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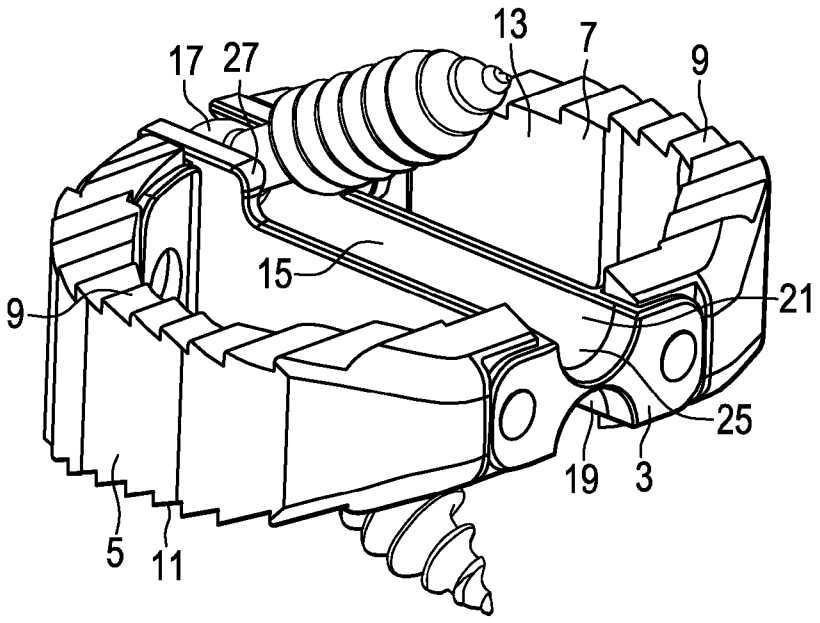
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(54) Title: ZERO PROFILE SPINAL FUSION CAGE

FIG. 1



(57) Abstract: An interbody fusion cage having upper and lower canals for receiving the heads of bone screws that have been pre- installed in opposing vertebral body endplates. The proximal wall of the cage preferably has a vertical slot that communicates with each canal and is adapted to allow access by a screwdriver and tightening of the screws.

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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Zero Profile Spinal Fusion Cage

BACKGROUND OF THE INVENTION

The natural intervertebral disc contains a jelly-like nucleus pulposus surrounded by a fibrous annulus fibrosus. Under an axial load, the nucleus pulposus compresses and radially transfers that load to the annulus fibrosus. The laminated nature of the annulus fibrosus provides it with a high tensile strength and so allows it to expand radially in response to this transferred load.

In a healthy intervertebral disc, cells within the nucleus pulposus produce an extracellular matrix (ECM) containing a high percentage of proteoglycans. These proteoglycans contain sulfated functional groups that retain water, thereby providing the nucleus pulposus within its cushioning qualities. These nucleus pulposus cells may also secrete small amounts of cytokines such as interleukin-1β and TNF-α as well as matrix metalloproteinases ("MMPs"). These cytokines and MMPs help regulate the metabolism of the nucleus pulposus cells.

In some instances of disc degeneration disease (DDD), gradual degeneration of the intervetebral disc is caused by mechanical instabilities in other portions of the spine. In these instances, increased loads and pressures on the nucleus pulposus cause the cells within the disc (or invading macrophages) to emit larger than normal amounts of the above-mentioned cytokines. In other instances of DDD, genetic factors or apoptosis can also cause the cells within the nucleus pulposus to emit toxic amounts of these cytokines and MMPs. In some instances, the pumping action of the disc may malfunction (due to, for example, a decrease in the proteoglycan concentration within the nucleus pulposus), thereby retarding the flow of nutrients into the disc as well as the flow of waste products out of the disc. This reduced capacity to eliminate waste may result in the accumulation of high levels of toxins that may cause nerve irritation and pain.

As DDD progresses, toxic levels of the cytokines and MMPs present in the nucleus pulposus begin to degrade the extracellular matrix, in particular, the MMPs (as mediated by the cytokines) begin cleaving the water-retaining portions of the

proteoglycans, thereby reducing its water-retaining capabilities. This degradation leads to a less flexible nucleus pulposus, and so changes the loading pattern within the disc, thereby possibly causing delamination of the annulus fibrosus. These changes cause more mechanical instability, thereby causing the cells to emit even more cytokines, thereby upregulating MMPs. As this destructive cascade continues and DDD further progresses, the disc begins to bulge ("a herniated disc"), and then ultimately ruptures, causing the nucleus pulposus to contact the spinal cord and produce pain.

One proposed method of managing these problems is to remove the problematic disc and replace it with a porous device that restores disc height and allows for bone growth therethrough for the fusion of the adjacent vertebrae. These devices are commonly called "fusion devices" or "fusion cages".

Current interbody fusion techniques typically include not only an interbody fusion cage, but also supplemental fixation hardware such as fixation screws. This hardware adds to the time, cost, and complexity of the procedure. It also can result in tissue irritation when the cage's profile extends out of the disc space, thereby causing dysphonia/dysphagia in the cervical spine and vessel erosion in the lumbar spine. In addition, the fixation hardware typically includes a secondary locking feature, which adds to the bulkiness of the implant and time required for the procedure. Furthermore, existing fixation hardware may prevent the implantation of additional hardware at an adjacent location, and so require removal and potentially extensive revision of a previous procedure.

US Published Patent Application 2008-0312698 (Bergeron) discloses a device and system for stabilizing movement between two or more vertebral bodies and methods for implanting. Specifically, the embodiments provide medical professionals with the ability to selectively position and orient anchors in bony tissue and then attach a plate to the pre-positioned anchors. The plate assembly, once positioned on the anchors, prevents the anchors from backing out of the bony tissue. Furthermore, in situations in which it is desirable to provide spacing between two vertebral bodies, a spacer may be fixedly connected to the plates for positioning between two vertebral bodies. The spacer may further function as a lock out mechanism, or may be rotatably connected to the plates to maintain rotational freedom. The spacer may incorporate connection features or attachment features.

US Patent No. 4904261 (Dove) discloses a spinal implant, e.g., to replace an excised disc, comprising a rigid generally horseshoe shape of biocompatible material, such as carbon-fibre reinforced plastics, having upper and lower planar faces converging towards the ends of the horseshoe, and at least one hole from each planar face emerging in the outer curved face of the horseshoe, to enable the horseshoe to be fixed by screws inserted through one or more selected holes in each plurality from the ends in the outer curved face into respective adjacent vertebrae, with the screw heads bearing against shoulders, and with the space bounded by the inner curved face of the horseshoe available for the insertion of bone graft or a bone graft substitute.

US Patent No. 6579290 (Hardcastle) discloses a surgical implant for fusing adjacent vertebrae together comprising a body portion with spaced arms. The body portion has passages to receive surgical fixing screws engaged in holes drilled in the vertebrae for securing the body portion to the anterior faces of the vertebrae to be fused. The arms extend into a prepared space between the vertebrae to be fused. Graft material is packed between the arms. Each surgical fixing screw has an externally screw-threaded shank divided into wings which can be outwardly deformed to anchor the shank in the hole. Each surgical fixing screw also has a head which can be transformed between a laterally expanded condition and a laterally contracted condition to permit the head to be interlocked with the implant.

US Patent No. 6342074 (Simpson) discloses a spinal fusion implant and method for maintaining proper lumbar spine curvature and intervertebral disc spacing where a degenerative disc has been removed. The one-piece implant comprises a hollow body having an access passage for insertion of bone graft material into the intervertebral space after the implant has been affixed to adjacent vertebrae. The implant provides a pair of screw-receiving passages that are oppositely inclined relative to a central plane. In one embodiment, the screw-receiving passages enable the head of an orthopedic screw to be retained entirely within the access passage. A spinal fusion implant embodied in the present invention may be inserted anteriorly or laterally.

US Patent No. 6972019 (Michelson) discloses a spinal fusion implant for insertion between adjacent vertebral bodies that has opposed upper and lower surfaces adapted to contact each of the adjacent vertebral bodies from within the disc space, a leading end for insertion between the adjacent vertebral bodies, and a trailing end opposite the leading end. The trailing end has an exterior surface and an outer

perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, and a plurality of bone screw receiving holes. At least one of the bone screw receiving holes is adapted to only partially circumferentially surround a trailing end of a bone screw received therein. At least one of the bone screw receiving holes passes through the exterior surface and one of the edges so as to permit the trailing end of the bone screw to protrude beyond one of the edges.

US Patent Publication 2009-0030520 (Biedermann) discloses a fixation device for bones that includes a member which is to be fixed to one or more bones and has at least one bore for receiving a bone screw, wherein the at least one bore comprises a first internal thread portion. The bone screw has a first shaft section provided with a first external thread portion arranged to cooperate with the internal thread portion of the at least one bore, and a head section having a diameter larger than that of the shaft section to provide a catch arranged to engage with a stop formed in the bore. The bone screw further has a second shaft section which includes a clearance groove extending between the catch of the head section and the external thread of the first shaft section. The clearance groove allows disengagement of the two thread portions, such that the bone screw is prevented from being unscrewed off the bore when it is loosened within the adjacent bone. The member can also include a side wall of a cage used in an intervertebral implant device, or can represent a plate of a bone plate assembly.

SUMMARY OF THE INVENTION

The present invention is directed to a method of fixing an intervertebral fusion cage in a disc space. In this method, a pair of fixation screws are first inserted into the opposing vertebral endplates within the disc space so that only their heads are exposed. These screw heads do not extend out of the disc space. Next, a novel cage (which has upper and lower longitudinal depressions that act as screw guide surfaces) is slid into the disc space using the screw heads as guides. When the cage is fully inserted, each screw head becomes seated in a distal (preferably, deeper) portion of the depression located in the proximal portion of the cage, thereby locking the cage in place. In this fixed condition, both the cage and the screw heads are located fully within the disc space and thereby provide a zero-profile assembly.

Therefore, in accordance with the present invention, there is provided an intervertebral fusion cage comprising:

a) a proximal wall and a distal wall;

b) first and second side walls connecting the proximal and distal walls, an upper bearing surface adapted for gripping an upper vertebral endplate and a lower bearing surface adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion, and

c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, the canal adapted for distal reception of a first screw head.

Also in accordance with the present invention, there is provided an intervertebral fusion cage , comprising:

a) a proximal wall and a distal wall,

b) first and second side walls connecting the proximal and distal walls , an upper bearing surface adapted for gripping an upper vertebral endplate, and a lower bearing surface adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion,

c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, and

d) a first rail adapted for slidable reception in the first canal and having an outward opening recess adapted for reception of a first screw head.

