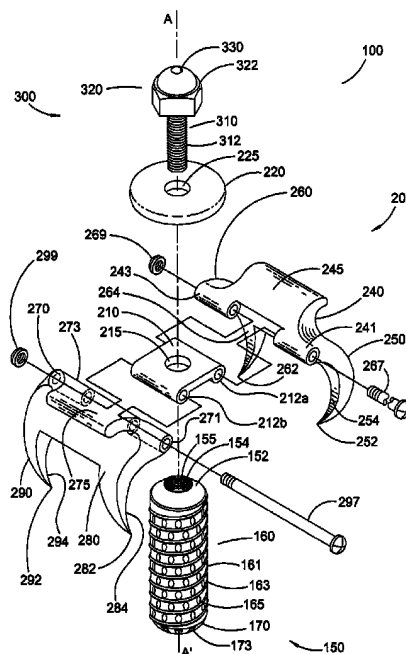




(10) **Patent No.:** **US 8,080,046 B2**
(45) **Date of Patent:** **Dec. 20, 2011**

- | | | | | |
|-----------|-----|---------|-----------------|-----------|
| 4,401,112 | A | 8/1983 | Rezaian | |
| 5,015,247 | A | 5/1991 | Michelson | |
| 5,496,318 | A | 3/1996 | Howland et al. | |
| 5,645,599 | A | 7/1997 | Samani | |
| 5,772,661 | A | 6/1998 | Michelson | |
| 5,840,078 | A | 11/1998 | Yerys | |
| 5,916,267 | A * | 6/1999 | Tienboon | 623/17.11 |
| 6,001,130 | A | 12/1999 | Bryan et al. | |
| 6,156,037 | A | 12/2000 | LeHuec et al. | |
| 6,235,059 | B1 | 5/2001 | Benezech et al. | |
| 6,770,096 | B2 | 8/2004 | Bolger et al. | |

