. By way of example only and not limitation, the rotation of rotatable member 120 can be limited to a range of approximately 25 degrees to approximately 65 degrees to move bone engaging projections from a retracted to a deployed position. Abutment surfaces 136 also may be configured to limit the rotation of rotatable member 120 to approximately 90 degrees or less about its axis of rotation so that it takes a quarter turn or less of the rotatable member to deploy the bone engaging projections. Interior surface 134 of hollow interior 114 preferably has spaces 135 within the hollow interior 114 of housing 101 configured to receive bone engaging projections 132 in the retracted position such that the apex of each bone engaging projection is substantially in a corner of hollow interior 114. In this position, the bone engaging projections are retained substantially within the hollow interior of housing 101.

Abutment surfaces 136 also preferably form a shoulder 138 within hollow interior 114 proximate trailing end 104 of housing 101 that is configured to permit and support the insertion of rotatable member 120 into hollow interior 114 and retain rotatable member 120 therein in the deployed position. Shoulder 138 also is preferably configured to contact implant an engagement surface 212 of inserter 200 as will be described below. The interior surface of hollow interior 114 also preferably has a pair of opposed grooves 140 proximate trailing end 104 that are adapted to engage tabs 214 of inserter 200. It is appreciated that trailing end 104 may have any configuration known to those skilled in the art suitable for cooperatively engaging an appropriate insertion instrument.

As shown in FIGS. 5 and 6, rotatable member 120 is insertable into hollow interior 114 of housing 101. After rotatable member 120 is inserted into hollow interior 114 and implant 100 is inserted into the disc space, rotatable member 120 is rotated such that bone engaging projections 132 extend through openings 118 to project above upper and lower surfaces 106, 108 of housing 101. It is appreciated that upper and lower surfaces 106, 108 can have any openings suitable for the intended purpose of deploying bone engaging projections or other means for achieving the same purpose. Further, openings 118 can be in the form of slots wherein the slots are configured to be in dose tolerance with bone engaging projections 132 when deployed.

As shown in FIG. 4, hollow interior 114 of housing 101 and open interior 128 of rotatable member 120 are config-

ured to hold bone growth materials therein. Examples of such bone growth materials include, but are not limited to, any of, or any combination of, bone in any of its forms, materials derived from bone, bone morphogenetic proteins, mineralizing proteins, genetic materials coding for the pro- 5 duction of bone or any substance capable of inducing the formation of bone or useful for achieving fusion for the intended purpose. The rotation of rotatable member 120, when rotated between a retracted and a deployed position, does not substantially displace bone growth material from 10 within hollow interior 114 of housing 101 and/or open interior 128 of rotatable member 120. Accordingly, implant 100 and rotatable member 120 can be loaded with bone growth material prior to insertion of the implant into the disc space and prior to deployment of the bone engagement 15 projections. Alternatively, housing 101 and rotatable member 120 can be loaded with bone growth material after insertion of the implant at least in part within the disc space either before or after rotation of rotatable member 120 and may be further loaded after deployment of the bone engag- 20 ing projections as desired.

FIGS. 1, 2 and 5 show a preferred implant inserter 200 for use with the implant of the present invention. Inserter 200 preferably has an outer shaft 202 with a distal end 204, a proximal end 206, and a reduced diameter medial portion <sup>25</sup> 208. Distal end 204 preferably has a head portion 210 with an implant engagement surface 212 located distally thereto. Head portion 210 preferably has a cross section transverse to the longitudinal axis of inserter 200 corresponding to the transverse cross sectional configuration of at least the outer <sup>30</sup> perimeter of trailing end 104 of implant 100.

Implant engagement surface 212 is preferably sized and shaped to cooperatively contact shoulder 138 of hollow interior 114 of housing 101. Implant engagement surface 212 also preferably has opposed tabs 214 that are adapted to snap into grooves 140 of housing 101.

Head portion **210** also preferably has a pair of longitudinal recesses **216** extending between an upper surface **218** and a lower surface **220** of head portion **210**. Recesses **216** permit head portion **210** to be resiliently compressed so that tabs **214** may be inserted into grooves **140** of housing and then locked into place when released. Outer shaft **202** also preferably has a handle **222** at its proximal end **206**.

Inserter 200 also has an inner shaft 224 that is rotatable 45 within outer shaft 202. Inner shaft 224 has a distal end 226 and a proximal end 228. Distal end 226 of inner shaft 224 has rotational engagement surface 230 that is preferably configured to cooperatively engage trailing end 124 of rotatable member 120. In a preferred embodiment, rotational 50 engagement surface 230 is hex-shaped. Proximal end 228 of inserter 200 preferably has a handle 232 with an outer perimeter corresponding to the outer perimeter of handle 222 of outer shaft 202. Handle 232 is preferably proximal of handle 222 so that the surgeon may rotate inner shaft 224 via 55 handle 232 while holding handle 222. In a preferred embodiment, inserter 200 preferably stabilizes housing 101 of implant 100 while rotating rotatable member 120 to deploy bone engaging projections 132. Inserter 200 is preferably a combination holder, driver, extractor, housing 60 stabilizer, and rotator all in one.

While a preferred embodiment of an inserter **200** is shown, it is appreciated that any other inserter suitable for the intended purpose known to those skilled in the art may be used to insert the implants of the present invention.

In FIGS. 7-9, another preferred embodiment of the implant of the present invention is shown and generally

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referred to by the reference number 300. Implant 300 is similar to implant 100 but has a height that is greater than its width. Implant 300 preferably has a housing 301 with upper and lower surfaces 306, 308 that are angled with respect to one another so as to maintain the natural lordosis of the spine after implantation. For example, upper and lower surfaces 306, 308 may be in a diverging or converging angular relationship to each other along at least a portion of the longitudinal axis of implant 300. Similarly, sides 310, 312 can be angled relative to one another. It is appreciated that implant upper and lower surfaces 306, 308 and sides 310, 312 need not be angled.

Implant 300 has a rotatable member 320 that is preferably frustoconical in shape. Rotatable member 320 has bone engaging projections 332 adapted to penetrably engage the bone of the adjacent vertebral bodies. Bone engaging projections 332 are preferably configured such that in a retracted position, implant 300 may be linearly inserted into the disc space. After implant 300 is inserted into the disc space, bone engaging projections 332 are moved to a deployed position to penetrably engage the endplates of each adjacent vertebral body and prevent the expulsion of implant **300** from the disc space. The rotation of rotatable member 320 can be limited to approximately 180 degrees or less about its axis of rotation so that it takes a half turn or less of the rotatable member to deploy the bone engaging projections. By way of example only and not limitation, the rotation of rotatable member 320 can be limited to a range of approximately 25 degrees to approximately 65 degrees to move bone engaging projections from a retracted to a deployed position.

To support and facilitate the rotation of rotatable member 320, hollow 314 of housing 301 preferably has a second shoulder 342 proximate to a first shoulder 338. First shoulder 338 is preferably configured for engagement with the distal end of a suitably configured inserter 200. Second shoulder 342 supports a trailing end 324 of rotatable member 320. A leading end 322 of rotatable member 320 preferably has a cylindrical extension 344 for insertion into an opening 346 at leading end 302 of housing 301. Cylindrical extension 344 serves as an axle to support leading end 322 and permit rotation of rotatable member 320 within hollow 314 of implant 300. Rotatable member 320 may have openings in its surface along its longitudinal axis to permit bone to grow through rotatable member 320 and have an open interior.

In FIGS. 10–12, another preferred embodiment of the implant of the present invention for insertion into the spine from an anterior approach is shown and generally referred to by the reference number 400. Implant 400 is similar to implant 300 except that it has a width greater than its height and has two rotatable members 420 within hollow interior 414 of housing 401. Housing 101 preferably has upper and lower surfaces 406, 408 that are angled with respect to one another and an overall width that is generally greater than one half the width of the disc space into which implant 400 is to be inserted.

Trailing end **404** of housing **401** may have an anatomical configuration to utilize the apophyseal rim bone around the perimeter of each vertebral body to help support the implant, and/or avoid the need to deeply countersink the implant so as to avoid a lateral corner of the implant from protruding beyond the perimeter of the vertebral bodies. Examples of such configurations are in U.S. Pat. No. 6,241,770 to Michelson, entitled "Implant with Anatomically Conformed Trailing End," the disclosure of which is hereby incorporated by reference. Housing **401** has internal openings **446** 

proximate leading end **402** configured to support rotatable members **420** and are preferably configured to have a wider diameter portion **452** and a reduced diameter portion **454**. Wider diameter portion **452** is configured to receive and support leading end **422** of a rotatable member **420** while 5 reduced diameter portion **454** acts as a stop to prevent rotatable member **420** from moving toward leading end **402** of housing **401**.

