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(54) **SPINAL FIXATION DEVICES AND METHODS OF USE**

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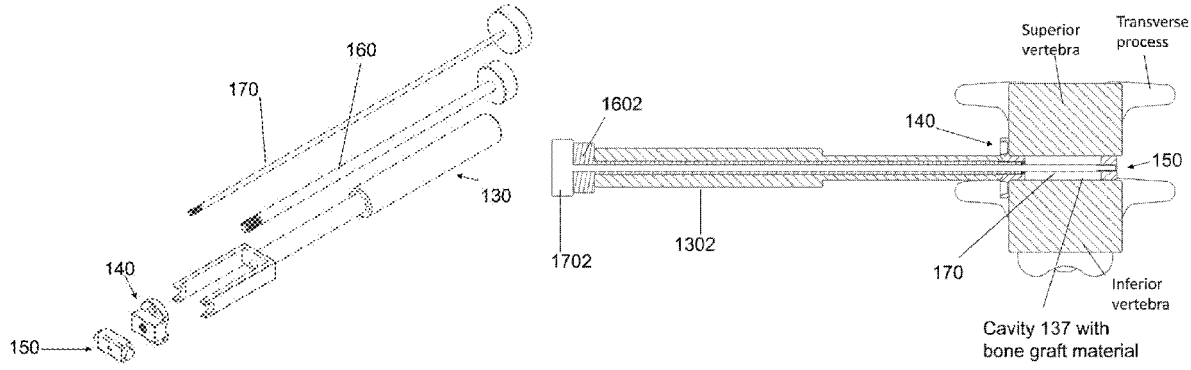
(57) **ABSTRACT**

Placement apparatus and methods of use for implantation of spacers within an inter-vertebral disc space. In one embodiment, the load-bearing superstructure of the implant is subdivided and the bone forming material is positioned within an internal space of the placement instrument but external to the load bearing elements themselves. At least a portion of the bone graft material is freely contained within the disc space. A method of using the device is also described. In one embodiment, the placement device is used to place the implantable spacers at opposing ends of the disc space using a directly lateral surgical approach.

30 Claims, 44 Drawing Sheets



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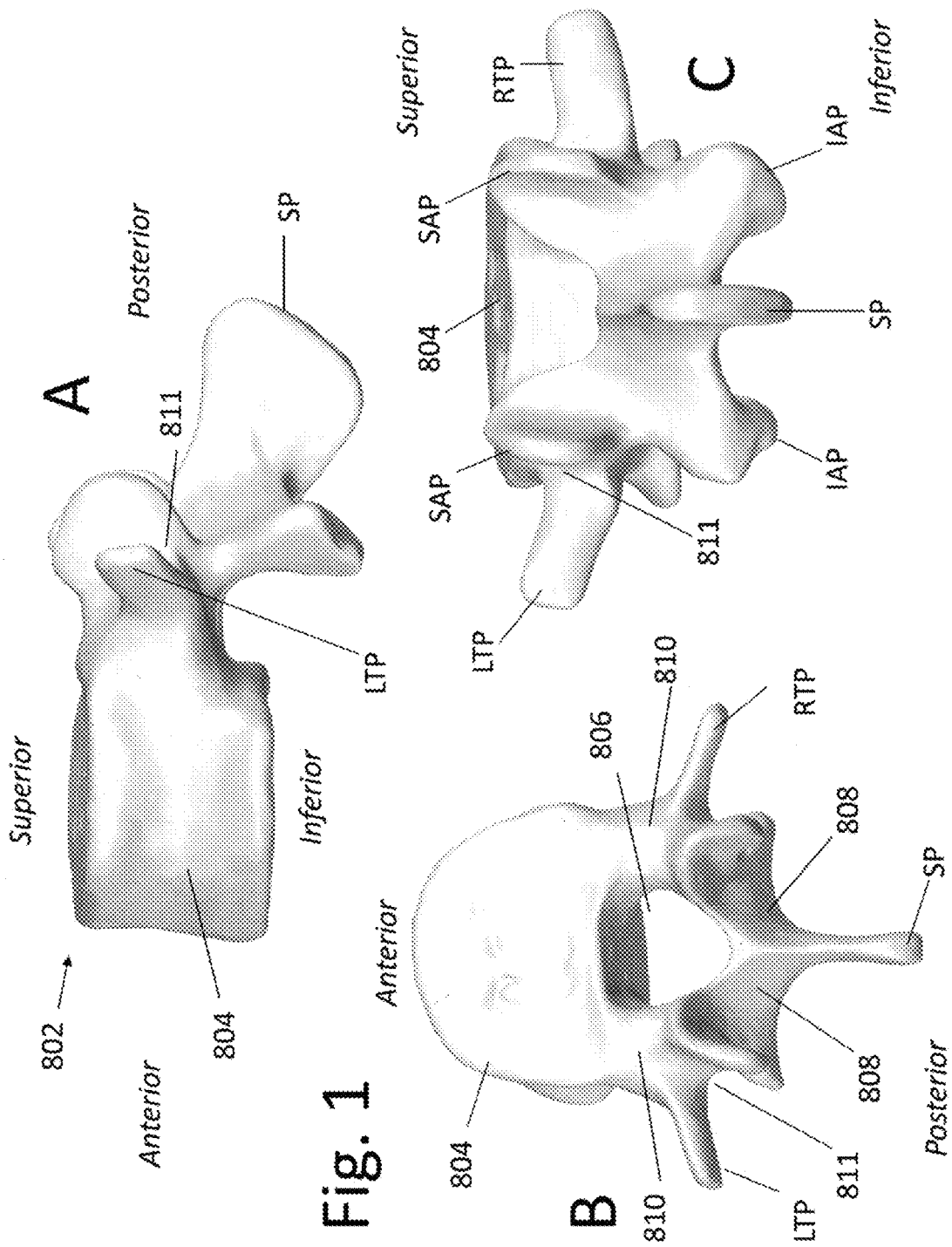

A
Superior
Posterior
Anterior
Inferior
802
804
811
LTP
SP
B
Anterior
Posterior
804
806
810
808
811
LTP
RTP
SP
C
Superior
Inferior
SAP
804
811
LTP
RTP
IAP
SP

Fig. 1

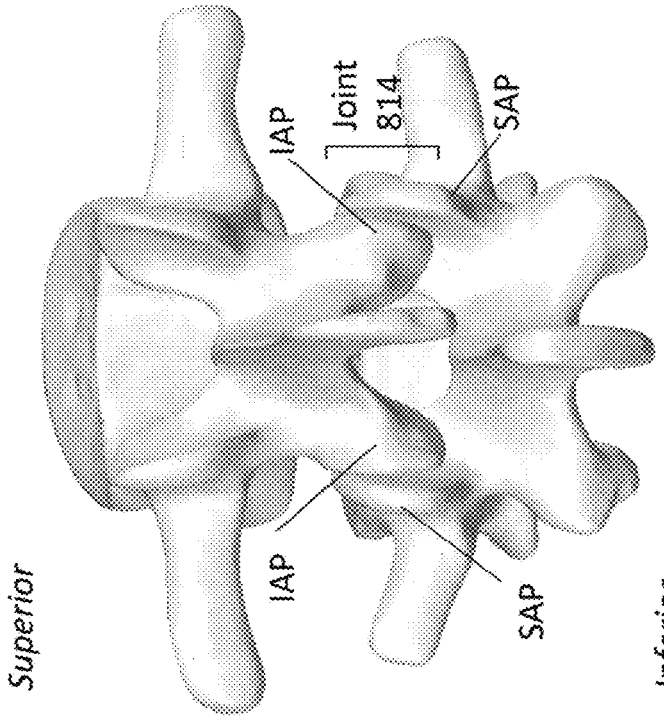

Superior
IAP
Joint
814
SAP
IAP
SAP
Inferior

Fig. 2A

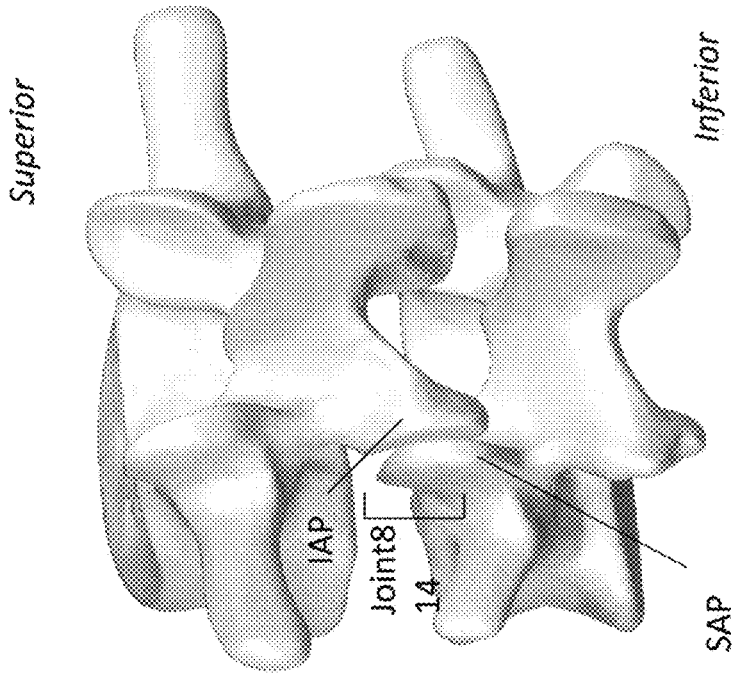

Superior
IAP
Joint8
14
SAP
Inferior

Fig. 2B

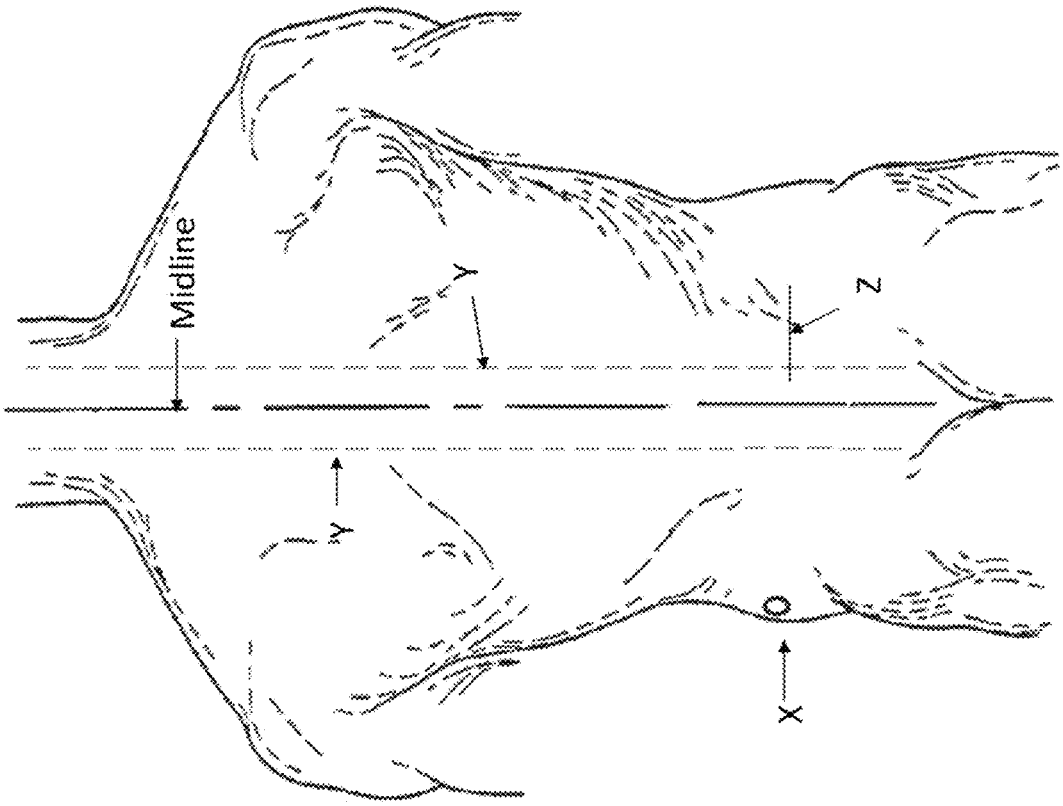


Fig. 3

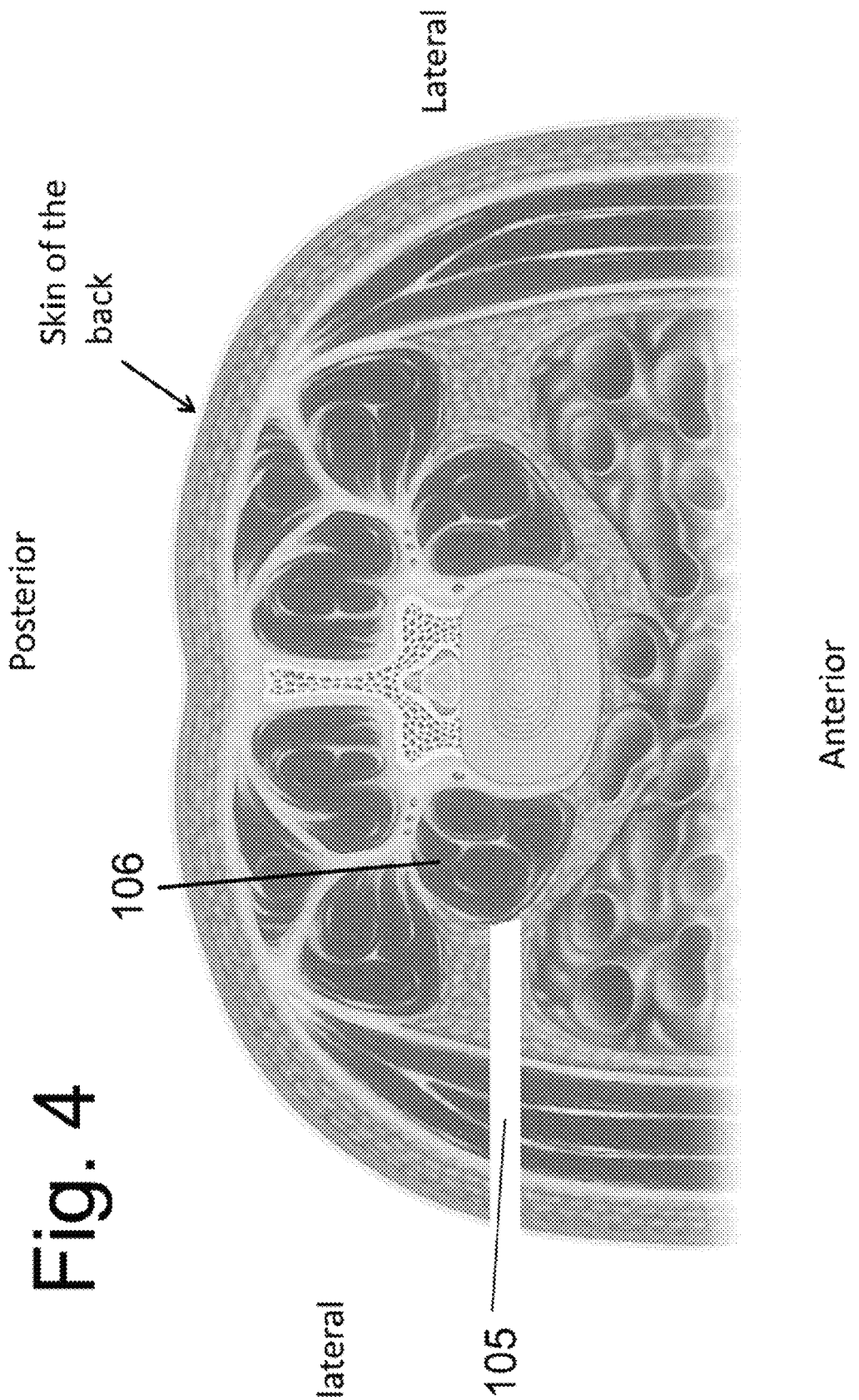

Lateral
Skin of the back
Posterior
Anterior
106
lateral
105

Fig. 4

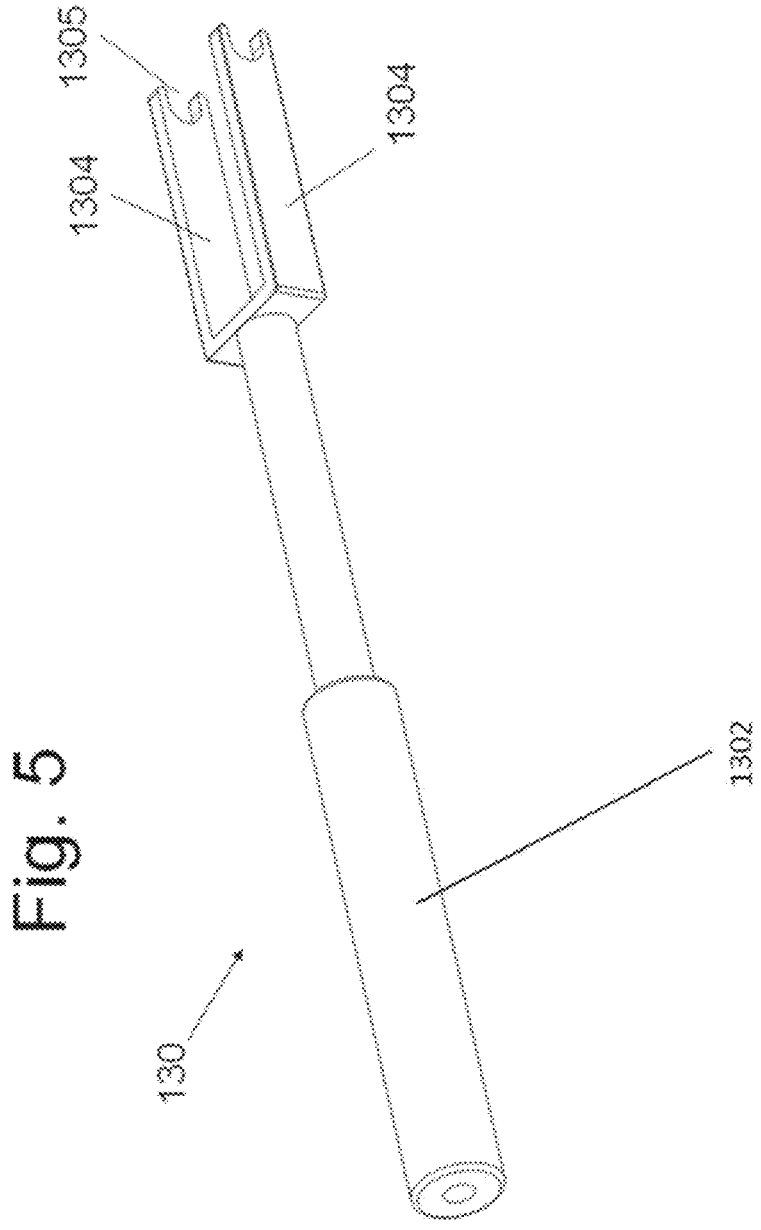


Fig. 5

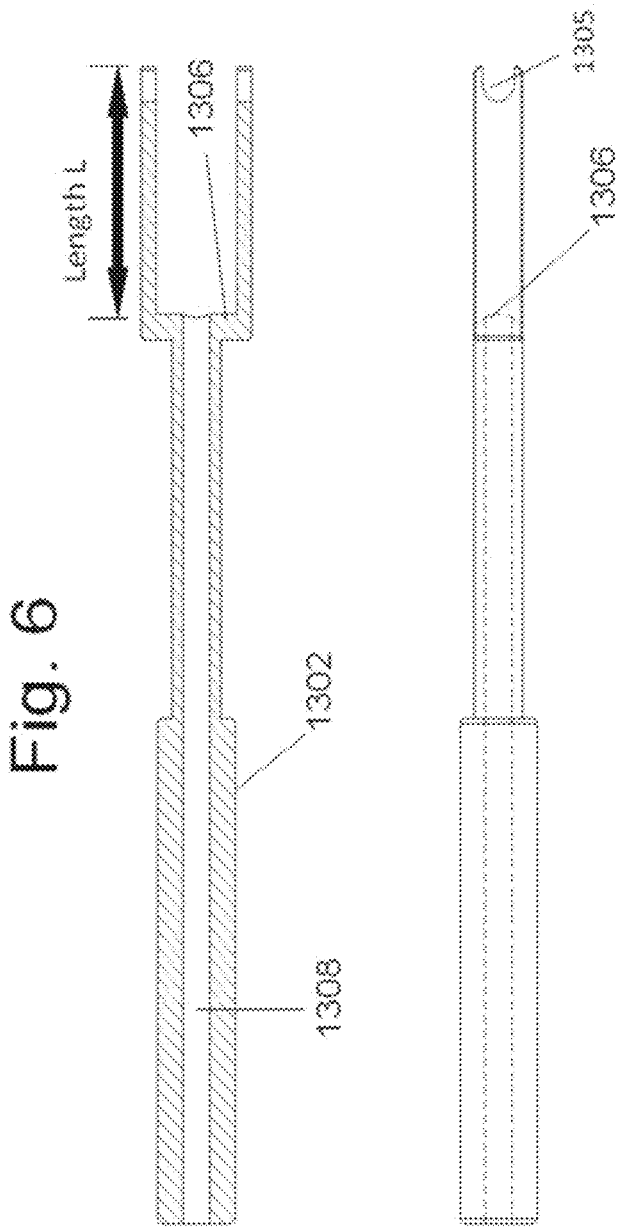


Fig. 6

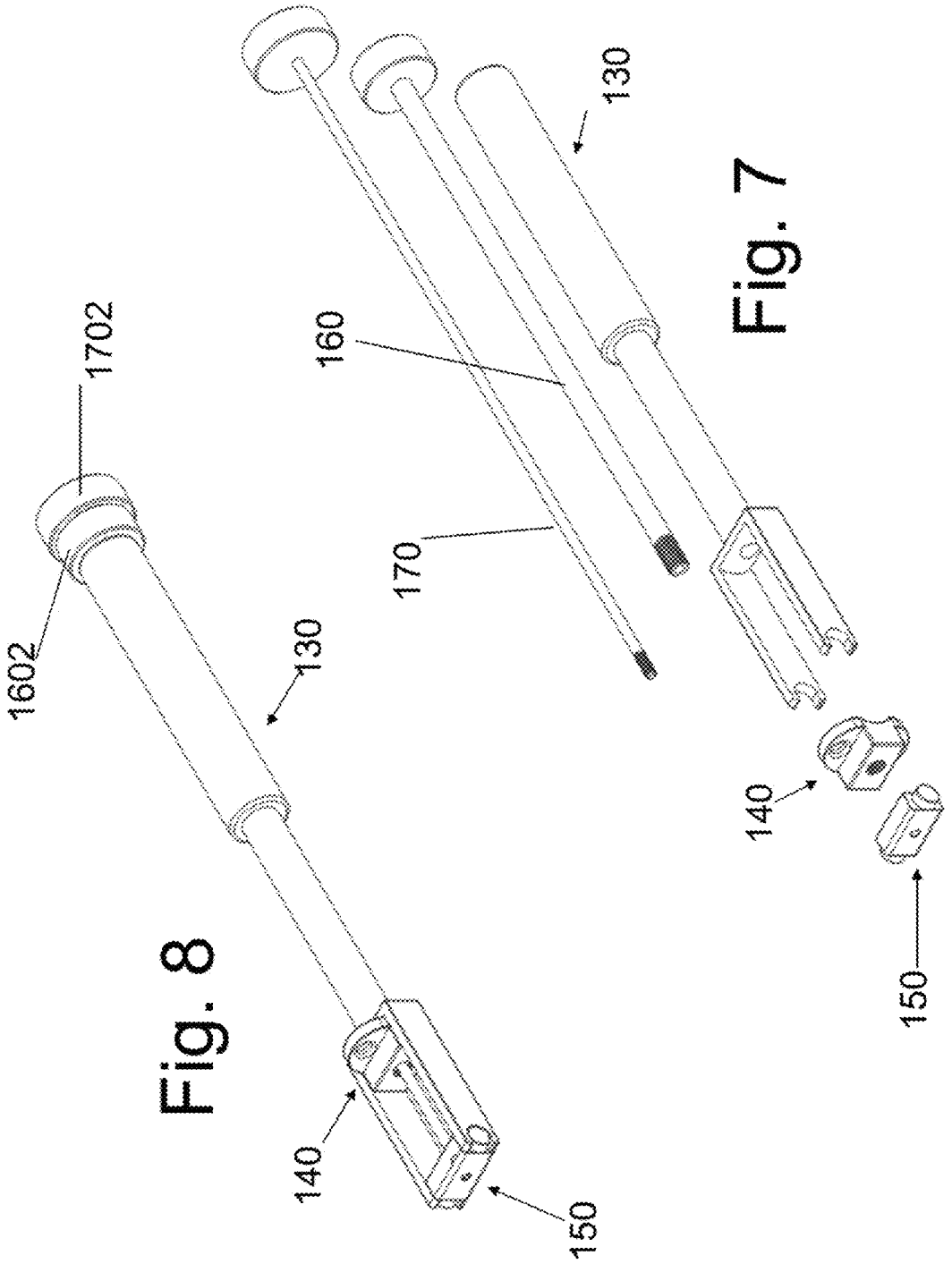
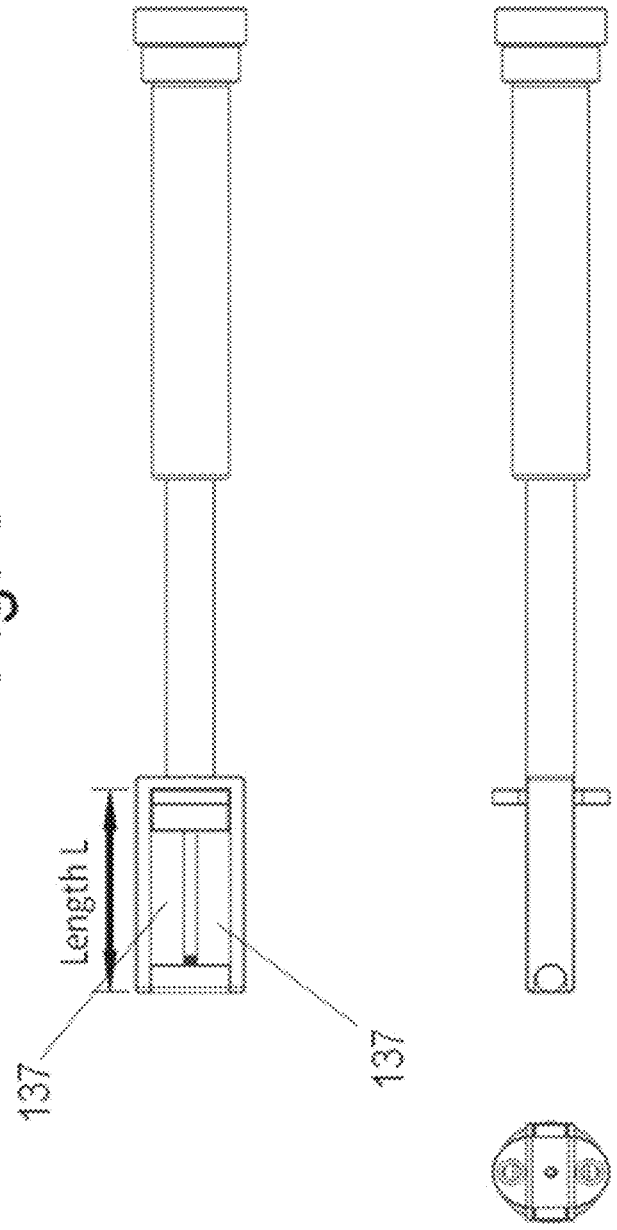