- 17 Claims, 13 Drawing Sheets**



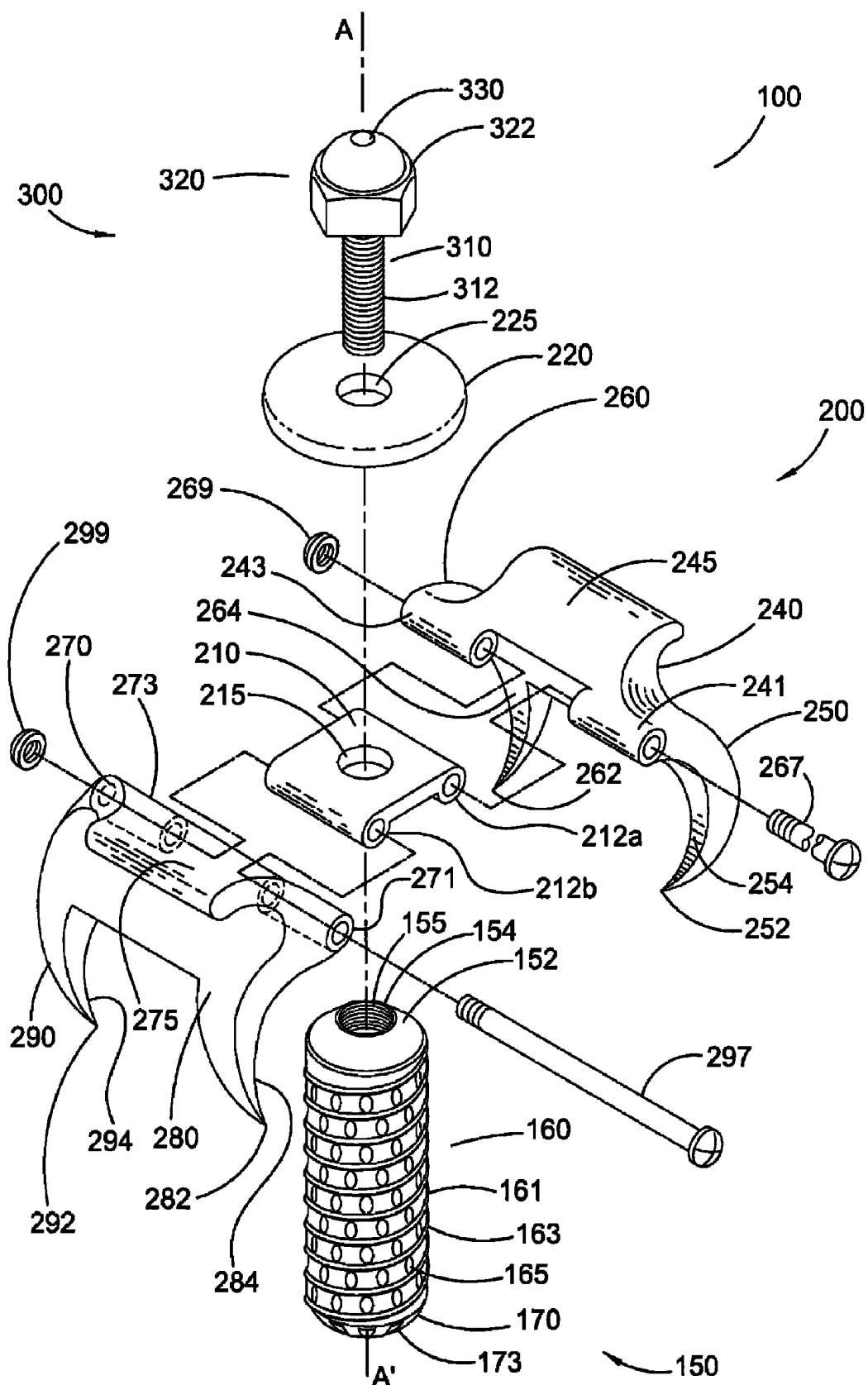


Fig. 1

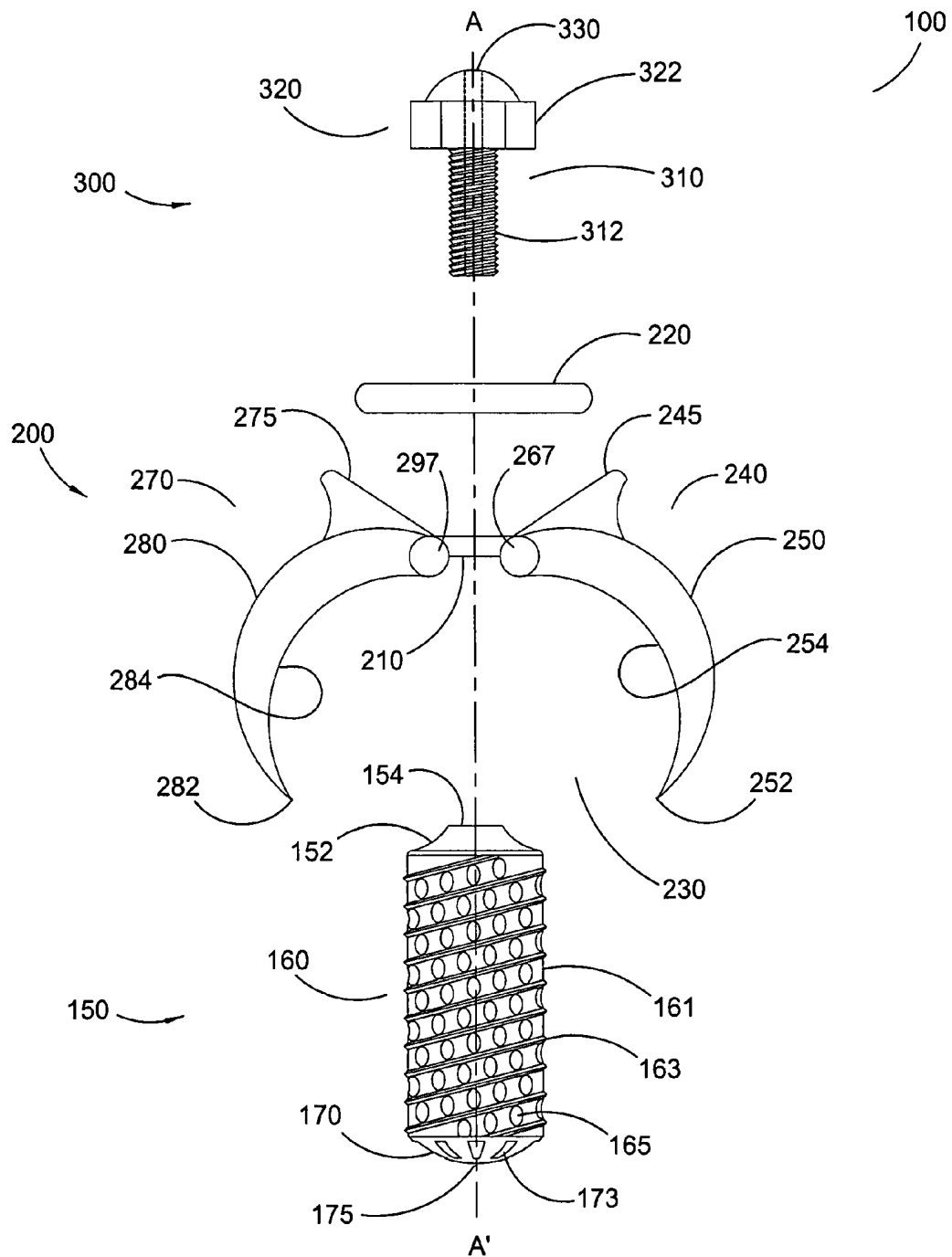


Fig. 2

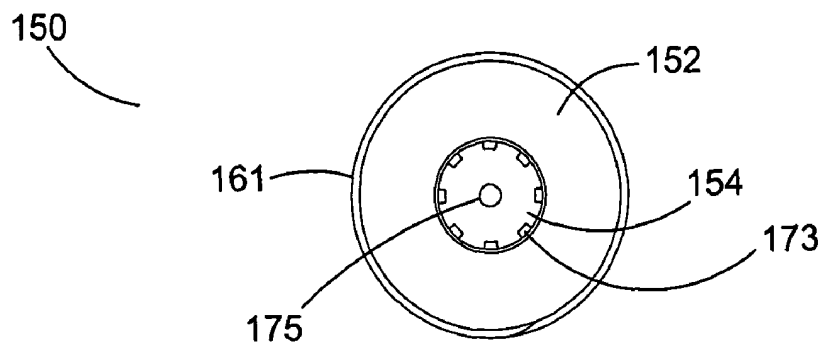


Fig. 3

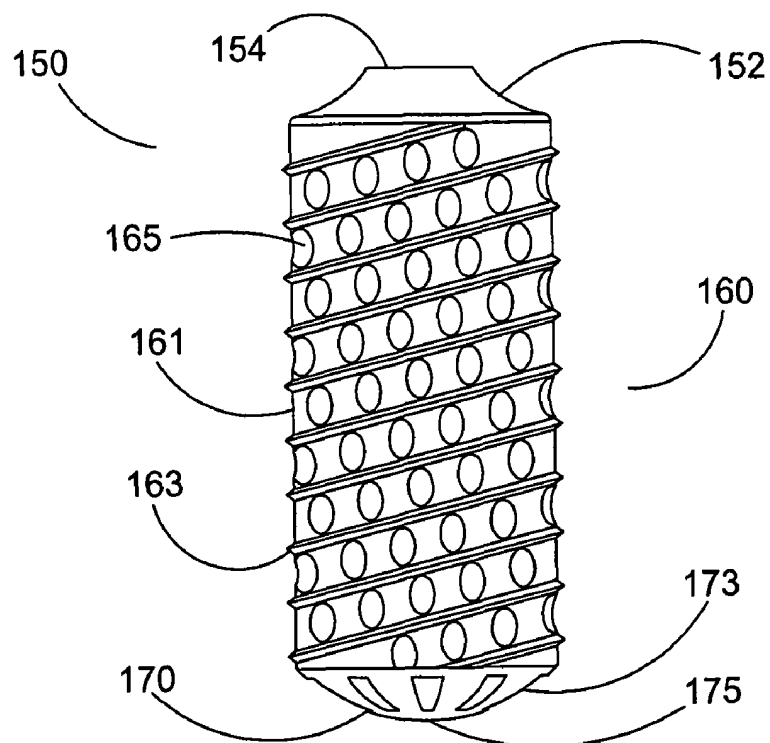


Fig. 4

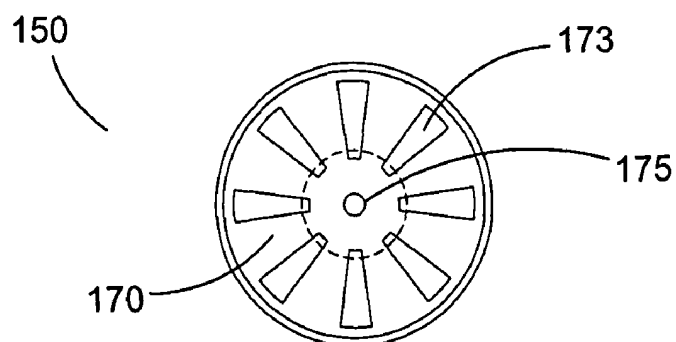


Fig. 5

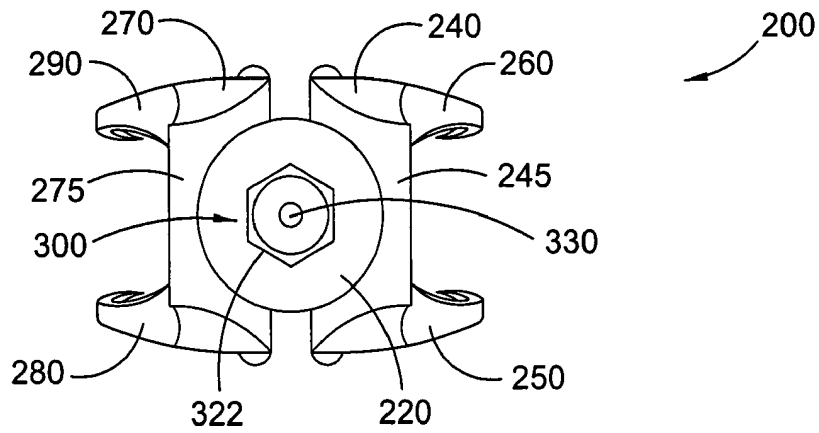


Fig. 6

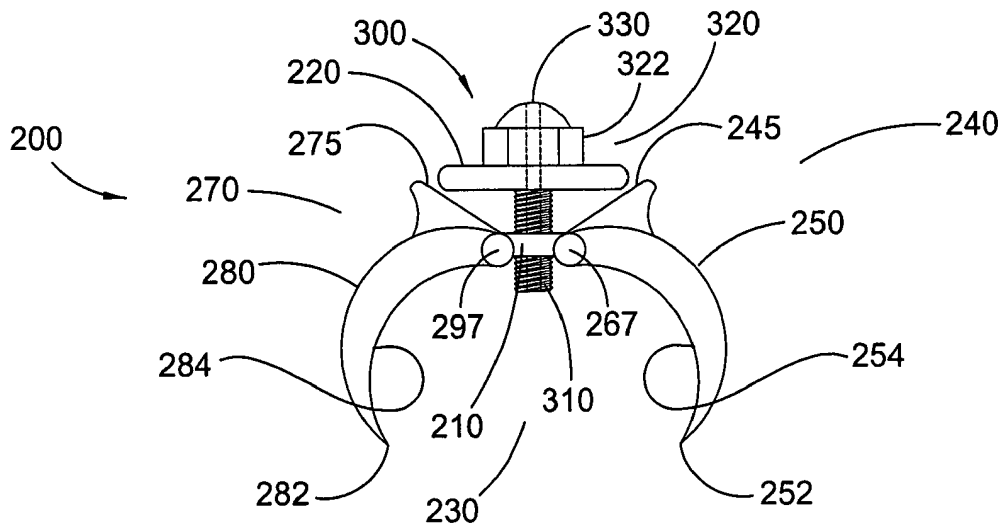