Rotatable members **420** are positioned to either side of the mid-longitudinal axis of housing **401**. The rotatable mem-<sup>10</sup> bers may be adapted to rotate in the same or opposite directions.

In FIGS. 13-15, another preferred embodiment of the implant of the present invention is shown and generally referred to by the reference number **500**. Implant **500** has an external housing 501 with a leading end 502 for insertion first into the disc space between two adjacent vertebral bodies of the human spine, a trailing end 504 opposite leading end 502, an upper surface 506, a lower surface 508, 20 and sides 510, 512 between upper and lower surfaces 506, 508. Housing 501 of implant 500 has a hollow interior 514 configured to hold bone growth promoting material. In this embodiment, upper and lower surfaces 506, 508 each preferably have at least an arcuate portion 507 and at least a non-arcuate portion 509 near sides 510, 512. Non-arcuate portions 509 of upper and lower surfaces 506, 508 are adapted to be oriented toward the endplates adjacent the disc space and are configured to support the adjacent vertebral bodies when implant 500 in inserted into the disc space. Arcuate portions 507 of upper and lower surfaces 506, 508 are adapted to be inserted into an implantation space formed across the height of the disc space and into the adjacent vertebral bodies. Such an implantation space may be formed with a bone removal device, such as but not limited to, a 35 drill, a trephine, a reamer, a burr, and any other bone removal device known to those skilled in the art suitable for its intended purpose.

Upper and lower surfaces **506**, **508**, of implant **500** preferably each have at least one opening **516** in communication with hollow interior **514** of housing **501** and adapted to permit the growth of bone from adjacent vertebral body to adjacent vertebral body through implant **500**. Upper and lower surfaces **506**, **508** further preferably have a plurality of openings **518** configured to permit the passage therethrough of bone engaging projections **532** described below from hollow interior **514** to the exterior of housing **501**. Sides **510**, **512** of implant **500** can also have openings **516**.

Implant **500** has an internal rotatable member **520** configured to be inserted into hollow interior **514** of housing **501** preferably through an opening at trailing end **504** of implant housing **501**. Alternatively, housing **501** of implant **500** need not be one piece, such as for example housing **501** may be split into upper and lower portions. With the upper and lower portions apart, rotatable member **520** can be placed into hollow interior **514** and then housing **501** can be reassembled by putting together upper and lower portions and implant **500** can then be inserted into the disc space. In this manner, bone engaging projections **532** may be at least in openings **518** and not extend beyond the exterior of implant **500** in the retracted position.

Rotatable member **520** is preferably substantially hollow and has a leading end **522**, a trailing end **524**, an exterior 65 surface **526**, and an open interior **528**. Trailing end **524** preferably is configured to cooperatively engage an instru-

ment for rotating rotatable member **520** such as, for example, an inserter similar to inserter **200** described above. Exterior surface **526** of rotatable member **520** preferably has at least one opening **530** that permits bone to grow therethrough. Preferably, at least one of openings **530** in rotatable member **520** is configured to generally align with at least one of openings **516** in housing **501** to allow bone to grow from adjacent vertebral body to adjacent vertebral body through housing **501** and through rotatable member **520**.

The upper and lower surfaces of rotatable member 520 have at least one bone engaging projection 532 adapted to penetrably engage the bone of the adjacent vertebral bodies similar to bone engaging projections 132 described above. Bone engaging projections 532 are preferably configured such that when rotatable member 520 is in a retracted position, implant 500 may be linearly inserted into the disc space. After implant 500 is inserted into the disc space, rotatable member 520 is moved to a deployed position so that bone engaging projections 532 penetrably engage into the adjacent vertebral bodies. The rotation of rotatable member 520 can be limited to approximately 180 degrees or less about its axis of rotation so that it takes a half turn or less of the rotatable member to deploy the bone engaging projections. By way of example only and not limitation, the rotation of rotatable member 520 can be limited to a range of approximately 45 degrees to approximately 100 degrees to move bone engaging projections from a retracted to a deployed position.

Bone engaging projections 532 are preferably oriented on opposite sides of rotational member 520 and may, but need not, be diametrically opposite one another. Bone engaging projections 532 may be arranged such that at least the apexes of two opposite bone engaging projections 532 are on opposite sides of a mid-line passing therethrough. Such an over-center arrangement of bone engaging projections 532 creates a more stable configuration of the implant when the bone engaging projections are fully deployed. Greater energy is required to de-rotate a rotatable member with opposed bone engaging projections when in an over-center arrangement as the apex of each bone engaging projection has to be moved through the mid-line to move from a deployed to a retracted position.

As shown in FIG. 14A, interior surface 534 of hollow interior 514 of housing 501 preferably forms a pair of opposed abutment surfaces 536. Abutment surfaces 536 are configured to support and permit rotatable member 520 to rotate within hollow interior 514 from a retracted to a deployed position to deploy bone engaging projections 532. The rotation of rotatable member 520 is limited when bone engaging projections 532 contact abutment surfaces 536. The rotation of rotatable member 520 can be limited to approximately 180 degrees or less about its axis of rotation so that it takes a half turn or less of the rotatable member to deploy the bone engaging projections. Abutment surfaces 536 also may be configured to limit the rotation of rotatable member 520 to approximately 90 degrees or less about its axis of rotation so that it takes a quarter turn or less of the rotatable member to deploy the bone engaging projections. Interior surface 534 of hollow interior 514 preferably has spaces configured to receive bone engaging projections 532 in the retracted position such that the apex of each bone engaging projection is substantially in a corner of hollow interior 514. In this position, the bone engaging projections are retained substantially within the hollow interior of housing 501.

In FIG. 14B, another preferred embodiment of the implant in accordance with the present invention is shown and

generally referred to by the reference number 500'. Implant 500' is similar to implant 500, except that upper and lower surfaces 506', 508' each preferably having at least two arcuate portions 507' and at least some non-arcuate portion 509' either between or lateral to arcuate portions 507' and/or near sides 510', 512'. Non-arcuate portions 509' of upper and lower surfaces 506', 508' are adapted to be oriented toward the vertebral bodies and, if still present, the endplates adjacent the disc space and are configured to support the adjacent vertebral bodies when implant 500' is inserted into the disc space. Arcuate portions 507' of upper and lower surfaces 506', 508' are preferably located on opposite sides of the mid-longitudinal axis of implant 500'. Such a configuration helps to further reduce or eliminate any potential rocking motion that might otherwise occur with an implant 15 having a centrally placed single arcuate portion. Arcuate portions 507' may be generally parallel to each other or at an angle to each other. Having two or more arcuate portions 507' provides for more surface area of implant 500' to contact the bone of the adjacent vertebral bodies and may  $_{20}$ also provide for access to the vascular bone of the adjacent vertebral bodies. Implant 500' having at least two arcuate portions 507' has a height that is less than an implant with a single arcuate portion having the same combined width of two arcuate portions 507'. Furthermore, implant 500' having 25 at least two arcuate portions 507' provides the added advantage of utilizing the stronger more dense bone of the adjacent vertebral bodies located closer to the disc space.

Implant 500' preferably has at least two internal rotatable members 520' configured to be inserted into hollow interior 30 514' of housing 501' preferably through an opening at one of the trailing and leading ends of implant housing 501' or the implant may be opened, such as by way of example only by having the upper and lower portions of the housing configured to be separable, to permit the placement of rotatable 35 members 520' into hollow interior 514'. Then, housing 501' can be reassembled by putting together upper and lower portions and implant 500' can then be inserted into the disc space.