Also in accordance with the present invention, there is provided a spinal assembly comprising:

i) a first bone anchor comprising:

a) a distal shaft, and

b) a proximal screw head, and

ii) an intervertebral fusion cage comprising:

a) a proximal wall and a distal wall,

b) first and second side walls connecting the proximal and distal walls, an upper bearing surface adapted for gripping an upper vertebral endplate and a lower bearing surface adapted for gripping a lower vebrtebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion,

c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, the canal adapted for distal reception of the proximal screw head,

wherein the first screw head is received in the canal.

DESCRIPTION OF THE FIGURES

FIG.1 discloses a first perspective view of a device of the present invention having a single screw and a single guide surface depression on each of the upper and lower bearing surfaces.

FIG. 2 discloses a second perspective view of the device of FIG. 1.

FIG. 3 discloses a device substantially similar to FIG.1, but with teeth lining bearing surfaces bordering the guide surface depression.

FIG. 4 discloses a device substantially similar to FIG.1, but with a discontinuous guide surface depression.

FIG.5 discloses a device substantially similar to FIG. 4, but in a lateral cage configuration.

FIG. 6 discloses a first device substantially similar to FIG.1, but with a cervical cage configuration.

FIG.7 discloses a second device substantially similar to FIG.1, but with a cervical cage configuration.

FIG.8 discloses a first perspective view of a device substantially similar to FIG.1, but with a pair of screws inserted into the proximal wall of the device and extending through the respective upper and lower bearing surfaces.

FIG. 9 discloses a side view of the cage of FIG. 8.

FIG. 10 discloses a first perspective view of a device substantially similar to the cage of FIG. 8, but with a continuous guide surface depression.

FIG. 11 discloses a first perspective view of the device of FIG. 10.

FIG. 12 discloses the assembly comprising the components of FIGS. 13 and 14.

FIG. 13 discloses a second component of the rail-based device of the present invention.

FIG. 14 discloses a first component of the rail-based device of the present invention.

FIGS. 15a and 15B disclose another embodiment of the present invention.

FIG. 16 shows the device of the present invention being implanted into a disc space with a fusion cage inserter.

FIGS. 17a and 17b disclose a trial of the present invention.

FIGS. 18a-18d disclose various views of the inserter of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Now referring to FIGS.1 and 2, there is provided an intervertebral fusion cage comprising:

a) a proximal wall 1 and a distal wall 3,

b) first 5 and second 7 side walls connecting the proximal and distal walls, an upper bearing surface 9 adapted for gripping an upper vertebral endplate and a lower bearing surface 11 adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening 13 therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening (not shown) therethrough adapted to promote bony fusion,

c) a first guide surface depression 15 formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, the depression adapted for distal reception of a first screw head 17, and

d) a second guide surface depression 19 formed in the lower bearing surface and extending substantially from the proximal wall to the distal wall, the second depression adapted for distal reception of a second screw head.

Typically, the guide surface depression forms a longitudinal canal in each bearing surface. The distal portion 21 of the guide surface depression acts as a means for guiding the more proximal portion of the canal to the screw head. When the proximal

portion 23 of the canal is slid over the screw head, it envelops the screw head, thereby locking the cage in place. Further tightening of the screw can be performed to further lock the cage in place.

In some embodiments, the cross-sectional profile of the depression or canal is substantially equivalent to the cross-sectional profile of the screw head, so that the first depression is well adapted for distal-to-proximal translation of the first canal towards the screw head. In some preferred embodiments thereof, the screw head is substantially spherical, while the transverse cross-section of the first canal substantially forms a portion of a circle, thereby providing a substantially matching fit of the canal and screw head.

In some embodiments, the first canal extends substantially along a centerline of the cage, thereby allowing the use of a single screw per bearing surface.

In some preferred embodiments, the first canal comprises a distal recess 25 and a proximal process 27 . The proximal process effectively acts to lock the cage in place when it slides over and envelops the screw head.

In some embodiments, the first canal includes an outwardly extending (longitudinal) bump (not shown) adapted to limit translational movement of the interbody device with respect to the screw. This bump acts as an additional means for guiding the deeper portion of the canal to the screw head, at which the cage becomes locked.

Now referring to FIG. 2 and 3, in some embodiments, additional strength is provided to the proximal portion 29 of the cage in order to withstand higher tensile forces and insertion forces. Preferably, this additional strength is achieved by using a stronger material in the proximal portion of the cage. In preferred embodiments thereof, the bearing surface 33 surrounding the proximal portion of the canal is formed from a metallic material.

In some embodiments, it is helpful to provide a final seating of the screw head once it becomes seated in the deeper proximal portion of the canal. In these embodiments, the proximal wall of the cage preferably has a vertical slot 35 that communicates with the horizontal guide surface canal and is adapted to allow access by a screwdriver. Thus, the surgeon has direct access to the screw head via a proximal route and can easily accomplish its final tightening.

In some embodiments (as in FIGS. 1-3), the guide surface canals are continuous longitudinal structures that guide the entry of the cage from the moment

the canal contacts the screw head to the moment the screw seats in the proximal portion of the canal. However, in other embodiments (as in FIG. 4), the canal 45a and 45b may be discontinuous.

It is believed that the device of the present invention can be advantageous used in implanting lateral cages. Therefore, now referring to FIG. 5, there is provided a lateral cage 49 of the present invention, wherein the length L of the lateral cage (distal end 47 to proximal end 48 distance) is at least two times greater than the width W of the lateral cage (side wall 49 to side wall 50 length). Preferably, the length of the lateral cage is at least three times greater than the width of the lateral cage. Also in FIG 5, the proximal portion 101 of the lateral cage is preferably made of a metal material such as titanium, while the distal portion 103 is made of a polymer-based material , such as CFRP.

It is believed that the device of the present invention can be advantageous used in implanting cervical cages. Therefore, now referring to FIGS. 6 and 7, there is provided a cervical cage of the present invention having a screw 51 extending from each guide surface depression 53.

In some embodiments, it is advantageous to add additional screws to the device in order to more completely secure the device to the vertebral endplates. Now referring to FIGS.8 and 9, there is provided a first perspective view of a device having a pair of screws 55 inserted into the proximal wall 57 of the device and extending through the openings in the respective upper 59 and lower 61 bearing surfaces.

FIG. 10 discloses a distal perspective view of a device substantially similar to the cage of FIG. 8, but with a continuous guide surface depression 63. FIG. 11 discloses a proximal perspective view of the device of FIG. 10.

Various aspects of the present invention include an implant/instrument system, and a method of implantation. The present invention also includes a kit comprising:

a) trial instruments comprising interbody spacing blocks having various sizes (height, angle, footprint), each with bone anchor placement guides.

b) at least two bone fixation anchors to be placed into adjacent vertebral bodies while trialing with the aforementioned instrument, and

c) an interbody implant configured for engaging with the heads of the implanted bone anchors after removing the trial instrument.

Now referring to FIGS. 17a and 17b, trial 101 has a handle attached to one side (not shown). Two pins are for the trial proper depth position. The vertebral body holes for anchoring the screws can be drilled through the guides.

The kit of the present invention allows the surgeon to fix the opposing vertebral bodies to one another through the interbody device without having the implant protrude outside of the disc space. Preferably, the heads of the bone anchors snap into proximal processes formed in canals located in the upper and lower surfaces of the interbody implant, thereby helping the implant resist migration. Preferably, the anchors can be inserted at various angles to accommodate anatomical differences as well as avoid any pre-existing hardware.

Preferably, the canals of the interbody implant sufficiently envelop the respective bone anchor heads so as to prevent back-out and pull-out of the anchor. In such situations, a secondary locking step/feature is not required. Preferably, the interbody implant allows passage therethrough of a driver to further seat and tighten the bone anchor into the bone after the implant has been placed. This is typically accomplished by a vertical slot 35 in the proximal wall that communicates with the canals. Preferably, the major diameter of the bone anchor is larger than the screw head diameter. In some embodiments, th major diameter is 5.5 mm). Larger major screw diameters can be used, as compared to conventional devices wherein the anchors are placed through the wall of the fixation device and limited by the height of the device. This is a major advantage.

The embodiments described herein are preferably designed for the cervical region, but also could be utilized for lumbar spine interbody fusion as well.

In a preferred embodiment of the invention shown in FIGS. 1 and 2, the bone anchor comprises a screw having a proximal head 17 that is substantially spherical such that it can accommodate variable angles and still engage with the interbody implant. Alternatively, other screw head shapes that match the shape of the canal recess and provide a reliable connection between two components may be used. Also, in preferred embodiments, the screws are positioned in the centerline so that they are less likely to interfere with an adjacent level plate with two screws in each vertebra, as

some plates have screws positioned laterally so the screws of the present invention can go in between them . In use, the screws are first installed and then the interbody implant is slid between the vertebrae, using the insertion tool that aligns the central canals of the cage with the screw heads. In preferred embodiments, a small radial bump (not shown) located in the canal limits translational movement of the interbody device with respect to the screw. In another preferred embodiment, the screws are positioned such that upon sliding the interbody device into the disc space, the interbody device slides primarily over the screw heads (instead of primarily contacting the endplates – the screws are inserted slightly proud to allow larger distraction) to ease insertion. At the end of insertion, the screw heads "drop" into a larger proximal process of the canals, thereby ensuring that the upper and lower surfaces of the interbody device abut the bony endplates and providing the means of preventing the interbody device from backing out. The interbody device preferably has internal spaces opening outward through the upper and lower bearing surfaces and onto the adjacent bony endplates. These spaces may be packed with bone graft or bone graft substitute prior to implantation in order to promote bony fusion of the opposing endplates.

In some embodiments, the proximal wall of the cage has a small vertical slot 35 that provides access by a screwdriver shaft to the guide surface canals (and thereby the screw heads). After interbody device insertion into the disc space, the screws are preferably tightened through these slots to ensure construct stability. Screw backout is prevented by design of the cage and method of cage installation, as the screw heads are seated on the inner surfaces of the respective canals.

FIGS. 12-14 show another embodiment of this invention. In this embodiment, each screw 201 is inserted into its respective endplates along with an additional rail component 203. The rail component has a cross-section configured to slidingly engage a mating canal in the main interbody device. In this exemplary embodiment, both the rail and the guide surface canal 205 of the main interbody device 207 have dovetail engagement features, although other reliable locking configurations may be used. The advantage of the rail lies in its ability to accommodate variable screw trajectories without the need for a spherical head to ensure alignment with the interbody device. Generally, the rail must be implanted first to envelop the screws, with the screws partially tightened. Then, after sliding the interbody device over the rails, the screws are finally tightened, thereby making the whole construct rigid and

properly attached to the vertebrae. The cage may be locked to the rails by the small springy or bump-like feature (not shown) incorporated into the rail and cage design. Preferably, the head of the screw seats on the inner wall of the dovetail canal, thereby preventing the screw from backing out.

Revision surgery can be performed by loosening the screws and removing the cage. In effect, the screws do not need to be removed during cage revision.