Fig. 7

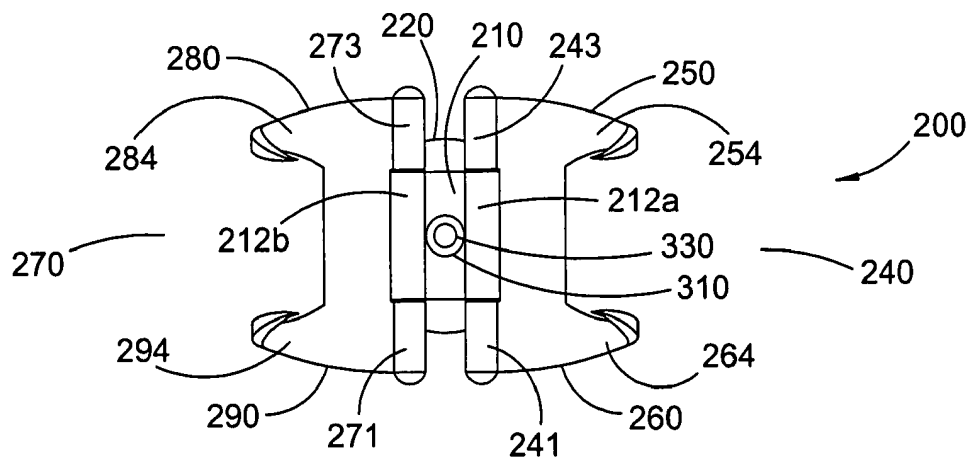


Fig. 8

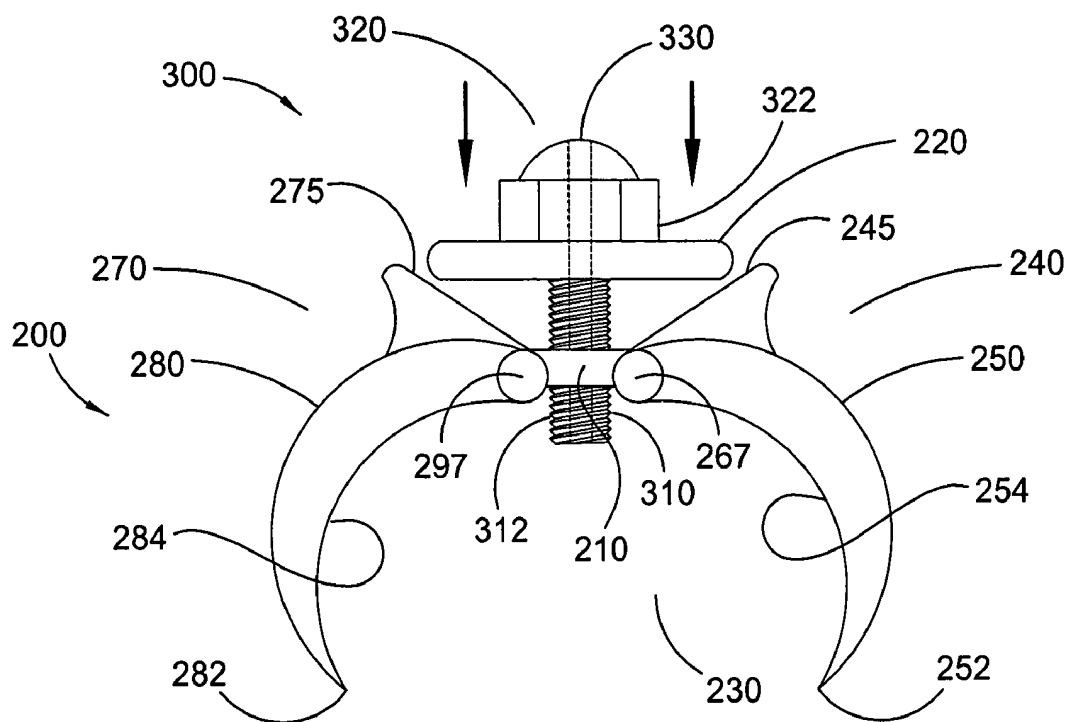


Fig. 8a

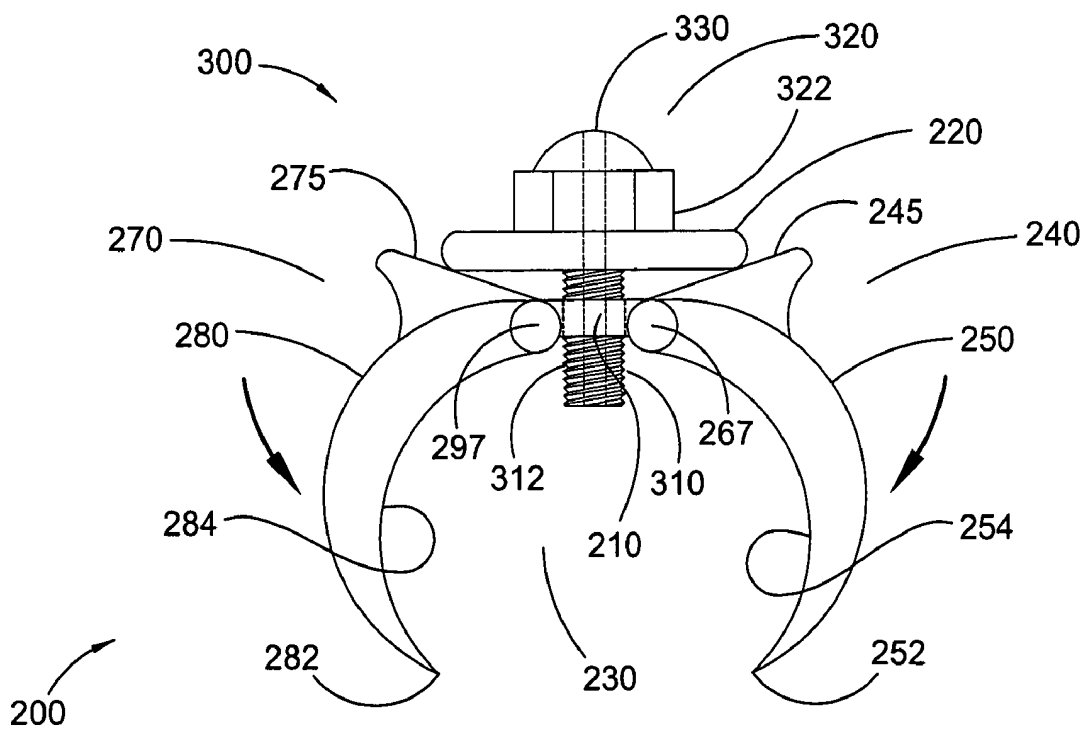


Fig. 8b

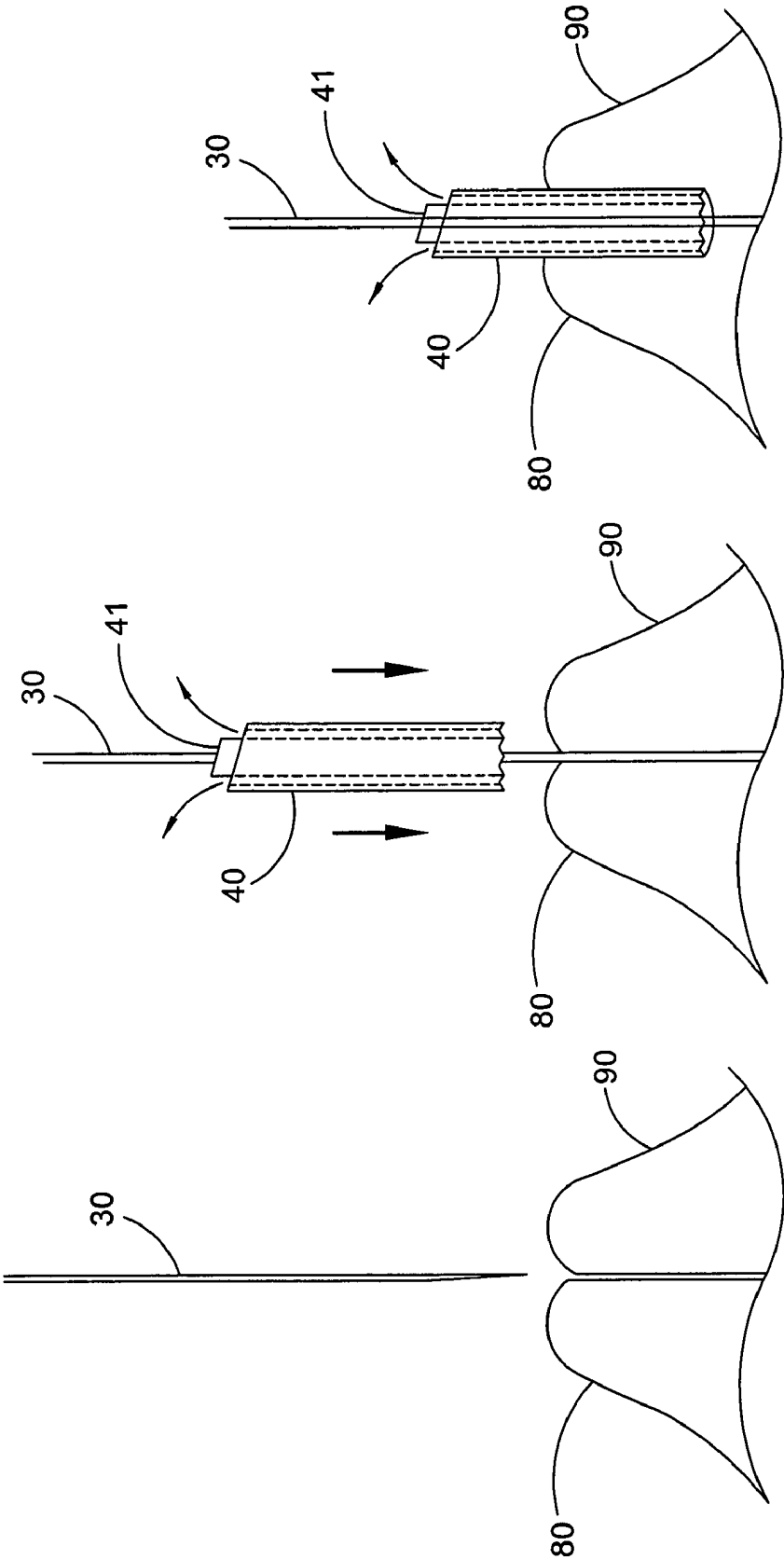


Fig. 9a

Fig. 9b

Fig. 9c

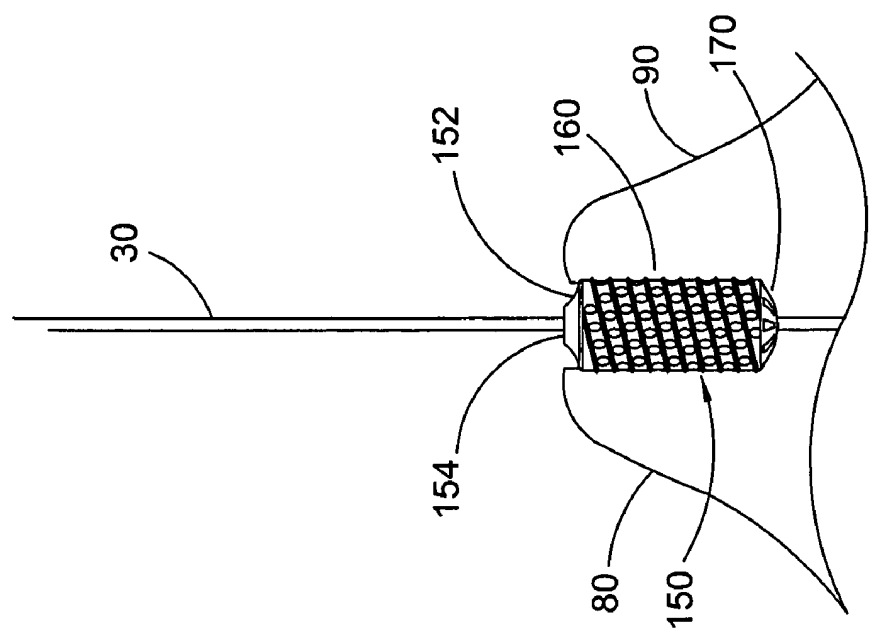


Fig. 9e

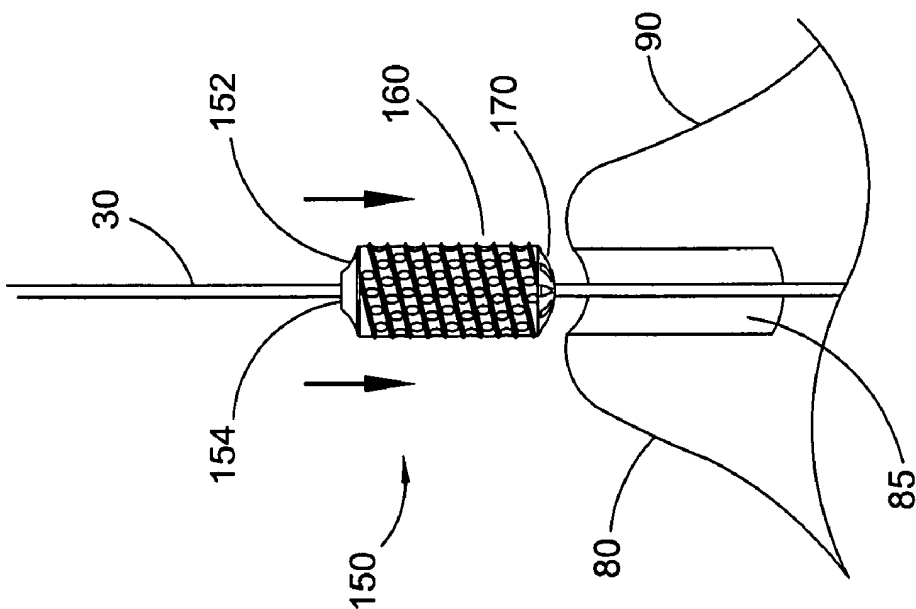


Fig. 9d