In FIGS. 16–19, another preferred embodiment of the 40 implant of the present invention is shown and generally referred to by the reference number 600. Implant 600 is similar to implant 500 except for the configuration of bone engaging projections 632. Bone engaging projections 632 preferably have a base portion that extends from rotatable 45 member 620 and terminates in a larger dimension upper portion. The upper portion of bone engaging projection 632 preferably has a transverse cross sectional dimension that is greater than the transverse cross sectional dimension of the base portion. By way of example only and not limitation, the 50 base portion and the upper portion of bone engaging projection 632 can have a T-shaped cross section as shown in FIG. 19. The transverse cross sectional configuration of bone engaging projections 632 can have other configurations, including but not limited to, C-shaped, 55 implant of the present invention is shown and generally V-shaped, W-shaped, Y-shaped, and any other configuration suitable for the intended purpose. Bone engaging projections 632 preferably have a leading edge 633 that is at least in part curved and the upper portion of bone engaging projection 632 is preferably tapered proximate leading edge 633 to 60 facilitate penetration of bone engaging projection 632 into the bone of the vertebral bodies. Similarly, openings 618 preferably have a configuration shaped to permit bone engaging projections 632 to extend from hollow interior 614 of housing 601 and through openings 618 when deployed. 65

Implant 600 is inserted into the disc space and bone engaging projections 632 are deployed to penetrably engage the bone of the adjacent vertebral bodies. The configuration of bone engaging projections 632 provide for increased stability of the implant relative to the adjacent vertebral bodies and of the vertebral bodies relative to each other. Further, the configuration of bone engaging projections 632 limit the ability of the vertebral bodies to move apart from one another to further enhance stability.

As shown in FIG. 20, in a further variation, the upper portion of the T-shaped configuration of bone engaging projections 632' increases in thickness at least in part from leading edge 633' to trailing edge 635' so that it is closer to the housing of implant 600 in the deployed position and brings the vertebral bodies closer together so as to compressively load the vertebral bodies towards the implant when the bone engaging projections are fully deployed. In this configuration the upper portion of bone engaging projection 632' has a decreased distance from housing of the implant at its trailing edge than at its leading edge when the bone engaging projections are in the deployed position.

As shown in FIG. 21, in a further alternative configuration, bone engaging projections 632" have a lower portion opposite the upper portion of the T-shaped configuration. The lower portion of the T-shaped configuration has an arc of radius that is less than the arc of radius of the upper portion of the T-shaped configuration resulting in a decreased distance from the housing of the implant proximate trailing edge 635" than proximate leading edge 633" when bone engaging projections 632" are in the deployed position. Such a configuration of bone engaging projections 632" provides for the compressive loading of the vertebral bodies towards the implant when the bone engaging projections are fully deployed.

In FIGS. 22 and 23, another preferred embodiment of the implant of the present invention is shown and generally referred to by the reference number 700. Implant 700 is similar to implant 600 except for the configuration of housing 701. Each of upper and lower surfaces 706, 708 of housing 701 preferably has an open area in communication with hollow interior 714 of housing 701. The open area preferably forms a window 703 (a large opening) in each of upper and lower surfaces 706, 708 over at least a portion of rotatable member 720. Rotatable member 720 is exposed to the adjacent vertebral bodies through windows 703. Rotatable member 720 may project at least in part through the windows 703 to contact the adjacent vertebral bodies. In a preferred embodiment, rotatable member 720 may protrude at least in part through windows 703 to be flush with the exterior of housing 701. Housing 701 is preferably configured to be opened to receive rotatable member 720 therein and closed to hold rotatable member 720 at least in part within housing 701. By way of example only and not limitation, housing 701 may be separable into upper and lower portions at seam 705.

In FIGS. 24 and 25, another preferred embodiment of the referred to by the reference number 800. Implant 800 is similar to implant 100 except that it preferably has at least two internal rotatable members 820 for deploying bone engaging projections 832 through upper and lower surfaces 806, 808 of housing 801. Rotatable members 820 are preferably at least in part within hollow interior 814 of housing 801 proximate upper and lower surfaces 806, 808, respectively. Rotatable members 820 are preferably held in rotational relationship to housing 801 by support structures 809. Each of rotatable members 820 preferably have at least one end 824 configured to cooperatively engage an instrument for rotating rotational members 820 to deploy bone

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engaging projections 832. The rotation of rotatable member 820 can be in the preferred range of approximately 200 degrees to approximately 25 degrees about its axis of rotation so that it takes less than a full turn of the rotatable member to deploy the bone engaging projections. By way of example only and not limitation, rotational member 820 can be rotated more than 180 degrees, for example approximately 195 degrees, to deploy bone engaging projections 832 in an over center position. While rotational members 820 can be solid or at least in part hollow, in this instance a generally solid configuration is preferred so that each of rotational members 820 preferably has a relatively small cross sectional dimension transverse to its longitudinal axis such that rotational members 820 occupy only a small portion of the interior of housing 801.

15 Housing 801 of implant 800 preferably has at least a portion along its longitudinal axis that has a generally square cross section transverse to the longitudinal axis. It is appreciated that housing 801 can have a generally rectangular cross section or other cross-sectional configuration suitable for its intended purpose. The implant may be inserted into 20 the disc space on its side and then flipped 90 degrees to orient the upper and lower surfaces of the implant toward the adjacent vertebral bodies, respectively. Such an implant would preferably have a reduced dimension between a pair of diagonally opposed corners. For example, such an 25 implant could have diagonal corners that are rounded to facilitate the 90 degree rotation of the implant between the adjacent vertebral bodies as taught by Michelson in U.S. application Ser. No. 09/429,628 for a "Self-Broaching, Rotatable, Push-In Interbody Spinal Fusion Implant and 30 Method for Deployment Thereof", the portions of the specification directed to the reduced dimension between a pair diagonally opposed corners are hereby incorporated by reference herein. Upper and lower surfaces 806, 808 of implant 800 are preferably at least in part non-arcuate and 35 are generally parallel to each other along at least a portion of the longitudinal axis of implant 800. Alternatively, upper and lower surfaces 806, 808 can be angled relative to one another along at least a portion of the longitudinal axis of implant 800.

FIGS. 1–5 show various steps of a preferred method for inserting implant 100 from a posterior approach to the spine and using associated instrumentation disclosed herein.

By way of example and not limitation, preferred steps of methods for installing the implants of the present invention 45 include but are not limited to the steps summarized below.

- 1. Identifying the disc space to be operated upon;
- 2. Providing access to the disc space;
- 3. Utilizing a guard or retractor to provide protected access to the disc space;
- Removing sufficient disc material to allow an implant to be inserted at least in part within and across the height of the disc space;
- 5. Distracting the disc space between the vertebral bodies to generally restore the height of the disc space with or 55 without the use of a distractor,
- Utilizing a guard with disc penetrating extensions to provide protected access to the disc and to distract the vertebral bodies adjacent the disc space;
- 7. Working upon the endplates of the adjacent vertebral 60 bodies, which may include for example scraping the endplates, decorticating the endplates, or cutting away at least a portion of the endplates;
- 8. Attaching the implant to an implant inserter;
- 9. Inserting the implant at least in part into the disc space; 65
- 10. Loading the implant with bone growth promoting material: (i) prior to implantation of the implant, (ii) after

implantation of the implant, or (iii) both prior to implantation and after implantation of the implant;

- 11. Packing bone growth promoting material around the implant and pushing bone through the implant and into the area around the implant;
- 12. Rotating the hollow internal member to deploy the bone engaging projections to penetrably engage the vertebral bodies adjacent the disc space, which may include rotating the internal member less than 180 degrees;
- 13. Removing the inserter from the implant; and/or
- 14. Repeating the procedure at same disc level if necessary. The methods for installing the implants of the present invention are not limited to the steps identified above, need not include all the steps recited above, and need not be performed in the order listed above. By way of example only and not limitation, two implants may be inserted into the disc space before either has its internal rotatable member

rotated to deploy the bone engaging projections, or the implant may be inserted into the disc space prior to being packed with bone growth promoting material or prior to the bone growth promoting material being forced through the openings in the implant. Other methods for installing implants known to those skilled in the art may be used to install the implants of the present invention may be used without departing from the scope of the present invention.

Preferred instruments and methods of preparing the disc space are disclosed and taught by Michelson in U.S. Pat. No. 6,159,214 entitled "Milling Instrumentation and Method for Preparing a Space Between Adjacent Vertebral Bodies"; U.S. Patent Application No. 60/255,463 entitled "Spinal Interspace Shaper"; U.S. Pat. No. 6,083,228 entitled "Device and Method for Preparing a Space Between Adjacent Vertebrae to Receive an Insert"; U.S. Pat. No. 6,224,607 entitled "Instrument and Method for Creating an Intervertebral Space for Receiving an Implant"; and WIPO publication WO 99/63891 entitled "Device for Preparing a Space Between Adjacent Vertebrae to Receive an Insert," the disclosures of which are all herein incorporated by reference. It is appreciated that other instruments and methods 40 may be used to prepare the disc space to receive the implant of the present invention.

Where it is desirable, the surgeon may utilize a guard such as guard **500** shown in FIG. 1 for protecting adjacent delicate neurological structures. Guard **500** may be left in place after the preparation of the disc space such that the described operation can be performed through guard **500** and be removed at its completion. The implantation space may have any configuration suitable to receive the implant to be inserted therein.

