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(12) **United States Patent**  
**Carl et al.**

(10) **Patent No.:** **US 9,393,127 B2**

(45) **Date of Patent:** **Jul. 19, 2016**

(54) **SYSTEMS, DEVICES AND APPARATUSES FOR BONY FIXATION AND DISK REPAIR AND REPLACEMENT METHODS RELATED THERETO**

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(73) Assignee: **K2M, Inc.**, Leesburg, VA (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 80 days.

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(65) **Prior Publication Data**

US 2014/0358236 A1 Dec. 4, 2014

**Related U.S. Application Data**

(60) Continuation of application No. 13/928,027, filed on Jun. 26, 2013, which is a division of application No. 12/087,912, filed as application No. PCT/US2007/001402 on Jan. 17, 2007, now Pat. No.

(Continued)

(51) **Int. Cl.**  
**A61F 2/44** (2006.01)  
**A61B 17/16** (2006.01)

(Continued)

(52) **U.S. Cl.**  
CPC ..... **A61F 2/4455** (2013.01); **A61B 17/1642** (2013.01); **A61B 17/1671** (2013.01);

(Continued)

(58) **Field of Classification Search**  
CPC ..... A61F 2/4455; A61B 17/1642; A61B 17/1671  
USPC ..... 606/79-85, 86 R, 87-89; 623/17.11-17.16  
See application file for complete search history.

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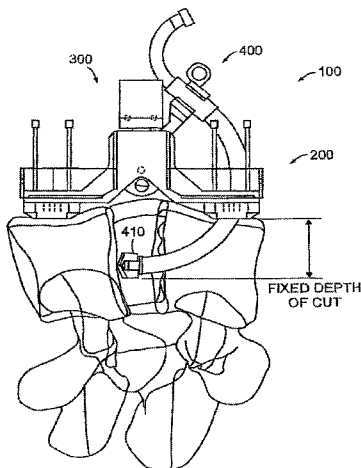
*Primary Examiner* — Christopher Beccia

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(57) **ABSTRACT**

The present invention features new methods, apparatuses and devices for fixing adjacent bone segments, segments of a bony structure and adjacent vertebrae of a spine. The methods, apparatuses and devices utilize an apparatus for forming a channel in a surface of the bone or bony structure segments or adjacent vertebra or a channel submerged within the bone or bony structure segments or adjacent vertebra. In more particular embodiments such apparatuses and methods including forming an arcuate channel and which channel can receive therein a curved rod or implant member. Also featured are systems, apparatuses and methods for removably suspending a spacer in the intervertebral space while forming such a channel as well as systems, apparatuses and methods for use of dynamized implant members.

**5 Claims, 69 Drawing Sheets**



**Related U.S. Application Data**

8,486,078, which is a continuation-in-part of application No. 10/968,867, filed on Oct. 18, 2004, now abandoned, and a continuation-in-part of application No. 10/601,014, filed on Jun. 20, 2003, now Pat. No. 8,021,401, which is a continuation of application No. 09/536,732, filed on Mar. 28, 2000, now Pat. No. 6,607,530.

(60) Provisional application No. 60/759,718, filed on Jan. 17, 2006, provisional application No. 60/512,134, filed on Oct. 17, 2003, provisional application No. 60/133,356, filed on May 10, 1999.

(51) **Int. Cl.**

*A61B 17/17* (2006.01)  
*A61B 17/32* (2006.01)  
*A61B 17/88* (2006.01)

(52) **U.S. Cl.**

CPC ..... *A61B17/1757* (2013.01); *A61B 17/1631* (2013.01); *A61B 17/32002* (2013.01); *A61B 17/8875* (2013.01)