FIGS. 15a and 15b show another embodiment with a pair of screws 221 placed to either side of cage midline. The cage is implanted by sliding the screw heads into the canals of the cage. The final tightening of the screws may be accomplished through the holes 223 provided on the cage's proximal wall after the cage is put in place. The holes have a smaller diameter than the screw head and provide access for a screwdriver shaft while preventing screw backout. The cage is locked in place by the screws' tension, though an additional feature in the form of a small bump (not shown) can be added to prevent cage expulsion. An injectable bone graft or substitute can be injected through the cage side window after final cage assembly. Alternatively, a bone graft substitute such as TCP may be incorporated into the graft at the situs of manufacture.

FIG. 16 shows the device of the present invention being implanted into a disc space with a fusion cage inserter. The screws 225 are held in place on tynes distal of the the device of the present invention , and are inserted into the vertebral endplate portion of the disc space so that substantially only their heads protrude from those endplates. Next, the device 227 is slid over the screw heads and is locked in place.

Now referring to FIGS. 18a – 18d, a preferred inserter for inserting the present invention comprises a body 103, two blades 105 attached to the body, a pusher 107 attached to the shaft 109 and a handle 111 attached to the shaft.

To implant the cage, the surgeon has to spread the blades and insert the cage in between the blades, aligning the cage's proximal opening with the pusher pin 112. The cage has to be positioned along the inserter so that the pedals are reasonably collapsed in order to be inserted into intervertebral space. The central slots 113 of the blades need to be aligned with the already-implanted screw heads, and the inserter needs to be as vertical as possible (i.e., perpendicular to the anterior plane of the vertebrae) and inserted as deep as the blades' stop surfaces 114 will allow. At this point, the inserter handle is turned clockwise, thereby pushing the pusher and the

cage forward. During insertion, pedals 115 become distracted, thereby making space for the cage. The cage is pushed into the disc space until the pusher "stops" contacting the vertebrae. The cage stops advancing forward and the blades withdraw from the disc space by continuing advance of the pusher until the blades are completely withdrawn.

The pusher blade 119 rides inside the pusher guiding slot 117, thereby preventing the pusher from spinning and aligning it properly to the blades. An impactor (not shown) is then used to advance the cage into the final position. At this point, the screw heads serve as stops for the impactor, and the cage cannot move any further distally. At this point, the anterior surface of the cage is flush with the screw heads' most protruding points. The final step is the tightening of the screws.

In some embodiments of the present invention, trialing occurs before implantation of the fusion cage. In particular, in accordance with the present invention, there is provided a method of inserting a fusion cage into an intervertebral disc space formed by upper and lower vertebral endplates, comprising the sequential steps of:

a) inserting a trial having a guide surface canal into the disc space,
b) drilling or awling the hole through the trial drill guides,
c) inserting a first and the second screws into the upper and lower vertebral endplates, the first screw having a shaft and a screw head,
d) removing the trial,
e) inserting a fusion cage having a guide surface canal into the disc space so that the screw head is received in a distal portion of the canal, and
f) distally translating the cage into the disc space so that the screw head becomes received in a proximal portion of the cage canal.

These cages of the present invention may be made from any non-resorbable material appropriate for human surgical implantation, including but not limited to, surgically appropriate metals, and non-metallic materials, such as carbon fiber composites, polymers and ceramics.

The interbody device and bone anchors are preferably made out of PEEK or CFRP or any other suitable material providing adequate strength and radiolucency. However, implantable metals such as titanium or stainless steel components may be required to ensure adequate strength for either the interbody device or bone anchors.

In some cases the interbody device can be made as a combination of PEEK and metal. The metal component is preferably used for screw head retaining feature. In some cases, resorbable materials such as polylactide, polyglycolide, and magnesium are preferred.

In some embodiments, the cage material is selected from the group consisting of PEEK, ceramic and metallic. The cage material is preferably selected from the group consisting of metal and composite (such as PEEK/carbon fiber).

If a metal is chosen as the material of construction for a component, then the metal is preferably selected from the group consisting of titanium, titanium alloys (such as Ti-6Al-4V), chrome alloys (such as CrCo or Cr-Co-Mo) and stainless steel.

If a polymer is chosen as a material of construction for a component, then the polymer is preferably selected from the group consisting of polyesters, (particularly aromatic esters such as polyalkylene terephthalates, polyamides; polyalkenes; poly(vinyl fluoride); PTFE; polyarylethyl ketone PAEK; polyphenylene and mixtures thereof.

If a ceramic is chosen as the material of construction for a component, then the ceramic is preferably selected from the group consisting of alumina, zirconia and mixtures thereof. It is preferred to select an alumina-zirconia ceramic, such as BIOLOX *delta* ™ , available from CeramTec of Plochingen, Germany. Depending on the material chosen, a smooth surface coating may be provided thereon to improve performance and reduce particulate wear debris.

In some embodiments, the cage member comprises PEEK. In others, it is a ceramic.

In some embodiments, the first component consists essentially of a metallic material, preferably a titanium alloy or a chrome-cobalt alloy. In some embodiments, the second component consists essentially of the same metallic material as the first plate.

In some embodiments, the components are made of a stainless steel alloy, preferably BioDur® CCM Plus® Alloy available from Carpenter Specialty Alloys, Carpenter Technology Corporation of Wyomissing, PA. In some embodiments, the outer surfaces of the components are coated with a sintered beadcoating, preferably Porocoat™, available from DePuy Orthopaedics of Warsaw, IN.

In some embodiments, the components are made from a composite comprising carbon fiber. Composites comprising carbon fiber are advantageous in that they

typically have a strength and stiffness that is superior to neat polymer materials such as a polyarylethyl ketone PAEK. In some embodiments, each component is made from a polymer composite such as a PEKK-carbon fiber composite.

Preferably, the composite comprising carbon fiber further comprises a polymer. Preferably, the polymer is a polyarylethyl ketone (PAEK). More preferably, the PAEK is selected from the group consisting of polyetherether ketone (PEEK), polyether ketone ketone (PEKK) and polyether ketone (PEK). In preferred embodiments, the PAEK is PEEK.

In some embodiments, the carbon fiber comprises between 1 vol% and 60 vol% (more preferably, between 10 vol% and 50 vol%) of the composite. In some embodiments, the polymer and carbon fibers are homogeneously mixed. In others, the material is a laminate. In some embodiments, the carbon fiber is present in a chopped state. Preferably, the chopped carbon fibers have a median length of between 1 mm and 12 mm, more preferably between 4.5 mm and 7.5 mm. In some embodiments, the carbon fiber is present as continuous strands.

In especially preferred embodiments, the composite comprises:

a) 40-99% (more preferably, 60-80 vol%) polyarylethyl ketone (PAEK), and

b) 1-60% (more preferably, 20-40 vol%) carbon fiber,

wherein the polyarylethyl ketone (PAEK) is selected from the group consisting of polyetherether ketone (PEEK), polyether ketone ketone (PEKK) and polyether ketone (PEK).

In some embodiments, the composite consists essentially of PAEK and carbon fiber. More preferably, the composite comprises 60-80 wt% PAEK and 20-40 wt% carbon fiber. Still more preferably the composite comprises 65-75 wt% PAEK and 25-35 wt% carbon fiber.

Although the present invention has been described with reference to its preferred embodiments, those skillful in the art will recognize changes that may be made in form and structure which do not depart from the spirit of the invention.

Alternatively, combinations of cage materials could be beneficial (i.e., – a ceramic bottom half with a PEEK top half).

In other embodiments, the components are made from resorbable materials, such as Biocryl Rapide TM, a PLA, PLG, TCP composite marketed by DePuy Mitek, located in Raynham,MA. .

When resorbable materials are selected, Preferred bioresorbable materials which can be used to make the sutures of the present invention include bioresorbable polymers or copolymers, preferably selected from the group consisting of hydroxy acids, (particularly lactic acids and glycolic acids; caprolactone; hydroxybutyrate; dioxanone; orthoesters; orthocarbonates; and aminocarbonates). Preferred bioresorbable materials also include natural materials such as chitosan, collagen, cellulose, fibrin, hyaluronic acid; fibronectin, and mixtures thereof. However, synthetic bioresorbable materials are preferred because they can be manufactured under process specifications which insure repeatable properties.

A variety of bioabsorbable polymers can be used to make the suture of the present invention. Examples of suitable biocompatible, bioabsorbable polymers include but are not limited to polymers selected from the group consisting of aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylenes oxalates, polyamides, tyrosine derived polycarbonates, poly(iminocarbonates), polyorthoesters, polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, biomolecules (i.e., biopolymers such as collagen, elastin, bioabsorbable starches, etc.) and blends thereof. For the purpose of this invention aliphatic polyesters include, but are not limited to, homopolymers and copolymers of lactide (which includes lactic acid, D-,L- and meso lactide), glycolide (including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, δ-valerolactone, β-butyrolactone, χ-butyrolactone, ε-decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, 2,5-diketomorpholine, pivalolactone, χ,χ-diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-1,4-dioxane-2,5-dione, 3,3-diethyl-1,4-dioxan-2,5-dione, 6,8-dioxabicycloctane-7-one and polymer blends thereof. Poly(iminocarbonates), for the purpose of this invention, are understood to include those polymers as described by Kemnitzer and Kohn, in the Handbook of Biodegradable Polymers, edited by Domb, et. al., Hardwood Academic Press, pp. 251-272 (1997). Copoly(ether-esters), for the purpose of this invention, are understood to include those copolyester-ethers as described in the Journal of Biomaterials Research, Vol. 22, pages 993-1009, 1988 by Cohn and Younes, and in

Polymer Preprints (ACS Division of Polymer Chemistry), Vol. 30(1), page 498, 1989 by Cohn (e.g. PEO/PLA). Polyalkylene oxalates, for the purpose of this invention, include those described in U.S. Patent Numbers 4,208,511; 4,141,087; 4,130,639; 4,140,678; 4,105,034; and 4,205,399. Polyphosphazenes, co-, ter- and higher order mixed monomer-based polymers made from L-lactide, D,L-lactide, lactic acid, glycolide, glycolic acid, para-dioxanone, trimethylene carbonate and ε-caprolactone such as are described by Allcock in The Encyclopedia of Polymer Science, Vol. 13, pages 31-41, Wiley Intersciences, John Wiley & Sons, 1988 and by Vandorpe, et al in the Handbook of Biodegradable Polymers, edited by Domb, et al, Hardwood Academic Press, pp. 161-182 (1997). Polyanhydrides include those derived from diacids of the form HOOC-C_6H_4 –O-$(CH_2)_m$-O-C_6H_4-COOH, where m is an integer in the range of from 2 to 8, and copolymers thereof with aliphatic alpha-omega diacids of up to 12 carbons. Polyoxaesters, polyoxaamides and polyoxaesters containing amines and/or amido groups are described in one or more of the following U.S. Patent Nos. 5,464,929; 5,595,751; 5,597,579; 5,607,687; 5,618,552; 5,620,698; 5,645,850; 5,648,088; 5,698,213; 5,700,583; and 5,859,150. Polyorthoesters such as those described by Heller in Handbook of Biodegradable Polymers, edited by Domb, et al, Hardwood Academic Press, pp. 99-118 (1997).