Prior to preparing the disc space, if it is desirable, the surgeon may distract the vertebral bodies with a distractor having disc penetrating extensions such as that taught by Michelson in U.S. Pat. No. 5,484,437 entitled "Apparatus and Method of Inserting Spinal Implants" and U.S. Pat. No. 5,797,909 (the '909 patent), entitled "Apparatus for Inserting Spinal Implants," the disclosures of which is herein incorporated reference. If necessary, the surgeon may impart an angulation to the adjacent vertebral bodies with a distractor having disc penetrating extensions with angled upper and lower surfaces such as that taught in the '909 patent to Michelson.

As shown in FIGS. 2 and 5, rotatable member 120 may be inserted into hollow interior 114 of implant 100 and distal end 204 of inserter 200 is cooperatively engaged to trailing end 104 of implant 100 such that tabs 214 of implant engagement surface 212 are engaged with grooves 140 of implant 100. It is appreciated that rotatable member 120 may be inserted into hollow interior 114 of housing 101 after implant 100 is inserted into the disc space. Implant 100 is inserted into the disc space preferably by linear insertion without substantial rotation of implant **100** to the appropriate depth as desired by the surgeon. Alternatively, the implant be 5 can be rotated at least in part during its implantation into the disc space, but is not screwed into the disc space. For example, the implant may be inserted into the disc space on its side and then rotated 90 degrees to place the upper and lower surfaces of housing 101 in contact with the adjacent 10 vertebral bodies, respectively. Bone engaging projections 132 can then be deployed. Trailing end 104 of implant 100 preferably does not protrude beyond the posterior aspects of the adjacent vertebral bodies, and preferably no substantial portion of implant 100 protrudes from the outer perimeter of 15 the adjacent vertebral bodies. During insertion of implant 100, bone engaging projections 132 are retained in the retracted position to facilitate linear insertion of implant 100 into the disc space.

After implant 100 is properly positioned in the implantation space, the bone engaging projections 132 can be deployed. In a preferred embodiment, inner shaft 224 of inserter 200 is rotated by the surgeon to rotate rotatable member 120 of implant 100 from a retracted position to a deployed position so that bone engaging projections 132 25 extend through upper and lower surfaces 106, 108 of implant 100 to penetrably engage the end plates of the adjacent vertebral bodies and prevent the expulsion of the implant from the disc space. In a preferred embodiment, rotatable member 120 is rotated one half turn or less to deploy the 30 bone engaging projections.

Implant inserter **200** is detached from implant **100** and removed. A cap may be installed to close at least part of the implant's trailing end to prevent bone from growing into the spinal canal, or to limit adhesions of the neurological 35 structures at the canal floor, or to otherwise protect the neurological structures. One of the purposes for a cap includes restricting the passage of fusion-promoting materials so that they remain loaded within the implant.

Preferably prior to insertion, hollow interior 114 of 40 implant 100 and open interior 128 of rotatable member 120 may be loaded with fusion promoting materials including any of, or any combination of, bone in any of its forms, materials derived from bone, bone morphogenetic proteins, mineralizing proteins, genetic materials coding for the pro- 45 duction of bone or any substance capable of inducing the formation of bone or useful for achieving fusion for the intended purpose. The fusion promoting materials may be loaded or preferably compressively loaded into hollow interior 114 of implant 100 and/or open interior 128 of rotatable 50 member 120 by use of an instrument such as, for example, a tamp, press, or piston at any time during the procedure as desired by the surgeon. Additionally, scar tissue-inhibiting and/or antimicrobial materials may be applied to the implant.

When said methods and instrumentation are used to install such implants posteriorly, the technique may further include the application of scar tissue inhibiting substances posterior to the implant trailing end and at the floor of the spinal canal.

When performing the procedure from a posterior 60 approach to the spine, it is generally preferred that the procedure be performed on both sides of the saggital midline of the disc space and that two implants **100**, each having a width less than half the width of the disc space be inserted from a posterior to anterior approach either generally par-65 allel or alternatively from a generally posterior to anterior approach in a "toed-in" configuration. Having completed the

procedure on a first side, the procedure is then repeated as already described on the opposite side of the saggital midline of the same disc space leading to the implantation of two implants **100** in the same disc space.

If implants **300** are being inserted into the disc space, then the procedure may preferably include distracting the adjacent vertebral bodies to impart an angulation to the adjacent vertebral bodies with a distractor such as that taught in the '909 patent to Michelson to accommodate the insertion of each of implants **300**. In another alternative method, both implants may be implanted from an anterior approach to the spine using many of the same steps already described.

When performing the method from the anterior approach, a plurality of implants **100** or **300** (for example two or three) or a single implant such as implant **400** may be used as the spinal cord is not in the path of insertion of the implant. When using a laparoscope or when it is difficult to mobilize the great vessels two or more smaller implants may be used in order to use a smaller working space.

The various features of the preferred embodiments of the present inventions described herein are combinable with one another and are not limited to a particular embodiment of the implant for which the features are described. By way of example only and not limitation, it is appreciated that for any of the embodiments of the implants of the present invention, the external housing may be formed of two or more pieces that can be separated to permit insertion of the internal rotatable member within the housing and then reassembled for installation into the disc space; and the various embodiments of the bone engaging projections described herein may be utilized with any of the embodiments of the implants of the present invention.

The spinal fusion implant of the present invention may comprise of any artificial or naturally occurring implant material suitable for implantation in a human being. The implant of the present invention can be formed of a material such as metal including, but not limited to, titanium and its alloys, surgical grade plastics, composites, ceramics, or other materials suitable for use as a spinal fusion implant. The implant of the present invention can comprise at least in part of a material that is resorbable by the human body. The implant of the present invention can be formed at least in part of a porous material or can be formed at least in part of a material that intrinsically participates in the growth of bone from one of adjacent vertebral bodies to the other of adjacent vertebral bodies.

Further, the implant of the present invention may be comprised of, treated with, coated, or filled with a fusion promoting substance. The implant may be used in combination with a fusion promoting substance including, but not limited to, bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone.

Where such implants are for posterior implantation, the 55 trailing ends of such implants may be treated with, coated with, or used in combination with substances to inhibit scar tissue formation in the spinal canal. The implants of the present invention may be adapted to facilitate the electrostimulation of the implant or a portion thereof and/or of the 60 fusion area into which they are inserted and the proximate bone thereabout. The implant of the present invention may be comprised at least in part of, coated with, or used in combination with materials to make it antimicrobial, such as, but not limited to, antibiotics, silver ions or any other 65 substance suitable for the intended purpose.

There is disclosed in the above description and the drawings implants and instruments and methods for use

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therewith, which fully and effectively accomplish the objectives of this invention. However, it will be apparent that variations and modifications of the disclosed embodiments may be made without departing from the principles of the invention.

What is claimed is:

1. An interbody spinal fusion implant for implantation at least in part within and across the generally restored height of a disc space between two adjacent vertebral bodies of a human spine, said spinal implant comprising:

- a housing having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis between said leading end and said trailing end of said horsing, an upper surface adapted to contact one of the adjacent vertebral bodies, 15 a lower surface opposite said upper surface adapted to contact another one of the adjacent vertebral bodies, a height between said upper and lower surfaces, and a hollow interior configured to hold bone growth promoting material therein, said upper and lower surfaces 20 each having at least one opening therein in communication with said hollow interior and with each other to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said housing, said hollow interior having a maximum width perpen- 25 dicular to the height and the mid-longitudinal axis of said housing; and
- a substantially hollow internal rotatable member configured to be at least in part within said hollow interior of said housing, said rotatable member having a leading 30 end, a trailing end, a mid-longitudinal axis between said leading end and said trailing end of said rotatable member, a top, a bottom, and an open interior between said top and said bottom, each of said top and said bottom of said rotatable member including at least one 35 bone engaging projection adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projection about the midlongitudinal axis of said rotatable member, said top and said bottom including at least one aperture therein in 40 communication with said open interior of said rotatable member and with each other to permit for the growth of bane from vertebral body to vertebral body therethrough, said rotatable member being adapted to rotate at least in part within said hollow interior of said 45 housing between a retracted position and a deployed position, said bone engaging projections extending through said upper and lower surfaces of said housing so as to penetrably engage the bone of the adjacent vertebral bodies when in the deployed position, said 50 bone therethrough. rotatable member having a first dimension measured from one of said bone engaging projections on said top to the mid-longitudinal axis along a line perpendicular to the mid-longitudinal axis and a second dimension measured from one of said bone engaging projections 55 on said bottom to the mid-longitudinal axis along a line perpendicular to the mid-longitudinal axis, the sum of said first and second dimensions being greater than the maximum width of said hollow interior of said housing.