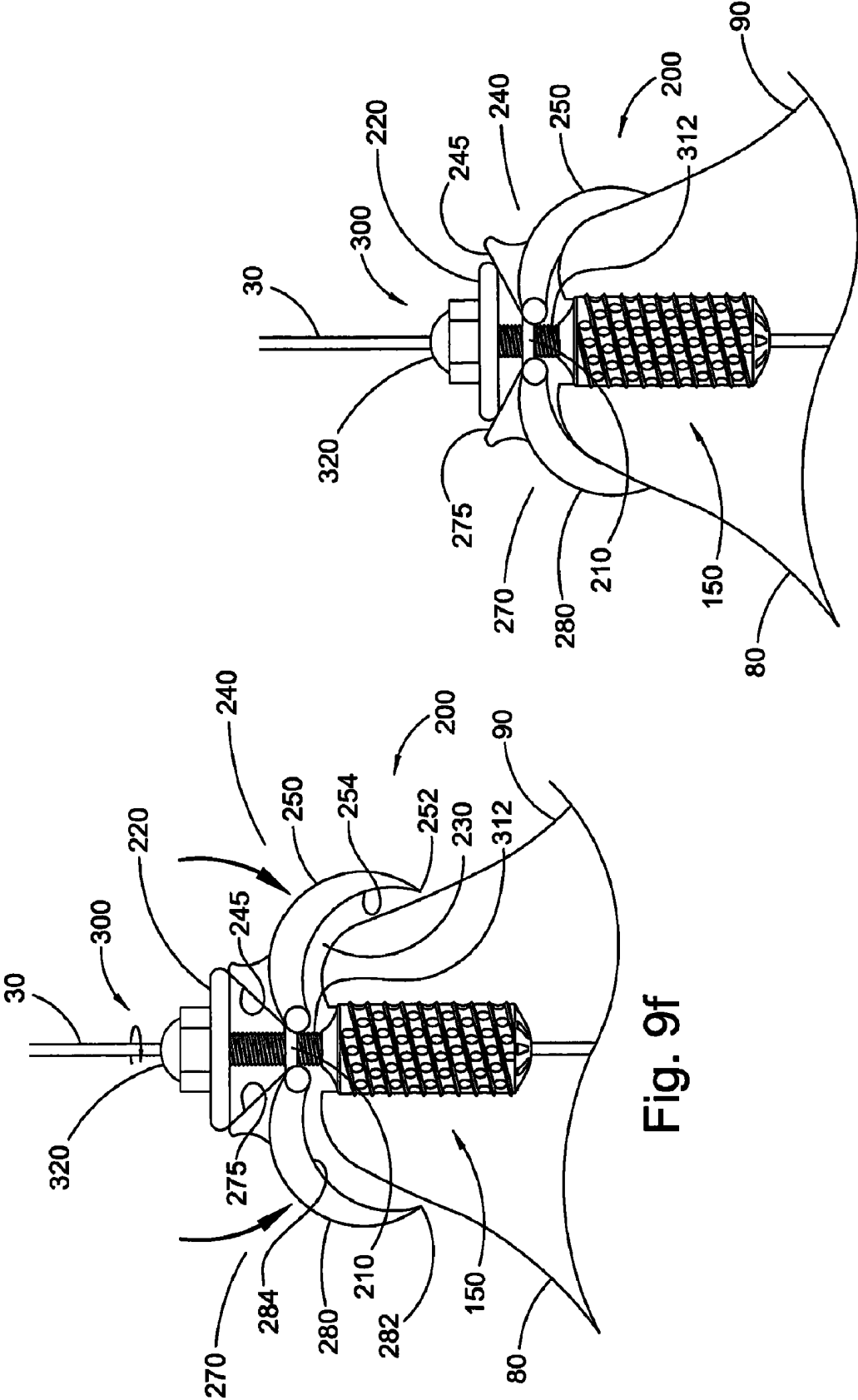


Fig. 9g

Fig. 9f

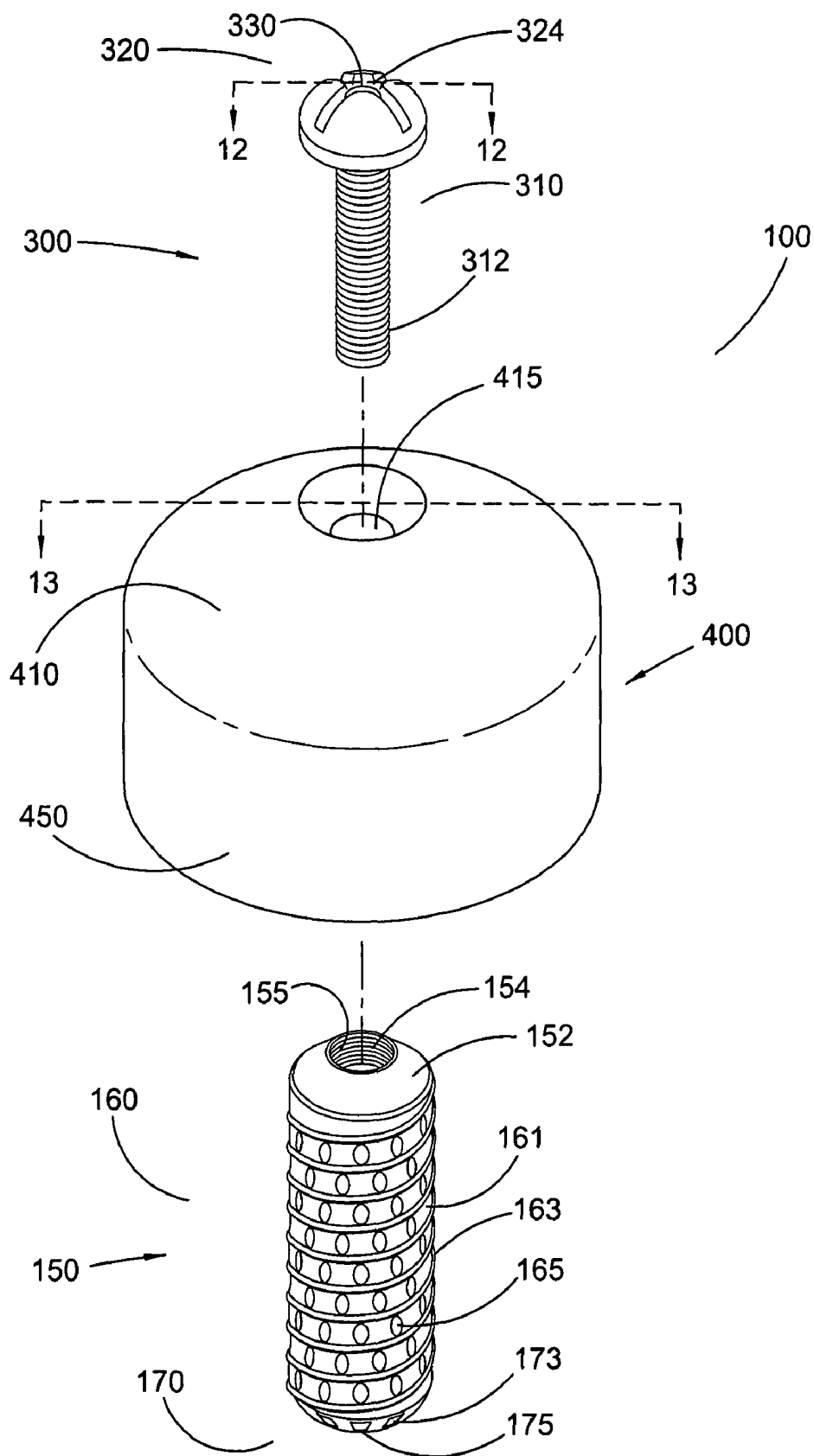


Fig. 10

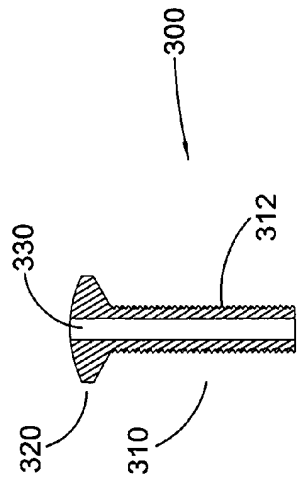


Fig. 12

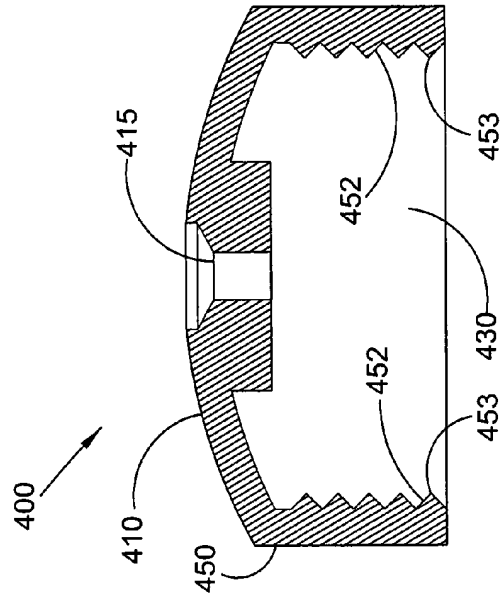


Fig. 13

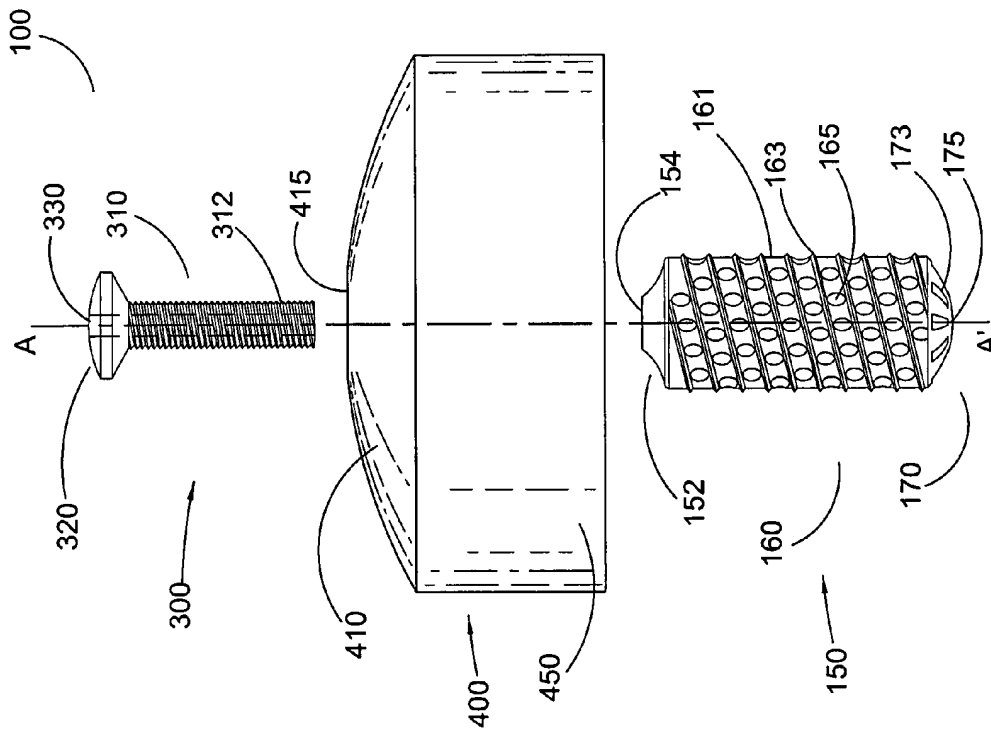


Fig. 11

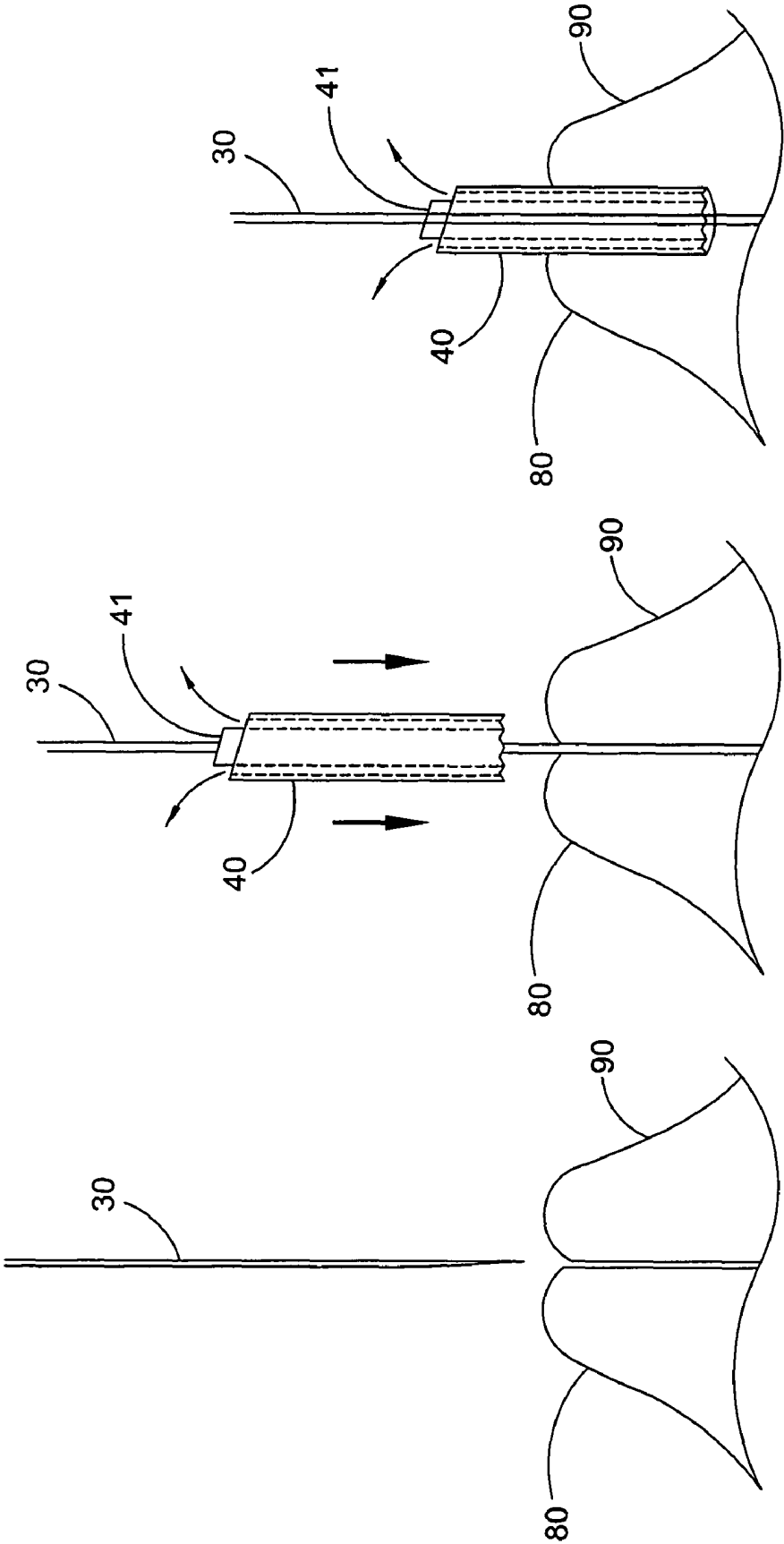


Fig. 14a

Fig. 14b

Fig. 14c

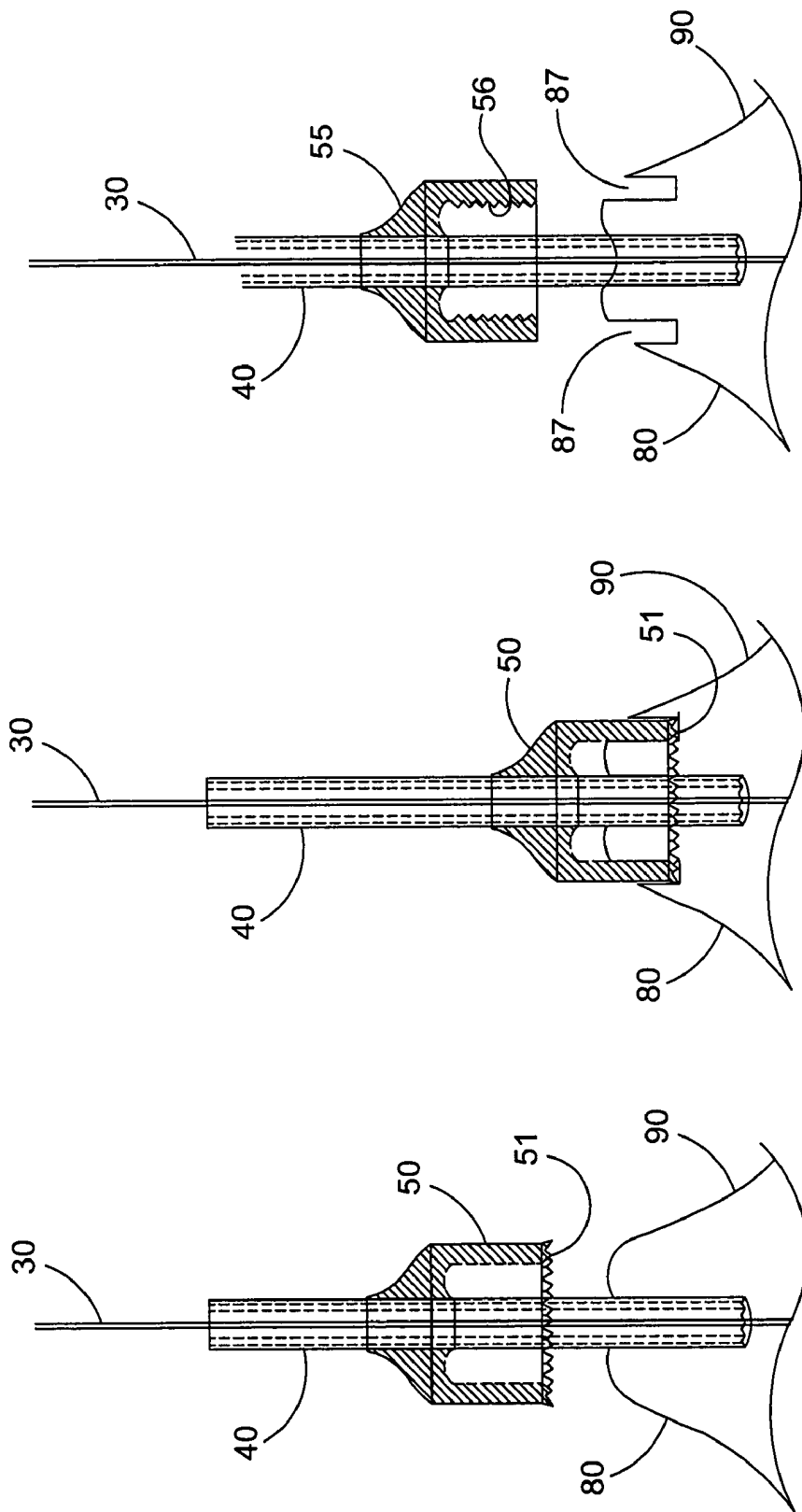