Advantages of the present invention include an ability to have a larger screw diameters. There is no need for a special screw locking mechanism. The screws are locked by the cage design, following a “screw first” concept. There is high reliability in the screw lock. The cage features screw dynamism, so that there is angle flexibility and no bending stress (tension only). The cage allows screw self-adjustment to the cage. The cage may have centrally aligned screws, so there is less risk to veins and arteries. The cage is strongly resistant to axial impact during insertion. The screws are closer to the anterior edge. Lastly, there is a possibility of reducing spondylothesis anteriorly.

We Claim:

1. An intervertebral fusion cage comprising:
   a) a proximal wall and a distal wall,
   b) first and second side walls connecting the proximal and distal walls, an upper bearing surface adapted for gripping an upper vertebral endplate and a lower bearing surface adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion,
   c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, the canal adapted for distal reception of a first screw head.

2. The cage of claim 1 wherein the first canal is further adapted for distal-to-proximal translation of the screw head in the first canal.

3. The cage of claim 1 wherein a transverse cross-section of the first canal substantially forms a portion of a circle.

4. The cage of claim 1 wherein the first canal extends substantially along a centerline of the cage.

5. The cage of claim 1 wherein the first canal includes an outwardly extending bump adapted to limit translational movement of the interbody cage with respect to the screw.

6. The cage of claim 1 wherein the first canal comprises a distal recess and a proximal recess, each recess having a depth, wherein the proximal recess depth is greater than the distal recess depth.

7. The cage of claim 6 wherein the distal recess is formed from a polymeric material and the proximal recess is formed from a metallic material.

8. The cage of claim 1 wherein the proximal wall has an opening that communicates with the screw head and is adapted to provide access by a screwdriver.

9. The cage of claim 1 further comprising:

d) a second guide surface canal formed in the lower bearing surface and extending substantially from the proximal wall to the distal wall, the second canal adapted for distal reception of a second screw head.

10. The cage of claim 1 wherein the first canal is discontinuous.

11. An intervertebral fusion cage, comprising:

a) a proximal wall and a distal wall,

b) first and second side walls connecting the proximal and distal walls, an upper bearing surface adapted for gripping an upper vertebral endplate and a lower bearing surface adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion,

c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall,

d) a first rail adapted for slidable reception in the first canal and having an outward opening recess adapted for reception of a first screw head.

12. The cage of claim 11 wherein a transverse cross-section of the first canal substantially forms a dovetail.

13. The cage of claim 11 wherein the first rail has a proximal wall having a first opening that communicates with the screw head and is adapted to provide access by a screwdriver to the screw head.

14. The cage of claim 13 wherein the first vertical slot has a diameter that is smaller than a diameter of the screw head.

15. The cage of claim 13 wherein the proximal wall has a second opening that communicates with the first opening and is adapted to provide access by a screwdriver to the screw head.

16. The cage of claim 11 further comprising:

e) a second guide surface canal formed in the lower bearing surface and extending substantially from the proximal wall to the distal wall.

17. The cage of claim 16 further comprising:

f) a second rail adapted for slidable reception in the second canal and having an outward opening recess adapted for reception of a first screw head.

18. A method of inserting a fusion cage into an intervertebral disc space formed by upper and lower vertebral endplates, comprising the sequential steps of:

a) inserting a trial having a guide surface canal into the disc space,

b) drilling or awling the hole through the trial drill guides,

c) inserting a first and the second screws into the upper and lower vertebral endplates, the first screw having a shaft and a screw head,

d) removing the trial,

e) inserting a fusion cage having a guide surface canal into the disc space so that the screw head is received in a distal portion of the canal, and

f) distally translating the cage into the disc space so that the screw head becomes received in a proximal portion of the cage canal.

19. A spinal assembly comprising:

i) a first bone anchor comprising:

a) a distal shaft and

b) a proximal screw head, and

ii) an intervertebral fusion cage, wherein the intervertebral fusion cage comprises:

a) a proximal wall and a distal wall,

b) first and second side walls connecting the proximal and distal walls, an upper bearing surface adapted for gripping an upper vertebral endplate and a lower

bearing surface adapted for gripping a lower vertebral endplate, the upper bearing surface having at least one upper opening therethrough adapted to promote bony fusion, the lower bearing surface having at least one lower opening therethrough adapted to promote bony fusion,

c) a first guide surface canal formed in the upper bearing surface and extending substantially from the proximal wall to the distal wall, the canal adapted for distal reception of the proximal screw head,

wherein the first screw head is received in the canal.

20. A method of inserting a fusion cage into an intervertebral disc space formed by upper and lower vertebral endplates, comprising the steps of:

a) inserting a first screw into the upper vertebral endplate, the first screw having a shaft and a screw head,

b) inserting a fusion cage having i) an upper bearing surface having a upper guide surface canal and ii) a lower bearing surface having a lower guide surface canal, into the disc space so that the first screw head is received in a distal portion of the upper canal and the second screw head is received in a distal portion of the lower canal,

c) distally translating the cage into the disc space so that the screw heads become received in a proximal portion of each canal.

21. The method of claim 20 comprising the additional step of :

-before step c), inserting a second screw into the lower vertebral endplate, the second screw having a shaft and a screw head.

22. A method of inserting a fusion cage into an intervertebral disc space formed by upper and lower vertebral endplates, comprising the sequential steps of:

g) inserting a first screw into the upper vertebral endplate, the first screw having a shaft and a screw head,

h) inserting a trial having a guide surface canal into the disc space so that the screw head is received in the canal of the trial,

i) removing the trial, and

j) inserting a fusion cage having a guide surface canal into the disc space so that the screw head is received in a distal portion of the canal.

23. The method of claim 22 further comprising the sequential step of:

c) distally translating the cage into the disc space so that the screw head becomes received in a proximal portion of the cage canal.