**2**. The implant of claim **1**, wherein said bone engaging 60 projections are fully contained within said hollow interior of said housing when in the retracted position.

**3**. The implant of claim **1**, wherein said bone engaging projections have a leading edge, when in the deployed position said leading edge of at least two of said bone 65 engaging projections on said top and said bottom of said rotatable member, respectively, are on opposite sides of a

plane aligned with the mid-longitudinal axis of said rotational member and passing through said top and said bottom of said rotatable member.

4. The implant of claim 1, wherein said bone engaging projections have a leading edge, when in the deployed position said leading edge of at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are oriented in an overcenter position.

5. The implant of claim 1, wherein at least one of said bone engaging projections has a base portion extending from said rotatable member and terminating in an upper portion having a length and width, said upper portion having a width that is greater than the width of said base portion.

6. The implant of claim 5, wherein at least a portion of said at least one bone engaging projection has at least one of a generally T-shaped, C-shaped, V-shaped, W-shaped, and Y-shaped configuration.

7. The implant of claim 5, wherein said upper portion of said bone engaging projection has a leading edge, a trailing edge, end a thickness that increases at least in part in a direction away from said leading edge along at least a portion of said length of said upper portion.

8. The implant of claim 5, wherein said upper portion of said bone engaging projection has a decreased distance from said housing proximate said trailing edge when said bone engaging projections are in the deployed position.

9. The implant of claim 5, wherein said bone engaging projection has a lower portion opposite said upper portion, said upper portion having an arc of radius and said lower portion having an arc of radius that is less than the arc of radius of said upper portion.

10. The implant of claim 5, wherein said base portion of said at least one bone engaging projection has a leading edge that is at least in part curved.

11. The implant of claim 5, wherein said upper portion of said at least one bone engaging projection has a leading edge that is at least in part tapered.

12. The implant of claim 5, further comprising at least one bone engaging projection receiving opening in said upper and lower surfaces of said housing having a configuration generally corresponding to the configuration of said at least one bone engaging projection.

13. The implant of claim 12, wherein at least one of said bone engaging projection receiving openings in said upper and said lower surfaces of said housing are slots.

14. The implant of claim 13, wherein at least one of said slots is adapted to contact one of said bone engaging projection.

15. The implant of claim 12, wherein said bone engaging projection receiving openings also permit for the growth of bone therethrough.

16. The implant of claim 1, wherein at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are radially offset along the mid-longitudinal axis of said rotatable member.

17. The implant of claim 1, wherein at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are diametrically opposed along the mid-longitudinal axis of said rotatable member.

18. The implant of claim 1, wherein at least one of said bone engaging projections has a sharp leading edge adapted to cut into bone.

**19**. The implant of claim **1**, wherein at least one of said bone engaging projections is a blade.

**20**. The implant of claim **1**, wherein at least a portion of said bone engaging projections are oriented transverse to the mid-longitudinal axis of said rotatable member.

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21. The implant of claim 1, wherein at least a portion of said bone engaging projections are oriented parallel to one another.

22. The implant of claim 1, wherein said rotatable member includes a plurality of said bone engaging projections spaced apart from one another along the longitudinal midlongitudinal axis of said rotatable member.

23. The implant of claim 1, wherein said housing and said rotatable member cooperate so as to limit rotation of said rotatable member to no more than 180 degrees.

**24**. The implant of claim **1**, wherein said housing and said <sup>10</sup> rotatable member cooperate so as to limit rotation of said rotatable member to no more than 90 degrees.

**25**. The implant of claim 1, wherein said bone engaging projections are fully deployed when said rotatable member is rotated less than 180 degrees.

26. The implant of claim 1, wherein said bone engaging projections are fully deployed when said rotatable member is rotated less than 360 degrees.

27. The implant of claim 1, wherein at least one of said leading and said trailing ends of said rotatable member is 20 open.

28. The implant of claim 1, wherein said trailing end of said rotatable member is configured to cooperatively engage an insertion instrument.

**29**. The implant of claim 1, wherein said trailing end of  $_{25}$ said housing is configured to cooperatively engage an insertion instrument.

30. The implant of claim 29, wherein said trailing end of said rotatable member is adapted to cooperatively engage an instrument for rotating said rotatable member.

**31**. The implant of claim 1, wherein said rotatable member is at least in part cylindrical.

32. The implant of claim 31, wherein said rotatable member has a root diameter that remains within said housing when in the deployed position.

**33**. The implant of claim 1, wherein said rotatable mem- <sup>35</sup> ber is at least in part frustoconical.

34. The implant of claim 1, wherein at least a portion of said apertures of said rotatable member when in said deployed position are configured to generally align with at least a portion of said openings of said housing to allow bone 40 to grow from adjacent vertebral body to adjacent vertebral body through housing implant and through said rotatable member.

35. The implant of claim 1, wherein said at least one opening in each of said upper and lower surfaces of said 45 housing form windows.

36. The implant of claim 35, wherein said rotatable member is exposed to the adjacent vertebral bodies through said windows.

37. The implant of claim 35, wherein said rotatable 50 member projects at least in part through said windows to contact the adjacent vertebral bodies.

38. The implant of claim 35, wherein said housing is configured to be opened to receive said rotatable member therein and closed to hold said rotatable member at least in 55 openings in said upper and said lower surfaces of said part within said housing.

**39**. The implant of claim 1, wherein said housing has a transverse cross section that is at least in part generally rectangular along at least a portion of the mid-longitudinal axis of said housing.

40. The implant of claim 1, wherein said housing has a transverse cross section that is at least in part generally square along at least a portion of the mid-longitudinal axis of said housing.

41. The implant of claim 1, further comprising at least one 65 arcuate portion in said upper and lower surfaces of said housing, respectively.

42. The implant of claim 41, wherein said at least one arcuate portion is along at least a portion of mid-longitudinal axis of said implant.

43. The implant of claim 41, wherein at least two of said arcuate portions are generally located side by side to one another.

44. The implant of claim 1, wherein at least one of said upper and said lower surfaces of said housing is at least in part non-arcuate.

45. The implant of claim 44, wherein at least onto of said upper and said lower surfaces of said housing is at least in part arcuate.

46. The implant of claim 1, wherein said upper and lower surfaces of said housing are at least in part parallel to each other in at least one plane.

47. The implant of claim 1, wherein said upper and lower surfaces of said housing are at least in part convergent.

48. The implant of claim 1, wherein said upper and lower surfaces of said housing are at least in part angled to each other.

49. The implant of claim 1, wherein at least one of aid leading and said trailing ends of said housing includes at least one opening.

50. The implant of claim 49, wherein said at least one opening of at least one of said leading and said trailing ends of said housing is configured to permit bone growth therethrough.

51. The implant of claim 1, wherein at least one of said leading and said trailing ends of said housing is open to permit for loading of bone growth promoting material into at least one of said hollow interior of said housing and said open interior of said rotatable member.

52. The implant of claim 51, further comprising an end cap for closing said open end of said housing.

53. The implant of claim 1, wherein at least one of said leading and said trailing ends of said housing is configured to permit said rotatable member to be inserted at least in part within said hollow interior of said housing.

54. The implant of claim 53, wherein said housing is separable into at least two portions to permit the placement of said rotatable member into said open interior of said housing.

55. The implant of claim 1, further comprising at least two bone engaging projection receiving openings in said upper and said lower surfaces of said housing configured to permit only for the passage of said bone engaging projections therethrough.

56. The implant of claim 55, wherein at least one of said bone engaging projection receiving openings in said upper and said lower surfaces of said housing are slots.

57. The implant of claim 56, wherein at least one of said slots is adapted to contact one of said bone engaging projections.

58. The implant of claim 1, wherein at least two of said housing are slots oriented transverse to the mid-longitudinal axis of said implant.

59. The implant of claim 1, wherein said hollow interior of said housing has an interior surface configured to facili-60 tate rotation of said rotatable member therein.

60. The implant of claim 1, wherein said hollow interior of said housing is configured to limit the degree of rotation of said rotatable member within said housing.

61. The implant of claim 1, wherein said hollow interior of said housing includes at least one abutment surface adapted to contact a portion of said rotatable member to limit the rotation of said rotatable member.

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**62**. The implant of claim **1**, wherein said leading end of said housing is tapered to facilitate insertion of said implant into the disc space.