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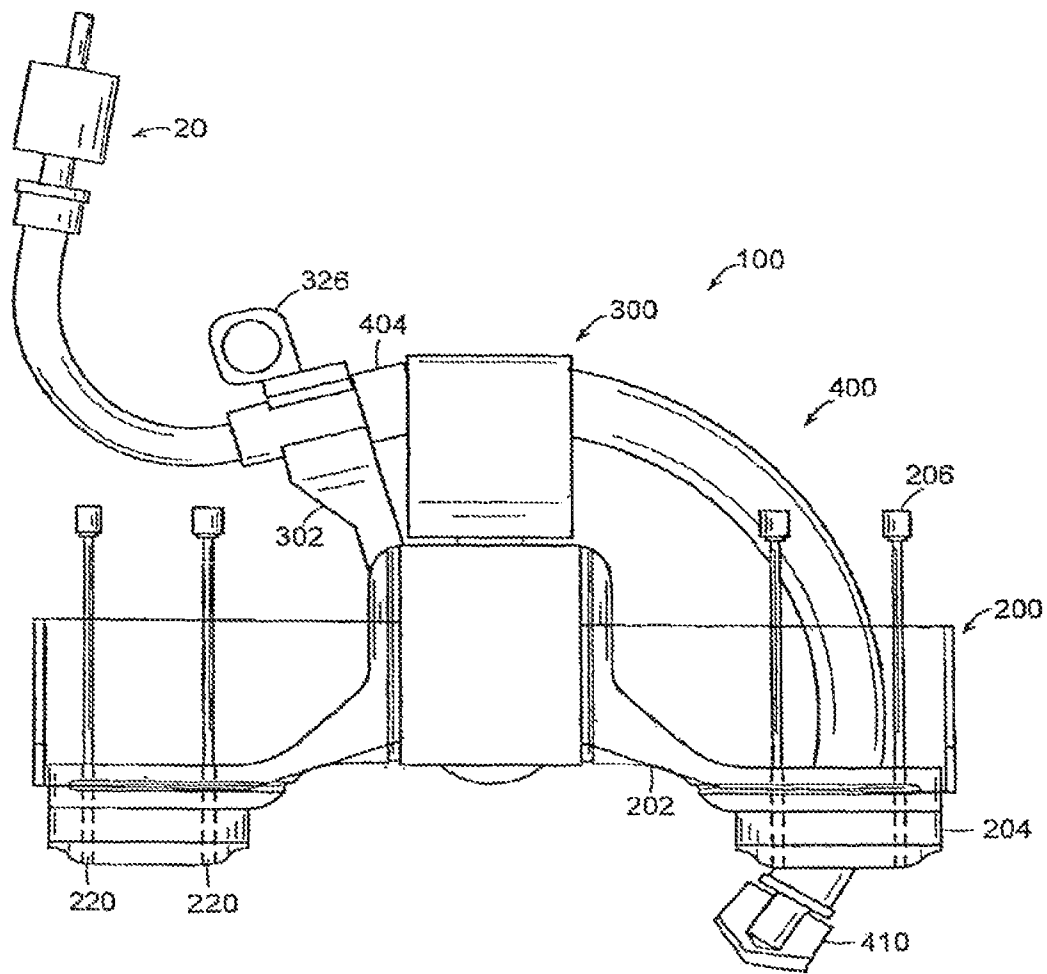