Fig. 7

Fig. 8

Fig. 6



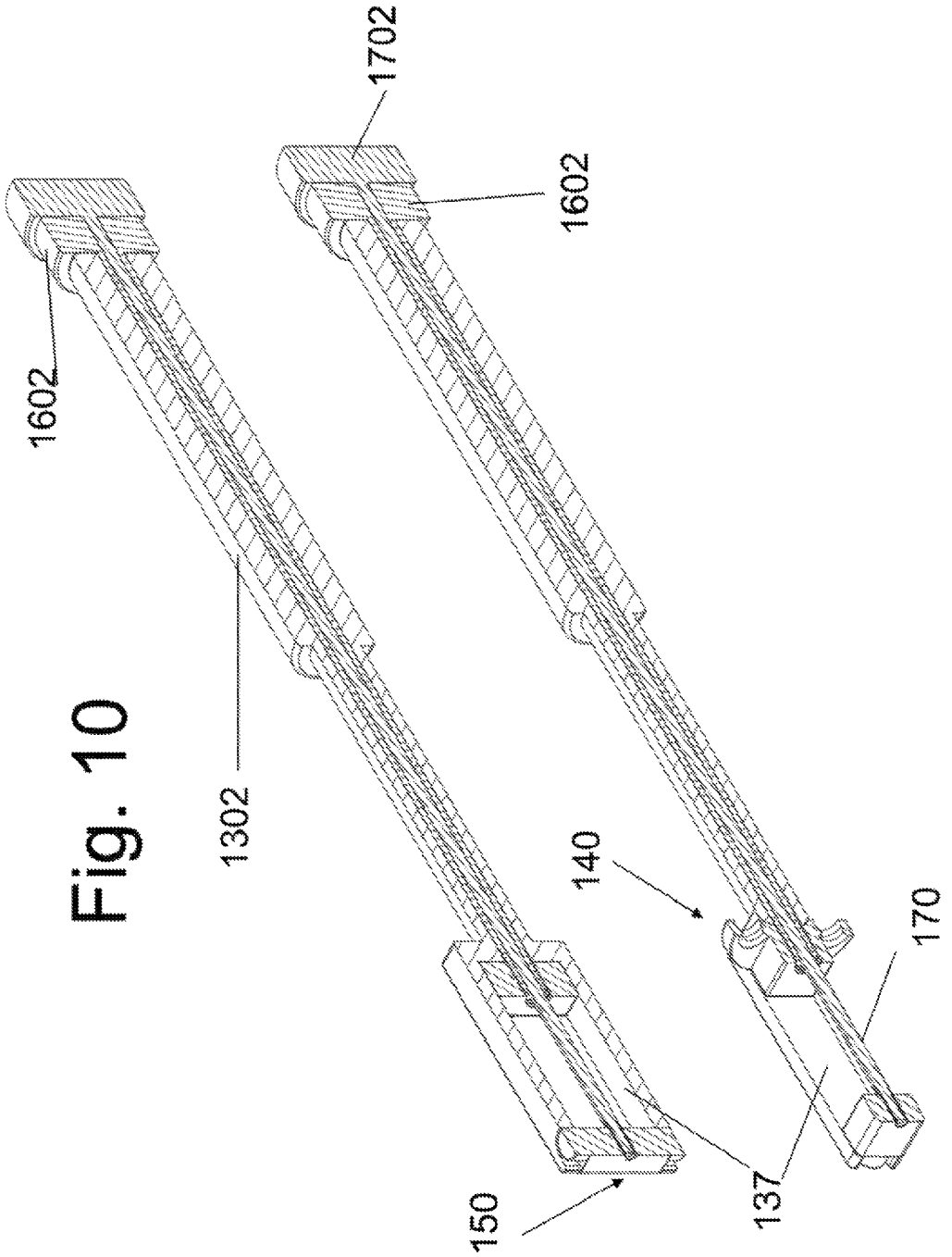


Fig. 10

Fig. 11

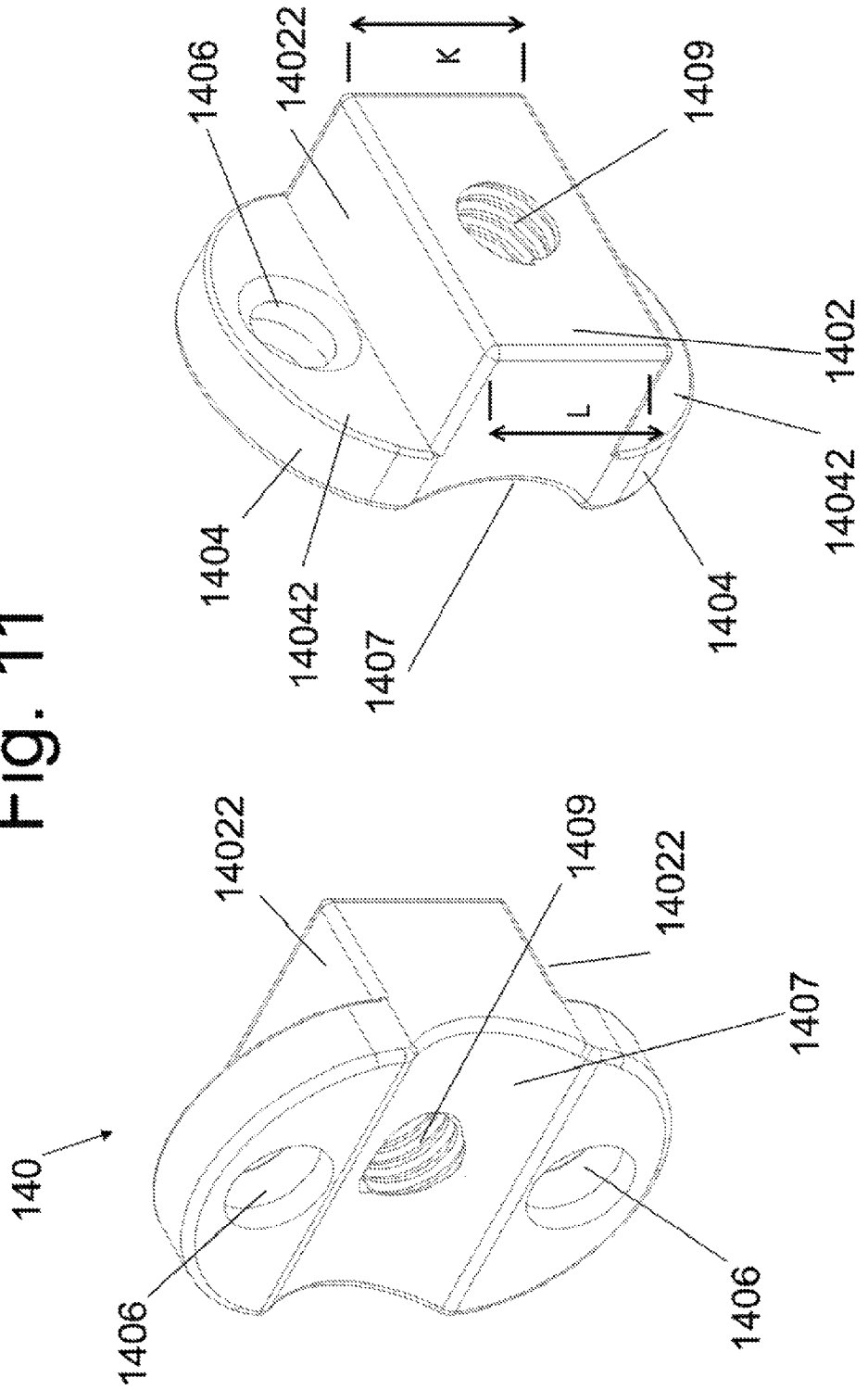
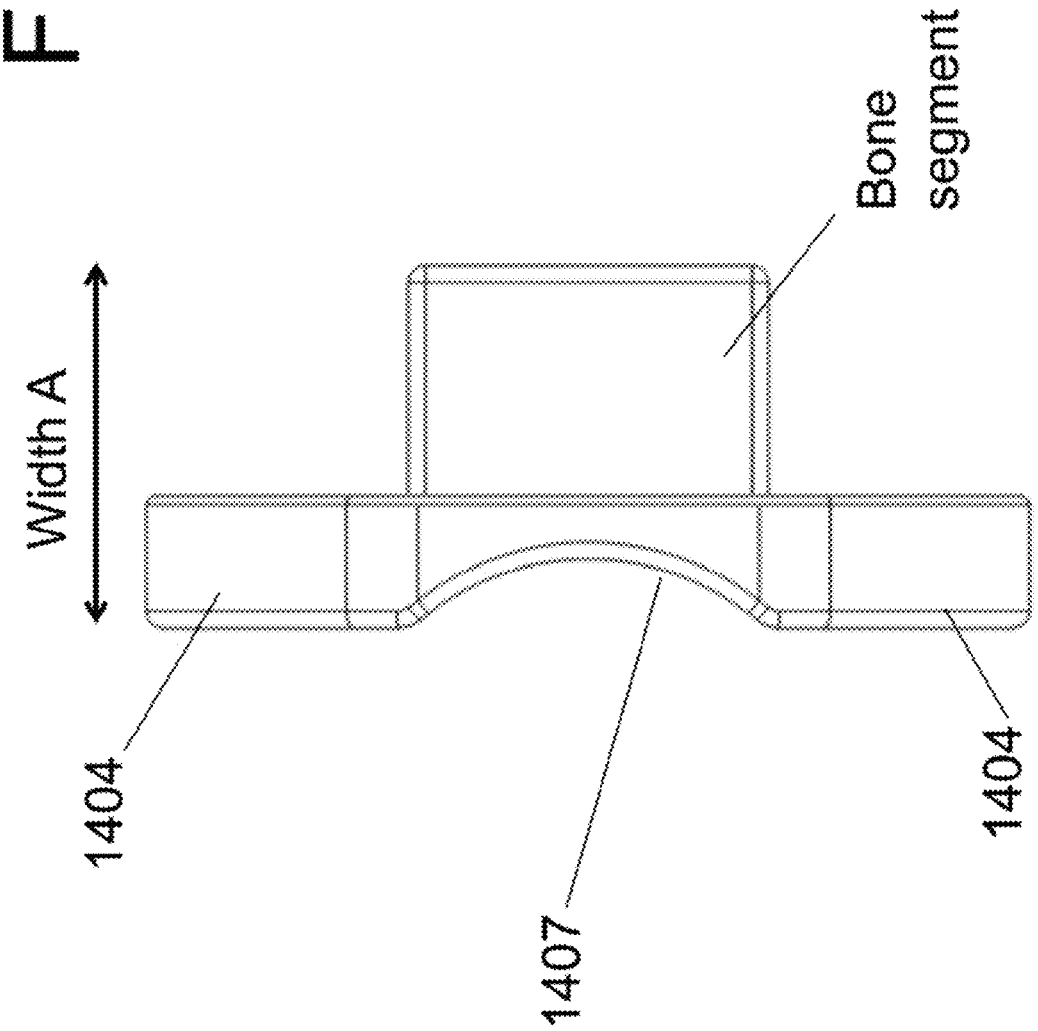

140
1406
14022
1409
14022
1407
1406
1406
14022
K
1409
1402
L
14042
1404
14042
1407
1404

Fig. 11A



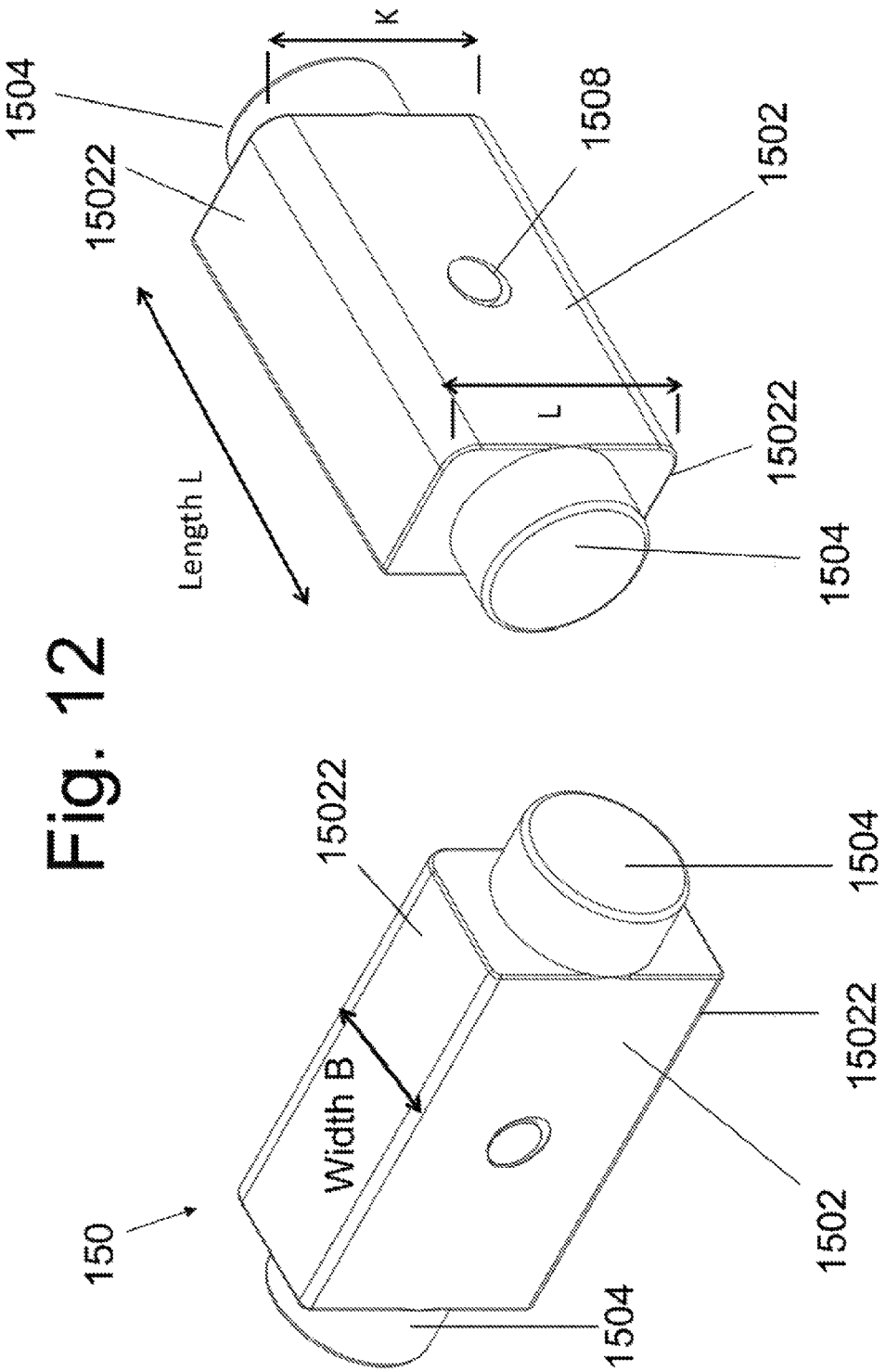

1504
15022
K
1508
1502
L
15022
1504
Length L
150
15022
1504
Width B
15022
1502
1504

Fig. 12

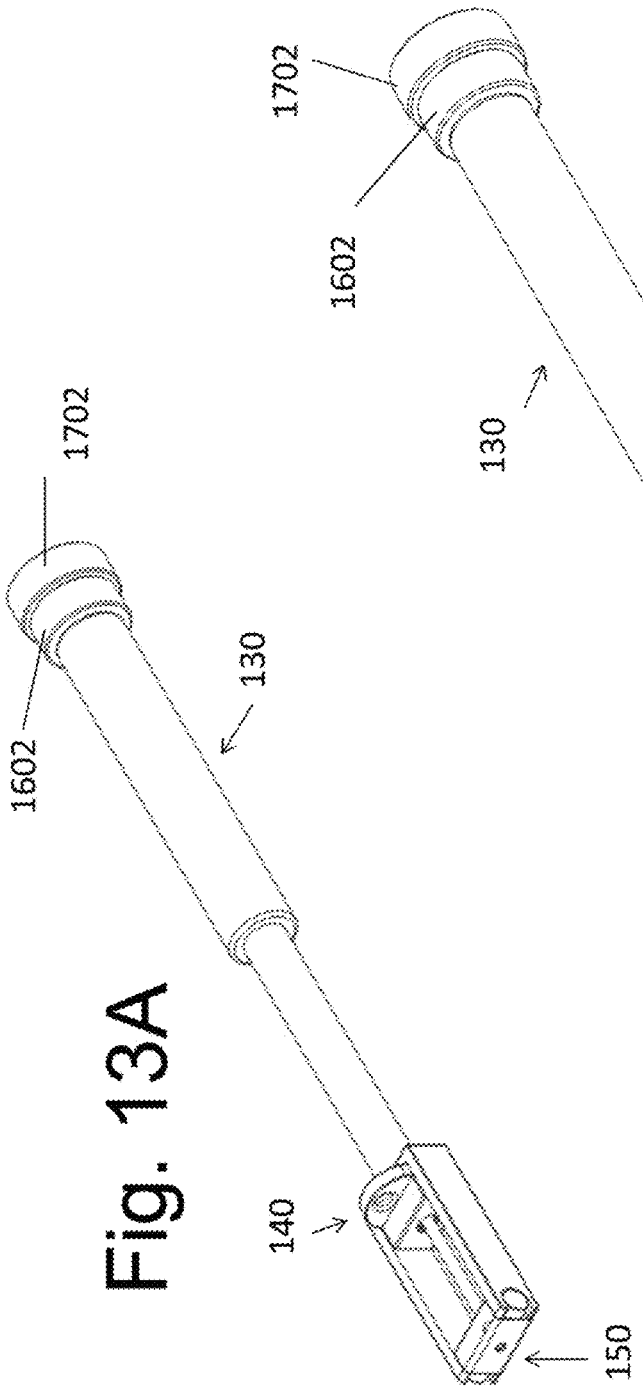


Fig. 13A

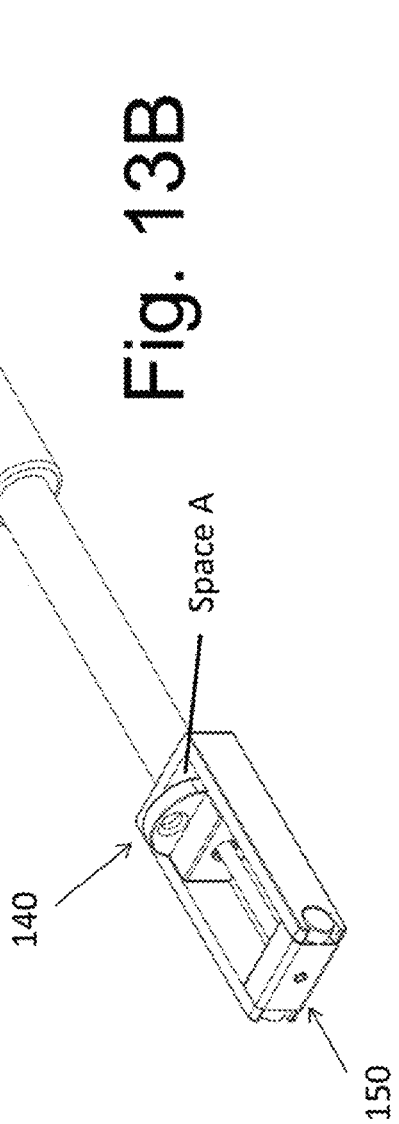


Fig. 13B

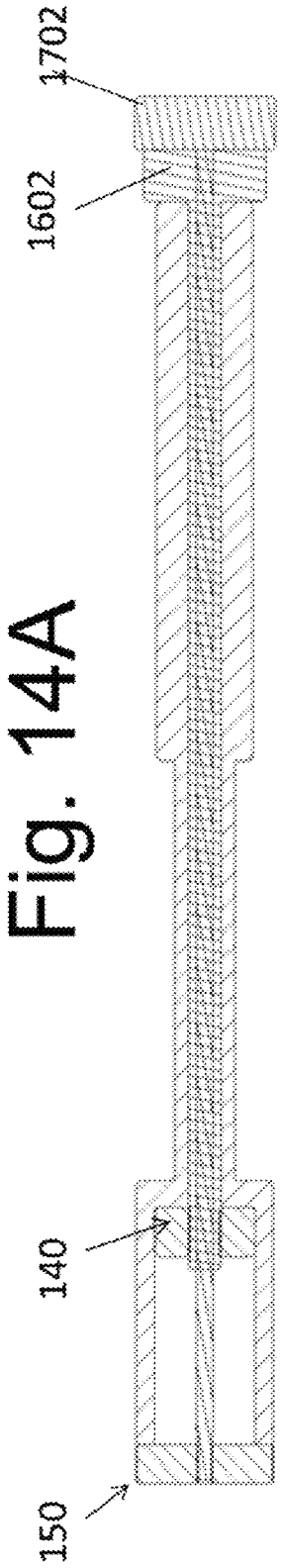


Fig. 14A

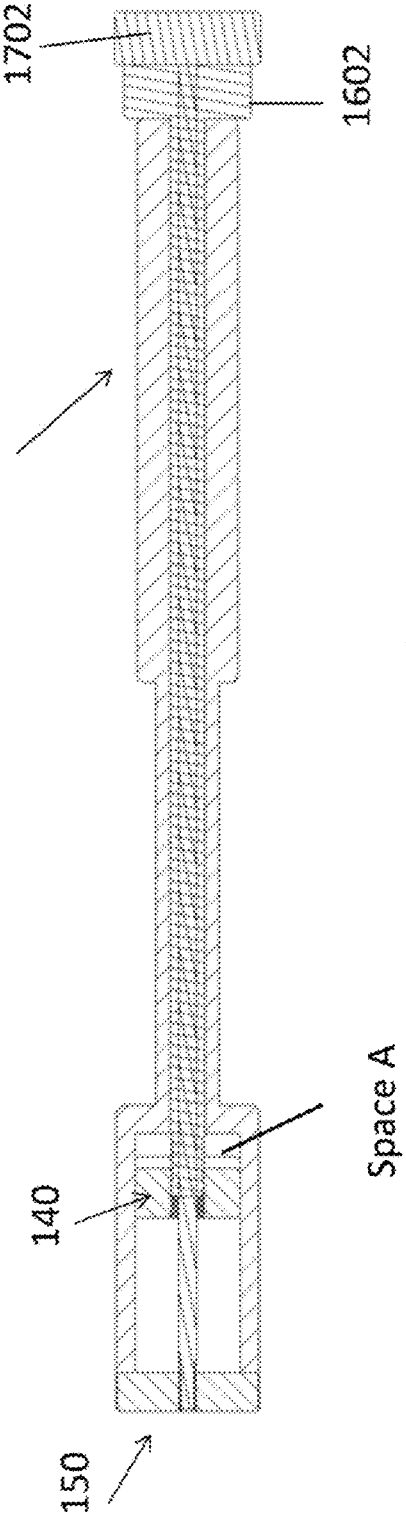
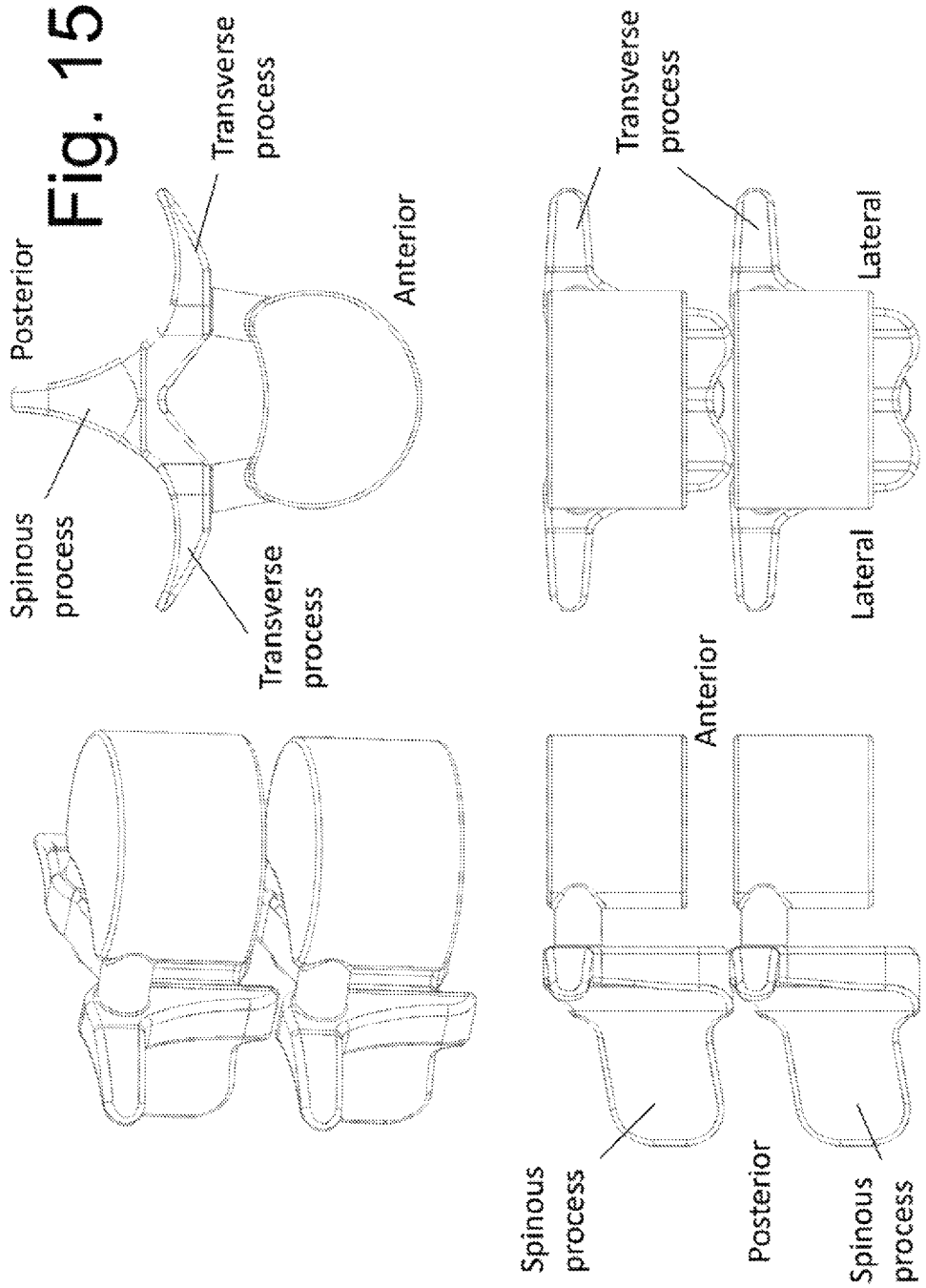