**63**. The implant of claim 1, wherein said implant has a width that is greater than the height of said implant.

**64**. The implant of claim **1**, wherein said implant has a height of said implant is greater than the width of said implant.

**65**. The implant of claim **1**, wherein said implant has a width that is greater than one-half of the transverse width of the disc space into which said implant is adapted to be  $^{10}$  inserted.

**66.** The implant of claim **1**, wherein said implant has a width that is less than one-half of the transverse width of the disc space into which said implant is adapted to be inserted to permit at least two of said implants to be implanted into  $^{15}$  the disc space.

67. The implant of claim 1, wherein said implant comprises at least in part of one of bone and bone growth promoting material.

**68**. The implant of claim **67**, wherein said bone growth 20 promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

**69**. The implant of claim **1**, in combination with a bone <sub>25</sub> growth promoting material.

70. The implant of claim 69, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

71. The implant of claim 1, wherein said implant is treated with a bone growth promoting substance.

**72.** The implant of claim **1**, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in <sup>35</sup> the human body.

**73**. The implant of claim **1**, wherein said implant is at least in part resorbable.

74. The implant of claim 1, wherein said implant is formed of a porous material.

**75.** The implant of claim **1**, in combination with a chemical substance adapted to inhibit scar formation.

76. The implant of claim 1, in combination with an antimicrobial material.

**77**. The implant of claim **1**, wherein said hollow interior 45 of said housing is a chamber for holding bone growth promoting material.

**78**. The implant of claim **1**, wherein each of said upper and lower surfaces is substantially smooth.

**79.** The implant of claim **1**, wherein said implant is 50 configured to be pushed into the disc space.

**80**. The implant of claim **1**, wherein said implant is adapted to be inserted into the disc space without any element of rotation.

**81**. The implant of claim **1**, wherein said bone engaging 55 projections are non-threaded.

**82**. The implant of claim **1**, in combination with a guard having a passage for providing protected access to the disc space.

**83.** The combination of claim **82**, further in combination 60 with a bone removal device having a portion sized for movement through said passage for forming through said guard an implantation space at least in part across the surgically corrected height of the disc space.

**84**. The combination of claim **83**, wherein said bone 65 removal device is one of a drill, a trephine, a reamer, and a burr.

**85**. The implant of claim **1**, in combination with a distractor adapted to urge apart the adjacent vertebral bodies.

86. The implant of claim 1, wherein a cross section of said rotatable member that is transverse to the mid-longitudinal axis of said rotatable member includes a pair of opposed corners connected by a first diagonal and a pair of opposed arcs connected by a second diagonal, the first and second diagonals being oriented generally 90 degrees relative to one another.

87. The implant of claim 86, wherein said pair of opposed arcs are each of the same radius.

**88**. The implant of claim **86**, wherein said pair of opposed corners form a 90 degree angle.

**89.** The implant of claim **1**, wherein at least one of said bone engaging projections includes two sides converging to form a vertex.

90. The implant of claim 89, wherein said vertex is generally 90 degrees.

**91.** The implant of claim **1**, wherein two of said bone engaging projections are generally diagonal to one another in a plane transverse to the mid-longitudinal axis of said rotatable member when said rotatable member is in the retracted position.

**92.** The implant of claim 1, wherein said rotatable member has a maximum height transverse to the mid-longitudinal axis and a maximum width transverse to the maximum height and the mid-longitudinal axis, the maximum width being generally equal to the maximum height in the retracted position.

**93.** The implant of claim **1**, wherein said housing has a maximum interior cross sectional dimension transverse to the mid-longitudinal axis of said housing, said rotatable member having a single maximum dimension perpendicular to the mid-longitudinal axis generally corresponding to the maximum interior cross sectional dimension of said housing.

94. The implant of claim 1, wherein said housing induces opposite sides between said upper and lower surfaces and between said leading and trailing ends, at least one of said 40 upper and lower surfaces of said housing forming a right angle with at least one of said opposite sides.

**95**. The implant of claim **1**, wherein said upper and lower surfaces are generally non-arcuate from side to side.

**96**. An interbody spinal fusion implant for implantation at least in part within and across the generally restored height of a disc space between two adjacent vertebral bodies of a human spine, said spiral implant comprising:

- a housing having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis between said leading end and said trailing end of said housing, an upper surface adapted to contact one of the adjacent vertebral bodies, a lower surface adapted to contact another one of the adjacent vertebral bodies, a height between said upper and lower surfaces, and a hollow interior configure to hold bone growth promoting material therein, said upper and lower surfaces; each having at least one opening therein in communication with said hollow interior and with each other to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said housing, said hollow interior having a maximum width perpendicular to the height and the mid-longitudinal axis of said housing; and
- an internal rotatable member configured to be at least in part within said hollow interior of said housing, said rotatable member having a leading end, a trailing end, a mid-longitudinal axis between said leading end and

said trailing end of said rotatable member, a top, and a bottom, each of said top and said bottom of said rotatable member including a plurality of bone engaging projections spaced apart from one another along the mid-longitudinal axis of said rotatable member, each of 5 said top and said bottom of said rotatable member including at least one aperture therein to permit or the growth of bone from vertebral body to vertebral body through said rotatable member, said bone engaging projections adapted to penetrably engage the bone of 10 the adjacent vertebral bodies by rotating said bone engaging projections about the longitudinal midlongitudinal axis of said rotatable member, said rotatable member being adapted to rotate within said hollow interior of said housing between a retracted position 15 and a deployed position, said bone engaging projections extending through said upper and lower surfaces of said housing so as to penetrably engage the bone of the adjacent vertebral bodies when in the deployed position, said rotatable member having a first dimen- 20 sion measured from one of said bone engaging projections on said top to the mid-longitudinal axis along a line perpendicular to the mid-longitudinal axis and a second dimension measured from one of said bone engaging projections on said bottom to the mid- 25 longitudinal axis along a line perpendicular to the mid-longitudinal axis, the sum of said first and second dimensions being greater than the maximum width of said hollow interior of said housing.

**97**. The implant of claim **96**, wherein said bone engaging 30 projections are fully contained within said hollow interior of said housing when in the retracted position.

**98.** The implant of claim **96**, wherein said bone engaging projections have a leading edge, when in the deployed position said leading edge of at least two of said bone 35 engaging projections on said top and said bottom of said rotatable member, respectively, are on opposite sides of a plane aligned with the longitudinal mid-longitudinal axis of said rotational member and passing through said top and said bottom of said top and said bottom of said rotatable member.

**99.** The implant of claim **96**, wherein said bone engaging projections have a leading edge, when in the deployed position said leading edge of at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are oriented in an over- 45 center position.

**100.** The implant of claim **96**, wherein at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are radially offset along the longitudinal mid-longitudinal axis of said rotatable 50 member.

**101.** The implant of claim **96**, wherein at least two of said bone engaging projections on said top and said bottom of said rotatable member, respectively, are diametrically opposed along the mid-longitudinal axis of said rotatable 55 member.

**102**. The implant of claim **96**, wherein at least one of said bone engaging projections has a sharp leading edge adapted to cut into none.

**103**. The implant of claim **96**, wherein said bone engaging 60 projections are fully deployed when said rotatable member is rotated less than 180 degrees.

**104**. The implant of claim **96**, wherein said bone engaging projections are fully deployed when said rotatable member is rotated less than 360 degrees.

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**105**. The implant of claim **96**, wherein said rotatable member is at least in part cylindrical.

**106.** The implant of claim **105**, wherein said rotatable member has a root diameter that remains within said housing when in the deployed position.

107. The implant of claim 96, wherein said rotatable member is at least in part frustoconical.

108. The implant of claim 96 wherein at least a portion of said apertures of said rotatable member when in said deployed position are configured to generally align with at least a portion of said openings of said housing to allow bone to grow from adjacent vertebral body to adjacent vertebral body through said housing and through said rotatable member.

109. The implant of claim 96, wherein said at least one opening in each of said upper and lower surfaces of said housing form windows.

110. The implant of claim 96, wherein said housing has a transverse cross section that is at least in part generally rectangular along at least a portion of the mid-longitudinal axis of said housing.

111. The implant of claim 96, wherein said housing has a transverse cross section that is at least in part generally square along at least a portion of the mid-longitudinal axis of said housing.

112. The implant of claim 96, further comprising at least one arcuate portion in said upper and lower surfaces of said housing, respectively.

**113**. The implant of claim **112**, wherein said at least one arcuate portion is along at least a portion of mid-longitudinal axis of said implant.