FIG. 1

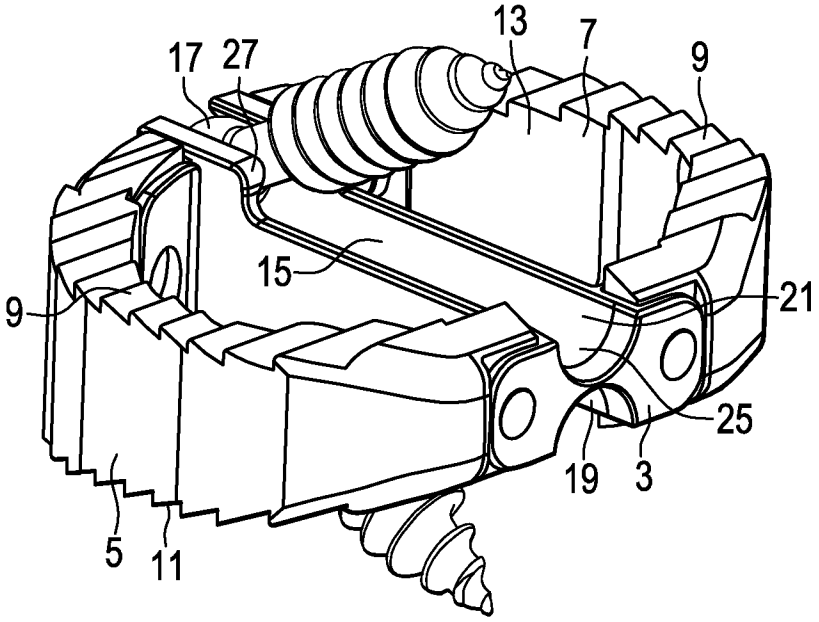


FIG. 2

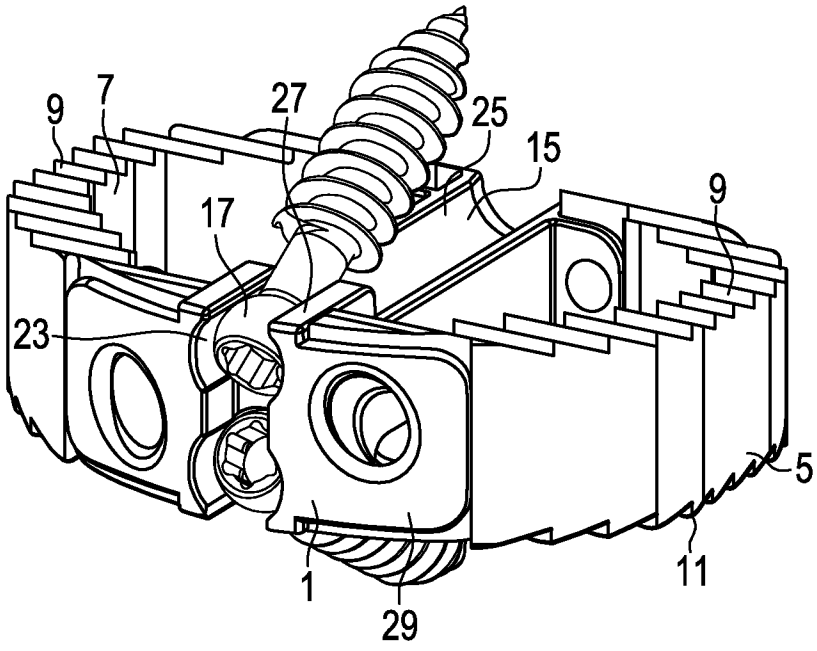


FIG. 3

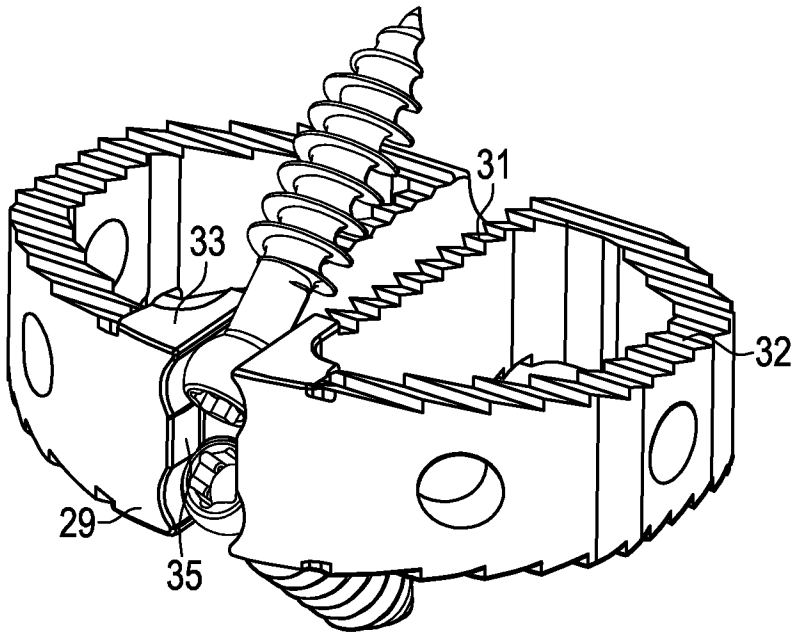


FIG. 4

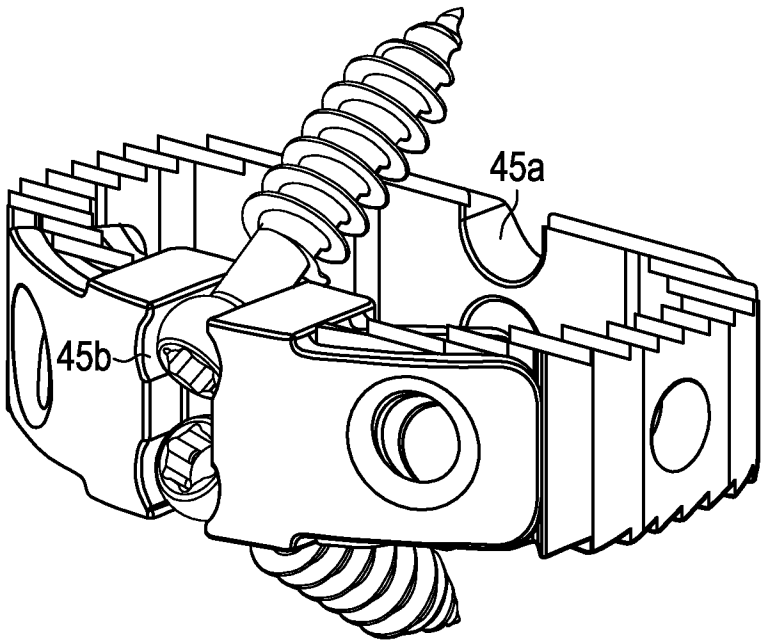


FIG. 5

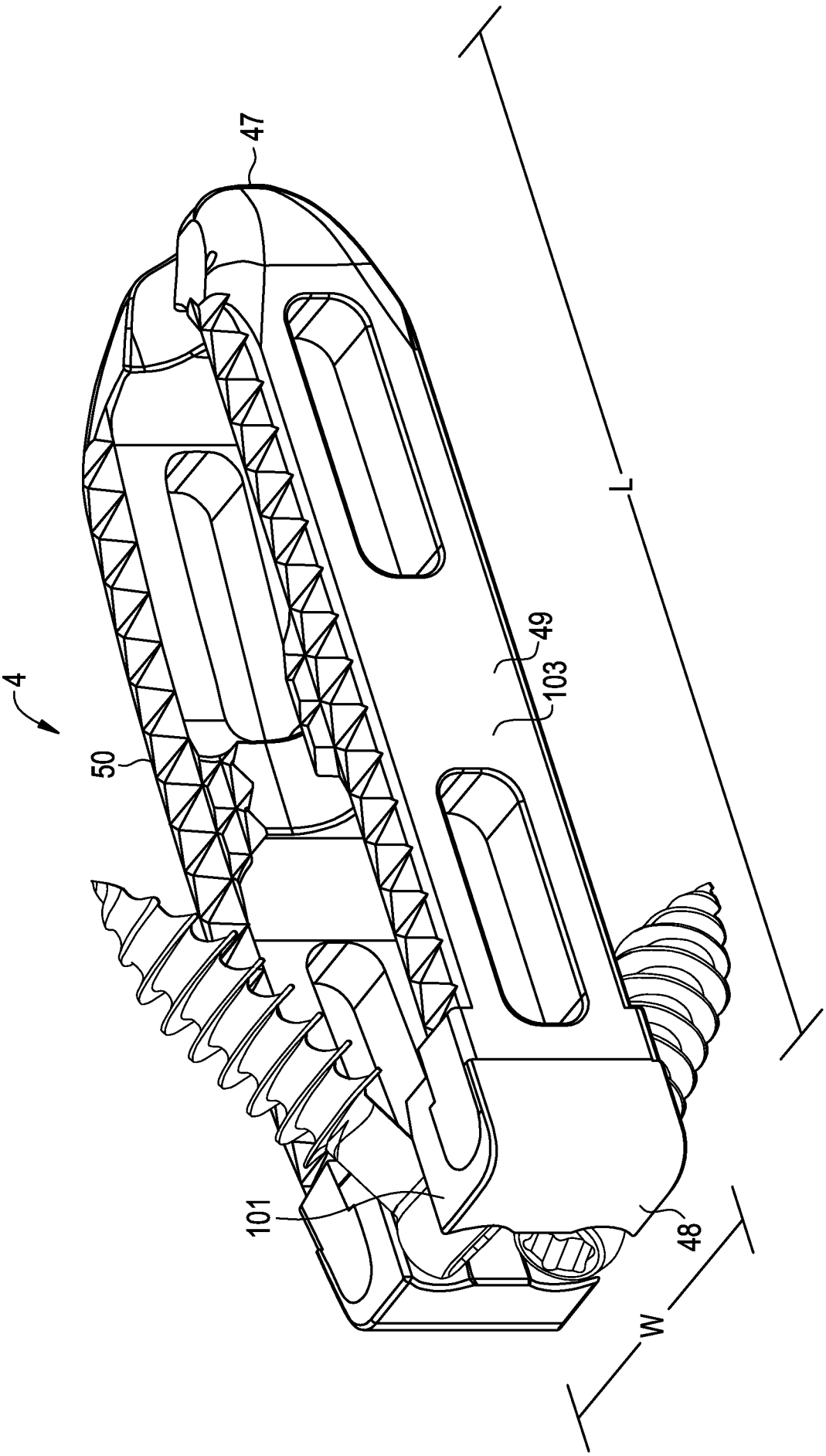


FIG. 6

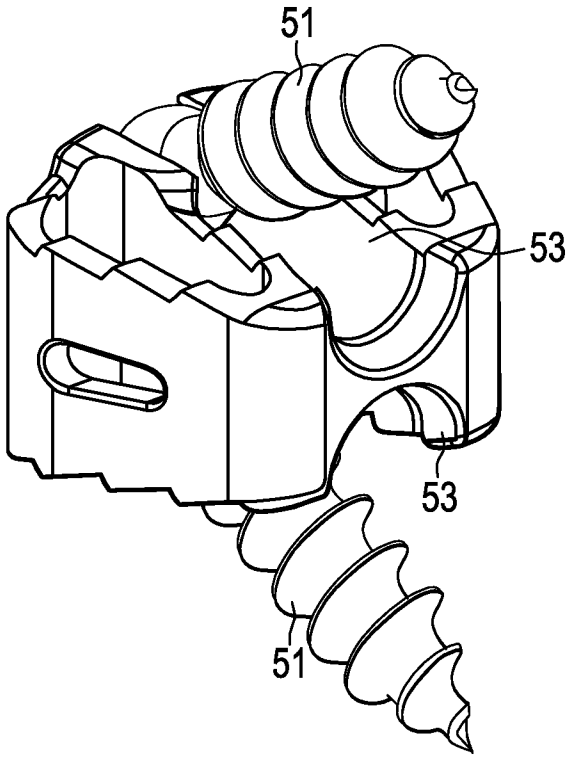


FIG. 7

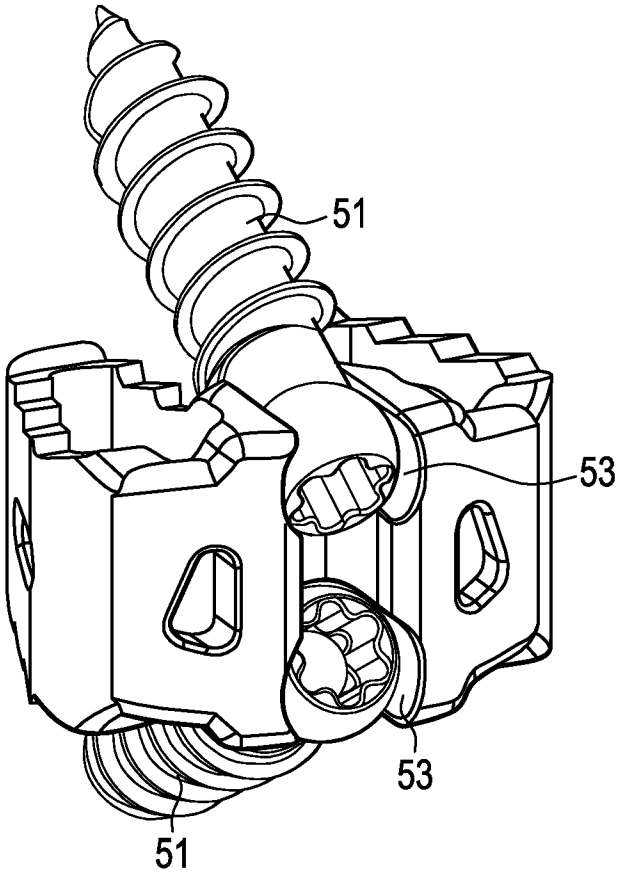


FIG. 8

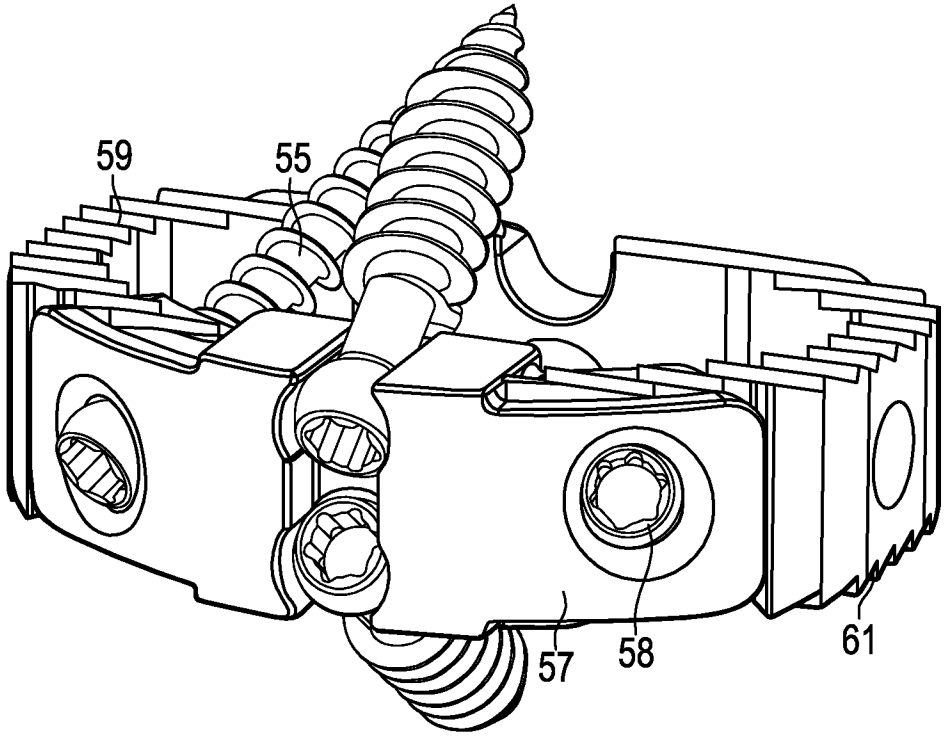


FIG. 9

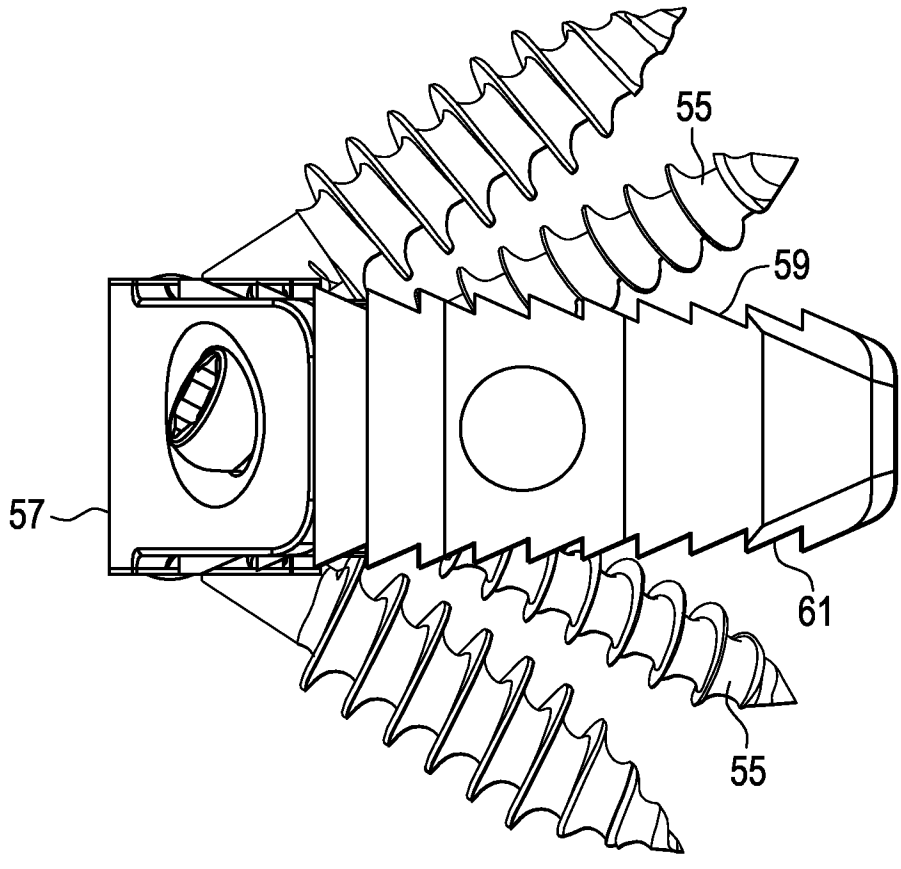


FIG. 10

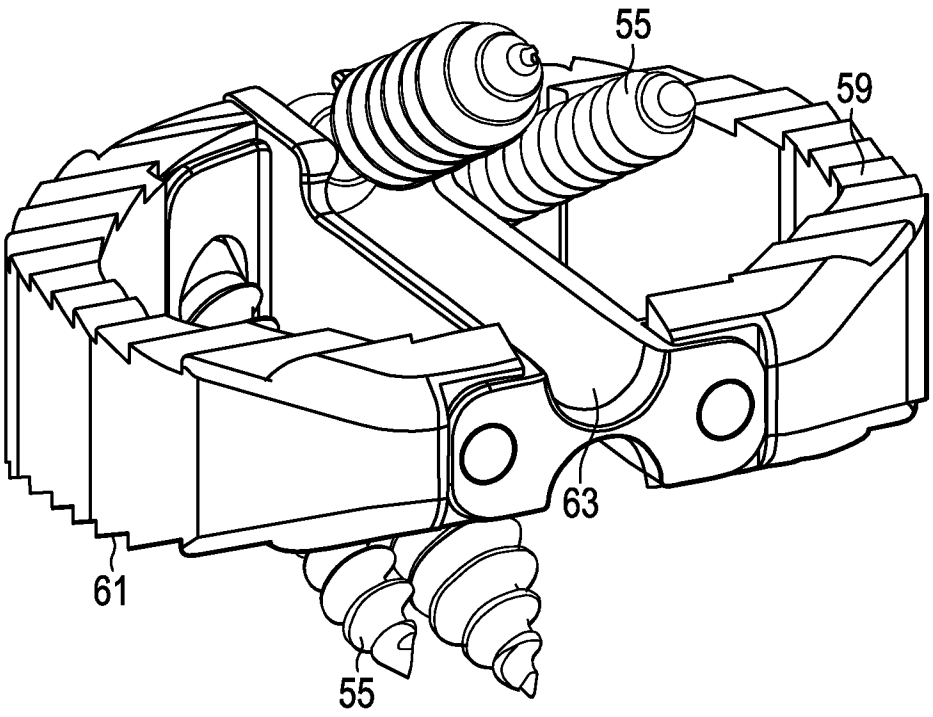


FIG. 11

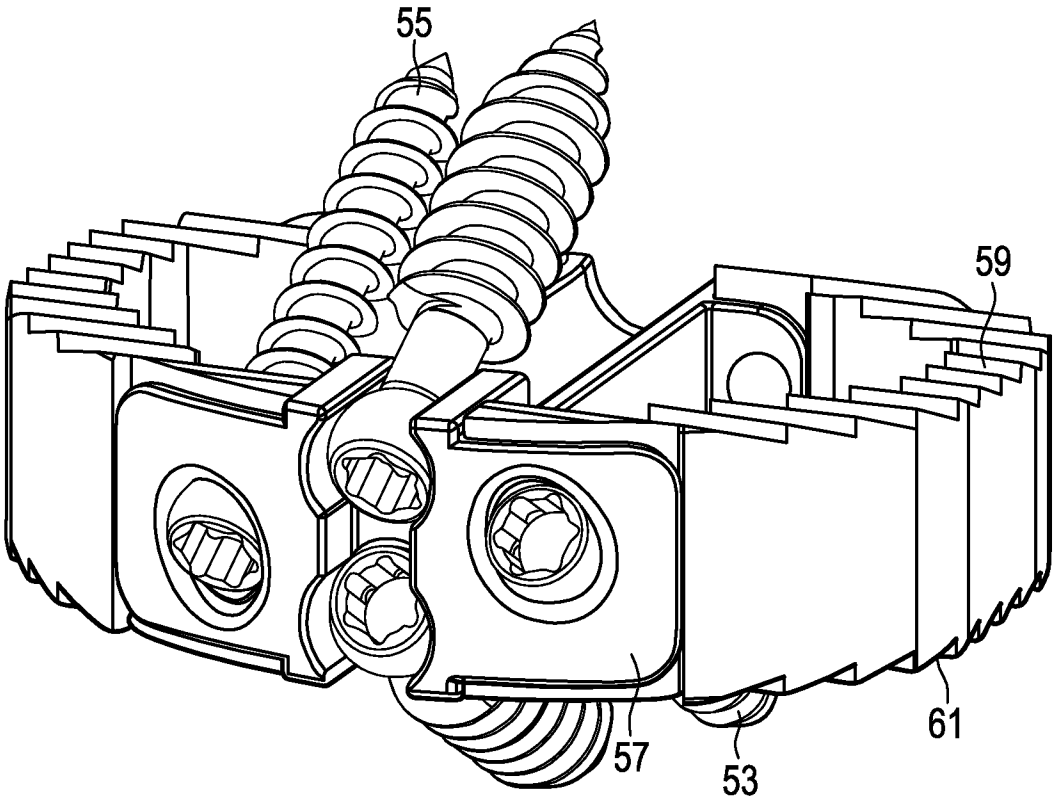


FIG. 12

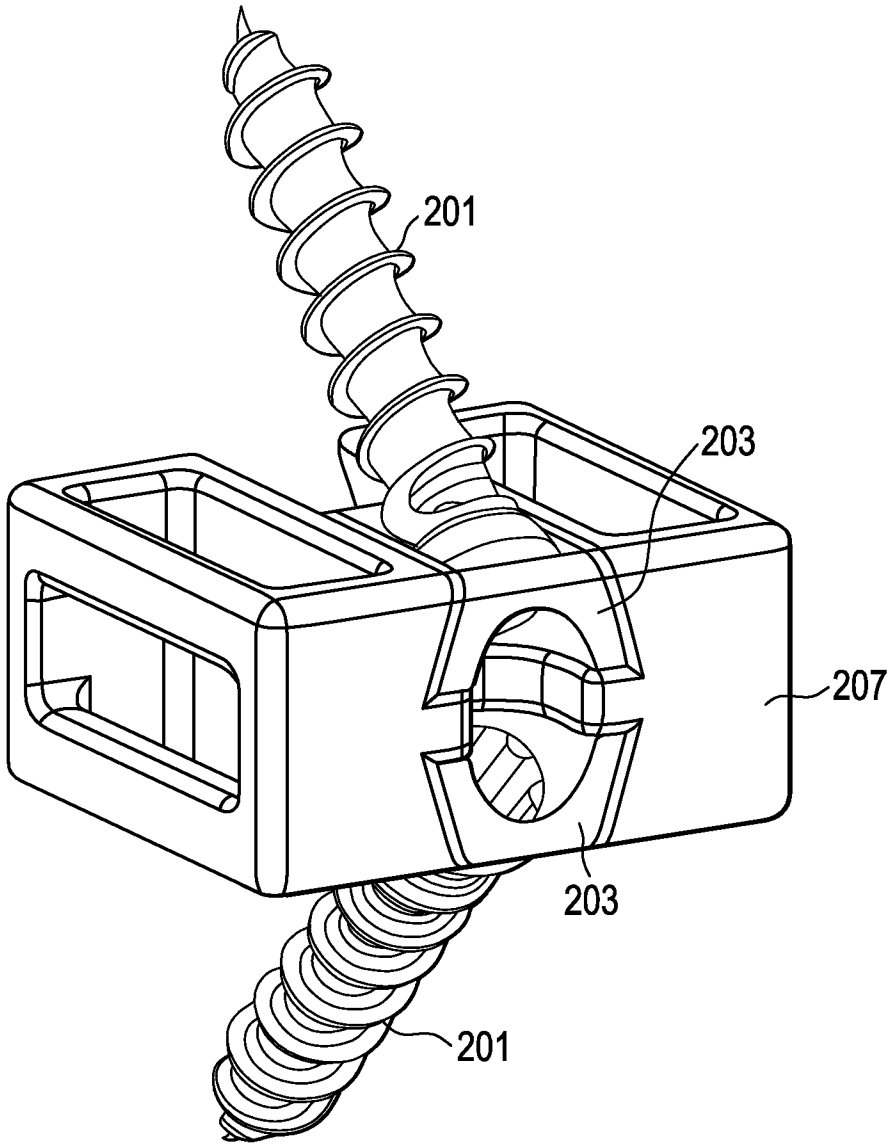


FIG. 13

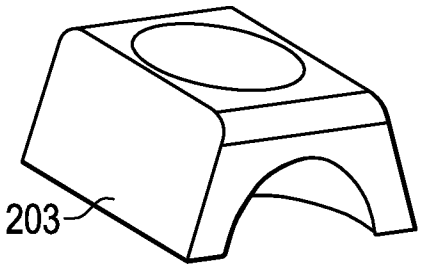


FIG. 14

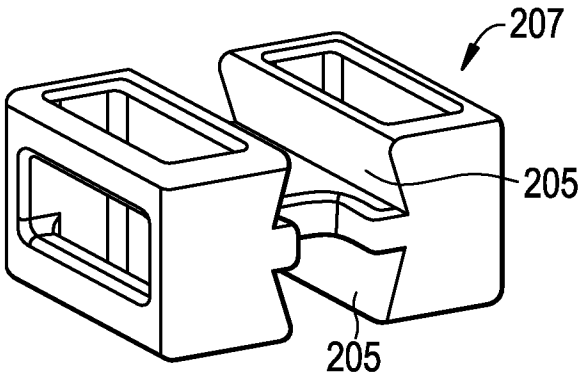