Fig. 14B

Fig. 15


Posterior
Transverse process
Anterior
Spinous process
Transverse process
Transverse process
Lateral
Lateral
Anterior
Spinous process
Posterior
Spinous process

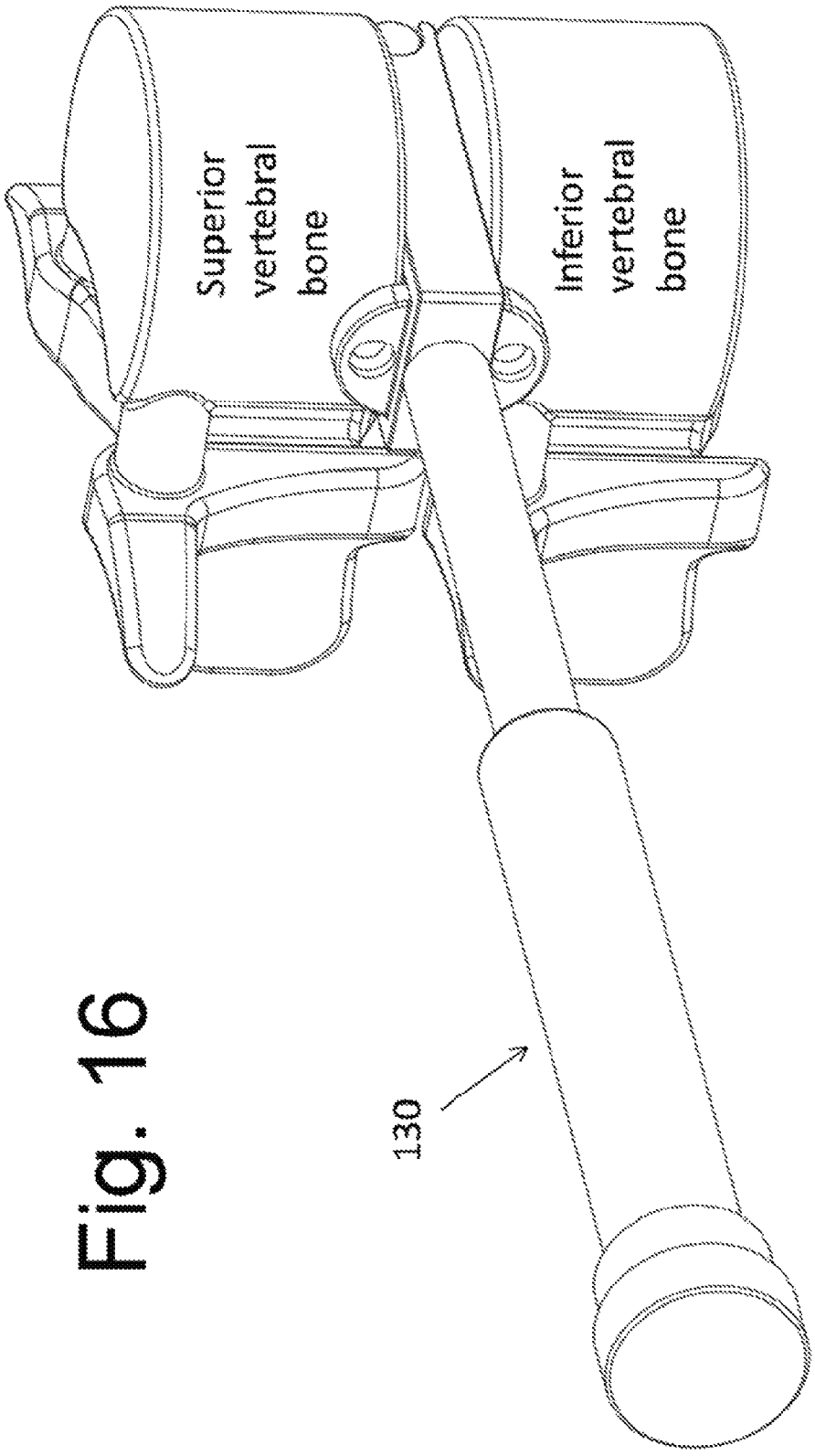

Superior vertebral bone
Inferior vertebral bone
130
Implant placement via a lateral corridor 105

Fig. 16

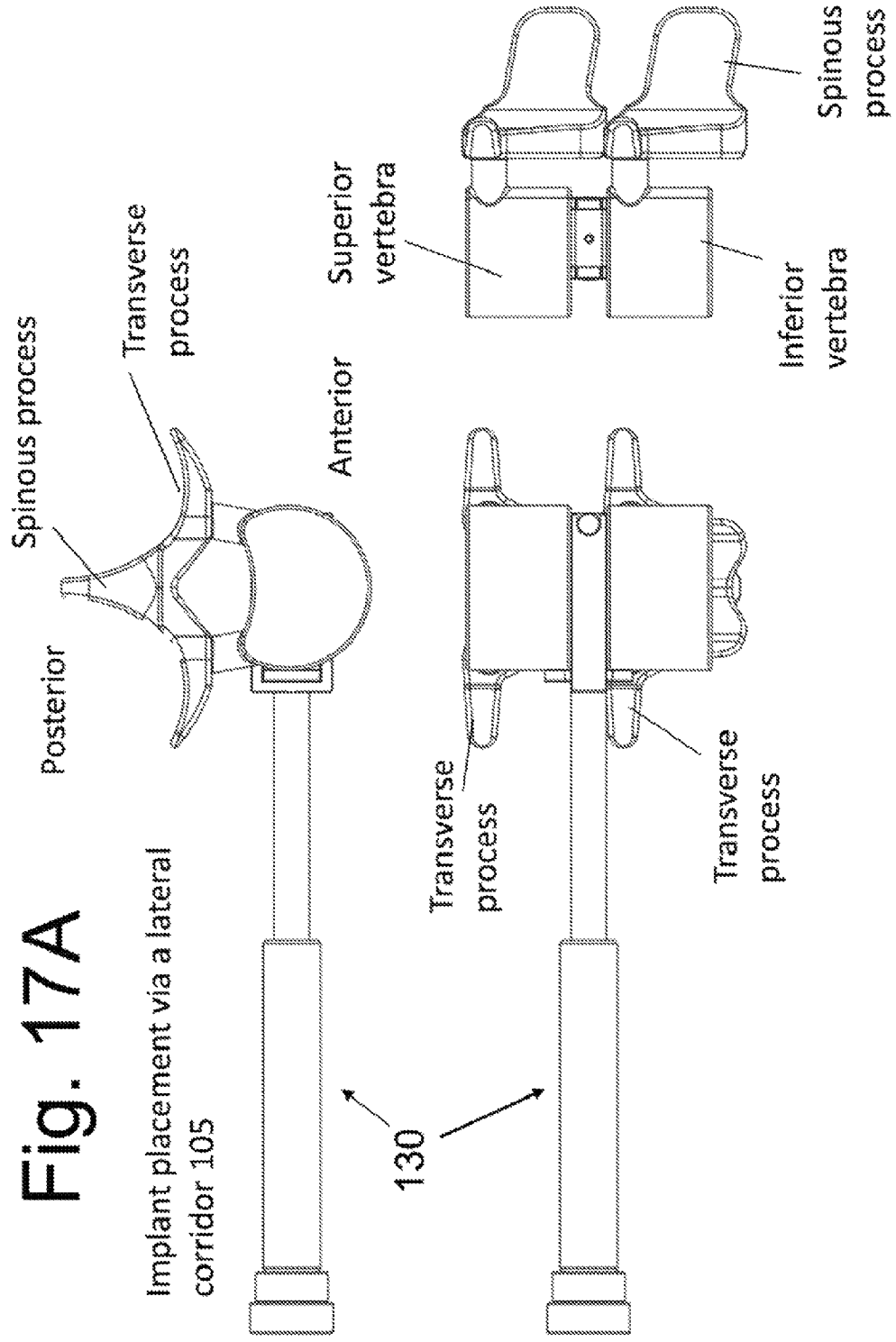

Spinous process
Transverse process
Superior vertebra
Spinous process
Posterior
Anterior
Inferior vertebra
Implant placement via a lateral corridor 105
Transverse process
Transverse process
130

Fig. 17A

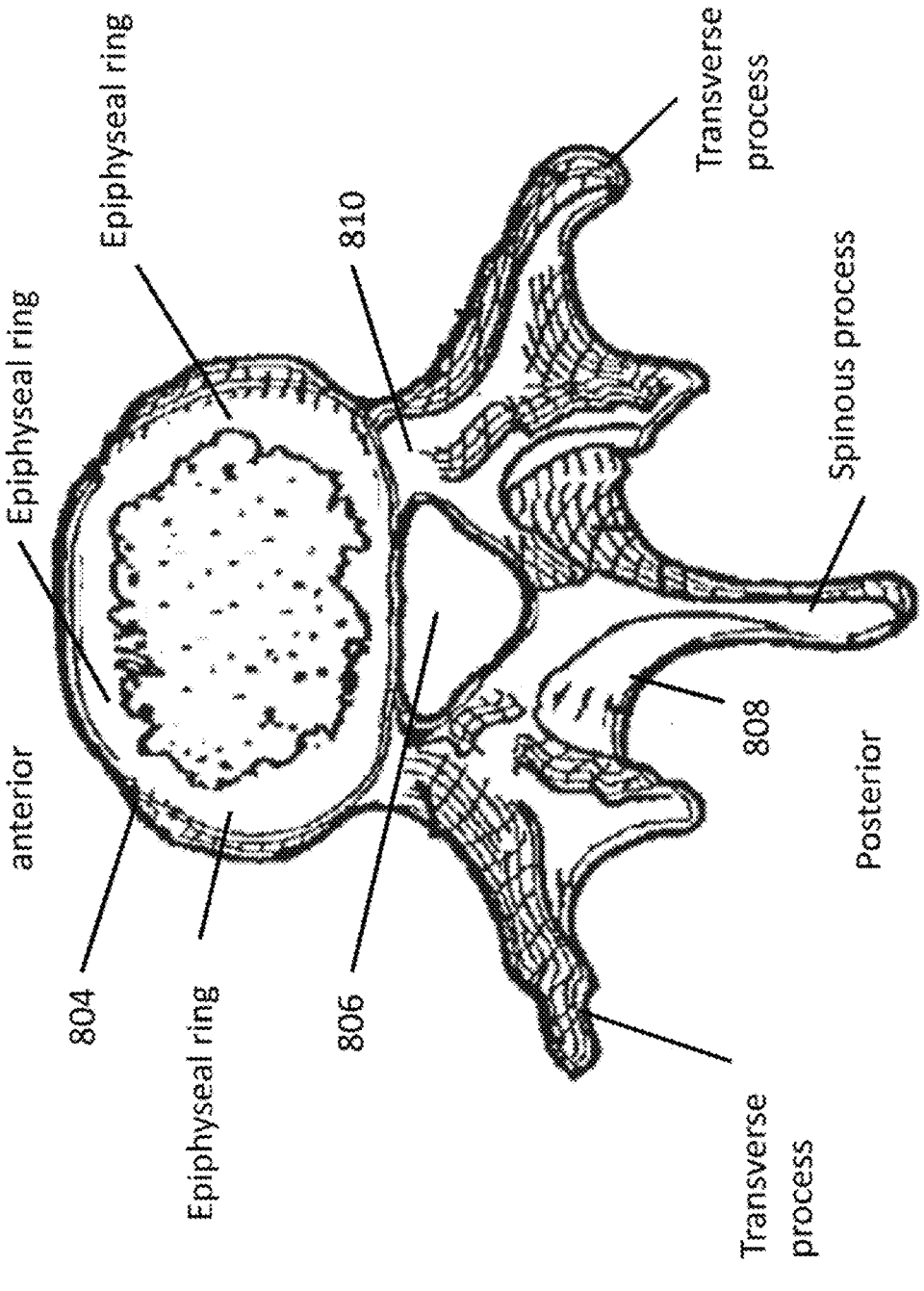

Epiphyseal ring
Epiphyseal ring
810
Transverse process
Spinous process
anterior
804
Epiphyseal ring
806
808
Posterior
Transverse process

Fig. 17B

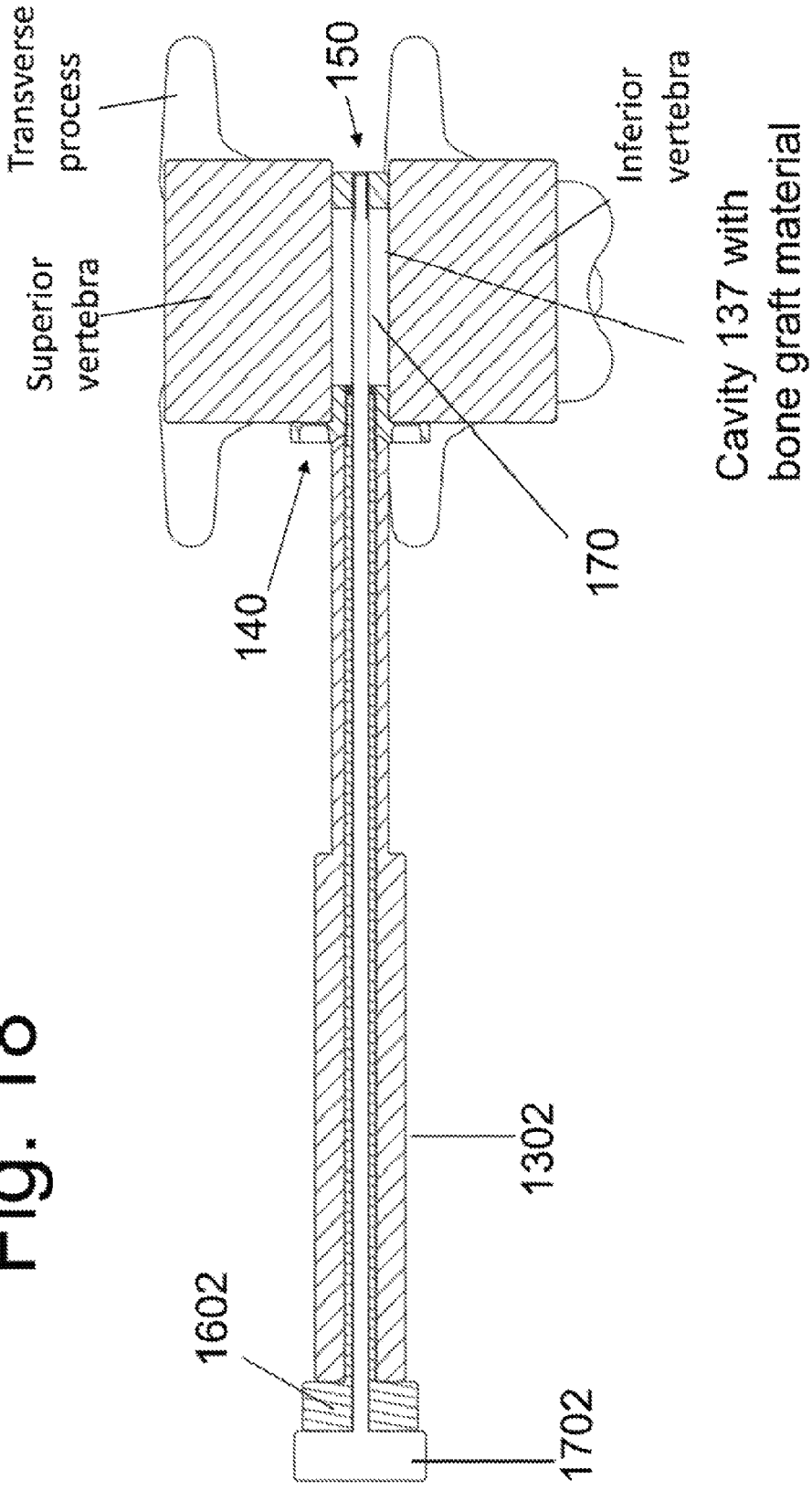

Transverse process
150
Inferior vertebra
Superior vertebra
Cavity 137 with bone graft material
140
170
1302
1602
1702

Fig. 18

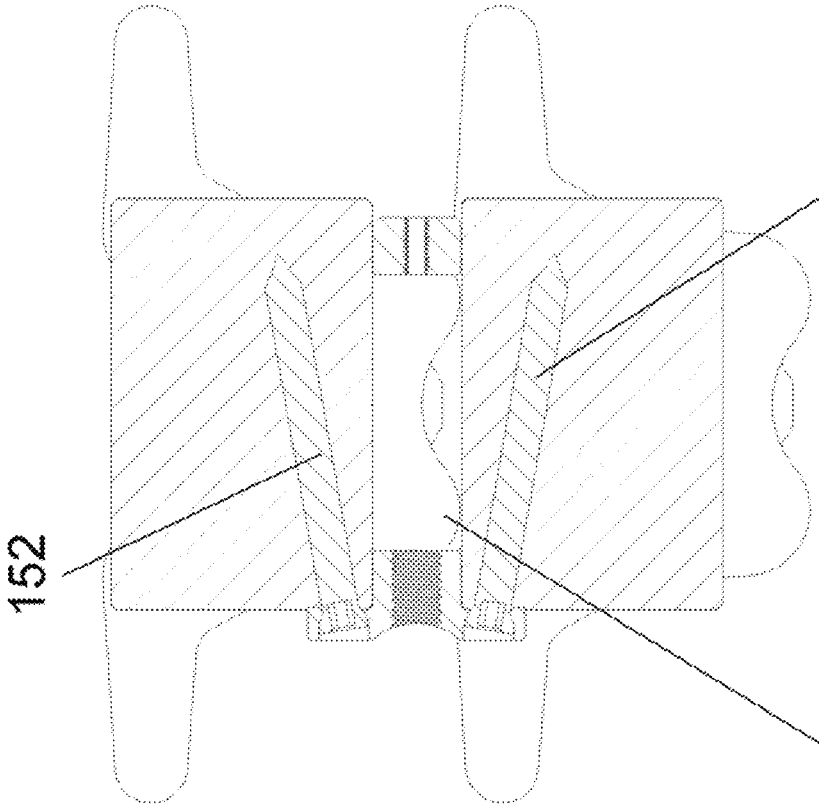


Fig. 19B

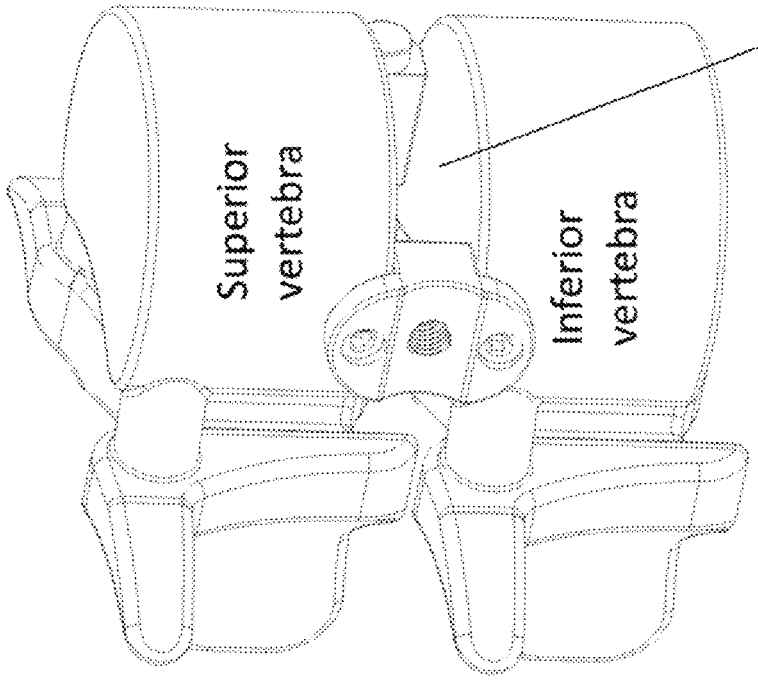
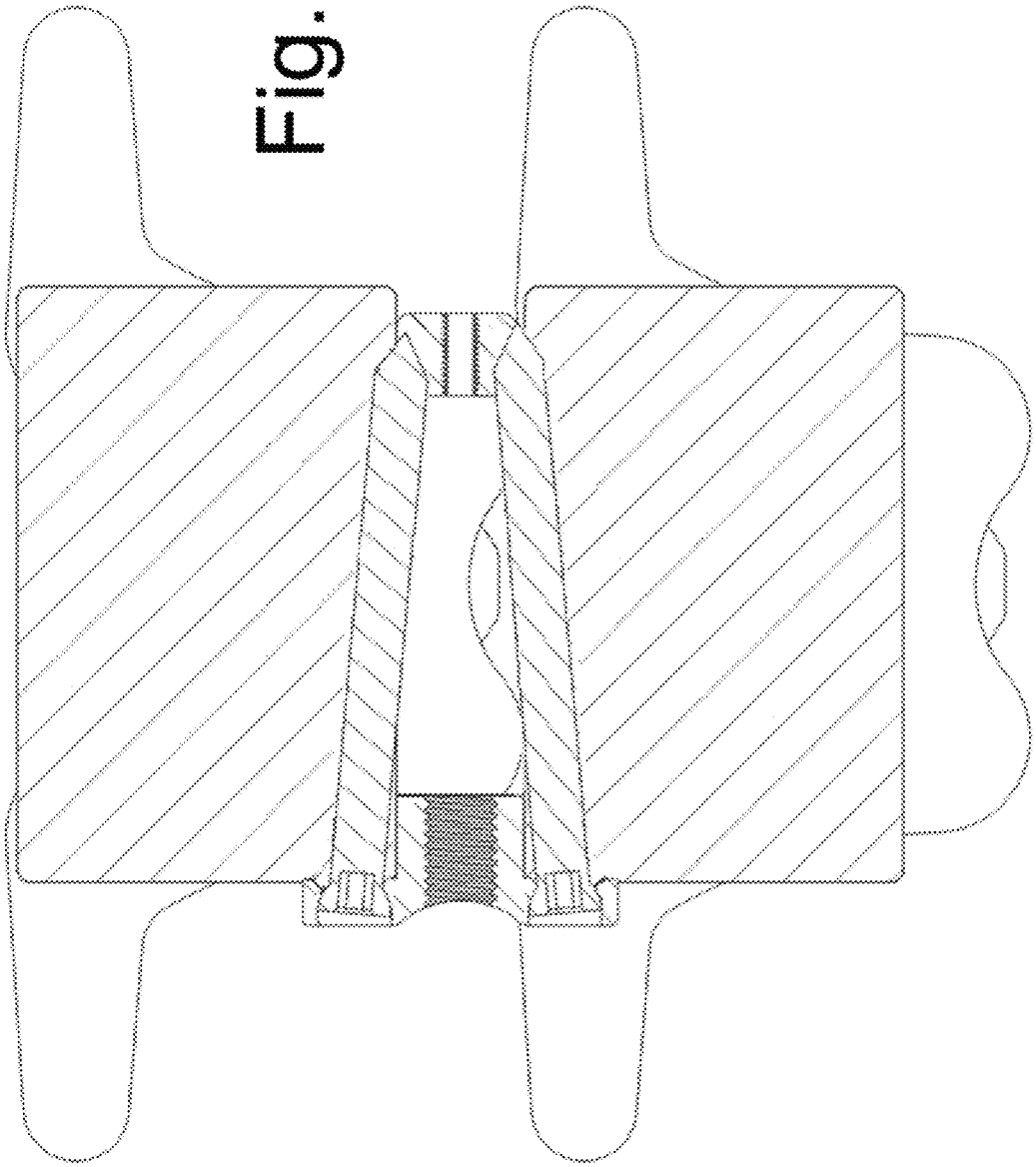