Fig. 14f

Fig. 14e

Fig. 14d

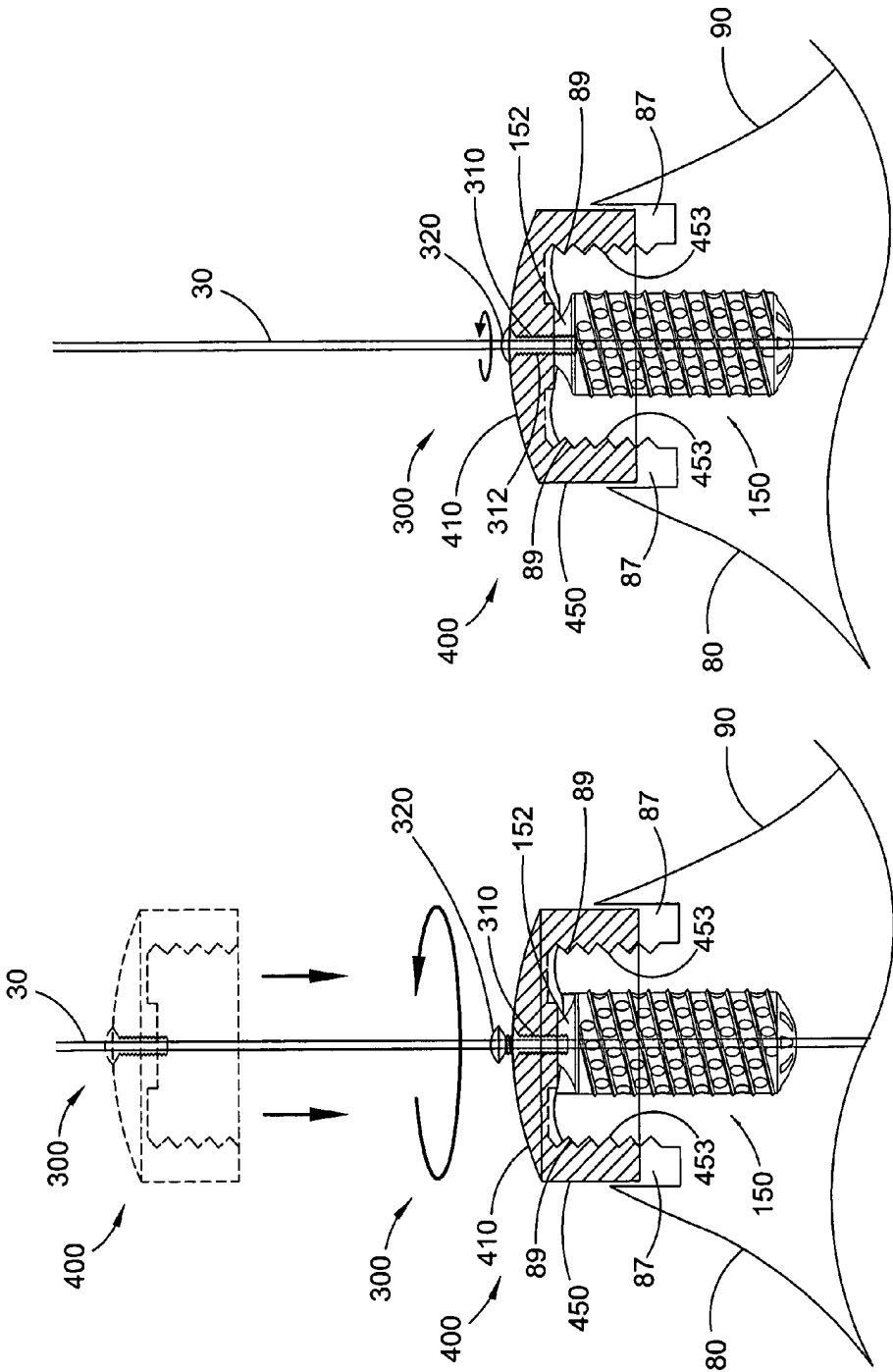


Fig. 14h

Fig. 14g

1

FACET JOINT FIXATION DEVICE**FIELD OF THE INVENTION**

This invention relates to the field of orthopedic surgery and, particularly, to inter-bone fixation and fusion devices and, even more particularly, to interarticular facet joint fixation and fusion devices.