FIG. 15A

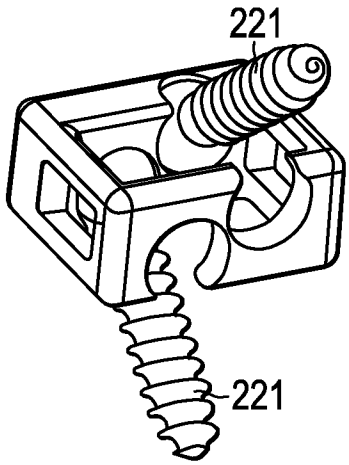


FIG. 15B

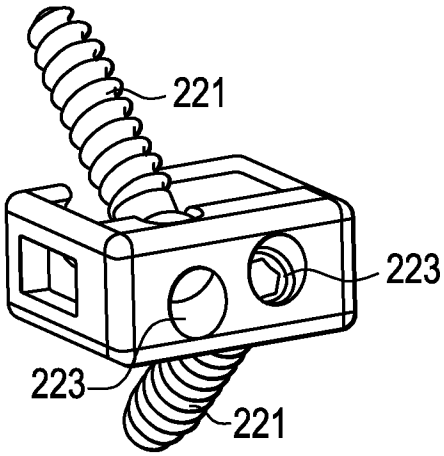


FIG. 16

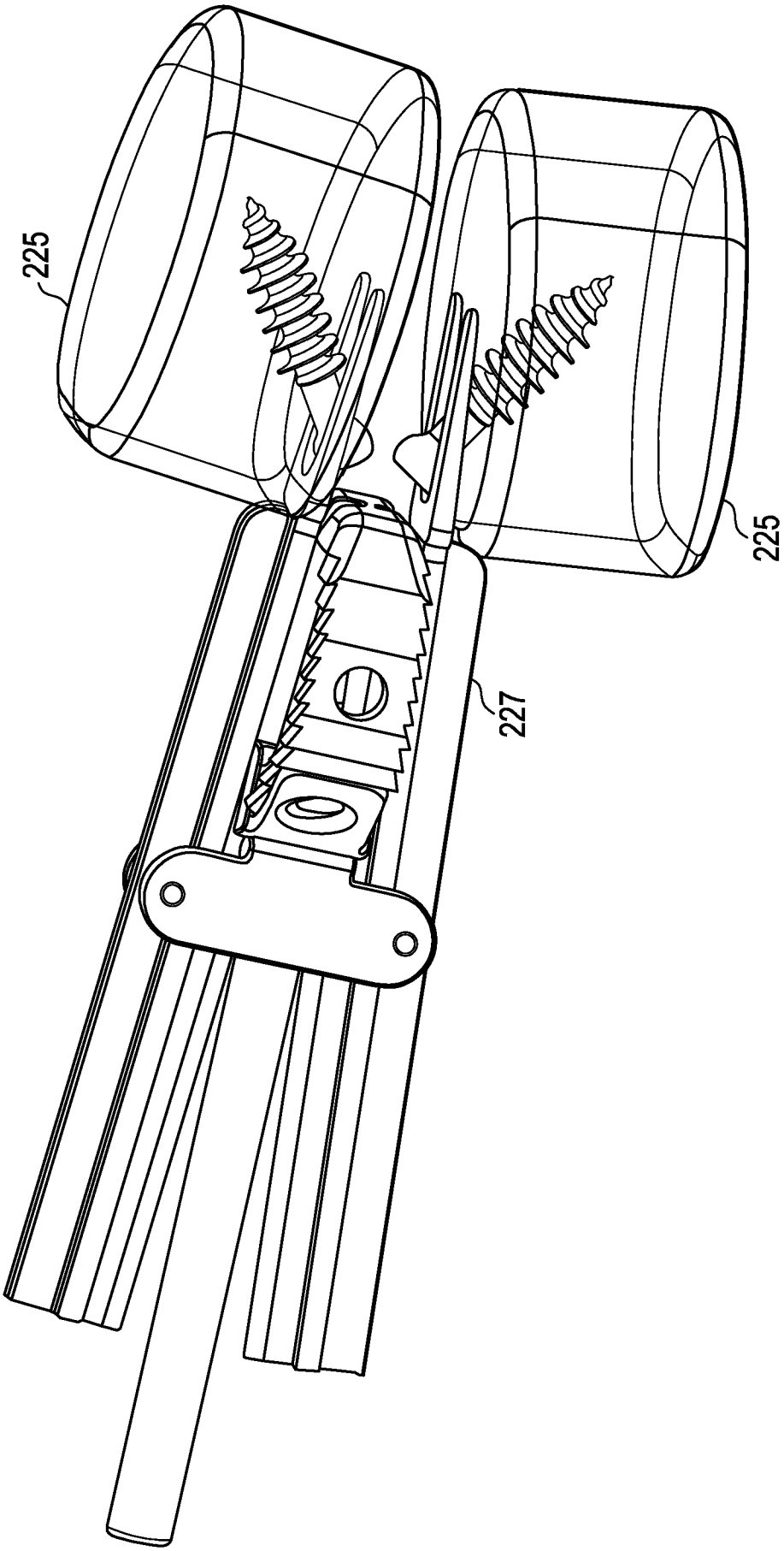


FIG. 17A

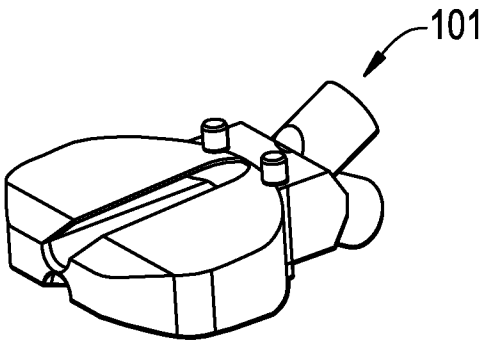


FIG. 17B

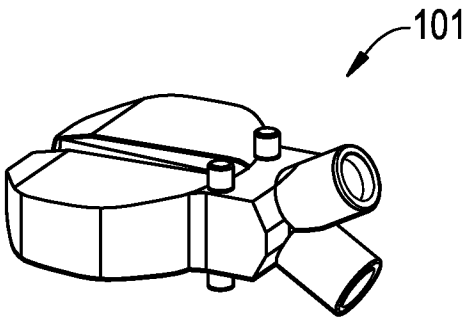


FIG. 18A

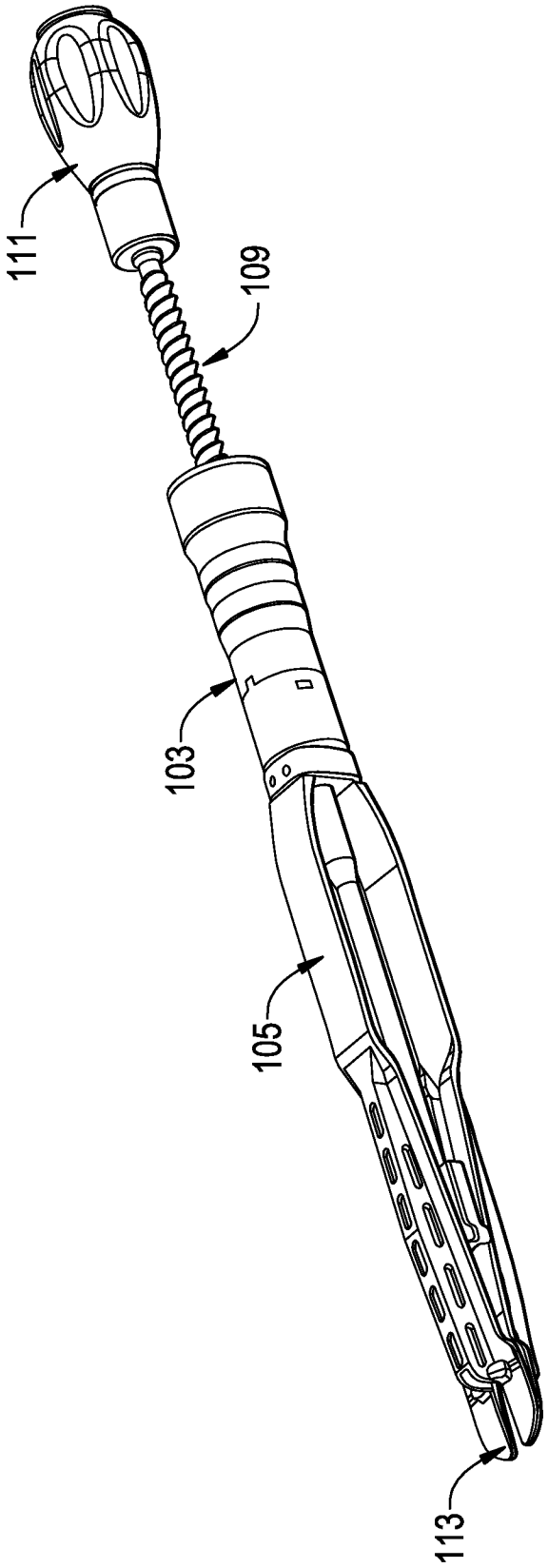


FIG. 18B

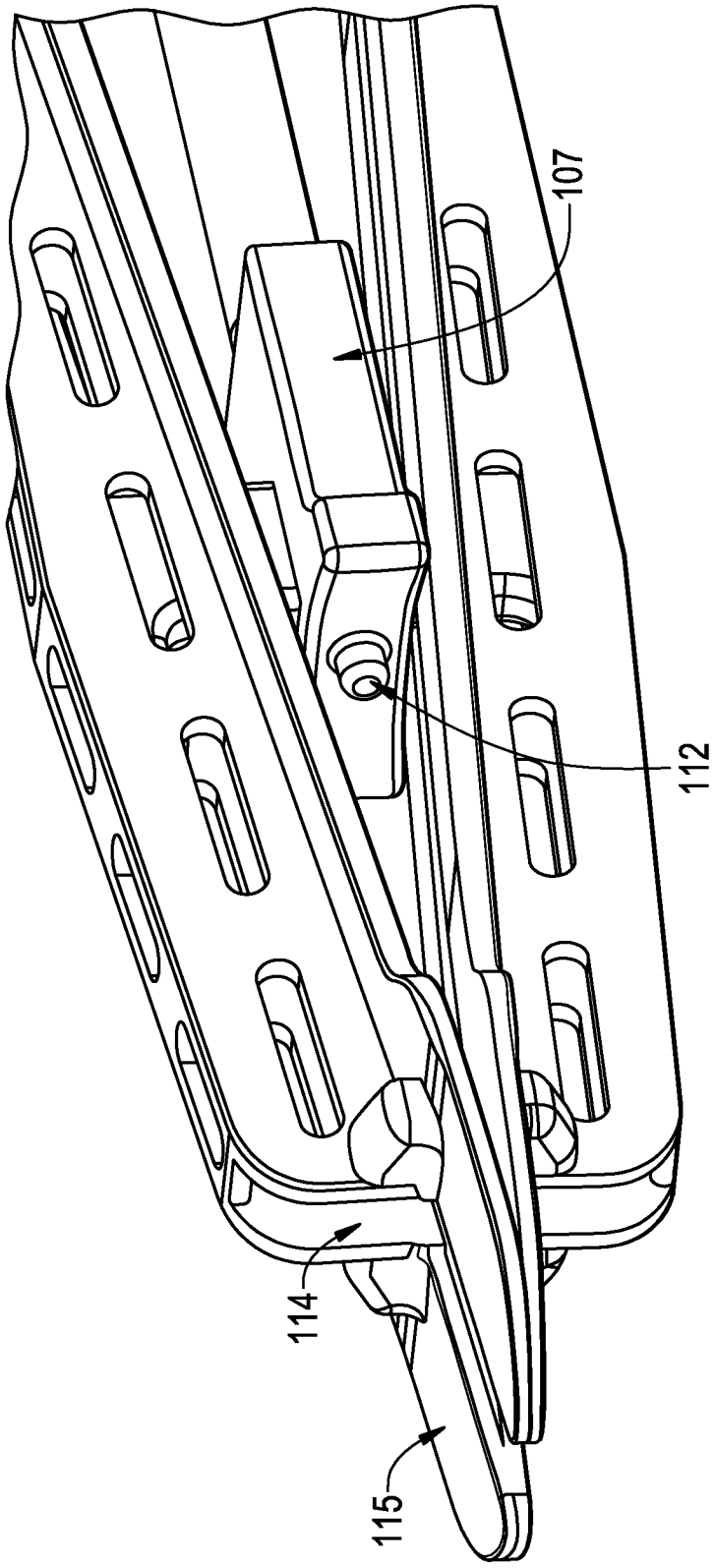
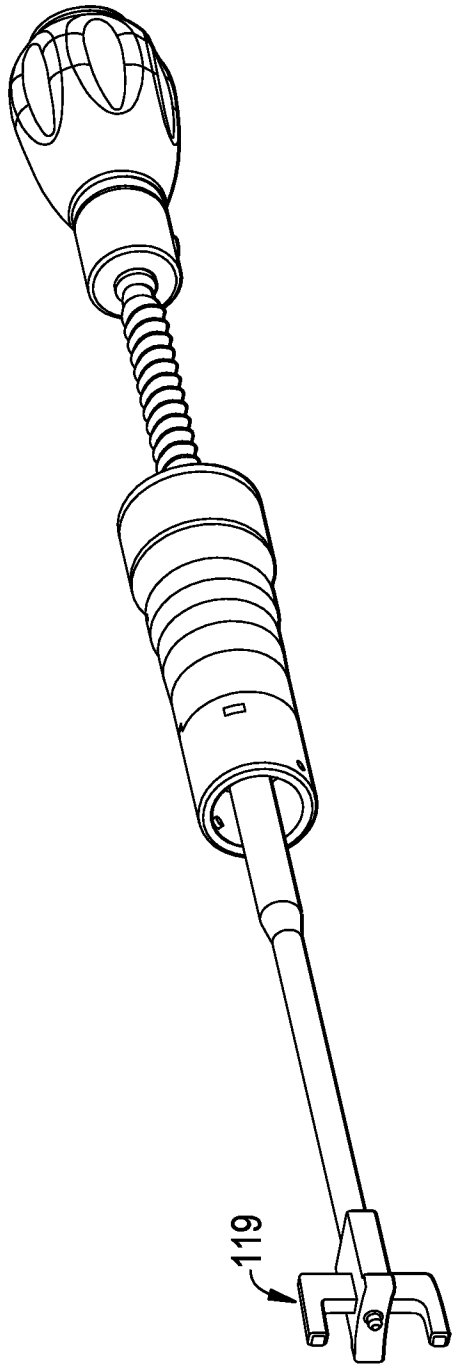


FIG. 18C



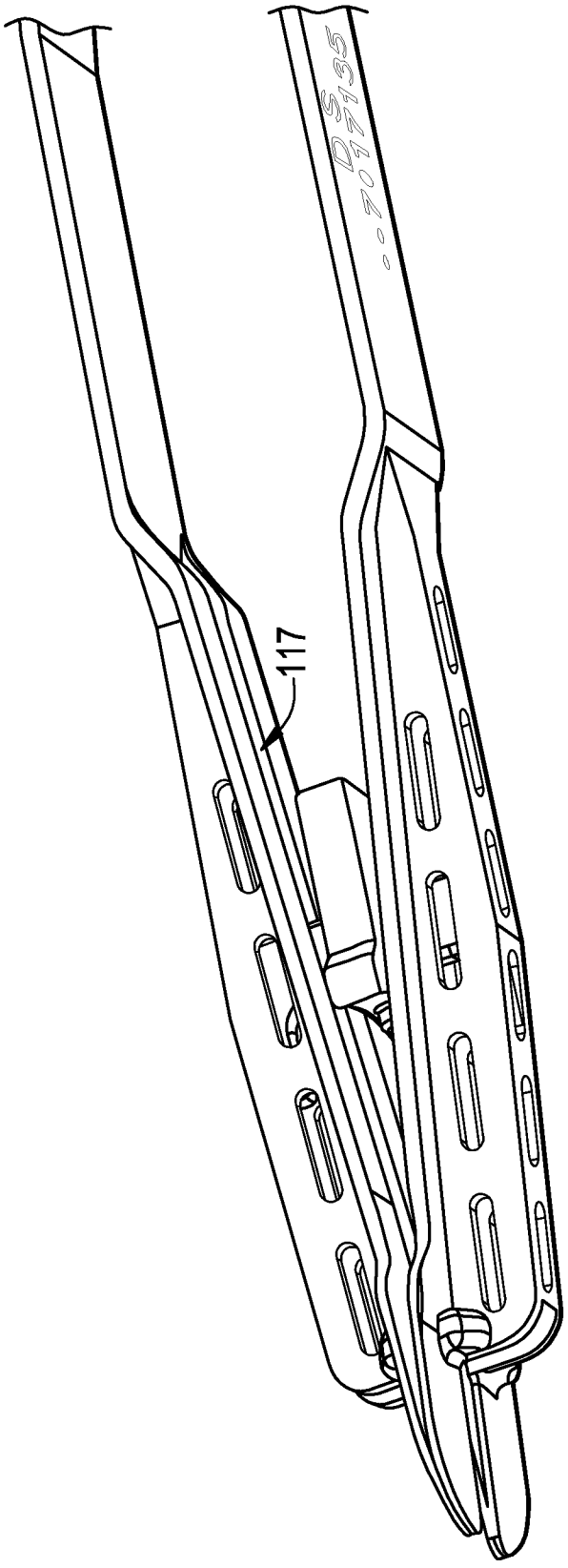


FIG. 18D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/28389

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2010.01)
USPC - 623/17.16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC8 : A61F 2/44 (2010.01)