Fig. 19A

Fig. 20



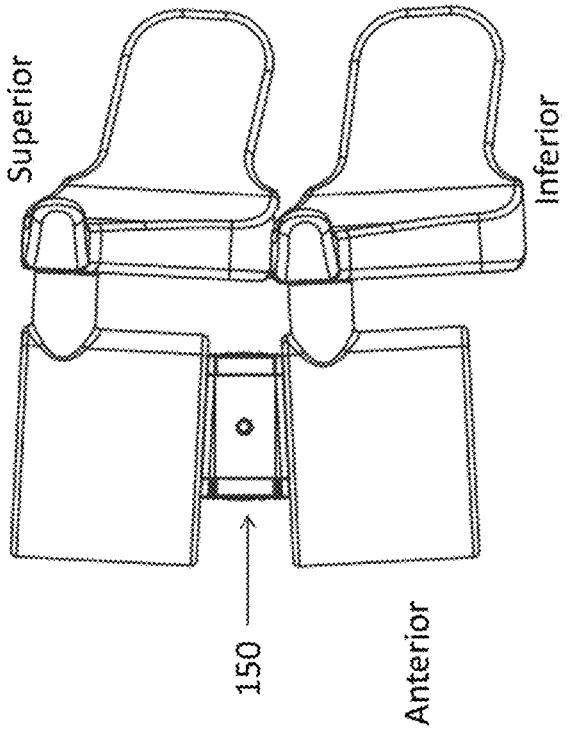


Fig. 21A

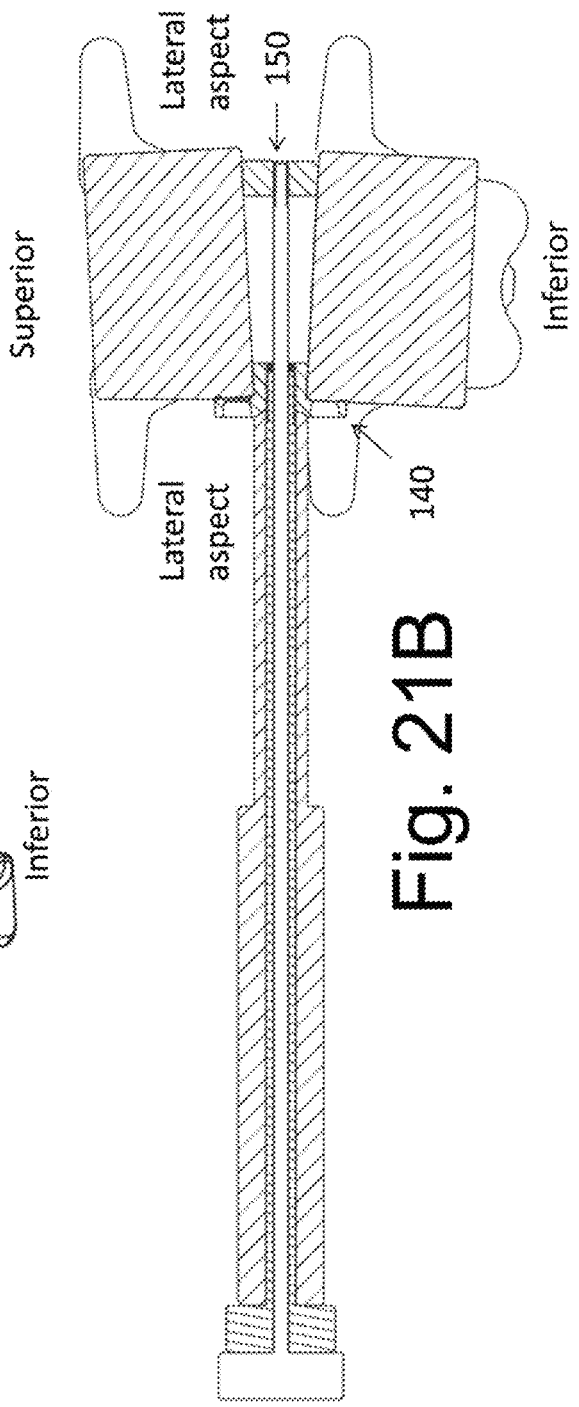


Fig. 21B

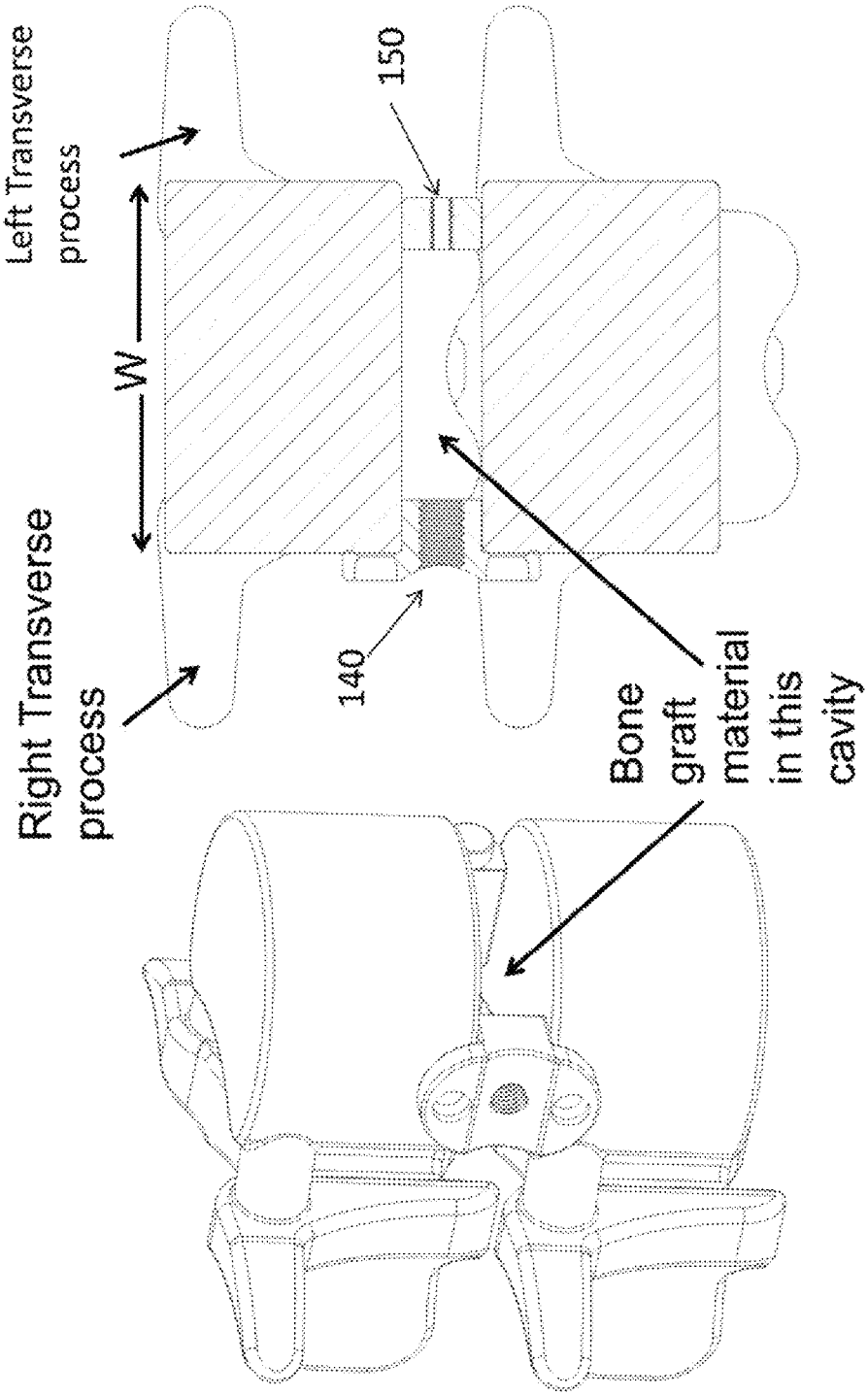


Fig. 22A

Fig. 22B

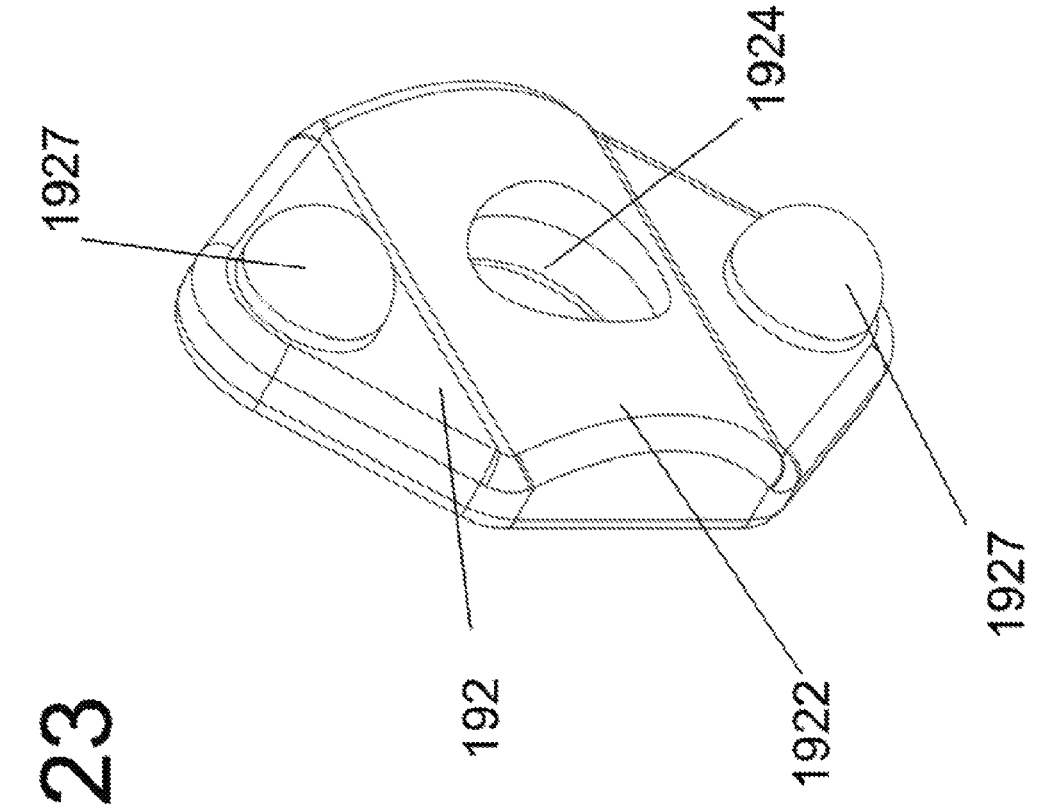
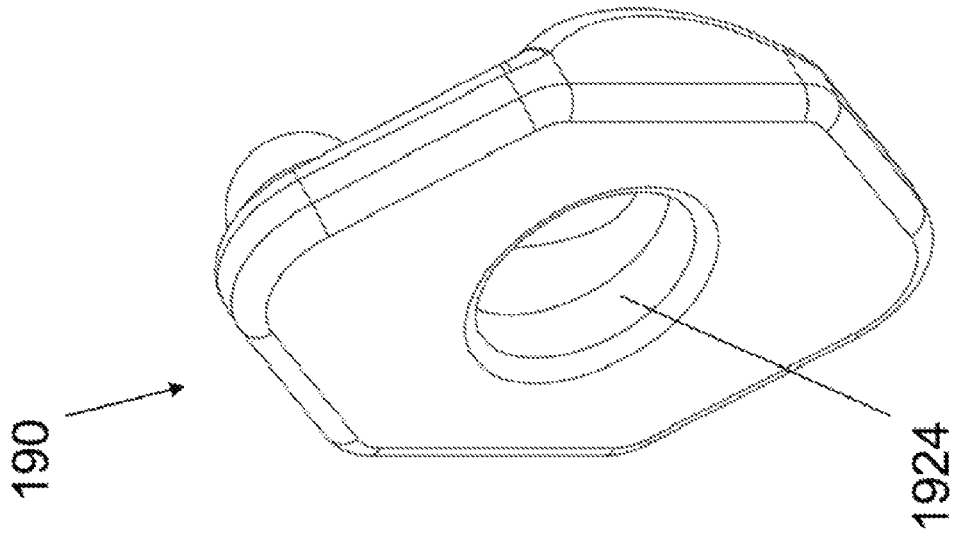


Fig. 23



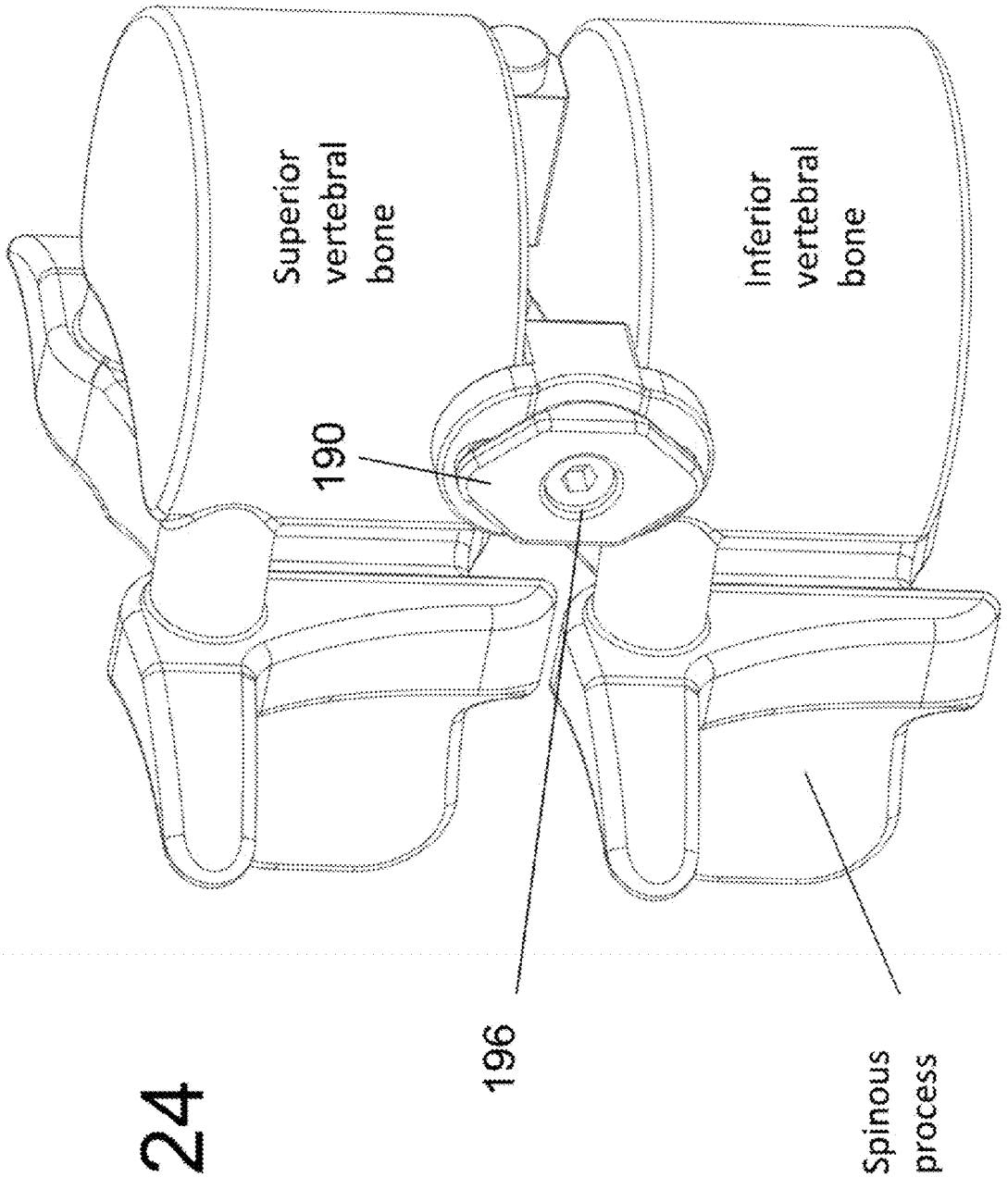

Superior vertebral bone
Inferior vertebral bone
190
196
Spinous process

Fig. 24

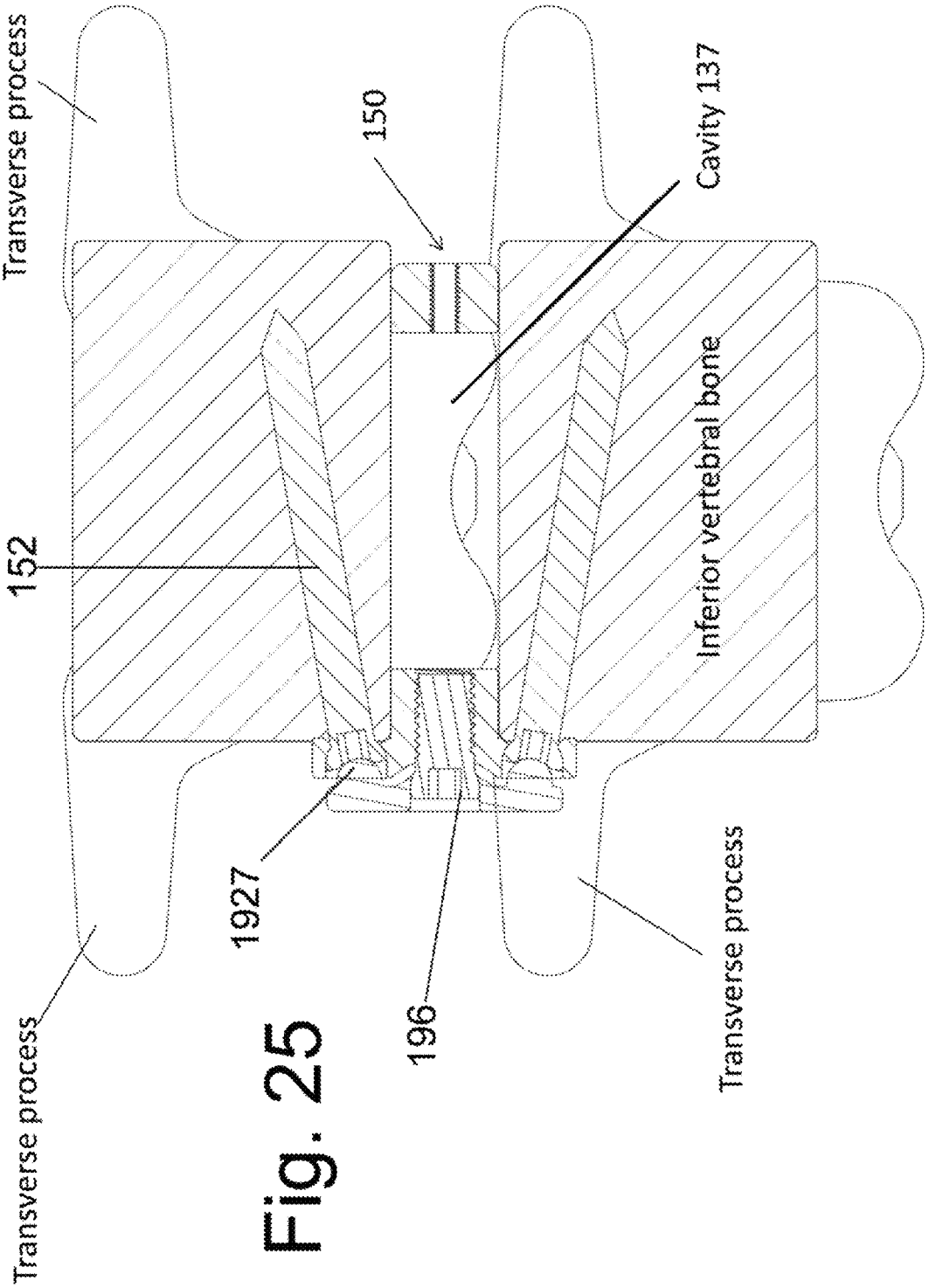

Transverse process
150
Cavity 137
152
Inferior vertebral bone
1927
196
Transverse process
Transverse process

Fig. 25

Fig. 26

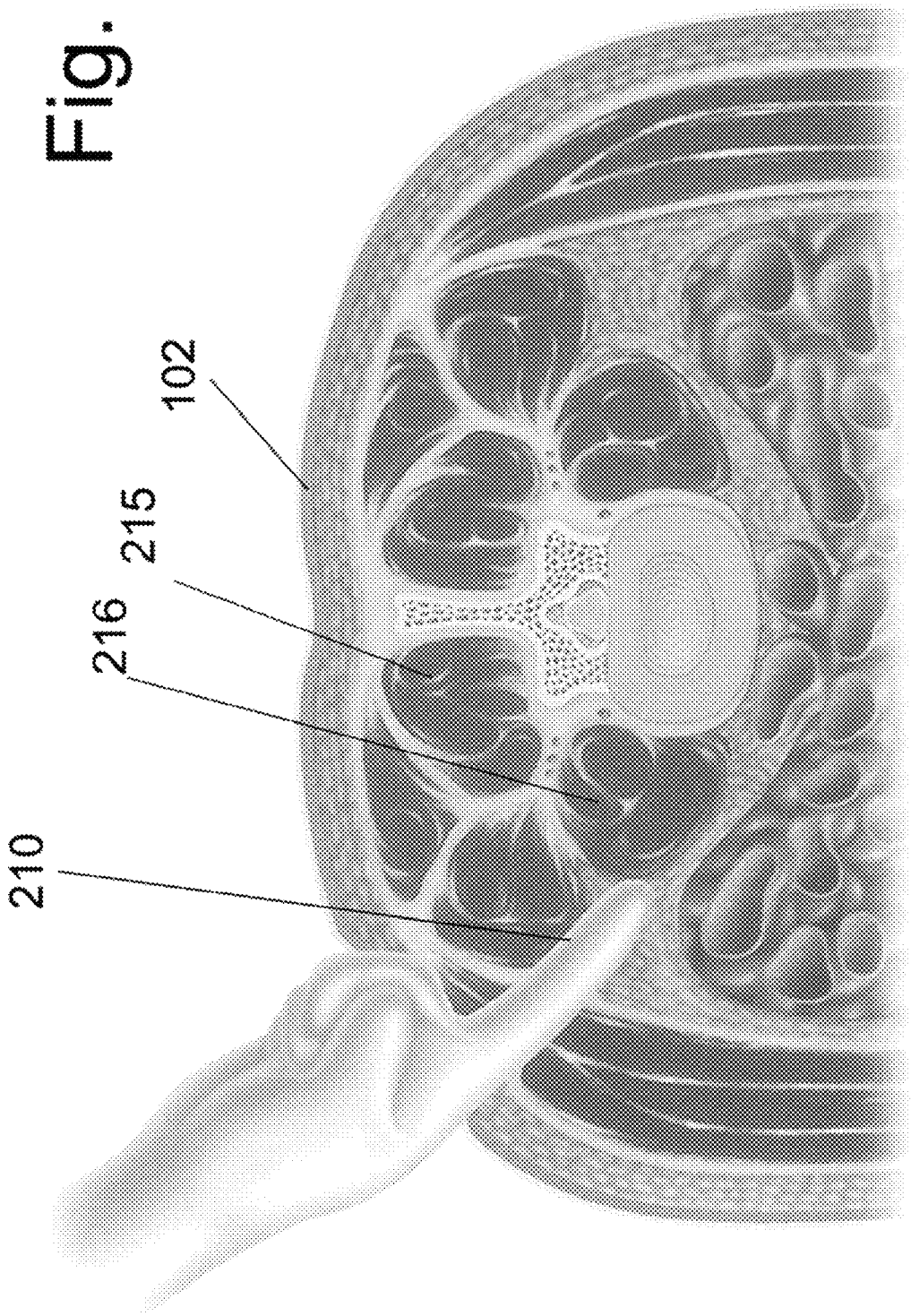
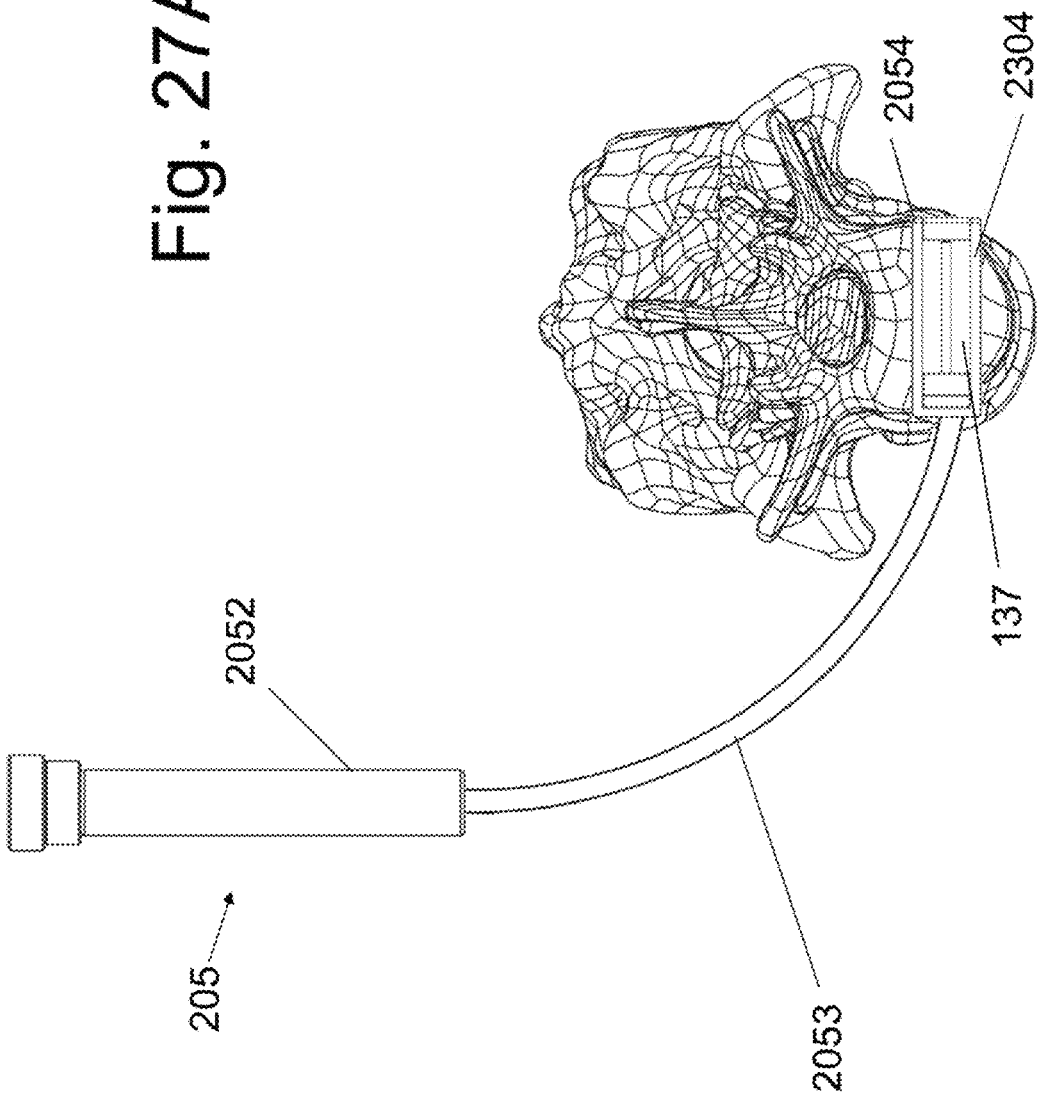