BACKGROUND OF THE INVENTION

The intervertebral discs of the human spine are prone to degeneration. In particular, the intervertebral discs located in highly mobile regions of the spine are disproportionately prone to degeneration, primarily due to overt and covert trauma to the tissue that occurs in the course of repetitive activities. Such trauma tends to disrupt the internal architecture of the disc and leads to bulging, herniation or protrusion of pieces of the disc, and the eventual collapse of the disc space. The resultant mechanical and/or chemical irritation of the surrounding neural elements, such as the spinal cord and nerves, may cause pain, inflammation and varying degrees of osteoarthritis and disability. Additionally, the loss of disc space height relaxes tension on the longitudinal spinal ligaments, thereby contributing to varying degrees of spinal instability.

Various treatments have been developed to treat such intervertebral disc degeneration. Many of these treatments involve the fusion of adjacent vertebra in order to limit their ability to move independently from each other, as such independent movement tends to exacerbate the degeneration of the interposed disc. These prior spinal fusion operations often involve either the passive grafting of bone between the surfaces of proximate articular processes in a facet joint that is denuded of synovium, or they involve the mechanical fixation of the facet joint with a simple screw.

These prior treatments, while fairly adequate for their purpose, suffer from a number of drawbacks. For example, operations that involve the passive grafting of bone require additional instrumented fixation of the spine to prevent dislodgement of the bone grafts from between the articular surfaces of the joint. Operations involving the mechanical fixation with a simple screw are largely adjunctive, that is, the screw alone is not sufficient as a means for fixing the facet joint. The long term success of this procedure is usually dependent upon bony union occurring elsewhere between the adjacent vertebral elements being fused, i.e., interbody or inter-transverse postero-lateral fusions.

Thus, there is a longfelt need for a facet fixation device that can be utilized either directly in a stand alone facet fusion procedure or as an adjunctive fixator to be utilized when other forms of spinal fusion are employed, e.g., as back up for an anterior fusion. There is also a longfelt need for such a device that may be deployed radiographically or through endoscopically-assisted minimally invasive approaches.

BRIEF SUMMARY OF THE INVENTION

The present invention is a device for fixing the positions of proximate bone elements, which is particularly adapted for the fixation of proximate articular processes in a facet joint (hereinafter referred to as the "facet fixation device" or, simply, the "device"). The device broadly comprises: an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the inter-bone implant comprising an internally threaded aperture; a bone fixation apparatus comprising a base having an eyelet and a means

2

connected to the base for mechanically fixing the positions of the proximate bone elements relative to each other, the eyelet being substantially aligned with the internally threaded aperture; and, a screw comprising a head and a threaded shaft extending therefrom, wherein the shaft is operatively arranged to extend through the eyelet and threadingly engage the internally threaded aperture, and the screw is operatively arranged to secure the bone fixation apparatus to the inter-bone implant.

The means for mechanically fixing the positions of the proximate bone elements relative to each other generally comprises substantially opposed surfaces, between which at least a portion of each of the proximate bone elements is immovably secured. The substantially opposed surfaces may be provided by an integral form, such as the inner annular surface of an annular wall, or by separate structures, such as the inner surfaces of opposed jaws.

It is a general object of the present invention to provide a facet fixation device that can be utilized either directly in a stand alone facet fusion procedure or as an adjunctive fixator to be utilized when other forms of spinal fusion are employed, e.g., as back up for an anterior fusion. It is also the object of this invention to provide for deployment of the device either radiographically or through endoscopically assisted minimally invasive approaches.

These and other objects and advantages of the present invention will be readily appreciable from the following description of preferred embodiments of the invention and from the accompanying drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The nature and mode of operation of the present invention will now be more fully described in the following detailed description of the invention taken with the accompanying drawing figures, in which:

FIG. 1 is an exploded perspective view of a first embodiment of the present invention facet fixation device;

FIG. 2 is an exploded, side elevational view of a first embodiment facet fixation device;

FIG. 3 is a top plan view of an inter-bone implant of the facet fixation device;

FIG. 4 is a side elevational view of the inter-bone implant;

FIG. 5 is a bottom plan view of the inter-bone implant;

FIG. 6 is a top plan view of the first embodiment bone fixation apparatus;

FIG. 7 is a side elevational view of the first embodiment bone fixation apparatus;

FIG. 8 is a bottom plan view the first embodiment bone fixation apparatus;

FIG. 8a is a side elevational view of a screw and the first embodiment bone fixation apparatus illustrating the screw moving downwardly;

FIG. 8b is a side elevational view of the screw and bone fixation apparatus shown in FIG. 8a illustrating the actuation of the bone fixation apparatus by the screw;

FIG. 9a is a side view showing a first step in the implementation of the first embodiment facet fixation device;

FIG. 9b is a side view showing a second step in the implementation of the first embodiment facet fixation device;

FIG. 9c is a side view showing a third step in the implementation of the first embodiment facet fixation device;

FIG. 9d is a side view showing a fourth step in the implementation of the first embodiment facet fixation device;

FIG. 9e is a side view showing a fifth step in the implementation of the first embodiment facet fixation device;

3

FIG. 9f is a side view showing a sixth step in the implementation of the first embodiment facet fixation device;

FIG. 9g is a side view showing a seventh step in the implementation of the first embodiment facet fixation device;

FIG. 10 is an exploded perspective view of a second embodiment of the present invention facet fixation device;

FIG. 11 is an exploded, side elevational view of the second embodiment facet fixation device;

FIG. 12 is a cross-sectional view taken generally along line 12-12 in FIG. 10;

FIG. 13 is a cross-sectional view taken generally along line 13-13 in FIG. 10;

FIG. 14a is a side view showing a first step in the implementation of the second embodiment facet fixation device;

FIG. 14b is a side view showing a second step in the implementation of the second embodiment facet fixation device;

FIG. 14c is a side view showing a third step in the implementation of the second embodiment facet fixation device;

FIG. 14d is a side view showing a fourth step in the implementation of the second embodiment facet fixation device;

FIG. 14e is a side view showing a fifth step in the implementation of the second embodiment facet fixation device;

FIG. 14f is a side view showing a sixth step in the implementation of the second embodiment facet fixation device;

FIG. 14g is a side view showing a seventh step in the implementation of the second embodiment facet fixation device; and,

FIG. 14h is a side view showing an eighth step in the implementation of the second embodiment facet fixation device for the fixation of proximate bone elements.

DETAILED DESCRIPTION OF THE INVENTION

At the outset, it should be appreciated that like drawing numbers on different drawing views identify identical, or functionally similar, structural elements of the invention. While the present invention is described with respect to what is presently considered to be the preferred aspects, it is to be understood that the invention as claimed is not limited to the disclosed aspects.

Furthermore, it should be understood that this invention is not limited to the particular methodology, materials and modifications described and as such may, of course, vary. It should also be understood that the terminology used herein is for the purpose of describing particular aspects only, and is not intended to limit the scope of the present invention, which is limited only by the appended claims.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any methods, devices or materials similar or equivalent to those described herein can be used in the practice or testing of the invention, the preferred methods, devices, and materials are now described.

As stated supra, the present invention device broadly comprises: an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the implant having a threaded aperture; a bone fixation apparatus adapted to mechanically fix the position of the proximate bone elements relative to each other and to the inter-bone implant, the bone fixation apparatus including a base having an eyelet substantially aligned with the internally threaded aperture; and, a screw comprising a head and a threaded shaft extending therefrom, the shaft being arranged through the eyelet and threadingly engaged in the internally threaded

4

aperture, and the screw is operatively arranged to fixedly secure the bone fixation apparatus to the inter-bone implant.

The inter-bone implant is operatively arranged to promote the fusion or bony union of the proximate bone elements, and the bone fixation apparatus is operatively arranged to fix the respective position of the proximate bone elements relative to each other and, possibly to the implant, in order to enhance the efficacy of the inter-bone implant. It should be noted that the bone fixation apparatus is not merely supplementary to the inter-bone implant, but is operatively arranged to independently fix the positions of the proximate bone element relative to each other, which may be advantageous in situations where an inter-bone implant is not necessary, not feasible, or simply unwanted due to the nature of the treatment.

Multiple embodiments of the bone fixation apparatus have been contemplated, two of which are shown and described in detail herein. Regardless of the particular embodiment, the bone fixation apparatus comprises a base and a means connected thereto for mechanically fixing the positions of the proximate bone elements relative to each other and, when applicable, to the inter-bone implant. When used in conjunction with the inter-bone implant, the base is preferably in the form of an arcuate or planar plate which includes an eyelet. The eyelet is arranged to receive the shaft of the screw there-through and allow at least portion of the shaft to reach and threadingly engage the internally threaded aperture of the inter-bone implant.

The means for mechanically fixing the positions of the proximate bone elements relative to each other generally comprises at least two substantially opposed surfaces, between which at least a portion of each of the proximate bone elements is immovably secured. The substantially opposed surfaces may be provided by an integral form, such as the inner annular surface of an annular wall, or by separate structures, such as the inner surfaces of opposed jaws.

The following provides a detailed description of two embodiments of the present invention, which are differentiated from each other primarily by the particular bone fixation apparatus employed. The first embodiment bone fixation apparatus comprises a plurality of opposed jaws, which are operatively arranged to provide the at least two substantially opposed surfaces. The second embodiment bone fixation apparatus comprises an annular wall having an inner annular surface, which is operatively arranged to provide the at least two substantially opposed surfaces.

The first embodiment facet fixation device 100 is best understood in view of FIGS. 1-9g. FIG. 1 is a perspective view of facet fixation device 100 broadly comprising inter-bone implant 150, screw 300, and bone fixation apparatus 200, hereinafter referred to as clamp 200.

Screw 300, which may be any suitable screw, broadly includes head 320, shaft 310 having threads 312, and, preferably, through-bore 330. The screw drive of screw 300 may be of any type, but is preferably hex cap screw 322 when used in combination with clamp 200. Screw 300 may further include plate 220, the function of which is described in detail infra. Plate 220 may be a separate component, as shown in the figures, or integrally formed with head 320.

As shown in FIGS. 3-5, inter-bone implant 150 comprises body 160, which is preferably hollow and either cylindrical or frustoconical, first end 152, and second end 170. First end 152 includes aperture 154 having internal threads 155, which are operatively arranged to threadingly engage threads 312 of screw 300. Second end 170 preferably includes one or more apertures 173, which are arranged to accept residual bone material into hollow body 160, and central aperture 175.