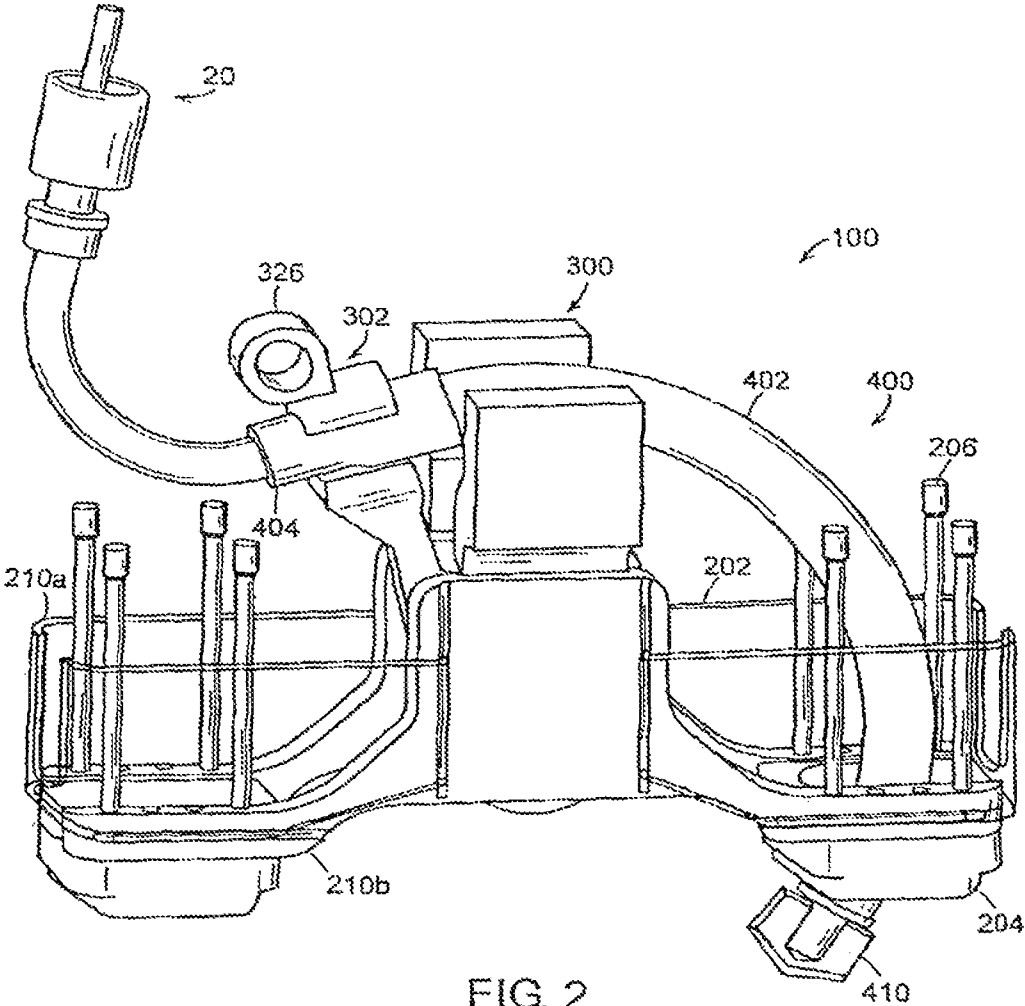
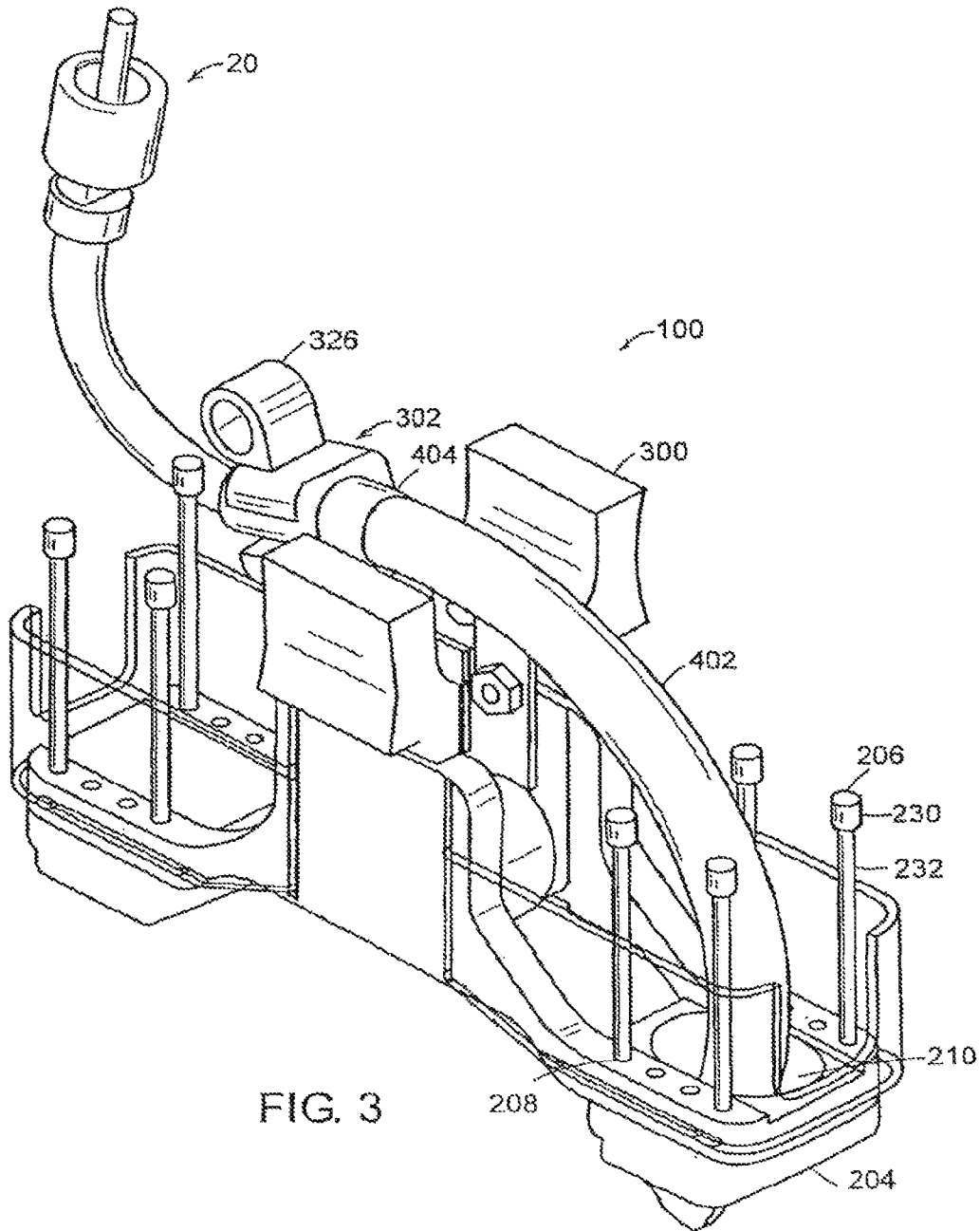