Fig. 27A



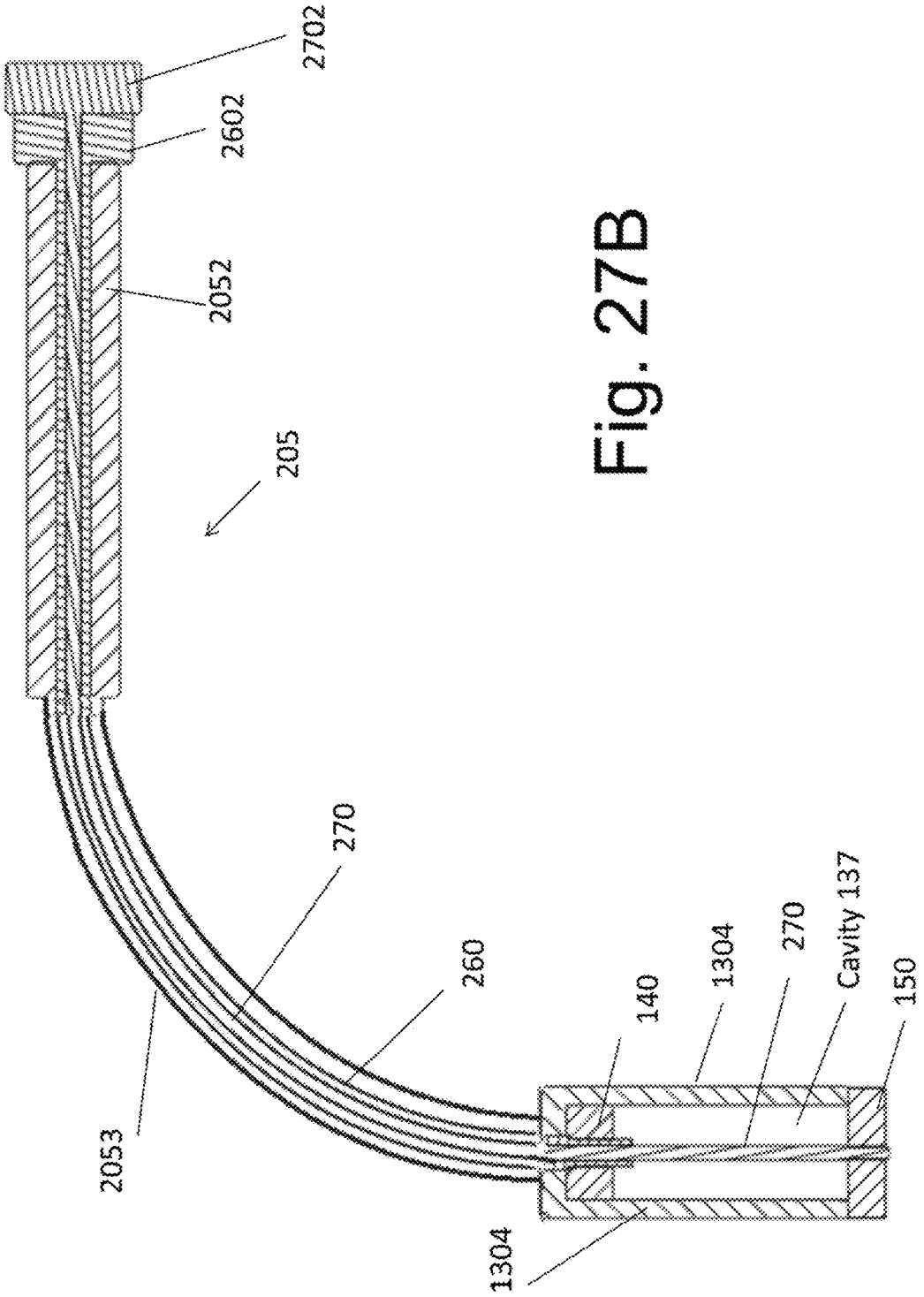

2702
2602
2052
205
270
260
2053
1304
140
1304
270
Cavity 137
150

Fig. 27B

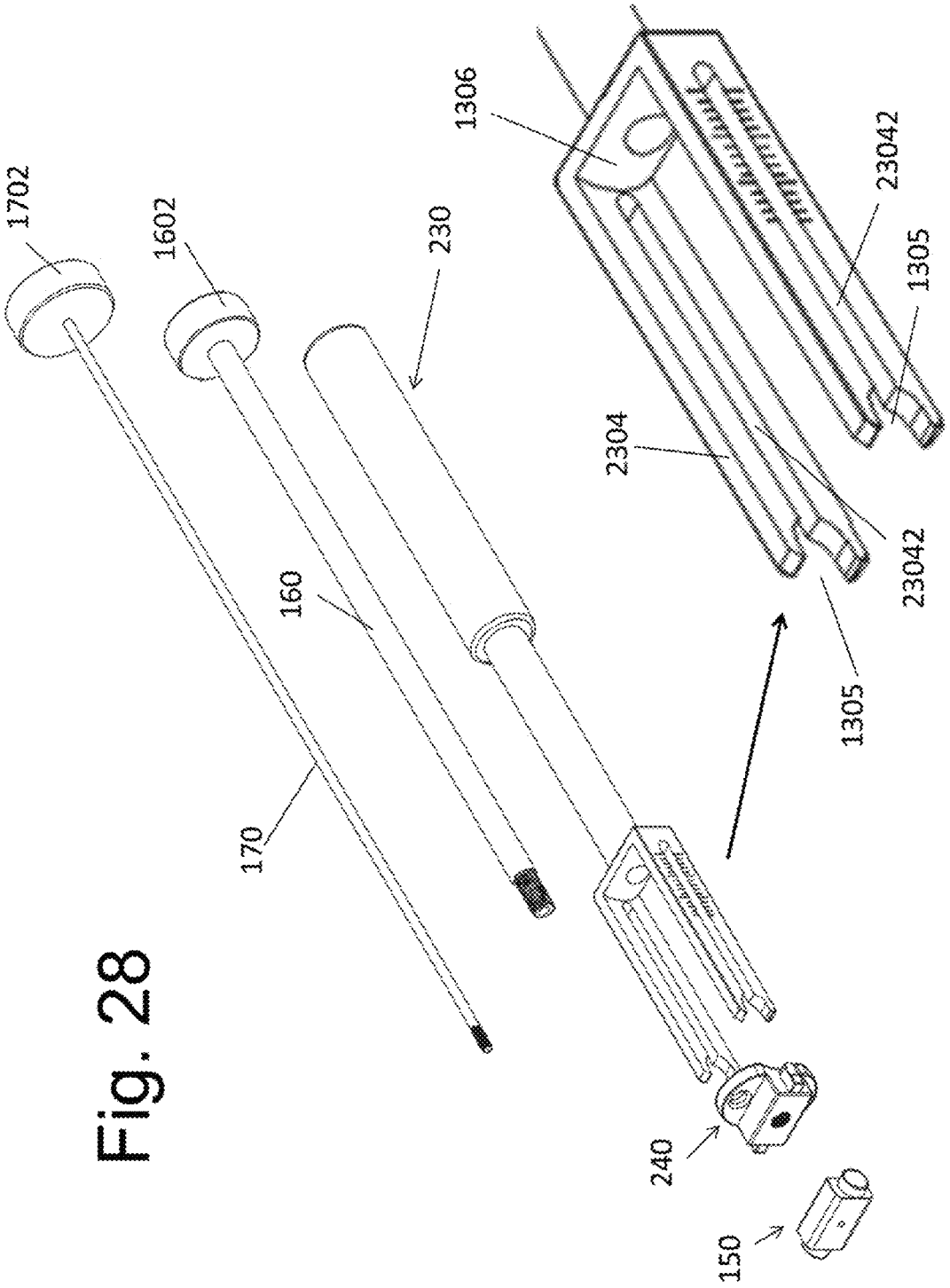
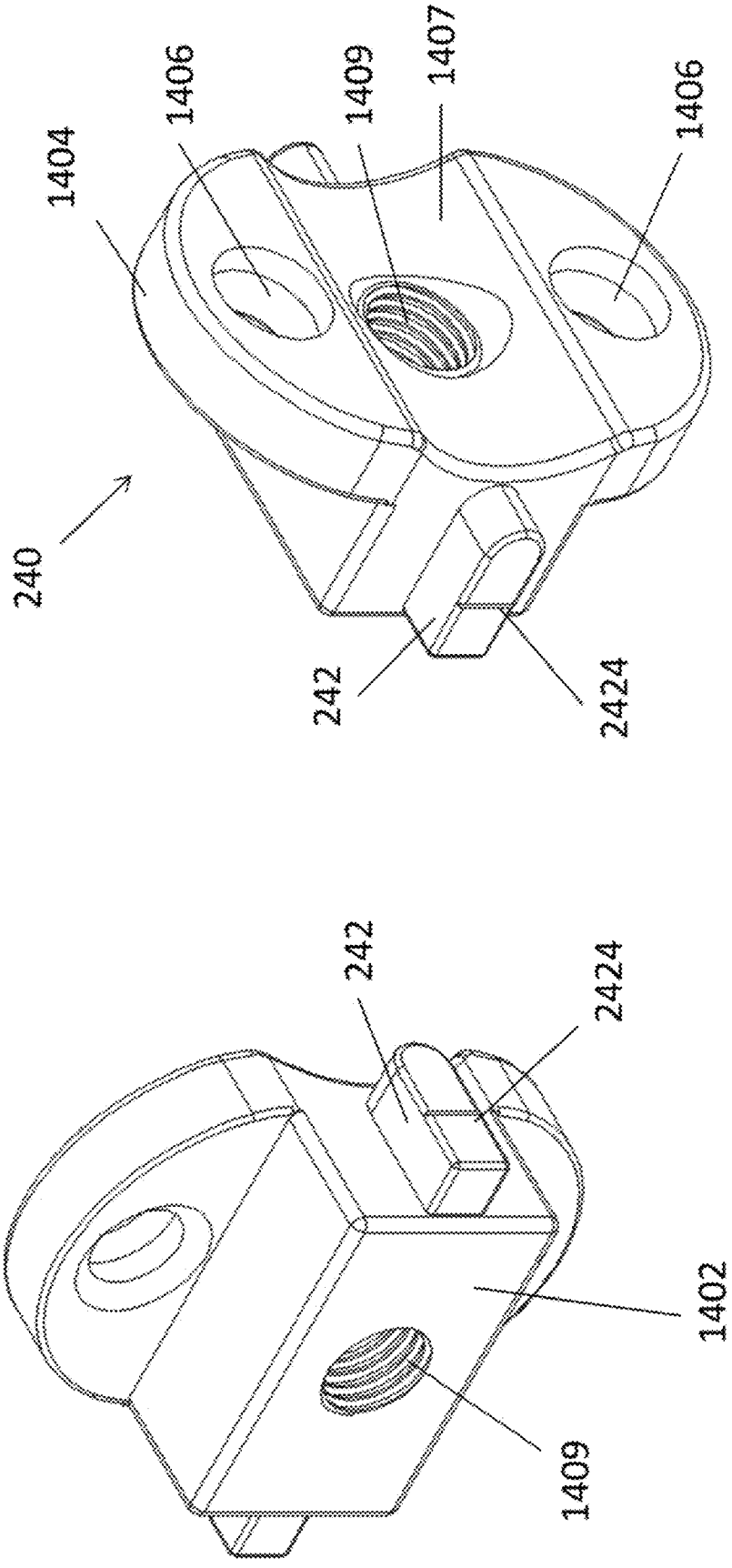