5

Residual bone material is often produced when preparing proximate bone elements for the implantation of inter-bone implant **150** therebetween, as described in detail infra. The residual bone material often contains viable osteocytes, which can help rebuild bony matrix and enable the proximate bone elements to form a bony union therebetween and, ultimately, fuse. Implant **150** may also include bone morphogenic proteins, such as BMP-2 and BMP-7, which serve to induce such bony union. Outer surface **161** of body portion **160** is preferably irregular and includes at least one, but preferably a plurality, of apertures **165**. The irregularity of outer surface **161** may be in the form of protuberances, for example, threads **163** as shown in the figures. The irregularity of outer surface **161** helps secure implant **150** between proximate bone elements by creating a frictional engagement between implant **150** and the bone elements. Apertures **165** are also arranged to receive residual bone material into body **160**.

Clamp **200** comprises: base **210**, which is preferably in the form of a substantially planar plate, and includes eyelet **215** operatively arranged to receive shaft **310** therethrough; and, a pair of opposed jaws, **240** and **270**, pivotally connected to base **210**. Jaws **240** and **270** may comprise any number of teeth, the shape and structure of which may be adapted for particular bone elements, such as, a superior articular process and an inferior articular process of a facet joint. Additionally, clamp **200** may comprise more than the two jaws shown and described herein, and may also comprise as few as one pivotally connected jaw. Regardless of the particular adaptation, the teeth of the jaws comprise substantially opposed surfaces, between which at least a portion of each of the proximate bone elements is immovably secured, as described in further detail infra.

In the particular embodiment shown and described herein, jaw **240** preferably comprises two teeth, namely, first tooth **250** and second tooth **260**. First tooth **250** comprises first inner surface **254** and terminates at first pointed tip **252**. Second tooth **260** comprises second inner surface **264** and terminates second pointed tip **262**. First and second pointed tips **252** and **262**, respectively, are arranged to frictionally engage and/or pierce the surface of the proximate bone elements.

Likewise, jaw **270** preferably comprises two teeth, namely, third tooth **280** and fourth tooth **290**. Third tooth **280** comprises third inner surface **284** and terminates at third pointed tip **282**. Fourth tooth **290** comprises fourth inner surface **294** and terminates fourth pointed tip **292**. Third and fourth pointed tips **282** and **292**, respectively, are arranged to frictionally engage and/or pierce the surface of the proximate bone elements.

Jaws **240** and **270** may be pivotally connected to base **210** by any means known in the art. In the particular embodiment shown and described herein, base **210** includes barrels **212a** and **212b**. Barrel **212a** is operatively arranged to fit between, and align with, barrels **241** and **243** of jaw **240**, and pivot pin **267** is operatively arranged to extend through barrels **241**, **212a**, and **243**. Together, barrels **241**, **212a**, **243**, and pivot pin **267** form a hinge bearing which provides a pivotable connection between jaw **240** and base **210**. Pivot pin **267** may include cap **269** affixed to one end to prevent it from sliding out of the barrels.

Likewise, barrel **212b** is operatively arranged to fit between, and align with, barrels **271** and **273** of jaw **270**, and pivot pin **297** is operatively arranged to extend through barrels **271**, **212b**, and **273**. Together, barrels **271**, **212b**, **273**, and pivot pin **297** form a hinge bearing which provides a pivotable

6

connection between jaw **270** and base **210**. Pivot pin **297** may include cap **299** affixed to one end to prevent it from sliding out of the barrels.

Jaw **240** is arranged substantially opposed to jaw **270**, such that first and second inner surfaces **254** and **264**, respectively, of jaw **240** are arranged substantially opposed to third and fourth inner surfaces **284** and **294**, respectively, of jaw **270**, thereby defining mouth **230**. It is between these opposed surfaces that at least a portion of each of the proximate bone elements is immovably secured, as described in further detail infra. Jaws **240** and **270** are also arranged to pivot toward and/or away from each other.

In a preferred embodiment, jaws **240** and **270** further comprise actuators **245** and **275**, respectively. Jaw **240** is operatively arranged to pivot toward jaw **270** when a force is applied to actuator **245**. Likewise, jaw **270** is operatively arranged to pivot toward jaw **240** when a force is applied to actuator **275**. In one embodiment, head **320** is operatively arranged to apply mechanical force to actuator **245** and/or actuator **275** as head **320** moves toward base **210**. In a further embodiment, head **320** applies such mechanical force simultaneously to actuators **245** and **275**, thereby causing each actuator to simultaneously pivot toward each other.

In a preferred embodiment, device **100** includes plate **220**, which is arranged between head **320** and base **210**. Plate **220** is operatively arranged to provide a mechanical connection between head **320** and actuators **245** and **275**, i.e., head **320** is operatively arranged to apply mechanical force to plate **220**, which, in turn, is operatively arranged to apply mechanical force to actuators **245** and **275**, as head **320** moves toward base **210**. Plate **220** preferably includes aperture **225**, which is substantially aligned with eyelet **215** and internally threaded aperture **154**, and is arranged to receive shaft **310** therethrough. As shown in the figures, plate **220** may be embodied as a simple washer.

The arrows in FIG. **8a** illustrate head **320** moving toward base **210** in order to apply mechanical force to plate **220**, and the arrows in FIG. **8b** illustrate the pivoting of jaws **240** and **270** pivoting toward each other in response to the application of mechanical force on actuators **245** and **275** by plate **220**.

Broadly, FIGS. **9a-9g** illustrate the preferred method or procedure by which device **100** is implemented. Particularly: FIGS. **9a-9c** illustrate the method by which proximate bone elements **80** and **90** are suitably prepared for the implementation of device **100**; FIGS. **9d-9e** illustrate the method by which inter-bone implant **150** is implanted between the suitably prepared proximate bone elements **80** and **90**; and, FIGS. **9f-9g** illustrate the method by which the bone fixation apparatus, specifically, clamp **200**, is arranged to mechanically fix the positions of proximate bone elements **80** and **90** relative to each other, and the method by which screw **300** is operatively arranged to secure clamp **200** to inter-bone implant **150**.

As shown in FIG. **9a**, the initial step in the procedure includes inserting a Kirschner wire, hereinafter referred to as K-wire **30**, between proximate bone elements **80** and **90**. K-wire **30** is operatively arranged to guide the tools involved in suitably preparing proximate bone elements **80** and **90**, as well as, the various components of device **100**, toward proximate bone elements **80** and **90**. FIG. **9b** illustrates the second step in the procedure wherein first drill **40** is guided by K-wire **30** toward bone elements **80** and **90**, as indicated by the arrows. First drill **40** is preferably hollow so that K-wire **30** can be arranged in its interior, in order to guide it toward proximate bone elements **80** and **90**. Additionally, first drill **40** may include suction channel **41**, which is operatively arranged to remove excess bone material created by the drilling process, as is illustrated by the arrows proximate to chan-

nel 41 in FIGS. 9b and 9c. FIG. 9c illustrates the third step in the procedure wherein first drill 40 removes bone material from both proximate bone elements 80 and 90.

As shown in FIG. 9d, first drill 40 is operatively arranged to remove bone material from bone elements 80 and 90, thereby generating cavity 85, which is defined by bone elements 80 and 90. Cavity 85 is arranged to receive inter-bone implant 150 therein. FIG. 9d illustrates the fourth step in the procedure wherein inter-bone implant 150 is guided by K-wire 30 toward cavity 85. Since implant 150 includes apertures 154 and 175 at opposite ends, and body portion 160 is preferably hollow, K-wire 30 can be arranged inside implant 150 in order to guide it toward cavity 85, as indicated by the arrows in FIG. 9d.

FIG. 9e illustrates the fifth step in the procedure wherein implant 150 is arranged between suitably prepared bone elements 80 and 90. Implant 150 is preferably arranged such that outer surface 161 is in contact with proximate bone elements 80 and 90, particularly by means of a frictional engagement of threads 163 with bone elements 80 and 90, thereby mitigating any movement of implant 150 within cavity 85.

Clamp 200 and screw 300 are arranged to be guided by K-wire 30 toward implant 150 and proximate bone elements 80 and 90. Particularly, K-wire 30 can be threaded through eyelet 215 in order to guide clamp 200 toward implant 150 and proximate bone elements 80 and 90. In a preferred embodiment, screw 300 includes through-bore 330, through which K-wire 30 can be threaded in order to guide screw 300 toward eyelet 215 and internally threaded aperture 154.

FIG. 9f illustrates the sixth step in the procedure wherein shaft 310 is arranged through eyelet 215 and is threadingly engaging internally threaded aperture 154, as illustrated by the semicircular arrow around K-wire 30. As threads 312 of shaft 310 positively engage internally threaded aperture 154, head 320 is drawn toward base 210 and applies mechanical force to plate 220. Plate 220, in turn, applies mechanical force to actuators 245 and 275, which cause jaws 240 and 270 to pivot toward each other, as illustrated by the arrows proximate the jaws.

FIG. 9g illustrates the seventh, and relatively final, step in the procedure wherein inter-bone implant 150 is arranged between suitably prepared proximate bone elements 80 and 90; clamp 200, is fixing the positions of proximate bone elements 80 and 90 relative to each other by immovably securing at least a portion of bone elements 80 and 90 between substantially opposed surfaces 254 and 284, eyelet 215 is substantially aligned with internally threaded aperture 154, and screw 300 is securing clamp 200 to inter-bone implant 150.

The second embodiment facet fixation device 100, is best understood in view of FIGS. 10-14h. FIG. 10 is a perspective view of device 100 broadly comprising inter-bone implant 150, screw 300, and bone fixation apparatus 400, hereinafter referred to as cap 400.

Screw 300, which may be any suitable screw, broadly includes head 320, shaft 310 having threads 312, and, preferably, through-bore 330, as shown in FIGS. 11 and 12. The screw drive of screw 300 may be of any type, but is preferably cruciform screw drive 324 when used in combination with cap 400.

As in the first embodiment, inter-bone implant 150 includes body 160, which is preferably hollow and either cylindrical or frustoconical, first end 152, and second end 170. First end 152 includes aperture 154 having internal threads 155, which are operatively arranged to threadingly engage threads 312 of screw 300. Second end 170 preferably includes one or more apertures 173, which are arranged to

accept residual bone material into hollow body 160, and central aperture 175. Outer surface 161 of body portion 160 is preferably irregular and includes at least one, but preferably a plurality, of apertures 165. The irregularity of outer surface 161 may be in the form of protuberances, for example, threads 163 as shown in the figures. The irregularity of outer surface 161 helps secure implant 150 between proximate bone elements by creating a frictional engagement between implant 150 and the bone elements. Apertures 165 are also arranged to receive residual bone material into body 160.