FIG. 1





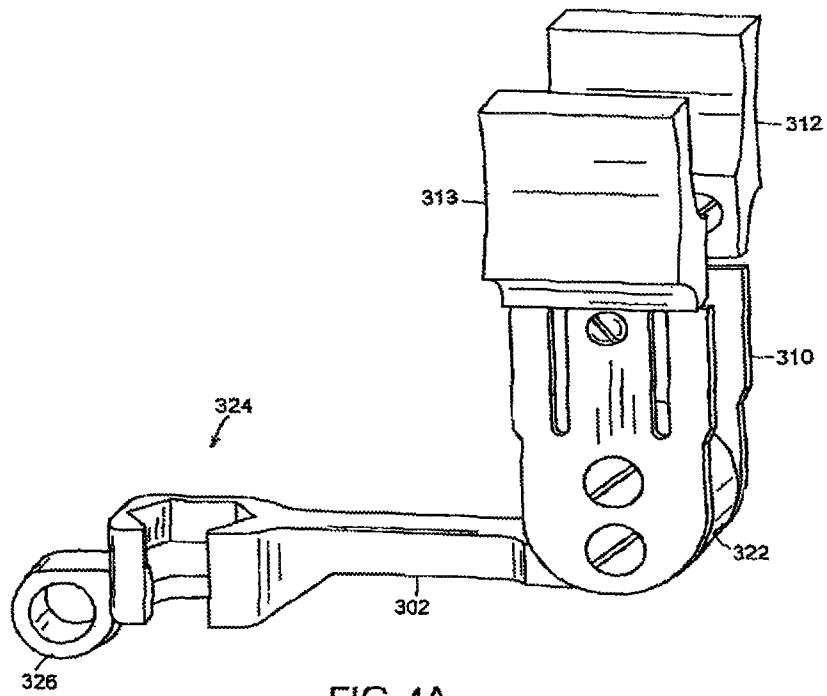


FIG. 4A

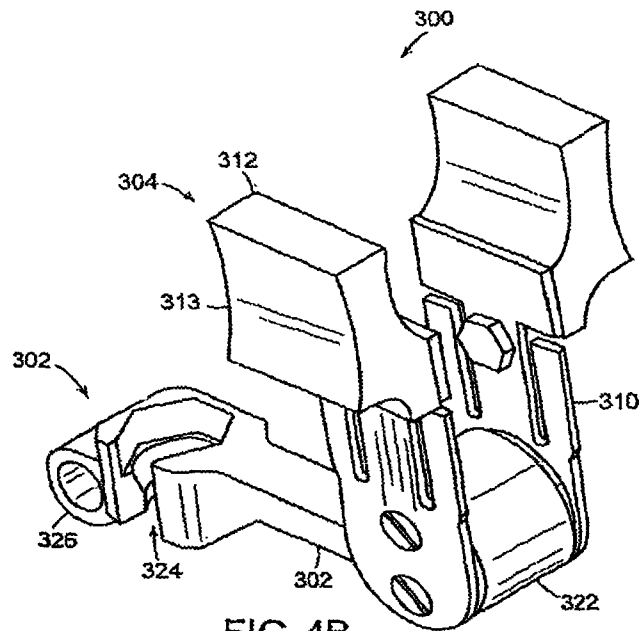