Fig. 28

Fig. 29



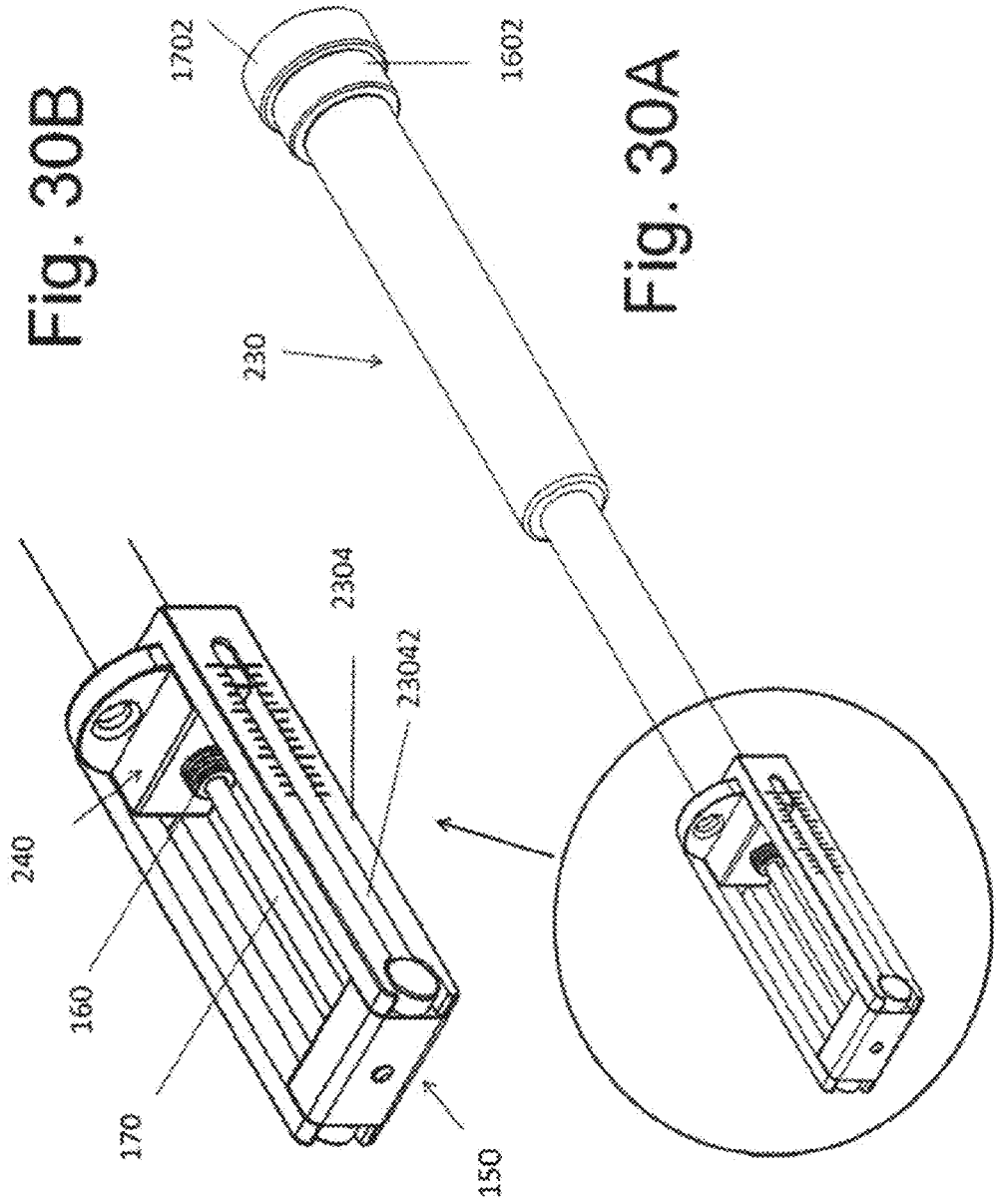


Fig. 30B

Fig. 30A

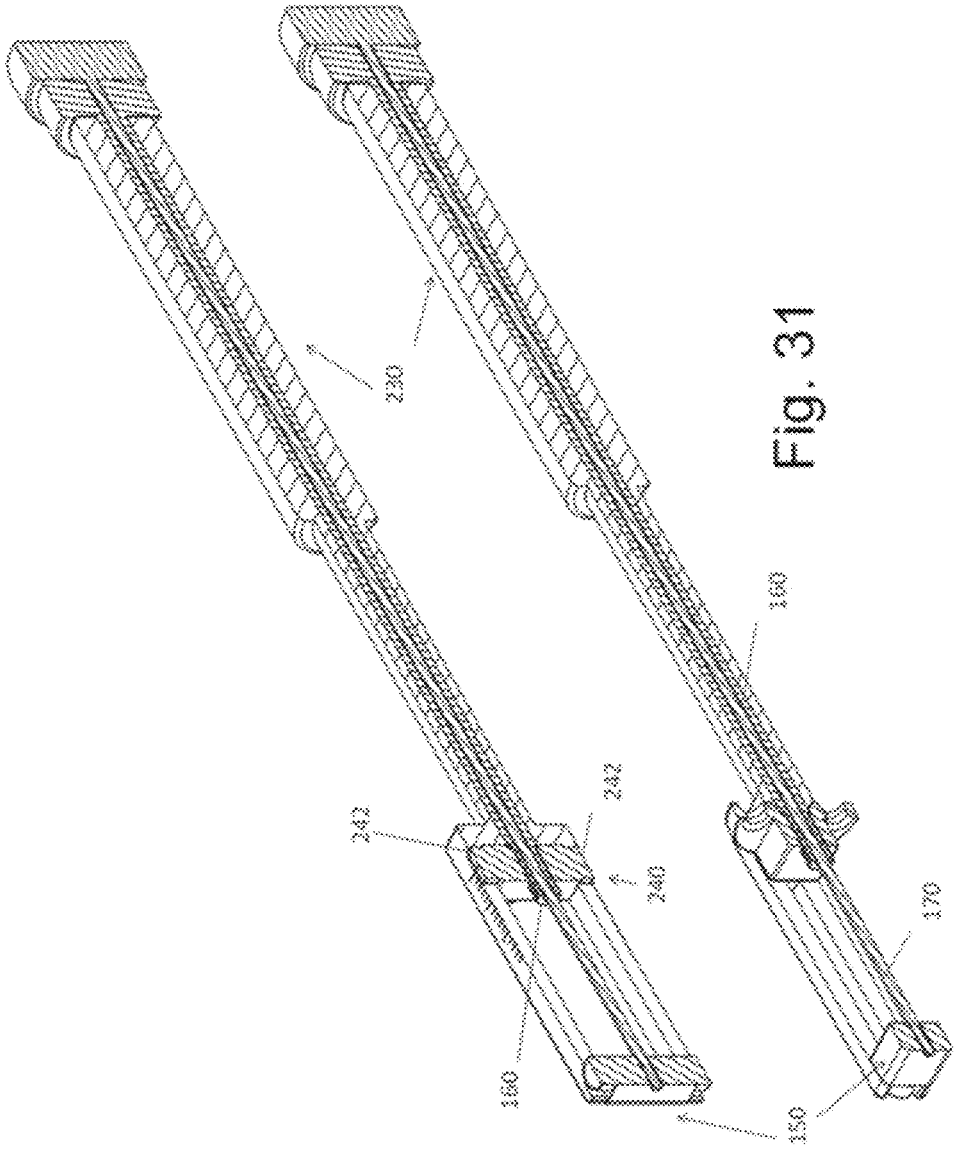


Fig. 31

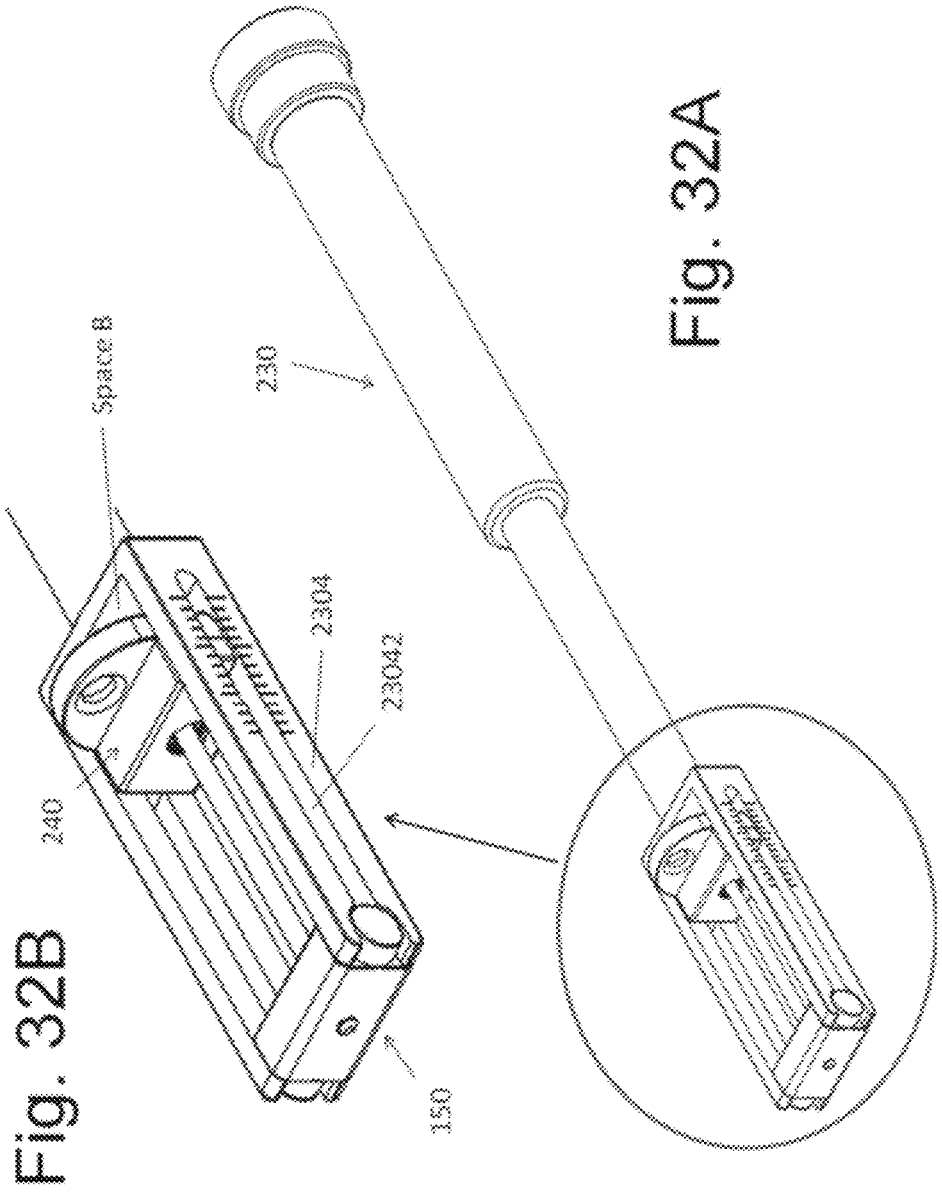


Fig. 32A

Fig. 32B

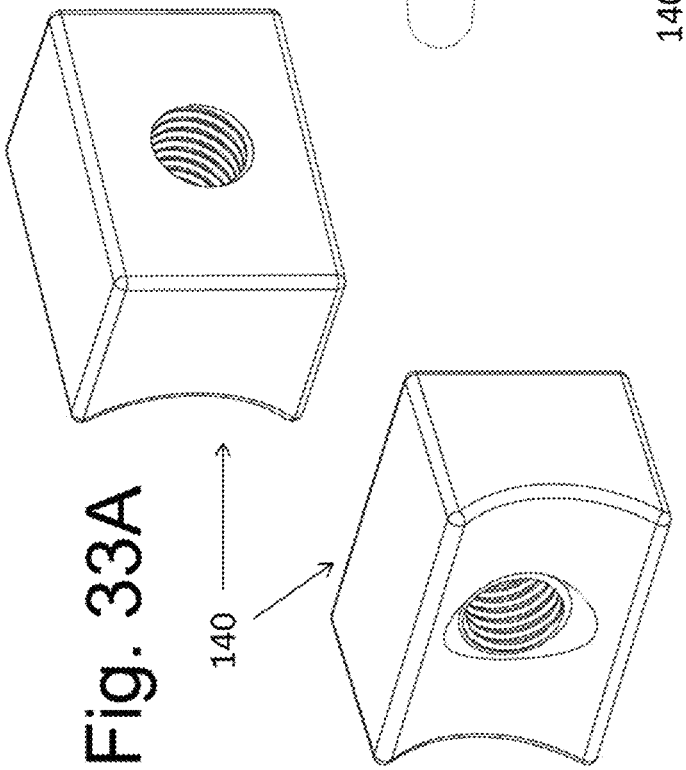


Fig. 33A

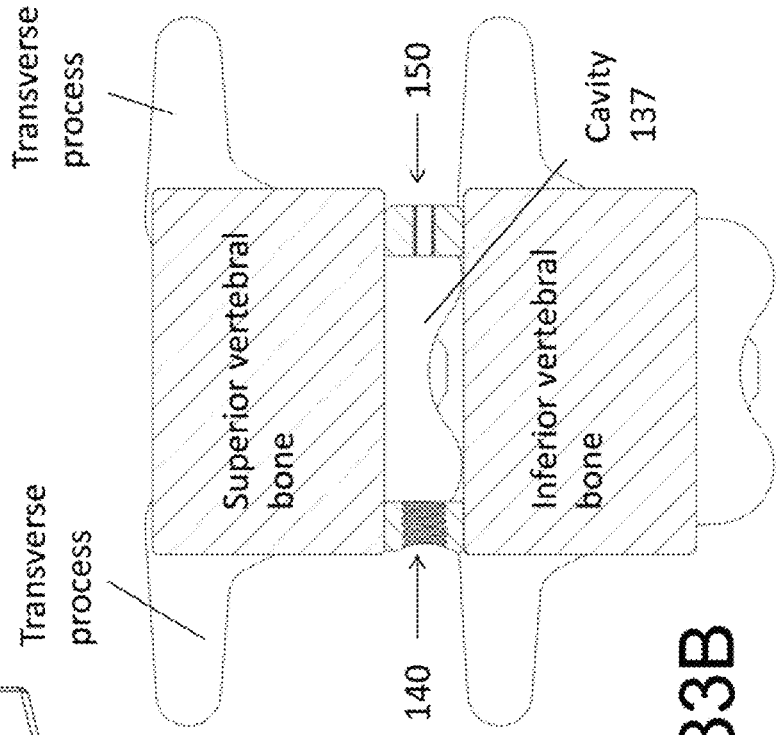


Fig. 33B

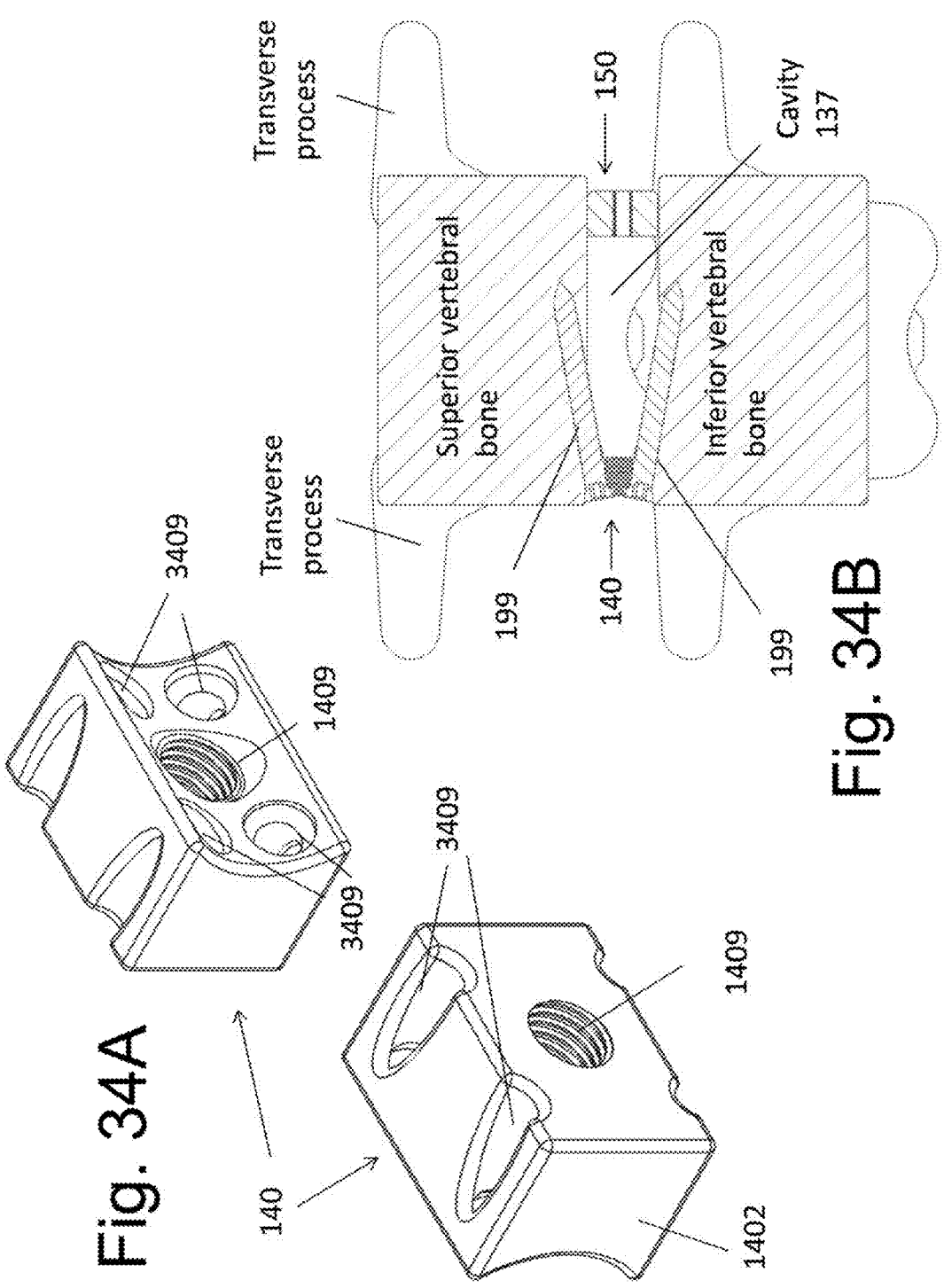


Fig. 34A

Fig. 34B

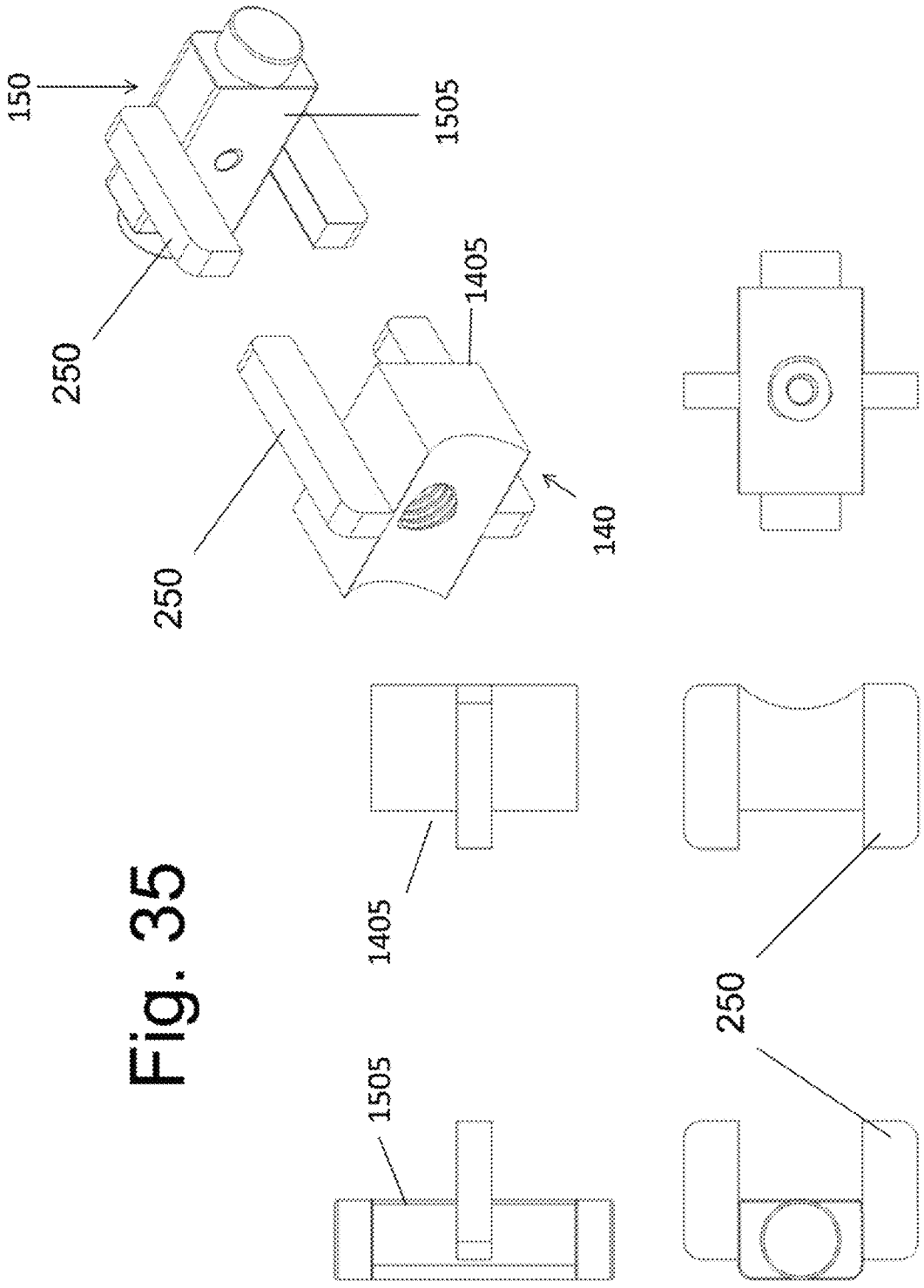


Fig. 35

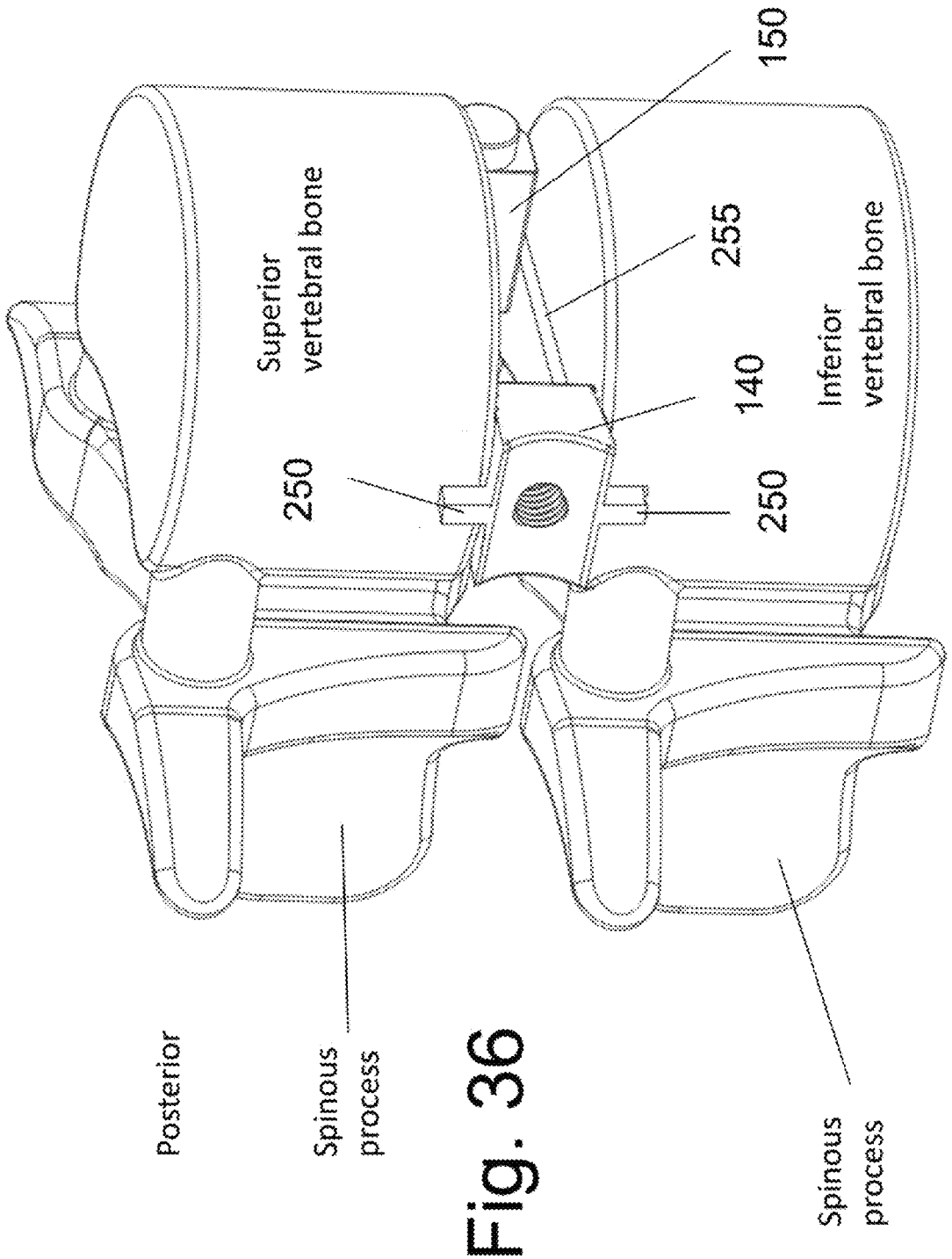

150
255
140
250
250
Superior vertebral bone
Inferior vertebral bone
Posterior
Spinous process
Spinous process

Fig. 36

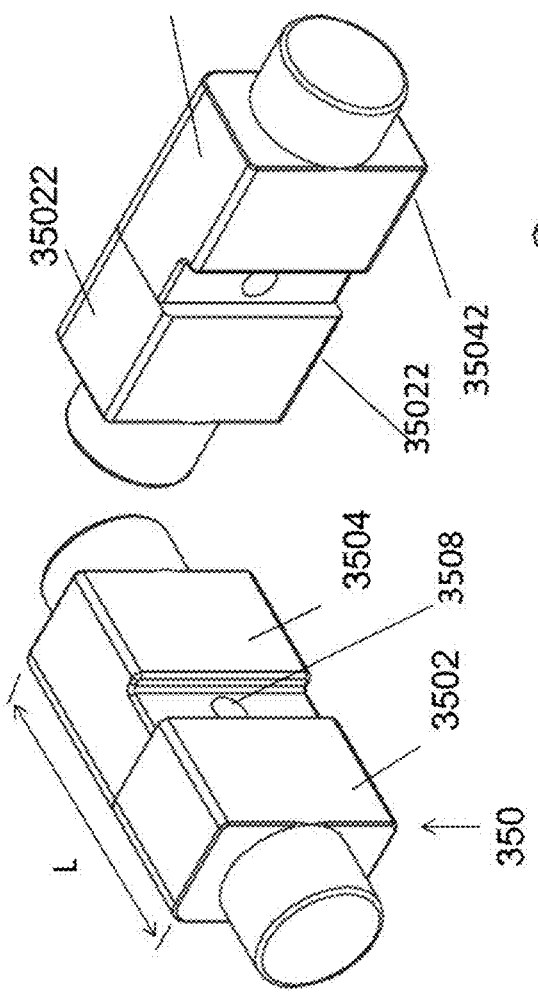


Fig. 37A

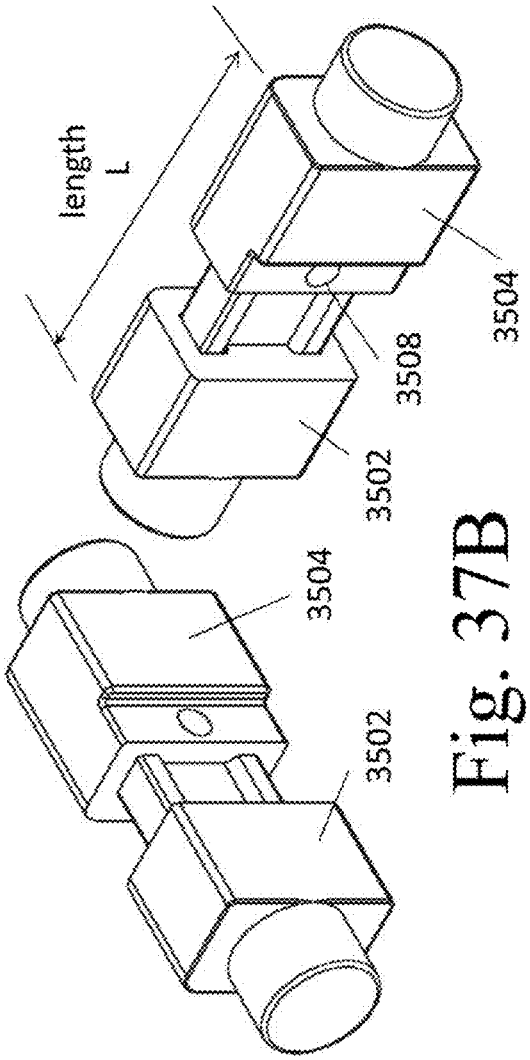
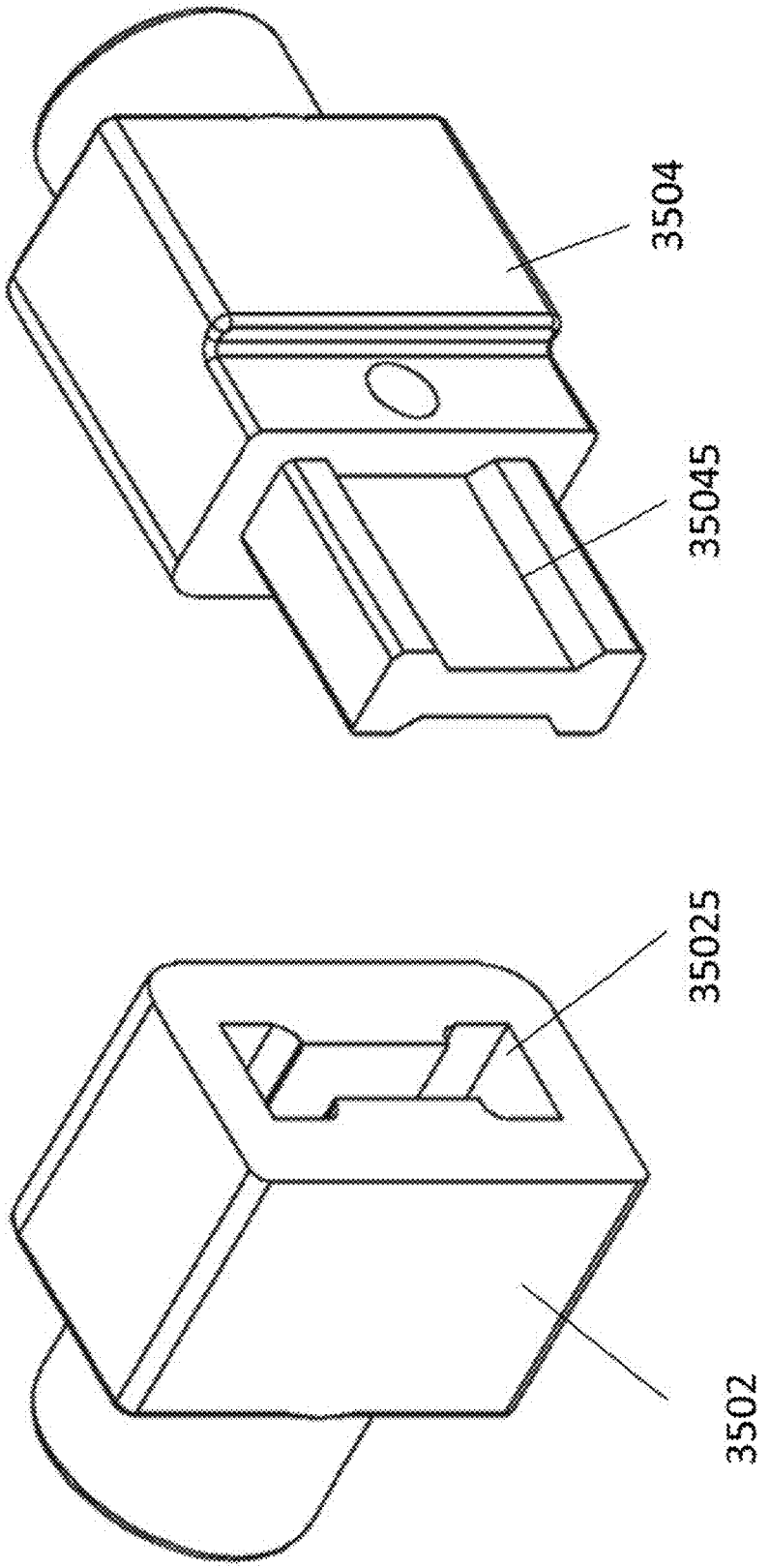


Fig. 37B

Fig. 38



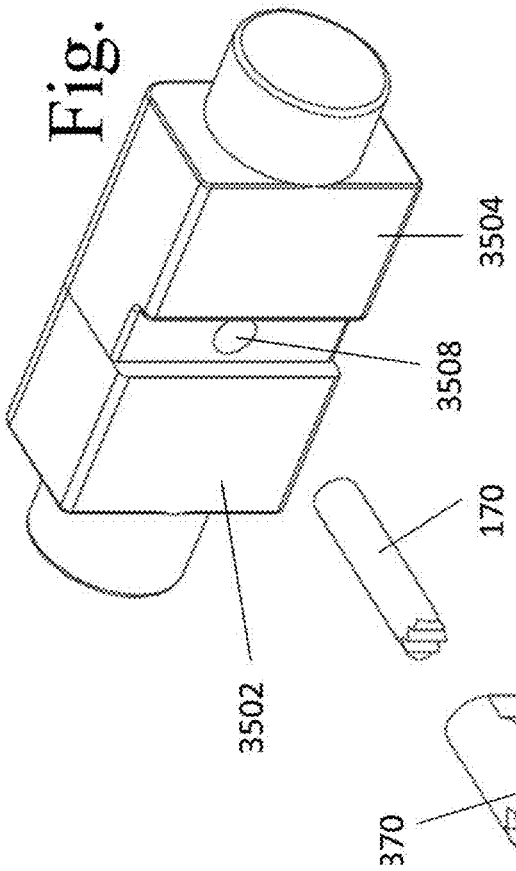


Fig. 39A

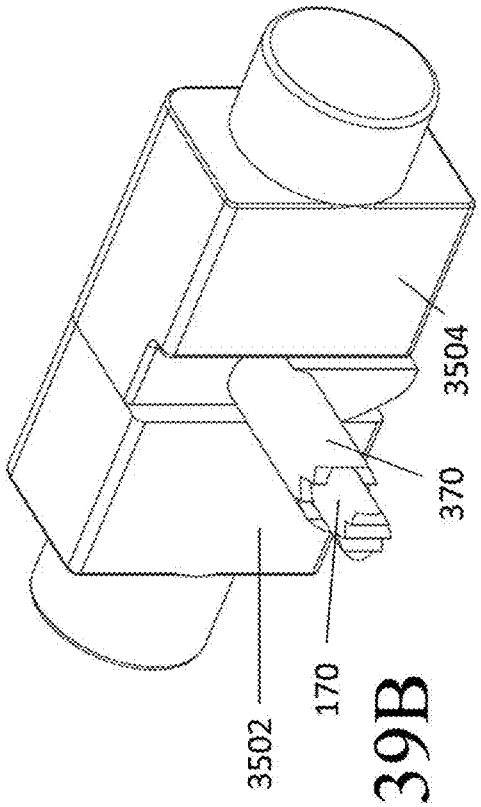


Fig. 39B

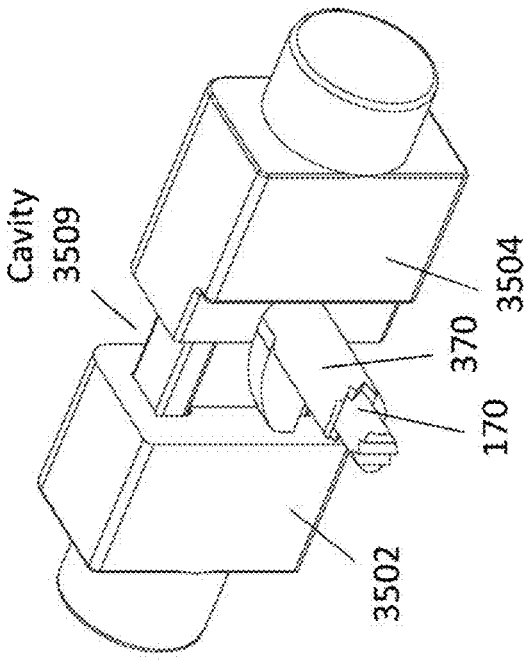


Fig. 40A

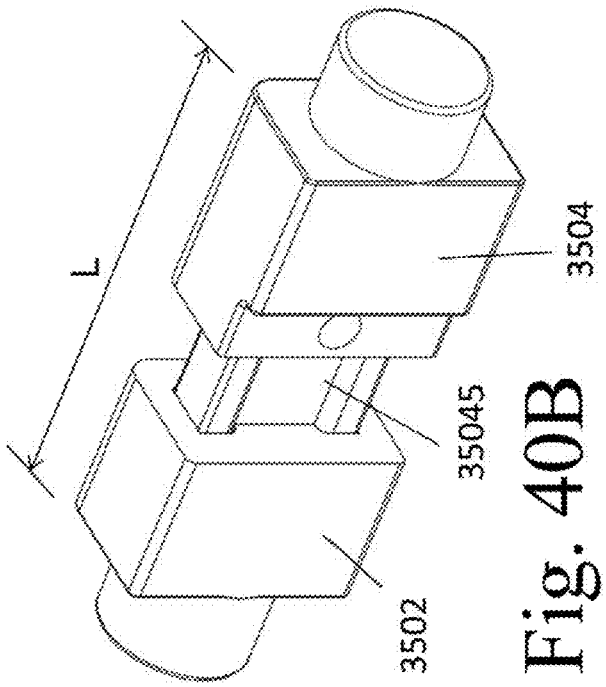


Fig. 40B

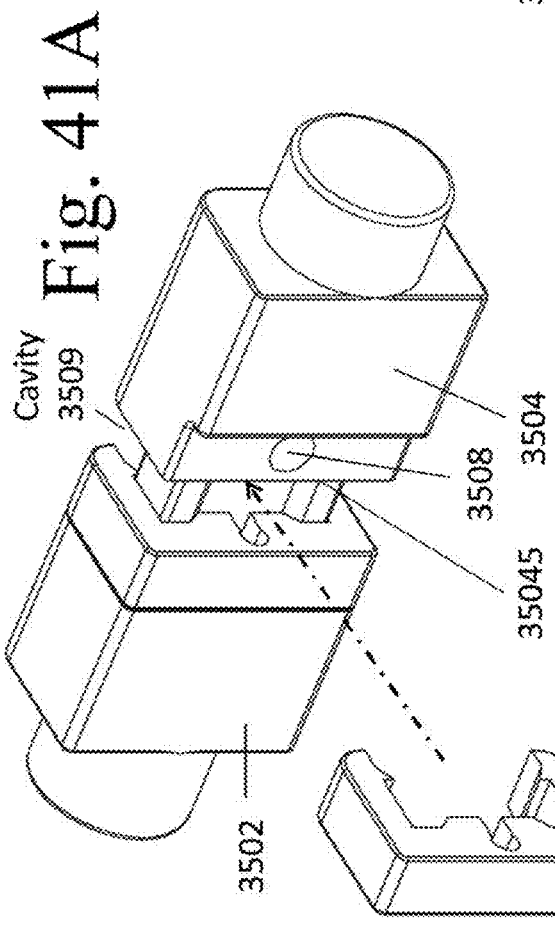


Fig. 41A

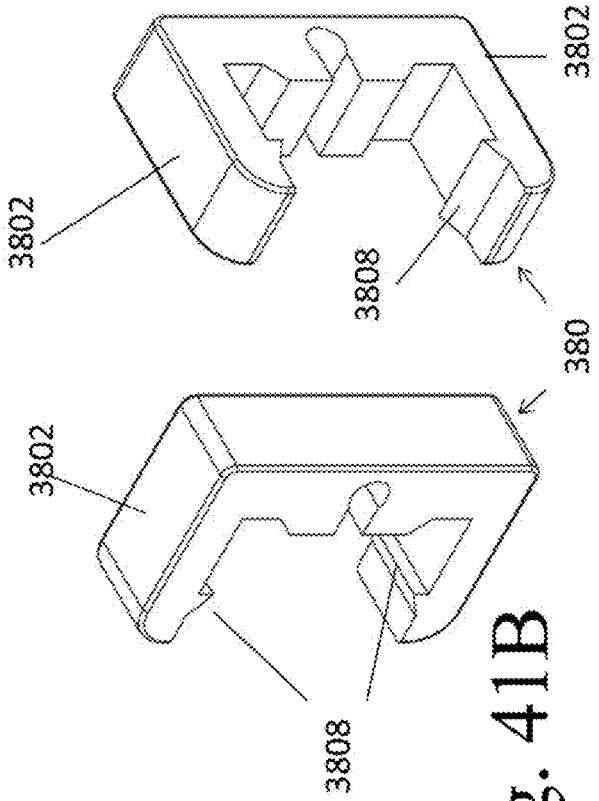


Fig. 41B

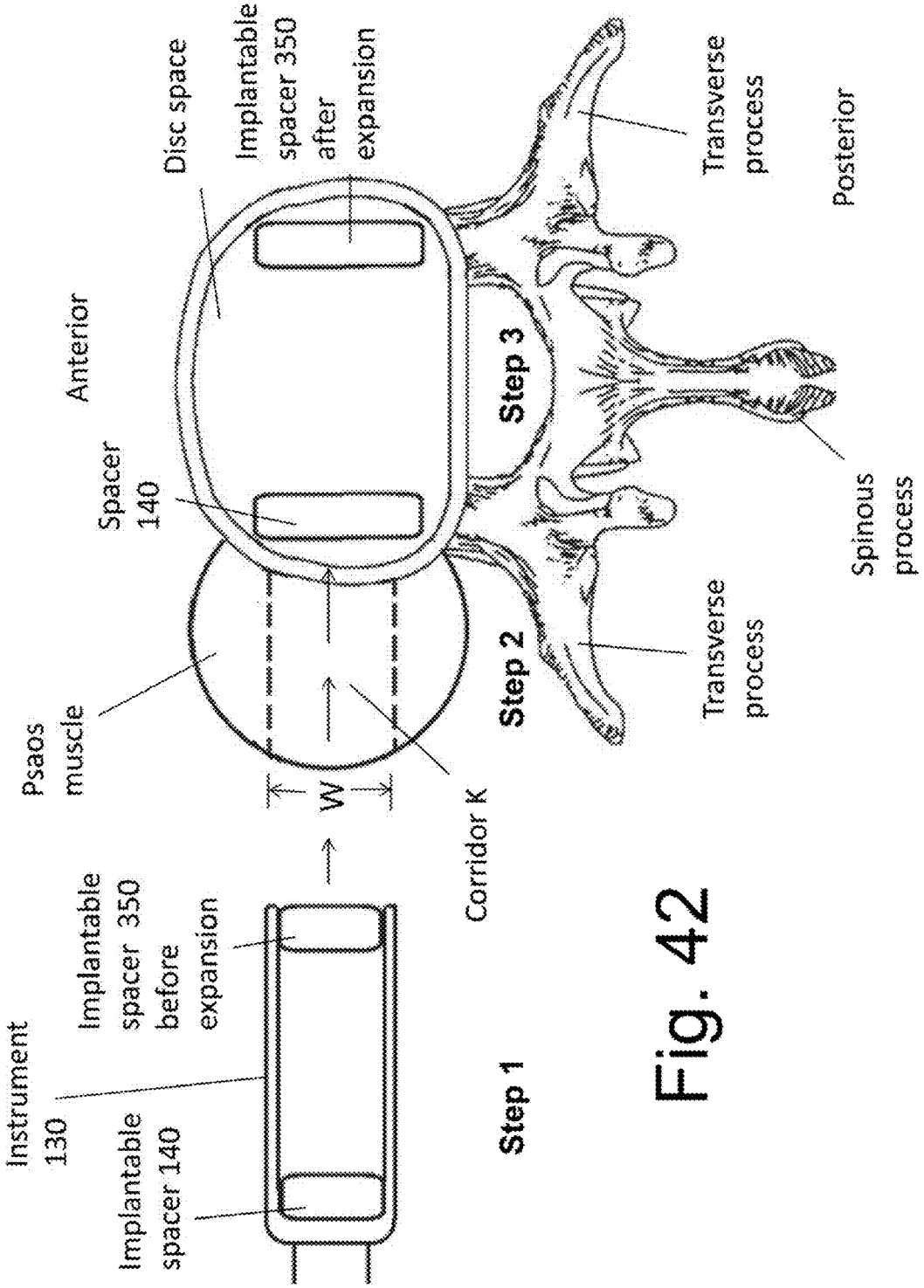

Instrument 130
Implantable spacer 140
Implantable spacer 350 before expansion
Step 1
W
Corridor K
Psaos muscle
Anterior
Spacer 140
Disc space
Implantable spacer 350 after expansion
Step 2
Step 3
Transverse process
Transverse process
Posterior
Spinous process

Fig. 42

SPINAL FIXATION DEVICES AND METHODS OF USE

RELATED APPLICATIONS

This application is a divisional of and claims priority to co-pending U.S. patent application Ser. No. 15/478,088 filed on Apr. 3, 2017 entitled "SPINAL FIXATION DEVICES AND METHODS OF USE", which is incorporated herein by reference in its entirety. U.S. patent application Ser. No. 15/478,088 is a divisional of U.S. patent application Ser. No. 15/132,095 filed on Apr. 18, 2016 and issued as U.S. Pat. No. 9,610,176 on Apr. 4, 2017, which is a divisional of and claims priority to U.S. patent application Ser. No. 14/500,815 filed on Sep. 29, 2014 and issued as U.S. Pat. No. 9,314,350 on Apr. 19, 2016, which is a continuation of and claims priority to U.S. patent application Ser. No. 13/624,792 filed on Sep. 21, 2012 and issued as U.S. Pat. No. 8,845,728 on Sep. 30, 2014, each of the same title and each also incorporated herein by reference in its entirety. U.S. patent application Ser. No. 13/624,792 claims priority to U.S. Provisional Patent Application Ser. No. 61/626,340 entitled "DEVICES AND METHODS FOR INTER-VERTEBRAL ORTHOPEDIC DEVICE PLACEMENT" by Samy Abdou and filed Sep. 23, 2011, which is additionally incorporated herein by reference in its entirety.