Cap 400 comprises: base 410, which is preferably in the form of a substantially arcuate plate, and includes eyelet 415 operatively arranged to receive shaft 310 therethrough; and, annular wall 450 extending from base 410, which, in conjunction with base 410, defines inner chamber 430. Eyelet 415 is preferably recessed so that head 320 fits substantially flush with the surface of base 410 when assembled together. Annular wall 450 may be a cylindrical form, as shown and described, but may also be adapted for different proximate bone elements, the particular structure of which may necessitate a different shape for annular wall 450, such as, a frustoconical form.

Regardless of the particular adaptation, annular wall 450 comprises inner annular surface 452, which preferably includes threads 453, as shown in FIG. 13. Inner annular surface 452 provides a continuum of substantially opposed surfaces, since any location on inner annular surface 452 has a complimentary location, diametrically opposed across chamber 430, on surface 452. Thus, inner annular surface 452 provides a continuum of diametrically opposed surfaces, between which at least a portion of each of the proximate bone elements is immovably secured, as described in further detail infra.

Broadly, FIGS. 14a-14h illustrate the preferred method or procedure by which device 100 is implemented. Particularly: FIGS. 14a-14f illustrate the method by which proximate bone elements 80 and 90 are suitably prepared for the implementation of device 100; FIGS. 14g-14h illustrate the method by which the bone fixation apparatus, namely, cap 400, is arranged to mechanically fix the positions of proximate bone elements 80 and 90 relative to each other, and the method by which screw 300 is operatively arranged to secure cap 400 to inter-bone implant 150. The method by which inter-bone implant 150 is implanted between the suitably prepared proximate bone elements 80 and 90 is not shown in these figures as it is substantially identical to steps described supra and shown in FIGS. 9d-9e.

The first three steps for suitably preparing proximate bone elements 80 and 90 are illustrated in FIGS. 14a-14c, and are substantially identical to the first three respective steps for implementing the first embodiment, as described supra and shown in FIGS. 9a-9c. Particularly, FIG. 14a shows the initial step wherein K-wire 30 is inserted between proximate bone elements 80 and 90. K-wire 30 is operatively arranged to guide the tools involved in suitably preparing proximate bone elements 80 and 90, as well as, the various components of device 100, toward proximate bone elements 80 and 90. FIG. 14b illustrates the second step in the procedure wherein first drill 40 is guided by K-wire 30 toward bone elements 80 and 90, as indicated by the arrows. First drill 40 is preferably hollow so that K-wire 30 can be arranged in its interior, in order to guide it toward proximate bone elements 80 and 90. Additionally, first drill 40 may include suction channel 41, which is operatively arranged to remove excess bone material created by the drilling process, as is illustrated by the arrows proximate to channel 41 in FIGS. 14b and 14c. FIG. 14c illustrates the third step in the procedure wherein first drill 40

9

removes bone material from both proximate bone elements **80** and **90**, thereby generating cavity **85**.

To suitably prepare proximate bone elements **80** and **90** for the implantation of second embodiment device **100**, the additional steps shown in FIGS. **14d-14f** are required. FIG. **14d** illustrates a fourth step wherein second drill **50** is guided by K-wire **30** toward proximate bone elements **80** and **90**. Second drill **50** comprises an annular wall having a ring of teeth **51** along its circular leading edge. As shown in FIGS. **14e** and **14f**, second drill **50** is operatively arranged to carve annular recess **87** into bone elements **80** and **90**.

FIG. **14f** shows the next step wherein third drill **55** is guided by K-wire **30** toward proximate bone elements **80** and **90**, particularly toward annular recess **87**. Third drill **55** is a threading tool comprising an annular wall having threaded inner annular surface **56**, which is operatively arranged to carve threads **89** into bone elements **80** and **90** within annular recess **87**, as shown in FIGS. **14g** and **14h**. Annular recess **87** is arranged to fittingly receive annular wall **450** of cap **400**. Additionally, **89** threads are operatively arranged to threadingly engage threads **453** of inner annular surface **452**.

FIGS. **14g-14h** show inter-bone implant **150** already implanted between proximate bone elements **80** and **90** within cavity **85**. Cap **400** and screw **300** are arranged to be guided by K-wire **30** toward implant **150** and proximate bone elements **80** and **90**, as illustrated with the parallel arrows shown in FIG. **14g**. Particularly, K-wire **30** can be threaded through eyelet **415** in order to guide cap **400** toward implant **150** and proximate bone elements **80** and **90**, as shown in FIG. **14g**. In a preferred embodiment, screw **300** includes through-bore **330**, through which K-wire **30** can be threaded in order to guide screw **300** toward eyelet **415** and internally threaded aperture **154**.

FIG. **14g** further illustrates how threads **453** of inner annular surface **452** threadingly engage threads **89** of annular recess **87**, as indicated by the large semicircular arrow around K-wire **30**. As threads **453** threadingly engage threads **89**, proximate bone elements **80** and **90** are immovably secured between the continuum of substantially opposed surfaces provided by inner annular surface **452**, as described supra.

FIG. **14h** illustrates the relatively final step in the procedure wherein shaft **310** is arranged through eyelet **415** and is threadingly engaging internally threaded aperture **154**, as indicated by the small semicircular arrow around K-wire **30**. As threads **312** of shaft **310** positively engage internally threaded aperture **154**, head **320** is drawn toward base **410** until cap **400** is secured to inter-bone implant **150**.

Thus, it is seen that the objects of the present invention are efficiently obtained, although modifications and changes to the invention should be readily apparent to those having ordinary skill in the art, which modifications are intended to be within the spirit and scope of the invention as claimed. It also is understood that the foregoing description is illustrative of the present invention and should not be considered as limiting. Therefore, other embodiments of the present invention are possible without departing from the spirit and scope of the present invention.

What is claimed is:

1. A device for fixing the positions of proximate bone elements comprising:

an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the inter-bone implant comprising an internally threaded aperture;

a bone fixation apparatus comprising a base having an eyelet and a means connected to the base for mechanically fixing the positions of the proximate bone elements

10

relative to each other, the eyelet being substantially aligned with the internally threaded aperture; and, a screw comprising a head and a threaded shaft extending therefrom, wherein the shaft is operatively arranged to extend through the eyelet and threadingly engage the internally threaded aperture, and the screw is operatively arranged to secure the bone fixation apparatus to the inter-bone implant; and,

wherein the means for fixing the proximate bone elements relative to each other comprises a plurality of opposed jaws pivotably connected to the base, and the plurality of opposed jaws are operatively arranged to immovably secure at least a portion of each of the proximate bone elements therebetween.

2. The device recited in claim 1 wherein at least one jaw of the plurality of opposed jaws comprises an actuator operatively arranged to pivot the at least one jaw when force is applied to the actuator.

3. The device recited in claim 2 wherein the head of the screw is operatively arranged to apply force to the actuator.

4. The device recited in claim 3 further comprising a plate having a central aperture substantially aligned with the eyelet and the internally threaded aperture, wherein the plate is arranged between the head of the screw and the base, the shaft is arranged through the central aperture, the head of the screw is operatively arranged to apply force to the plate, and the plate is operatively arranged to apply force to the actuator.

5. The device recited in claim 4 wherein the plate comprises a washer.

6. The device recited in claim 1 wherein the inter-bone implant further comprises a body portion having an irregular outer surface.

7. The device recited claim 6 wherein the outer surface is threaded.

8. The device recited in claim 6 wherein the body portion has a hollow interior and includes a plurality of apertures extending from the outer surface to the interior.

9. The device recited in claim 1 wherein the screw includes a longitudinal through-bore.

10. A device for fixing the positions of proximate bone elements comprising:

an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the inter-bone implant comprising an internally threaded aperture;

a bone fixation apparatus comprising a base having an eyelet and a means connected to the base for mechanically fixing the positions of the proximate bone elements relative to each other, the eyelet being substantially aligned with the internally threaded aperture, and,

a screw comprising a head and a threaded shaft extending therefrom, wherein the shaft is operatively arranged to extend through the eyelet and threadingly engage the internally threaded aperture, and the screw is operatively arranged to secure the bone fixation apparatus to the inter-bone implant;

wherein the means for mechanically fixing the positions of the proximate bone elements relative to each other comprises a plurality of opposed jaws pivotably connected to the base, and the plurality of opposed jaws are operatively arranged to provide the at least two substantially opposed surfaces and,

wherein the means for mechanically fixing the positions of the proximate bone elements relative to each other comprises a plurality of opposed jaws pivotably connected to

11

the base, and the plurality of opposed jaws are operatively arranged to provide the at least two substantially opposed surfaces.

11. The device recited in claim 10 wherein at least one jaw of the plurality of opposed jaws comprises an actuator operatively arranged to pivot the at least one jaw when force is applied to the actuator. 5

12. The device recited in claim 11 wherein the head of the screw is operatively arranged to apply force to the actuator. 10

13. The device recited in claim 12 further comprising a plate having an aperture substantially aligned with the eyelet and the internally threaded aperture, wherein the plate is arranged between the head of the screw and the base, the shaft is arranged through the aperture, the head of the screw is operatively arranged to apply force to the plate, and the plate is operatively arranged to apply force to the actuator. 15

14. The device recited in claim 13 wherein the plate comprises a washer.

15. The device recited in claim 10 wherein the inter-bone implant further comprises a body portion having an irregular outer surface. 20

16. A device for fixing the positions of proximate bone elements comprising:

an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the inter-bone implant comprising an internally threaded aperture; 25

a bone fixation apparatus comprising a base having an eyelet and a means connected to the base for mechanically fixing the positions of the proximate bone elements relative to each other, the eyelet being substantially aligned with the internally threaded aperture; and, 30

a screw comprising a head and a threaded shaft extending therefrom, wherein the shaft is operatively arranged to extend through the eyelet and threadingly engage the

12

internally threaded aperture, and the screw is operatively arranged to secure the bone fixation apparatus to the inter-bone implant; and,

wherein the means for fixing the proximate bone elements relative to each other comprises a single annular wall extending from the base, the annular wall having an inner annular surface arranged to provide a continuum of diametrically opposed surfaces, between which at least a portion of each of the proximate bone elements is immovably securable.

17. A device for fixing the positions of proximate bone elements comprising:

an inter-bone implant adapted to be implanted between suitably prepared proximate bone elements, the inter-bone implant comprising an internally threaded aperture;

a bone fixation apparatus comprising a base having an eyelet and a means connected to the base for mechanically fixing the positions of the proximate bone elements relative to each other, the eyelet being substantially aligned with the internally threaded aperture, and,

a screw comprising a head and a threaded shaft extending therefrom, wherein the shaft is operatively arranged to extend through the eyelet and threadingly engage the internally threaded aperture, and the screw is operatively arranged to secure the bone fixation apparatus to the inter-bone implant;

wherein the means for mechanically fixing the positions of the proximate bone elements relative to each other and to the inter-bone implant comprises a single annular wall extending from the base, the single annular wall comprising an inner annular surface operatively arranged to provide at least two substantially opposed surfaces.

* * * * *