USPC : 623/17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61B 17/56, A61B 17/58, A61B 17/68, A61B 17/70 (2010.01)
USPC : 606/1, 606/53, 606/60, 606/246, 606/248, 606/249, 606/279, 623/11.11, 623/16.11, 623/17.11

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,EPAB,JPAB)
endplate, screwhead, screw, fusion cage, interbody, intervertebra, implant, device, dovetail, vertebra, spine, spinal, over, notch, slide, hook, first, socket, keyhole, guide, canal, channel, slot, rail, groove, passageway, spacer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0079961 A1 (MICHELSON) 13 April 2006 (13.04.2006) see especially para [0037]-[0040], [0042], [0043], [0046], [0047], [0055]-[0057], [0062]-[0064], figs 1, 5, 6, 9, 10	1-23
Y	US 2006/0142863 A1 (FRASER et al) 29 June 2006 (29.06.2006) see especially para [0036], [0038], [0046], [0048], [0050], [0051], fig 7B, 12B, 12D	1-23
Y	US 2006/0235535 A1 (FEREE et al) 19 October 2006 (19.10.2006) see especially para [0057], [0059], [0065], [0077]-[0080], [0083], [0097], [0098], [0102]	5-7
Y	US 2003/0187506 A1 (ROSS et al) 02 October 2003 (02.10.2003) see especially para [0041], [0046], fig 3A, 3B, 7	11-18, 20-23
A	US 2004/0210219 A1 (BRAY) 21 October 2004 (21.10.2004) see whole document	1-23
A	US 2006/0085071 A1 (LECHMANN et al) 20 April 2006 (20.04.2006) see whole document	1-23

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 June 2010 (08.06.2010)	29 JUN 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)