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BACKGROUND

1. Field of the Disclosure

The present disclosure relates generally to the field of to bone fixation systems, components thereof, and methods of implant placement used to adjust, align and maintain the spatial relationship(s) of adjacent bones or bony fragments after surgical reconstruction of skeletal segments. More particularly, the present disclosure is related in one exemplary aspect to devices that fixate the spinous processes at one vertebral level with the spinous process of another vertebra.

2. Description of Related Technology

Whether from degenerative disease, traumatic disruption, infection or neoplastic invasion, alteration in the anatomical relationships between the spinal vertebras can cause significant pain, deformity and disability. Spinal disease is a major health problem in the industrialized world and the surgical treatment of spinal pathology is an evolving discipline. The traditional surgical treatment of abnormal vertebral motion is the complete immobilization and bony fusion of the involved spinal segment and an extensive array of surgical techniques and implantable devices have been formulated to accomplish the treatment objective.

Vertebral fusion may be accomplished by using an anterior, lateral or posterior approach and each has particular advantages and draw backs. Frequently, circumferential fusion of the unstable level with fixation of both the anterior and posterior aspect of the spine is desired. This requires that patients undergo a combination of the aforementioned approaches. The anterior or lateral approaches are used to insert the bone graft and load bearing implants into the disc space between the adjacent vertebras while the posterior approach is used to place bone screws or similar fasteners that are used to immobilize the vertebral bodies.

Current implants to fuse the intervertebral disc space are usually comprised of an external superstructure that is capable of bearing the load transmitted across the implanted intervertebral disc space. An internal cavity is used to house and contain bone graft or bone graft substitute (collectively referred to as bone graft material) wherein the bone graft material is in contact with a bony surface of each of the vertebral bones that border the implanted disc space (i.e., the vertebral bones above and below the implant disc space). These devices are known in the art, see e.g. U.S. Pat. Nos. RE37,479; 4,820,305; 5,609,637; 5,749,916; 5,865,848; 5,888,224; 5,980,522; 6,071,310; 6,086,613; 6,159,244; 6,176,882; 6,206,922; 6,471,724; 6,582,431; 6,616,695, each of the foregoing being incorporated herein by reference in its entirety.

Given the large number of operative approaches and the substantial anatomical variation between vertebral levels within the same individual or across different individuals, the intervertebral disc implants must be manufactured and provided to the surgeon in a large range of sizes and configurations. This mandates that a large number of different sizes must be made and inventoried—adding to cost for manufacturer, vendor, and end user (hospitals). More importantly, the pre-manufactured devices may provide a suboptimal fit, since the surgeon must choose at the time of implantation from a series of pre-manufactured sizes and configurations that may not fit each and every patient.

SUMMARY

Disclosed herein are, inter alia, placement instruments and methods of use for implantation of spacers within an inter-vertebral disc space. In one embodiment, the load-bearing superstructure of the implant is subdivided and the bone forming material is positioned within an internal space of the placement instrument but external to the load bearing elements themselves. At least a portion of the bone graft material is freely contained within the disc space.

The disclosed exemplary devices and methods may be adapted for use in any known surgical approach to the vertebral column. By way of non-limiting example, the device and method of implantation will be illustrated in a lateral approach to the anterior column of the spinal column.

In another embodiment of this procedure, a lateral tissue corridor is used to position an implant at the lateral border of the vertebral column. The intervertebral disc space that has been targeted for implantation is entered at its lateral border.

The implant is in one embodiment comprised of at least one spacer that is used to bear at least a portion of the load transmitted through the vertebral bodies and across the disc space. The spacer in one variant does not contain a bone graft cavity. The spacer may contain at least one feature adapted to increase fixation to bone, such a bores for screw fixation, an affixed keel and/or rotatable bone fixation member.

In an embodiment, the bone graft material is contained within the placement instrument that is used to deliver the implant to the implantation site. The placement instrument

positions the bone graft material in a desired relationship to a spacer(s), wherein the latter is used to bear at least a portion of the vertical load transmitted across the implanted disc space. (The so-called "vertical load" refers to the load that would normally be transmitted across the disc space of a subject standing erectly. It is understood that the vertical load experienced by an individual disc space will vary with the level of that disc space in the vertebral column. In general, more caudal disc space levels will experience higher vertical loads than more cephalad disc space levels.) The spacer(s) and bone graft material are delivered into the disc space in the desired configuration. In another embodiment, the bone graft is positioned outside of one or more spacers that are collectively and concurrently delivered into the disc space by the placement instrument. In this embodiment, no additional bone graft material is enclosed within an internal cavity of any of the spacers.

In yet another embodiment, the bone graft material is positioned within the placement instrument both on the outside of the one or more spacers and also within a internal cavity of at least one spacer. In another embodiment, the bone graft material is positioned within the internal cavity of one or more spacers, but no additional graft material is positioned within the placement instrument and outside of the spacer(s).

After delivery of the implant assembly to the target disc space, the placement instrument is uncoupled from the implant/bone graft material and removed from the body cavity of the subject. The spacer(s) and bone graft material are left within the target disc space. In one embodiment, the implantation procedure is performed through a percutaneous or minimally invasive surgical procedure.

A method of device use is illustrated, wherein the placement device is used to place the implantable spacers at opposing ends of the disc space using a directly lateral surgical approach.

The details of one or more embodiments are set forth in the accompanying drawings and description below. Other features, objects, and advantages will be apparent from the following description, the accompanying drawings and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects will now be described in detail with reference to the following drawings. Generally speaking the figures are not to scale in absolute terms or comparatively but are intended to be illustrative. Also, relative placement of features and elements may be modified for the purpose of illustrative clarity.

FIG. **1** are a schematic representations of a vertebral bone.

FIGS. **2**A and **2**B are a schematic representations of a Functional Spinal Unit (FSU) comprised of two adjunct vertebral bones and an intervening disc space.

FIG. **3** illustrates the posterior aspect of a subject.

FIG. **4** is a schematic representation of a human torso in cross-section.

FIG. **5** illustrates an assembled embodiment of the present disclosure.

FIG. **6** illustrates section views of the disclosed instrument **130**.

FIGS. **7** and **8** are exploded and assembled views of the placement instrument **130** and the attached spacers/implants.

FIGS. **9** and **10** are perspective and orthogonal views of the device assembly.

FIGS. **11** and **11**A illustrate the implantable spacers of the present disclosure.

FIG. **12** illustrates views of the implantable spacer **150**.

FIGS. **13**A, **13**B, **14**A, and **14**B illustrate an exemplary instrument **130** configured to retain implantable spacers **140** at a variable distance relative to the spacer **150**.

FIGS. **15**, **16**, and **17**A show a Functional Spinal Unit (FSU) before and after implantation.

FIG. **17**B illustrates a top surface of a vertebral bone and the epiphyseal ring.

FIG. **18** is a cross sectional view of the implanted FSU with the instrument **130** in place.

FIGS. **19**A and **19**B illustrate the implantable spacers **140** and **150** after removal of the instrument **130**.

FIG. **20** illustrates an alternative screw trajectory in the placement of a larger tissue dilator over the tissue dilator of FIG. **19**B.

FIGS. **21**A and **21**B illustrate a change in vertebral alignment in the coronal and/or sagittal planes from placement of implantable spacers of varying sizes.

FIGS. **22**A and **22**B illustrate the implantable spacers **140** and **150** after removal of the disclosed instrument **130**.

FIGS. **23**, **24** and **25** illustrate the screw locking member **190** in perspective views and after attachment to the implantable spacer **140**.

FIGS. **26** and **27**A illustrate the use of a curvilinear embodiment of the present disclosure.

FIG. **27**B illustrates a cross section view of the curvilinear embodiment.

FIG. **28** illustrates an exploded view of an alternative device embodiment, wherein a placement instrument **230** is used.

FIG. **29** illustrates an alternative implantable spacer **240**.

FIGS. **30**A and **30**B illustrate the assembly comprising the instrument **230** and the implantable spacer **240**.

FIG. **31** illustrates sectional views of the assembly of FIG. **29**.

FIGS. **32**A and **32**B illustrate an exemplary instrument **230** configured to retain the implantable spacers **240** at a variable distance relative to the spacer **150**; the distance between the implantable spacers can be read directly from the instrument **230**.

FIGS. **33**A, **33**B, **34**A, and **34**B illustrate alternative embodiments of the implantable spacer **140**.

FIGS. **35** and **36** illustrate an additional embodiment of the implantable spacers.

FIGS. **37**A and **37**B illustrate an exemplary implantable spacer **350** in an expanded and non-expanded configuration.

FIG. **38** illustrates a protrusion **35045** of segment **3504** and the complimentary bore **35025** of segment **3502**.

FIGS. **39**A and **39**B illustrate an exemplary screw **170** which is configure to compliment the bore **3508**.

FIG. **40**A illustrates exemplary rotation of the expander **370** relative to the spacer **350** to increase the length L of the implant **350**.

FIG. **40**B illustrates the expanded implant **350** after removal of screw **170** and expander **370**.

FIG. **41**A illustrates an exemplary segment **380** coupled to an expanded spacer **350** and a second exemplary segment **380** positioned to be advanced into cavity **3509**.

FIG. **41**B illustrates an exemplary segment **380**,

FIG. **42** illustrates an exemplary procedure for using the instrument **130** to attach the implantable spacer **350** prior to expansion.

DETAILED DESCRIPTION

In order to promote an understanding of the principles of the disclosure, reference is made to the drawings and the

embodiments illustrated therein. Nevertheless, it will be understood that the drawings are illustrative and no limitation of the scope of the claims is thereby intended. Any such alterations and further modifications in the illustrated embodiments, and any such further applications of the principles of the disclosed devices as illustrated herein are contemplated as would normally occur to one of ordinary skill in the art.

Detailed Description of Exemplary Embodiments

FIG. **1** is a diagrammatic representation of a spinal vertebral bone **802** in multiple views. For clarity of illustration, the vertebral bone of FIG. **1** and those of other illustrations presented in this application are represented schematically, and those skilled in the art will appreciate that actual vertebral bodies may include anatomical details that are not shown in these figures.

Further, it is understood that the vertebral bones at a given level of the spinal column of a human or animal subject will contain anatomical features that may not be present at other levels of the same spinal column. The illustrated vertebral bones are intended to generically represent vertebral bones at any spinal level without limitation. Thus, the disclosed devices and methods may be applied at any applicable spinal level.

Vertebral bone **802** contains an anteriorly-placed vertebral body **804**, a centrally placed spinal canal and **806** and posteriorly-placed lamina **808**. The pedicle (**810**) segments of vertebral bone **802** form the lateral aspect of the spinal canal and connect the laminas **808** to the vertebral body **804**. The spinal canal contains neural structures such as the spinal cord and/or nerves. A midline protrusion termed the spinous process (SP) extends posteriorly from the medial aspect of laminas **808**. A protrusion extends laterally from each side of the posterior aspect of the vertebral bone and is termed the transverse process (TP). A right transverse process (RTP) extends to the right and a left transverse process (LTP) extends to the left. A superior protrusion extends superiorly above the lamina on each side of the vertebral midline and is termed the superior articulating process (SAP). An inferior protrusion extends inferiorly below the lamina on each side of the vertebral midline and is termed the inferior articulating process (IAP). Note that the posterior aspect of the pedicle can be accessed at an indentation **811** in the vertebral bone between the lateral aspect of the SAP and the medial aspect of the transverse process (TP). In surgery, it is common practice to anchor a bone fastener into the pedicle portion of a vertebral bone by inserting the fastener through indentation **811** and into the underlying pedicle.

FIGS. **2**A and **2**B illustrate a functional spinal unit (FSU), which includes two adjacent vertebrae and the intervertebral disc between them. The intervertebral disc resides between the inferior surface of the upper vertebral body and the superior surface of the lower vertebral body. (Note that a space is shown in FIGS. **2**A and **2**B where intervertebral disc would reside.) FIG. **2**A shows the posterior surface of the adjacent vertebrae and the articulations between them while FIG. **2**B shows an oblique view. Note that the FSU contains a three joint complex between the two vertebral bones, with the intervertebral disc comprising the anterior joint. The posterior joints include a facet joint **814** on each side of the midline, wherein the facet joint contains the articulation between the IAP of the superior vertebral bone and the SAP of the inferior bone.

The preceding illustrations and definitions of anatomical structures are known to those of ordinary skill in the art. They are described in more detail in *Atlas of Human Anatomy*, by Frank Netter, third edition, Icon Learning Systems, Teterboro, N.J. The text is hereby incorporated by reference in its entirety.

In one aspect of the present disclosure, instruments and methods that permit a surgeon to position an implant assembly within an intervertebral disc space are provided. In an embodiment, the bone graft material is contained within the placement instrument that is used to deliver the implant to the implantation site. The placement instrument positions the bone graft material in a desired relationship to a spacer (s), wherein the latter is used to bear at least a portion of the vertical load transmitted across the implanted disc space. (The vertical load refers to the load that would normally be transmitted across the disc space of a subject standing erectly. It is understood that the vertical load experienced by an individual disc space will vary with the level of that disc space in the vertebral column. In general, more caudal disc space levels will experience higher vertical loads than more cephalad disc space levels.) The spacer(s) and bone graft material are delivered into the disc space in the desired configuration.

In one embodiment, the bone graft is positioned outside of one or more spacers that are collectively and concurrently delivered into the disc space by the placement instrument. In this embodiment, no additional bone graft material is enclosed within an internal cavity of any of the spacers. In another embodiment, the bone graft material is positioned within the placement instrument both on the outside of the one or more spacers and also within a internal cavity of at least one spacer.

In yet another embodiment, the bone graft material is positioned within the internal cavity of one or more spacers, but no additional graft material is positioned within the placement instrument and outside of the spacer(s).

While the device and the procedure are illustrated using a lateral procedure to position the implant assembly into the disc space of the lumbar spine, it is understood that the device may be used to position a implant assembly into the disc space at any level and using any approach to the spinal column.

In preparation for percutaneous placement of the implant into a spinal level, the patient can be, but is not necessarily, placed in a prone or lateral decubitus position. The level of the spine that is to be implanted can be localized on X-ray in at least one plane. After the customary sterile preparation of the operative site, the surgeon can localize an incision point on the skin that is substantially directly lateral to the spinal segment that will be implanted. FIG. **3** shows a schematic representation of the posterior aspect of a subject. The skin overlying the back is shown. The midline is labeled and approximates the mid-sagittal plane of the vertebral column. Lines Y show the lateral extent of the transverse processes of the spinal column. Assuming that the spinal level to be accessed is at line Z, the surgeon can make an incision at or about circle X.

FIG. **4** illustrates a cross sectional view of the torso (positioned prone) at the level of the lumbar spine. For clarity of illustration, the contents are represented schematically and those skilled in the art will appreciate that an actual cross section of the human torso may include anatomical details not shown in FIG. **4**. A lateral corridor **105** can be made from the flank, through the psoas muscle **106** and onto the lateral aspect of the disc space at the spinal level to be implanted. An implant can be placed through the corridor **105** and into disc space or onto the spine. The procedure is known to those skilled in the art and known by differing

names, such as the "XLIF" procedure (see "Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion." By Ozgur, Aryan et al. in *Spine J.* 2006 July-August; 6(4):435-43, which is hereby incorporated by reference in its entirety.) Variations of the operation are also known as Direct Lateral Interbody Fusion (DLIF) and the like.

An instrument (not shown) is passed through corridor **105** and onto the lateral aspect of the psoas muscle **106**. The instrument is advanced through the muscle and into the disc space. Since important nerve structures may transverse the psoas muscle, the instrument (and/or a probe or device placed through a channel of the instrument) is connected to an Electromyography (EMG) apparatus (or any other electrical system that is used to localize nerve tissue), and used, at least partially, as an EMG probe during advancement through the muscle. In this way, the advancement of the instrument through the psoas muscle is performed under EMG guidance. Under X-ray visualization, the instrument is placed into the disc space. At least a portion of the disc material is removed from within the disc space through the established corridor. After the discectomy is performed and the bony end plates have been decorticated and prepared, at least one spacer and bone graft material (and/or bone graft substitute) is placed within the evacuated portion of the disc space. With time, the graft material will form a bony bridge between the two vertebral bodies and fuse them. As described, the procedure is performed in a percutaneous manner and under x-ray. A wider incision may be employed and portions of the procedure, such as the discectomy, may be performed under direct vision and using minimally invasive surgical technique.

Instrument **130** is used to position at least one spacer into the partially evacuated disc space. (The implantation is preferably, but not necessarily, performed in a percutaneous manner.) The implanted spacer functions to bear at least a portion of the load transmitted through the disc space. Instrument **130** also places the bone graft or bone graft substitute (collectively called bone graft material) into the disc space. The bone graft material is delivered in prescribed spatial relationship to the spacer(s). In the illustrated embodiment, the spacer(s) will not contain an internal cavity configured to house a bone graft material. However, it is understood that one or more of the implanted spacers may alternatively comprise an internal cavity configured to house bone graft material, wherein the house bone graft material is in communication with each of the vertebral bones that border the implanted disc space.

An embodiment of instrument **130** is shown in FIGS. **5** and **6**. Instrument **130** has handle **1302**, side members **1304** and an indentation **1305** at one end of each side member **1304**. Surface **1306** is positioned between side members **1304**. A bore **1308** transverses handle **1302**.

FIG. **7** shows instrument **130** and two spacer implants in the disassembled state while FIG. **8** shows the assembled device. Spacers (alternatively labeled "implant") **140** and **150** are attached to instrument **130** using screws **160** and **170**, respectively. The assembly is shown in three planes in FIG. **9**. Sectional views are shown in FIG. **10**. Spacer **140** is shown in FIG. **11** while spacer **150** is illustrated in FIG. **12**. Preferably, but not necessarily, each spacer does not have a medial to lateral dimension that is greater than one half of the medial to lateral dimension of the implanted disc space. That is, each of width A of spacer **140** (FIG. **11**A) and width B of spacer **150** (FIG. **12**) is less than on half of the value of the width W of the implanted disc space (the width of the disc space is the maximum disc space dimension in the coronal plane of the spine—as shown in FIG. **21**B).

Implantable spacer **140** has central body **1402** that is inserted into the disc space and maintains the distance between the adjacent bodies and the height of the disc space. Body **1402** may be comprised of any material that is adapted for biological implantation, including a segment of bone (allograft or autograft that is harvested and shaped at the same operation) that is affixed onto a side plate member (as shown in FIG. **11**A). In one variant, the upper and/or lower surfaces **14022** of body **1402** contain surface protrusions or textures (not shown) that increase fixation of these surfaces onto the abutting bone.

A side member **1404** is adapted to be positioned onto the side of each of the vertebral bodies. At least one bore **1406** is positioned within at least one side member **1404** and permits placement of bone screw into the side of at least one vertebral body. The surface (**14042**) that abuts the side surface of the vertebral bone may have one or more protrusions (not shown), such as, for example, spike, that penetrate and fixate into said bone. Spikes adapted for bone fixation are well known in the art and are shown in US 2004/0162558 and others. (The citation is hereby incorporated by reference in its entirety). A curvilinear surface **1407** permits interaction of the spacer **140** with curvilinear surface **1306** of instrument **130**. A threaded bore hole **1409** is contained within central body **1402** of spacer **140** and, in assembly with instrument **130**, accepts the threaded end of screw **160**.

While each of end height K and end height L of body **1402** (FIG. **11**) is shown as being of equal length, it is contemplated that each of heights K and L may alternatively be different. In this may, the implant may be used, for example to impart a greater height to the anterior disc space than the posterior disc space and impart a lordotic curvature onto the implanted FSU segment (FIG. **21**A—in sagittal view). It is further contemplated that spacer **140** may be alternatively comprised of a substantially solid member (for example, a rectangular or trapezoid member that is similar to body **1402**) without any side members **1404** that extend onto the side of vertebral bones.

Implantable spacer **150** has central body **1502** that is inserted into the disc space and maintains the distance between the adjacent bodies and the height of the disc space. Body **1502** may be comprised of any material that is adapted for biological implantation, including being at least partially comprised of a segment of bone (whether allograft or autograft). The upper and/or lower surfaces **15022** of body **1502** may contain surface protrusions or textures (not shown) that increase fixation of these surfaces onto the abutting bone. At least one side member **1504** is adapted to interact with indentation **1305** at one end of each side member **1304** of instrument **130**. A threaded bore hole **1508** is contained within central body **1502** of spacer **150** and, in assembly with instrument **130**, accepts the threaded end of screw **170**.

While each of end height K and end height L of body **1502** (FIG. **12**) is shown as being of equal length, it is contemplated that each of heights K and L may alternatively be different. In this way, the implant may be used, for example to impart a greater height to the anterior disc space than the posterior disc space and impart a lordotic curvature onto the implanted FSU segment (FIG. **21**A—in sagittal view). Further, the heights of bodies **1402** and **1502** may be different so as to change the vertebral alignment in the coronal plane of the spine—such as, for example, in scoliosis. The latter is illustrated in FIG. **21**B illustrates a coronal plane section of

the vertebral bones that surround an implanted disc space. Note the coronal plane curvature created by the different sized implants **140** and **150**.

FIGS. **13** and **14** illustrate how instrument **130** may be used to position implants **140** and **150** into the target disc space with a variable distance between them. FIGS. **9**, **10**, **13**A and **14**A illustrate implant **140** attached to screw **160** and threadedly attached with surface **1407** abutting surface **1306** of instrument **130**. Note that the end segment **1602** of screw **160** is positioned between the end of instrument **130** and end **1702** of screw **170**. With rotation of end **1602** in a first direction, implant **140** will be displaced towards implant **150** by the threads of screw **160**. With rotation of end **1602** in an opposite direction, implant **140** will be moved away from implant **150** until surface **1407** abuts surface **1306** of instrument **130**. In this way, instrument **130** may be used to position implants **140** and **150** into the target disc space with a variable distance between them. FIGS. **13**B and **14**B illustrate implant **140** having been displaced towards implant **150**. Note that space A is now positioned between implant **140** and surface **1306** on instrument **130**.

Method of Use

Patient positioning, incision placement, the surgical corridor used, and traversal of the psoas muscle (including under electrophysiological monitoring (EMG) and the like) were described above and will not be repeated herein.

FIG. **15** shows a diagrammatic representation of two vertebral bodies and an intervening disc space in multiple views. For clarity of illustration, the vertebral bodies are represented schematically and those skilled in the art will appreciate that actual vertebral bodies include anatomical details not shown in FIG. **15**. As mentioned, at least a partial removal of the disc material is performed before implantation of the spacers **140** and **150** and bone graft material between them. The area of disc space that is evacuated of disc material may be slightly larger than the distance between the outer surfaces of side members **1304** of instrument **130**. FIG. **16** illustrates the assembly of FIG. **9** (comprised of instrument **130**, spacer **140**, spacer **150**, screw **160** and screw **170**) inserted into the disc space between two vertebral bodies using a lateral approach (corridor **105**, FIG. **4**). Before insertion, a bone graft material is placed within cavity **137** that is contained between side members **1304**, spacer **140**, and spacer **150** in the assembled device. The bone graft material is at least partially delivered into the disc space while in cavity **137**. In one embodiment, the bone graft material is contained with a cavity of those members that will be left implanted in the disc space. The graft material is contained in a cavity of the placement instrument and the instrument, upon removal from the disc space, leaves the graft material freely positioned within the disc space and in between spacer **140** and **150** (see FIGS. **19**A and B). That is, in one embodiment, the bone graft material is not contained within an internal cavity of the implanted spacers themselves. FIG. **17**A illustrates the insertion in multiple orthogonal planes.

In one exemplary embodiment, the width of the disc space is first measured. The width of the disc space, W (FIG. **22**B), is equal to the greatest distance from a lateral side surface to an opposing lateral side surface of the target disc space when measured in a coronal plane of the disc space. The placement instrument is the selected so that the lateral length, L (FIGS. **6** and **9**), from surface **1306** to the end is substantially equal to the width, W, of the disc space. In this way, when spacers **140** and **150** are affixed to the instrument **130**, the total distance from the outside surface of spacer **140** to the outside surface of spacer **150** is substantially equal to the width, W, of the disc space. It is appreciated that in one embodiment the length L is at least equal to the width W. in another embodiment, the length L is slightly greater than the width W, in order to enable the device to allows for some accommodation of length—as is shown in FIGS. **14**B and **28** through **32**.