114. The implant of claim 112, wherein at least two of said arcuate portions are generally located side by side to one another.

115. The implant of claim 96, wherein at least one of said upper and said lower surfaces of said housing is at least in part non-arcuate.

**116**. The implant of claim **115**, wherein at least one of said upper and said lower surfaces of said housing is at least in part arcuate.

**117.** The implant of claim **96**, wherein said upper and lower surfaces of said housing are at least in part convergent.

**118.** The implant of claim **96**, wherein said housing is separable into at least two portions to permit the placement of said rotatable member into said open interior of said housing.

**119.** The implant of claim **96**, wherein said implant comprises at least in part of one of bone and bone growth promoting material.

**120.** The implant of claim **119**, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

121. The implant of claim 96, in combination with a bone growth promoting material.

**122.** The implant of claim **121**, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

**123**. The implant of claim **96**, wherein said implant is treated with a bone growth promoting substance.

**124.** The implant of claim **96**, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

**125**. The implant of claim **96**, wherein said implant is at least in part resorbable.

126. The implant of claim 96, wherein said implant is formed of a porous material.

127. The implant of claim 96, in combination with a chemical substance adapted to inhibit scar formation.

128. The implant of claim 96, in combination with an 5 antimicrobial material.

129. The implant of claim 96, wherein said hollow interior of said housing is a chamber for holding bone growth promoting material.

**130**. The implant of claim **96**, wherein at least one of said 10upper and lower surfaces of said housing is substantially smooth.

131. The implant of claim 96, wherein each of said upper and lower surfaces is substantially smooth.

132. The implant of claim 96, wherein said implant is  $_{15}$ configured to be pushed into the disc space.

133. The implant of claim 96, wherein said implant is adapted to be inserted into the disc space without any element of rotation.

134. The implant of claim 96, wherein said bone engaging  $_{20}$ projections are non-threaded.

135. The implant of claim 96, in combination with a guard having a passage for providing protected access to the disc space.

136. The combination of claim 135, further in combina- 25 tion with a bone removal device having a portion sized for movement through said passage for forming through said guard an implantation space at least in part across the surgically corrected height of the disc space.

**137**. The combination of claim **136**, wherein said bone  $_{30}$ removal device is one of a drill, a trephine, a reamer, and a burr.

138. The implant of claim 96, in combination with a distractor adapted to urge apart the adjacent vertebral bodies.

**139**. The implant of claim 1, wherein at least one of said  $_{35}$ upper and lower surfaces of said housing is substantially smooth.

140. An interbody spinal fusion for implantation at least in part within and across the generally restored height of a disc space between two adjacent vertebral bodies of a human 40 spine, said spinal implant comprising:

- a housing having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis between said leading end and said trailing end of said housing, an upper surface 45 adapted to contact one of the adjacent vertebral bodies, a lower surface opposite said upper surface adapted to contact another one of the adjacent vertebral bodies, and a hollow interior configured to hold bone growth promoting material therein, said upper and lower sur- 50 faces each having at least one opening therein in communication with said hollow interior and with each other to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said housing; and 55
- a substantially hollow internal rotatable member configured to be at least in part within said hollow interior of said housing, said rotatable member having a leading end, a trailing end, a mid-longitudinal axis between said leading end and said trailing end of said rotatable 60 member, a top, a bottom, and an open interior between said top and said bottom, each of said top and said bottom of said rotatable member including at least one bone engaging projection adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating 65 said bone engaging projection about the midlongitudinal axis of said rotatable member, said top and

said bottom including at least one aperture therein in communication with said open interior of said rotatable member and with each other to permit for the growth of bone from vertebral body to vertebral body therethrough, said rotatable member being adapted to rotate at least in part within said hollow interior of said housing between a retracted position and a deployed position, said bone engaging projections extending through said upper and lower surfaces of said housing so as to penetrably engage the bone of the adjacent vertebral bodies when in the deployed position, at least a portion of said apertures of said rotatable member when in said deployed position being configured to generally align with at least a portion of said openings of said housing to allow bone to grow from adjacent vertebral body to adjacent vertebral body through housing implant and through said rotatable member.

141. The implant of claim 140, wherein said bone engaging projections are adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projections about the mid-longitudinal axis of said rotatable member.

142. The implant of claim 140, wherein said at least one bone engaging projection of each of said top and said bottom includes a plurality of bone engaging projections spaced apart from one another along the mid-longitudinal axis of said rotatable member.

143. The implant of claim 140, wherein said bone engaging projections are fully contained within said hollow interior of said housing when in the retracted position.

144. The implant of claim 140, wherein at least one of said bone engaging projections has a base portion extending from said rotatable member and terminating in an upper portion having a length and width, said upper portion having a width that is greater than the width of said base portion.

145. The implant of claim 140, wherein at least one of said bone engaging projections has a sharp leading edge adapted to cut into bone.

146. The implant of claim 140, wherein at least one of said bone engaging projections is a blade.

147. The implant of claim 140, wherein said housing and said rotatable member cooperate so as to limit rotation of said rotatable member to no more than 180 degrees.

148. The implant of claim 140, wherein said rotatable member is at least in part frustoconical.

149. The implant of claim 140, wherein said housing is configured to be opened to receive said rotatable member therein and closed to hold said rotatable member at least in part within said housing.

150. The implant of claim 140, wherein at least one of said leading and said trailing ends of said housing is configured to permit said rotatable member to be inserted at least in part within said hollow interior of said housing.

151. The implant of claim 140, wherein said leading end of said housing is tapered to facilitate insertion of said implant into the disc space.

152. The implant of claim 140, wherein said implant having a width that is less than one-half of the transverse width of the disc space into which said implant is adapted to be inserted to permit at least two of said implants to be implanted into the disc space.

153. The implant of claim 140, in combination with a bone growth promoting material.

154. The implant of claim 153, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

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155. The implant of claim 140, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

**156**. The implant of claim **140**, wherein said implant is at  $_5$  least in part resorbable.

**157.** The implant of claim **140**, in combination with a chemical substance adapted to inhibit scar formation.

158. The implant of claim 140, in combination with an antimicrobial material.

**159**. The implant of claim **140**, wherein said implant is <sup>10</sup> configured to be pushed into the disc space.

**160**. The implant of claim **140**, in combination with a guard having a passage for providing protected access to the disc space.

**161**. The combination of claim **160**, further in combina-<sup>15</sup> tion with a bone removal device having a portion sized for movement through said passage for forming through said guard an implantation space at least in part across the surgically corrected height of the disc space.

162. The implant of claim 140, in combination with a 20 distractor adapted to urge apart the adjacent vertebral bodies.

163. The implant of claim 140, wherein said upper and lower surfaces are generally non-arcuate from side to side.

**164.** An interbody spinal fusion for implantation at least in part within and across the generally restored height of a <sup>25</sup> disc space between two adjacent vertebral bodies of a human spine, said spinal implant comprising:

- a housing having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis between said leading end and 30 said trailing end of said housing, an upper surface adapted to contact one of the adjacent vertebral bodies, a lower surface opposite said upper surface adapted to contact another one of the adjacent vertebral bodies, and a hollow interior configured to hold bone growth 35 promoting material therein, said upper and lower surfaces each having at least one opening therein in communication with said hollow interior and with each other to permit for the growth of bone from adjacent housing, said housing having a transverse cross section that is at least in part generally square along at least a portion of the mid-longitudinal axis of said housing; and
- a substantially hollow internal rotatable member config- 45 ured to be at least in part within said hollow interior of said housing, said rotatable member having a leading end, a trailing end, a mid-longitudinal axis between said leading end and said trailing end of said rotatable member, a top, a bottom, and an open interior between 50 said top and said bottom, each of said top and said bottom of said rotatable member including at least one bone engaging projection adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projection about the mid- 55 longitudinal axis of said rotatable member, said top and said bottom including at least one aperture therein in communication with said open interior of said rotatable member and with each other to permit for the growth of bone from vertebral body to vertebral body 60 therethrough, said rotatable member being adapted to rotate at least in part within said hollow interior of said housing between a retracted position and a deployed position, said bone engaging projections extending through said upper and lower surfaces of said housing 65 so as to penetrably engage the bone of the adjacent vertebral bodies when in the deployed position.

165. The implant of claim 164, wherein said bone engaging projections are adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projections about the mid-longitudinal axis of said rotatable member.

166. The implant of claim 164, wherein said at least one bone engaging projection of each of said top and said bottom includes a plurality of bone engaging projections spaced apart from one another along the mid-longitudinal axis of said rotatable member.