Note that at least a segment of each of spacers **140** and **150** may be positioned overlying the epiphyseal ring of the vertebral bones immediately superior and inferior (i.e., that border) the implanted disc space. The epiphyseal ring is illustrated in FIG. **17**B, wherein an view of the superior aspect of a vertebral bone is shown (the numbers are as shown in FIG. **1**). The epiphyseal ring forms the strongest portion of the superior and inferior surfaces of the vertebral body, which are the vertebral surfaces that border the intervertebral disc spaces. (The epiphyseal ring is more fully discussed in: *The epiphyseal ring: a long forgotten anatomical structure with significant physiological function*. Dar G, et al. Spine. 2011 May 15; 36(11):850-6. The article is hereby incorporated by reference in its entirety).

A cross sectional view (in the coronal plane of the spine) is shown in FIG. **17**B. Note that members **1406** abut the lateral aspect of the vertebral bodies. Each of spacers **140** and **150** are on opposing sides of the disc space. Cavity **137** is packed with bone graft material and rests between the two spacers **140** and **150**, wherein, in one embodiment, the bone graft material is not contained within a spacer cavity. (It is also contemplated that, in an embodiment, at least one of spacers **140** and **150** may contain a cavity for bone graft material—in addition to the bone graft material contained between then in cavity **137**.)

Bone screws **152** are placed through bore holes **1406** and into the underlying bone. Screws **170** and **160** are unthreaded and removed. Instrument **130** is then removed, leaving the bone graft material within the evacuated disc space. FIGS. **19**A and **19**B illustrate the implanted spacer (the bone graft material resides between the spacers). In an alternative screw trajectory, shown in FIG. **20**, the bone screws are aimed so that the distal aspect of at least one bone screw is aimed towards the disc space. In an embodiment, the distal end of at least one screw is anchored into spacer **150**. (Note that bores **1406** of implantable spacer **140** permit placement of the bone screws in the trajectory of FIG. **19**B or **20**. That is, the same device embodiment permits variable trajectory.)

Preferably, but not necessarily, a device member and/or feature may be added to lock the bone screws to spacer **140**. Plate-to-screw locking features are well known in the art and any applicable such feature/device may be used here. An illustrative example embodiment is shown in FIG. **23**. Locking plate **190** has a first surface **192** with curvilinear central protrusion **1922** that is adapted to face (but not contact) surface **1407** of spacer **140**. A non-threaded bore hole **1924** is adapted to accept a locking screw **196**. When seated, the threaded end of screw **196** interacts with complimentary threads of bore **1409** of spacer **140**. At least one additional protrusion **1927** extends from surface **192**. In use, protrusion **1927** is adapted to forcefully abut the (head) portion of a bone screw **152** that reside within bore hole **1406**. In this way, advancement of locking screw **196** into threaded hole **1409** provides a force that drives protrusion **1927** into bone screw **152** and immobilizes the bone screw relative spacer **140**. The implanted locking plate **190** and locking screw **196** are shown in FIG. **24**. A sectional view with locking plate **190** in the deployed position is shown in FIG. **25**. Note that the locking mechanism locks both the screw above and the screw bellow the implanted disc space.

While use of instrument **130** and attached spacers has been illustrated in a straight lateral approach to the inter-vertebral disc space, the devices may be used in an anterior, posterior, oblique or any other known approach to the disc space. Further, the device may be easily configured for use in a curvilinear approach to the disc space. An illustrative example of a curvilinear approach to the disc space is shown in FIG. **26**. In preparation for percutaneous placement of an orthopedic implant into a spinal disc space, the patient is placed in the prone position with spine and skin **102** in the superior position. The level of the spine that is to be implanted is localized on X-ray in at least one plane. After the customary sterile preparation of the operative site, the surgeon localizes an incision point that is lateral to the paraspinal muscles (the erector spinae muscle group **215** and/or others, for example) but not directly lateral to the side of the disc space. At least one finger **210** may be placed into the retro-peritoneal space and the lateral aspect of the psoas muscle **216** is palpated, as shown in FIG. **26**. Alternatively, the surgeon can identify the psoas muscle by inserting an instrument instead of using direct digital palpation.

A curvilinear instrument **205** is shown in FIG. **27**A. Instrument **205** is similar to instrument **130** but contains a curvilinear connection **2053** between the handle **2052** and the end segment that attaches the implants (the end segment contains side members **2054**). As in the prior embodiment of FIGS. **9** and **10**, member **260** affixes implant **140** to the instrument **205**, whereas member **270** affixes implant **150** to the instrument **205**. Member **260** has a first end **2602**, an opposing threaded end and is at least partially malleable there between. Similarly member **270** has a first end **2702**, an opposing threaded end and is at least partially malleable there between. As shown in the section view of FIG. **27***b*, members **260** and **270** are malleably configured to be positioned within the substantially linear portion of handle **2302** and also within the substantially non-linear portions of connection **2303**.

FIGS. **13** and **14** illustrated how instrument **130** can retain each of spacers **140** and **150** at a variable distance from one another. FIGS. **28** to **32** illustrate a device embodiment wherein the distance between each of implants **140** and **150** is displayed by the instrument. That is, the current embodiment differs from the prior embodiment in that contains an indicator of distance between implant **140** and **150**. Whereas the distance between the implants **140** and **150** of the prior was determined by measuring that distance with a separate measuring device (ruler, caliper, and the like), the current embodiment contains a distance indicator.

FIG. **28** illustrates an exploded view of the current embodiment. The exploded view is similar to that of FIG. **7**. Member **150**, **170** and **160** are unchanged. Instrument **130** is replaced by instrument **230**, wherein side members **2304** differ from side member **1304** in that each member **2304** contains a full thickness channel **23042** that extends proximally towards curvilinear surface **1306** from end indentation **1305**. (A magnification of the end segment on instrument **230** is also shown in FIG. **28**.) Markings are displayed on the outer side surface of each member **2304**, from which the distance between implant **140** and **150** may be ascertained. While the markings are shown as "hatch marks" in the illustrations, it is understood that numbers, letters or any other notation may be used to indicate the distance of the marking from implant **150**. The notations may express distance in a known unit of measure or they may use an arbitrary scale that is disclosed to the user in the instrument's instruction manual.

Implant **240** is illustrated in FIG. **29**. Because it's substantially similar to implant **140** (FIG. **11**), the same numbering scheme is used to illustrate it. It differs from implant **140** in having a side protrusion **242** on each side of the implant. Each protrusion **242** is sized and shaped to slidably move in one of each channel **23042** of instrument **230**. A marking **2424** is found on the outer side surface of protrusion **242** and functions as a pointer that displays implant **242**'s position relative to the markings on the side surface side member **2304** of instrument **230**. In this way, marking **2424** can be used to directly read the distance between implant **150** and **240**.

The device is show in the assembled configuration in FIG. **30** and in cross section in FIG. **31**. In FIG. **32**, screw **160** has been rotated (via end **1602**) and implant **240** has been moved towards implant **150** and away from curvilinear surface **1306**. With movement, space B is now positioned between implant **240** and surface **1306**. Comparison of FIGS. **30**B and **32**B show the movement of marking **2424** relative to the side markings of member **2304**.

As previously disclosed, spacer **140** need not have a side member **1404** for attachment onto the side of the vertebral bones. FIG. **33**A illustrates spacer **140** without either side members **1404**. In this embodiment, the totality of the spacer **140** may be contained within the implanted disc space. FIG. **33**B shows the section through the implanted vertebral bones and disc space.

FIG. **34** illustrate a spacer **140** that is similar to that of FIG. **33** but is configured to contain bore holes **1409** within body **1402**, wherein said bores are configured to accept bone screws **199** that can anchor the spacer **140** directly into the adjacent vertebral bones. At least two bore holes **1409** are positioned within implant **140** so that at least one bone screw **199** is anchored into each of the vertebral bones above and below the implanted disc space. The screws are not placed into bone in a parallel trajectory, so as to enhance the fixation strength of spacer **140**. The implanted spacer **140** may be contained within the disc space and may have no additional member positioned to abut additional side surfaces of the vertebral bones. While not specifically illustrated, each screw may be further locked to spacer **140** after implantation. Many screw to plate locking mechanism are known in the art and any applicable mechanism may be employed. The implanted device is shown in FIG. **34**B.

FIG. **35** illustrates an alternative embodiment of the implantable spacer implants. An extension member **250** is attached to the top (and/or bottom or side) surface to at least one of implant **140** and **150**. When attached to the top and/or bottom surface of at least one implant, the extension can be positioned into a cut bone channel **255**, as shown in FIG. **36**. The extension may be wholly contained within the cut channel **255** or some segment of said extension **250** may extend out of the vertebral bone, such as, for example, into the disc space. The extension **250** is less the total width (when measured at its greatest extent) of the upper and/or lower vertebral bone. The width W is shown in FIG. **22**B. While extension **250** is shown attached to the upper and lower surface of the implant in FIGS. **35** and **36**, it is alternatively attached to a side surface (such as surface **1505** of implant **150**, or surface **1405** of implant **140**) of said implants and rest at least partially within the disc space on implantation. In this embodiment, extension **250** would at least partially enclose bone graft cavity **137**.

An alternative embodiment of member **150** is illustrated as implantable spacer **350**. In this embodiment, spacer **350** is of variable length and is comprised of two slidable segments **3502** and **3504**. The body of slidable segment

3502 cooperatively interdigitates with the body of slidable segment 3504. The upper and/or lower surfaces 35022 and 35042 may contain surface protrusions or textures (not shown) that increase fixation of these surfaces onto the abutting bone. A threaded bore hole 3508 (threads not shown) is contained within the body of slidable segment 3505, wherein the bore hole receives the threaded end of screw 170.

FIG. 37A illustrates implantable spacer 350 in a non-expanded configuration whereas FIG. 37B shows spacer 350 after expansion. (Note that length L is greater in the expanded state than in the non-expanded state.) FIG. 38 shows protrusion 35045 of segment 3504 and the complimentary bore 35025 of segment 3502. FIG. 39 illustrate screw 170, wherein the distal end is configured to have threads complimentary to those of bore 3508 (threads not shown). In addition, cam expander 370 is also shown, wherein expander 370 has a bore 3702 adapted to accept screw 70 therein. Note that the distal end alone of each of screw 170 and expander 370 is shown. However, it is contemplated that a placement instrument 130 (not shown in FIG. 39) is configured to couple with spacer 350. Unlike the device of FIGS. 7-10, screw 170 would be positioned inside expander 370, and the latter would be in turn positioned within screw 160.

FIG. 40 A illustrates that rotation of expander 370 relative to spacer 350 will drive segment 3502 away from segment 3504 and increase the length L of implant 350. FIG. 40B shows the expanded implant 350 after removal of screw 170 and expander 370.

The expanded spacer may be left as shown in FIG. 40B or an additional segment 380 may be attached to spacer 350 within the cavity 3509 created by the separation of segments 3502 and 3504. The addition of segment 380 provides more bone contact/abutment surface than expanded spacer 350 alone, since top and bottom surfaces 3802 of segment 380 will at least partially fill cavity 3509. FIG. 41B illustrates segment 380, whereas FIG. 41A shows one segment 380 coupled to expanded spacer 350 and a second segment 380 positioned to be advanced into cavity 3509. Teeth 3808 are used to lock segment 380 onto extension 35045 on segment 3504.

While each of the segment 380 can be separate members that are added to expanded spacer 350 (as shown), they may alternative be wedge-shaped segments that are implanted as a sub-segment of implant 350, wherein advancement of the wedge-shaped segment between segments 3502 and 3504 is performed after positioning of spacer 350 into the disc space, and wherein the advanced segment 380 both creates a cavity 3509 and fills it in (this embodiment is not shown).

In use, the implantable spacer 350 is configured to be passed though the psoas muscle while in a first configuration and then to expand within the disc space to a second configuration, wherein the length of spacer 350 is greater in the second configuration than in the first configuration. (The length of the device refers to long axis of the spacer, which, in use, is substantially positioned in the direction of a sagittal plane through the implanted disc space and measured in the anterior to posterior direction.)

FIG. 42 schematically illustrates the exemplary procedure, wherein instrument 130 attaches implantable spacer 350 prior to expansion (as shown in FIG. 37A) and then guides said spacer 350 through Corridor K of the psoas muscle. After spacer 350 is positioned within the target disc space, it is transitioned into the second configuration (as shown in FIG. 37B), wherein the second configuration is of greater length than the first spacer configuration. While spacer 350 is shown in both the expanded and non-expanded state in FIG. 42, it is to be understood that three different steps of the procedure are illustrated and not two separate spacers 350. That is, step 1 shows spacers 140 and 350 attached instrument 130 and positioned within the body cavity of the individual but outside of the spine and the psoas muscle. In step 2, spacers 140 and 350 traverse the psoas muscle thought corridor K (instrument not shown while in the muscle). In step 3, spacers 140 and 350 have been positioned at opposing side of implanted disc space (and sitting on the epiphyseal ring) and transitioned into the expanded state—with subsequent complete removal of instrument 130. Note that the length of spacer 350 (as measured in the anterior to posterior plane of the disc space) in the second configuration is greater than the width W of corridor K, through which spacer 350 traversed the psoas muscle while being implanted into the disc space.

Note that spacer 140 is also shows as having been expanded to a greater length after being positioned within the disc space. While not separately illustrated, it is understood that spacer 140 can be made to expand in a manner similar to that illustrated for spacer 350. It is recognized, however, that many other mechanisms can be used to produce implantable spacers of expandable length. In one embodiment, the width of the expandable spacer (as measured in the coronal plane of the spine) may be less or equal to the width of the non-expanded spacer. In another embodiment, the width my greater in the expanded state than in the non-expanded state. That is, the width may change with transition from the first to the second configuration or it may remain constant.

In the herein-described exemplary embodiment of the method of device use, at least two implantable spacers are coupled to an implantation instrument (such as, for example, instrument 130) wherein at least one of the implantable spacers is configured to have an expandable length. The spacer width may be changeable or it may remain constant. The spacers are not directly attached to one another but are at least partially separated by a cavity configured to house bone graft material. The bone graft material is positioned outside at least one of said implantable implants but within a cavity of the implantation instrument. A direct lateral corridor (such as corridor 105; FIG. 4) to the target disc space is used to implant the spacers. (Note that trajectories other than a direct lateral approach may be alternatively used.) In the lumbar spine, the psoas muscle must be traversed in order to position the spacers in the target disc space. After placement of the spacers in the disc space, the at least one expandable spacer is increased in length and the placement instrument is removed from the disc space. In this way, a spacer is positioned on opposing lateral ends of the disc space with the bone graft material positioned there between. At least one of the implanted spacers has a length greater than the trans-psoas corridor used to deliver said spacer to the target disc space in one embodiment. At least one of the implanted spacers does not contain an internal cavity that also contains or is configured to contain bone graft material.

The disclosed devices or any of their components can be made for example of any biologically adaptable or compatible materials. Materials considered acceptable for biological implantation are well known and include, but are not limited to, stainless steel, titanium, tantalum, combination metallic alloys, various plastics, resins, ceramics, biologically absorbable materials and the like. Any components may be also coated/made with nanotube materials to further impart unique mechanical or biological properties. In addi-

tion, any components may be also coated/made with osteo-conductive (such as deminerized bone matrix, hydroxyapatite, and the like) and/or osteo-inductive (such as Transforming Growth Factor "TGF-B," Platelet-Derived Growth Factor "PDGF," Bone-Morphogenic Protein "BMP," and the like) bio-active materials that promote bone formation. Further, any surface may be made with a porous ingrowth surface (such as titanium wire mesh, plasma-sprayed titanium, tantalum, porous CoCr, and the like), provided with a bioactive coating, made using tantalum, and/or helical rosette carbon nanotubes (or other carbon nanotube-based coating) in order to promote bone in-growth or establish a mineralized connection between the bone and the implant, and reduce the likelihood of implant loosening. The system or any of its components can also be entirely or partially made of a shape memory material or other deformable material. Lastly, any of the implanted spaces that are disclosed may be partially or completely made out of bone and/or bone graft material.

It will be recognized that while certain aspects of the disclosure are described in terms of a specific sequence of steps of a method, these descriptions are only illustrative of the broader methods thereof, and may be modified as required by the particular application. Certain steps may be rendered unnecessary or optional under certain circumstances. Additionally, certain steps or functionality may be added to the disclosed embodiments, or the order of performance of two or more steps permuted. All such variations are considered to be encompassed within the present disclosure and claimed herein.

While the above detailed description has shown, described, and pointed out novel features of the disclosure as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or process illustrated may be made by those skilled in the art without departing from the disclosure. The foregoing description is of the best mode presently contemplated. This description is in no way meant to be limiting, but rather should be taken as illustrative of the general principles. The scope of the present disclosure should be determined with reference to the claims.

What is claimed is:

1. An orthopedic device assembly configured for delivery of a first implantable device and a second implantable device to an intervertebral disc space, said intervertebral disc space disposed between a superior vertebral bone and an inferior vertebral bone, the orthopedic device assembly comprising:

said first implantable device comprising: (i) a first surface configured to abut said superior intervertebral bone, and (ii) a second surface configured to abut said inferior vertebral bone;

said second implantable device being a separate component from the first implantable device and comprising at least one member having a first aperture configured to receive a fastener, said fastener configured to be advanced at least partially through said first aperture and into one of said superior vertebral bone or said inferior vertebral bone; and

a non-implantable placement instrument comprising an intermediate segment, a proximal segment and a distal segment, said placement instrument extended along a longitudinal axis from a proximal end of said proximal segment to said distal segment;

wherein:

said proximal segment comprises a handle;

said distal segment comprises a first surface configured to engage with said first implantable device; and

said intermediate segment comprises a second surface configured to engage with said second implantable device; and

wherein said non-implantable placement instrument is configured such that, as measured along said longitudinal axis, a distance between said first surface and said proximal end is greater than a distance between said second surface and said proximal end.

2. The orthopedic device assembly of claim **1**, wherein said first implantable device further comprises a cavity configured to house a bone forming material.

3. The orthopedic device assembly of claim **1**, wherein said intermediate segment comprises at least a pair of extension elements configured to straddle at least a portion of said second implantable device, said second surface of said intermediate segment comprising a surface of at least one of said pair of extension elements that is configured to engage said second implantable device.

4. The orthopedic device assembly of claim **3**, wherein:

said distal segment comprises a distal end of each of said pair of extension elements; and

said first surface of said distal segment comprises a first pair of engagement features, each of said first pair of engagement features being (i) disposed on one of said pair of extension elements and (ii) configured to engage with said first implantable device.

5. The orthopedic device assembly of claim **4**, wherein said first implantable device further comprises a pair of outer side surfaces and a second pair of engagement features having a complementary configuration to said first pair of engagement features.

6. The orthopedic device assembly of claim **1**, further comprising a second aperture formed within said second implantable device; and

wherein said placement instrument further comprises a retention apparatus, said retention apparatus comprising at least one elongate member configured to enable coupling of a distal end of said retention apparatus to said first implantable device, said distal end of said retention apparatus configured to extend through said second aperture of said second implantable device to couple to said first implantable device.

7. The orthopedic device assembly of claim **1**, further comprising a second aperture centrally formed within said second implantable device; and

wherein said second aperture is configured to receive a locking feature, said locking feature configured to limit backing out of said fastener after said fastener is received within said first aperture.

8. An orthopedic device assembly configured for delivery of a first implantable device and a second implantable device to an intervertebral disc space, said intervertebral disc space disposed at least partly between a superior vertebral bone and an inferior vertebral bone, the orthopedic device assembly comprising:

said first implantable device comprising: (i) a first surface configured to abut said superior intervertebral bone, and (ii) a second surface configured to abut said inferior vertebral bone;

said second implantable device being non-integrally formed with said first implantable device and comprising: (i) a first aperture, and (ii) at least one side member disposed adjacent to said first aperture, said at least one side member having a second aperture configured to receive a fastener that is sized to be at least partially

advanced through said second aperture and into one of said superior vertebral bone or said inferior vertebral bone; and

a non-implantable placement instrument configured to position said first implantable device and said second implantable device, said placement instrument extending along a longitudinal axis from a proximal end to a distal segment and comprising:

a proximal segment comprising a handle;

said distal segment configured to engage said first implantable device;

an intermediate segment positioned at least partially between said proximal segment and said distal segment, said intermediate segment comprising a second surface configured to engage said second implantable device; and

a retention apparatus comprising at least one elongated member capable of alignment with said longitudinal axis of said placement instrument, a distal end of said retention apparatus configured to extend through said first aperture of said second implantable device and couple to said first implantable device.

9. The orthopedic device assembly of claim **8**, wherein said distal end of said retention apparatus is configured to threadedly couple with said first implantable device.

10. The orthopedic device assembly of claim **8**, wherein said non-implantable placement instrument is configured such that a distance between said first surface and said proximal end is greater than a distance between said second surface and said proximal end, as measured along said longitudinal axis.

11. The orthopedic device assembly of claim **8**, wherein the at least one elongated member of the retention apparatus is sized to be at least partially seated within an internal channel of said handle.

12. The orthopedic device assembly of claim **8**, wherein said intermediate segment comprises at least a pair of extension elements configured to straddle at least a portion of said second implantable device.

13. The orthopedic device assembly of claim **8**, wherein said first aperture of said second implantable device is configured to receive a locking feature; and

said locking feature is configured to limit back-out of said fastener from a seated position within said second aperture of said second implantable device.

14. The orthopedic device assembly of claim **8**, wherein said first implantable device further comprises a cavity configured to seat a bone forming material.

15. An orthopedic device assembly configured for delivery of implants to an intervertebral disc space, said intervertebral disc space disposed between a superior vertebral bone and an inferior vertebral bone, the orthopedic device assembly comprising:

a first implantable device comprising (i) a first surface configured to abut said superior intervertebral bone and (ii) a second surface configured to abut said inferior vertebral bone;

a second implantable device separately formed from the first implantable segment and comprising (i) a pair of outer side surfaces and (ii) at least one segment having a first aperture configured to receive a fastener, said fastener configured to be advanced at least partially through said first aperture and into one of said superior vertebral bone or said inferior vertebral bone; and

a non-implantable placement instrument configured to position said first implantable device and said second implantable device, said placement instrument comprising:

a proximal segment comprising a handle;

a distal segment comprising a first surface, said first surface configured to engage with said first implantable device;

an intermediate segment comprising at least a pair of extension elements configured to straddle at least a portion of said second implantable device, at least one of said pair of side extension elements comprising a second surface configured to engage with one of said pair of outer side surfaces of said second member;

wherein said non-implantable placement instrument is extended from a proximal end of said proximal segment to said distal segment along a longitudinal axis; and

wherein, said non-implantable placement instrument is configured such that said first surface of the distal segment is a greater distance from said proximal end, as measured along said longitudinal axis, than said second surface of the intermediate segment.

16. The orthopedic device assembly of claim **15**, wherein said first implantable device further comprises a cavity configured to house a bone forming material.

17. The orthopedic device assembly of claim **15**, wherein said first implantable device is sized so as to be at least partially inserted within said intervertebral disc space.

18. The orthopedic device assembly of claim **15**, wherein:

said second implantable device further comprises a second aperture; and

said placement instrument further comprises a retention apparatus, said retention apparatus comprising a distal portion configured to (i) extend through said second aperture and (ii) couple with said first implantable device.

19. The orthopedic device assembly of claim **18**, wherein said first surface of said distal segment of the non-implantable placement instrument is at least partially comprised of an end segment of said distal portion of the retention member.

20. The orthopedic device assembly of claim **19**, wherein said end segment of said distal portion of said retention member is configured to threadedly engage with said first implantable device.

21. The orthopedic device assembly of claim **18**, wherein said distal portion of the retention member is configured to be positioned collinear with said longitudinal axis of said non-implantable placement instrument.

22. The orthopedic device assembly of claim **18**, wherein said second aperture is configured to receive a locking feature; and

said locking feature is configured to restrict unintended retraction of said fastener from the first aperture when the fastener is seated therein.

23. The orthopedic device assembly of claim **15**, wherein:

(i) said distal segment of the non-implantable placement instrument comprises a distal end of at least one of said pair of extension elements; and

(ii) said first surface of said distal segment comprises an engagement feature that is disposed on said distal end of the at least one of said pair of extension elements and is configured to engage with said first member.

24. The orthopedic device assembly of claim 15, wherein said second implantable device further comprises a spacer segment that is sized to be inserted within said intervertebral disc space.

25. An orthopedic device assembly, comprising:

a first implantable device sized to be positioned at least partly within an intervertebral disc space that is disposed between a superior vertebral bone and an inferior vertebral bone, the first implantable device comprising:

(i) a superior surface configured to abut said superior intervertebral bone, and

(ii) an inferior surface configured to abut said inferior vertebral bone;

a second implantable device, separately formed from the first implantable device and configured to be positioned at least partly on an outer surface of one or more of said superior vertebral bone and said inferior vertebral bone, said second implantable device comprising:

(i) a first aperture configured to seat a first fastener, a shank portion of said first fastener configured to be at least partially advanced through said first aperture and into said superior vertebral bone when said first fastener is an a first seated position;

(ii) a second aperture configured to seat a second fastener, a shank portion of said second fastener configured to be at least partially advanced through said second aperture and into said inferior vertebral bone when said second fastener is a second seated position;

(iii) a third aperture disposed between said first aperture and said second aperture, said third aperture configured to seat a locking feature that is adapted to limit undesired back out of at least one of said first and second fasteners from a respective seated position within said first and second apertures; and

a non-implantable placement instrument configured to position said first implantable device and said second implantable device at said intervertebral disc space, said placement instrument comprising:

a proximal segment comprising a handle;

a distal segment comprising a first surface, said first surface configured to engage with said first implantable device; and

an intermediate segment between said proximal segment and said distal segment, said intermediate segment comprising a second surface configured to engage with said second implantable device;

wherein said non-implantable placement instrument extends from said proximal segment to said distal segment along a longitudinal axis; and

wherein, said non-implantable placement instrument and said first and second implantable devices are configured such that, when engaged, said first implantable device and said second implantable are consecutively arranged along said longitudinal axis.

26. The orthopedic device assembly of claim 25, wherein said intermediate segment of said non-implantable placement instrument comprises at least a pair of extensions configured to straddle said second implantable device, said second surface of said intermediate segment comprising an inner surface of each of said pair of extensions.

27. The orthopedic device assembly of claim 26, wherein:

said distal segment of the non-implantable placement instrument comprises a distal end of at least one of said pair of extension elements; and

said first surface of said distal segment comprises an engagement feature that is disposed on said distal end of said at least one of said pair of extension elements, said engagement feature configured to engage with said first member.

28. The orthopedic device assembly of claim 25, wherein said non-implantable placement instrument further comprises a retention apparatus, the retention apparatus comprising a distal end that is (i) sized to extend through said third aperture of the second implantable device and (ii) configured to couple to said first implantable device.

29. The orthopedic device assembly of claim 28, wherein said first surface of said distal segment of said non-implantable placement instrument is at least partially comprised of said distal end of said retention member.

30. The orthopedic device assembly of claim 25, wherein said second implantable device further comprises a spacer segment that is sized to be inserted within said intervertebral disc space.

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