**167**. The implant of claim **164**, wherein said bone engaging projections are fully contained within said hollow interior of said housing when in the retracted position.

**168.** The implant of claim **164**, wherein at least one of said bone engaging projections has a base portion extending from said rotatable member and terminating in an upper portion having a length and width, said upper portion having a width that is greater than the width of said base portion.

169. The implant of claim 164, wherein at least one of said bone engaging projections has a sharp leading edge adapted to cut into bone.

**170**. The implant of claim **164**, wherein at least one of said bone engaging projections is a blade.

**171**. The implant of claim **164**, wherein said housing and said rotatable member cooperate so as to limit rotation of said rotatable member to no more than 180 degrees.

**172.** The implant of claim **164**, wherein said rotatable member is at least in part frustoconical.

**173.** The implant of claim **164**, wherein said housing is configured to be opened to receive said rotatable member therein and dosed to hold said rotatable member at least in part within said housing.

174. The implant of claim 164, wherein at least one of said leading and said trailing ends of said housing is configured to permit said rotatable member to be inserted at least in part within said hollow interior of said housing.

175. The implant of claim 164, wherein said leading end of said housing is tapered to facilitate insertion of said implant into the disc space.

other to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said housing, said housing having a transverse cross section that is at least in part generally square along at least a portion of the mid-longitudinal axis of said housing; 176. The implant of claim 164, wherein said implant has; a width that is less than one-half of the transverse width of the disc space into which said implant is adapted to be inserted to permit at least two of said implants to be implanted into the disc space.

177. The implant of claim 164, in combination with a bone growth promoting material.

**178.** The implant of claim **177**, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

**179**. The implant of claim **178**, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

**180**. The implant of claim **164**, wherein said implant is at least in part resorbable.

**181**. The implant of claim **164**, in combination with a chemical substance adapted to inhibit scar formation.

182. The implant of claim 164, in combination with an antimicrobial material.

**183**. The implant of claim **164**, wherein said implant is configured to be pushed into the disc space.

**184.** The implant of claim **164.** In combination with a guard having a passage for providing protected access to the disc space.

**185**. The combination of claim **184**, further in combination with a bone removal device having a portion sized for

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movement through said passage for forming through said guard an implantation space at least in part across the surgically corrected height of the disc space.

186. The implant of claim 164, in combination with a distractor adapted to urge apart the adjacent vertebral bodies.

187. The implant of claim 164, wherein said upper and lower surfaces are generally non-arcuate from side to side.

188. An interbody spinal fusion for implantation at least in part within and across the generally restored height of a disc space between two adjacent vertebral bodies of a human spine, said spinal implant comprising:

- a housing having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis between said leading end and said trailing end of said housing, an upper surface adapted to contact one of the adjacent vertebral bodies, a lower surface opposite said upper surface adapted to contact another one of the adjacent vertebral bodies, and a hollow interior configured to hold bone growth promoting material therein, said upper and lower surfaces each having at least one opening therein in 20 communication with said hollow interior and with each other to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said housing; and
- a substantially hollow internal rotatable member config- 25 ured to be at least in part within said hollow interior of said housing, said rotatable member having a leading end, a trailing end, a mid-longitudinal axis between said leading end and said trailing end of said rotatable member, a top, a bottom, and an open interior between 30 said top and said bottom, each of said top and said bottom of said rotatable member including at least one bone engaging projection adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projection about the mid- 35 longitudinal axis of said rotatable member, said top and said bottom including at least one aperture therein in communication with said open interior of said rotatable member and with each other to permit for the growth of bone from vertebral body to vertebral body 40 therethrough, said rotatable member being adapted to rotate at least in part within said hollow interior of said housing between a retracted position and a deployed position, said bone engaging projections extending through said upper and lower surfaces of said housing 45 so as to penetrably engage the bone of the adjacent vertebral bodies when in the deployed position, said hollow interior of said housing being configured to limit the degree of rotation of said rotatable member within said housing. 50

189. The implant of claim 188, wherein said hollow interior of said housing includes at least one abutment surface adapted to contact a portion of said rotatable member to limit the rotation of said rotatable member.

190. The implant of claim 188, wherein said bone engag- 55 ing projections are adapted to penetrably engage the bone of the adjacent vertebral bodies by rotating said bone engaging projections about the mid-longitudinal axis of said rotatable member.

191. The implant of claim 188, wherein said at least one 60 bone engaging projection of each of said top and said bottom includes a plurality of bone engaging projections spaced apart from one another along the mid-longitudinal axis of said rotatable member.

192. The implant of claim 188, wherein said bone engag- 65 lower surfaces are generally non-arcuate from side to side. ing projections are fully contained within said hollow interior of said housing when in the retracted position.

193. The implant of claim 188, wherein at least one of said bone engaging projections has a base portion extending from said rotatable member and terminating in an upper portion having a length and width, said upper portion having a width that is greater than the width of said base portion.

194. The implant of claim 188, wherein at least one of said bone engaging projections has a sharp leading edge adapted to cut into lone.

195. The implant of claim 188, wherein at least one of said bone engaging projections is a blade.

196. The implant of claim 188, wherein said housing and said rotatable member cooperate so as to limit rotation of said rotatable member to no more than 180 degrees.

197. The implant of claim 188, wherein said rotatable member is at least in part frustoconical.

198. The implant of claim 188, wherein said housing is configured to be opened to receive said rotatable member therein and configured to hold said rotatable member at least in part within said housing.

199. The implant of claim 188, wherein at least one of said leading and said trailing ends of said housing is configured to permit said rotatable member to be inserted at least in part within said hollow interior of said housing.

200. The implant of claim 188, wherein said leading end of said housing is tapered to facilitate insertion, of said implant into the disc space.

201. The implant of claim 188, wherein said implant has a width that is less than one-half of the transverse width of the disc space into which said implant is adapted to be inserted to permit at least two of said implants to be implanted into the disc space.

202. The implant of claim 188, in combination with a bone growth promoting material.

203. The implant of claim 202, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

204. The implant of claim 188, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

205. The implant of claim 188, wherein said implant is at least in part resorbable.

206. The implant of claim 188. In combination with a chemical substance adapted to inhibit scar formation.

207. The implant of claim 188, in combination with an antimicrobial material.

208. The implant of claim 188, wherein said implant is configured to be pushed into the disc space.

209. The implant of claim 188, in combination with a guard having a passage for providing protected access to the disc space.

210. The combination of claim 209, further in combination with a bone removal device having a portion sized for movement through said passage for forming through said guard an implantation space at least in part across the surgically corrected height of the disc space.

211. The implant of claim 188. In combination with a distractor adapted to urge apart the adjacent vertebral bodies.

212. The implant of claim 188, wherein said upper and

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# UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO.: 6,923,830 B2DATED: August 2, 2005INVENTOR(S): Gary K. Michelson

Page 1 of 2

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

<u>Column 17,</u> Line 14, change "horsing" to -- housing --; and Line 43, change "bane" to -- bone --.

<u>Column 18,</u> Line 21, change "end" to -- and --; and Line 49, change "projection" to -- projections --.

<u>Column 19,</u> Line 6, delete "longidutinal".

<u>Column 20,</u> Line 10, change "onto" to -- one --; and Line 21, change "aid" to -- said --.

<u>Column 21,</u> Line 6, change "said implant has a" to -- the --.

<u>Column 22,</u> Line 13, change "90 degree" to -- 90-degree --; Line 37, change "induces" to -- includes --; Line 55, change "configure" to -- configured --; and Line 57, change "surfaces;" to -- surfaces --.

<u>Column 23,</u> Line 7, change "or" to -- for --; Line 12, delete "longitudinal"; Lines 38 and 50, delete "longitudinal" (first occurrence); and Line 59, change "none" to -- bone --.

<u>Column 26.</u> Line 58, change "having" to -- has --.

<u>Column 28.</u> Line 31, change "dosed" to -- closed --; Line 40, change "has;" to -- has --; and Line 52, change "claim 178" to -- claim 164 --.

# UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,923,830 B2 DATED : August 2, 2005 INVENTOR(S) : Gary K. Michelson Page 2 of 2

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

<u>Column 30,</u> Line 8, change "lone" to -- bone --; Line 18, change "configured" to -- closed --; Line 25, change "insertion," to -- insertion --; and Lines 45 and 59, change "claim **188**. In" to -- claim **188**, in --.

Signed and Sealed this

Twenty-fifth Day of October, 2005

JON W. DUDAS Director of the United States Patent and Trademark Office