FIG. 4B

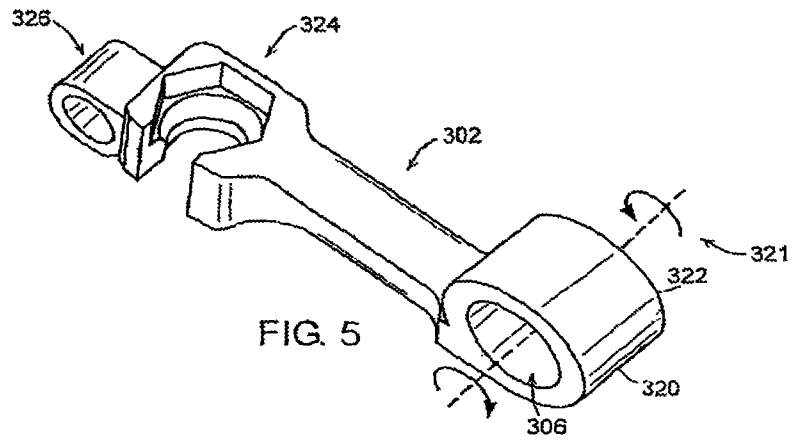
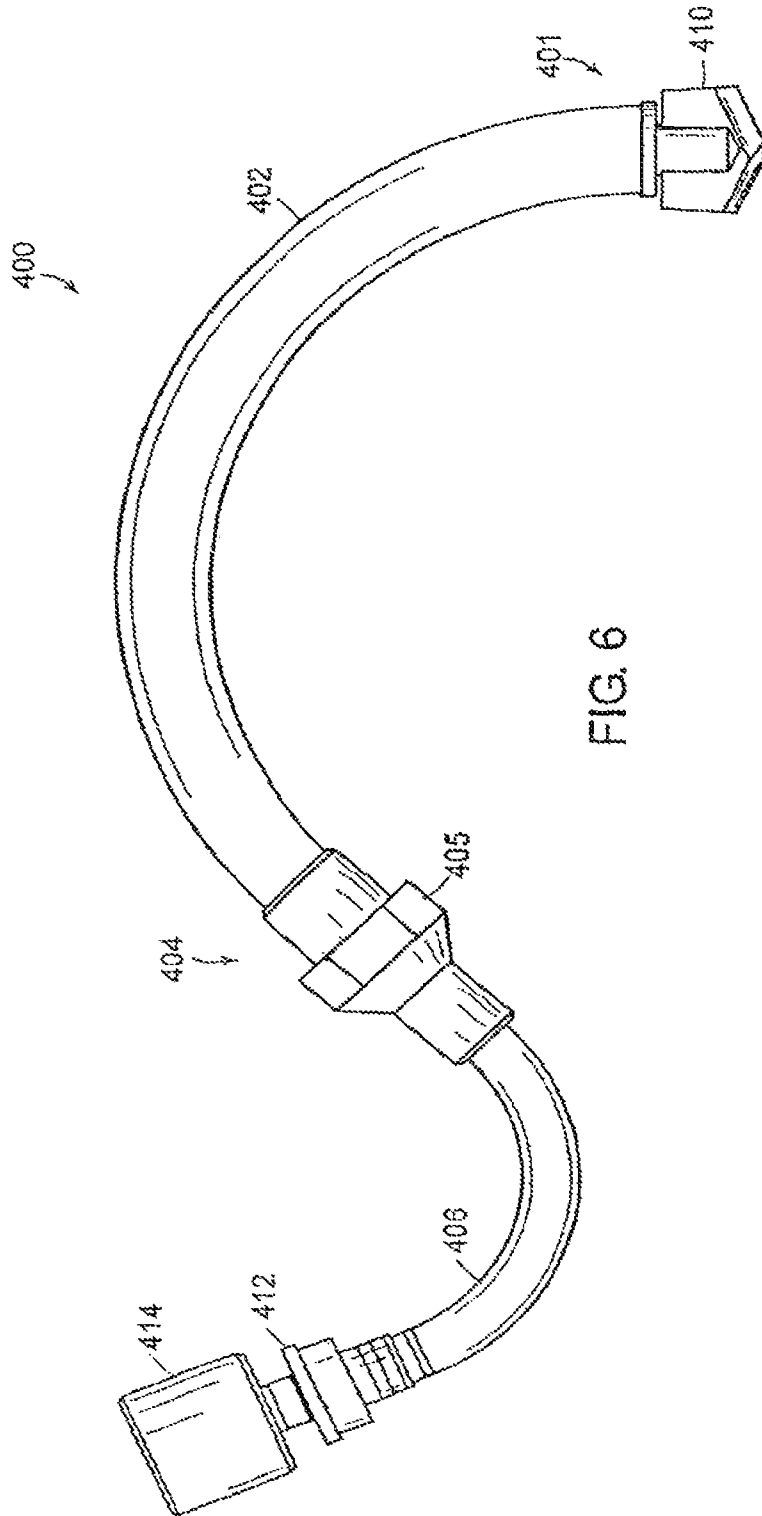


FIG. 5





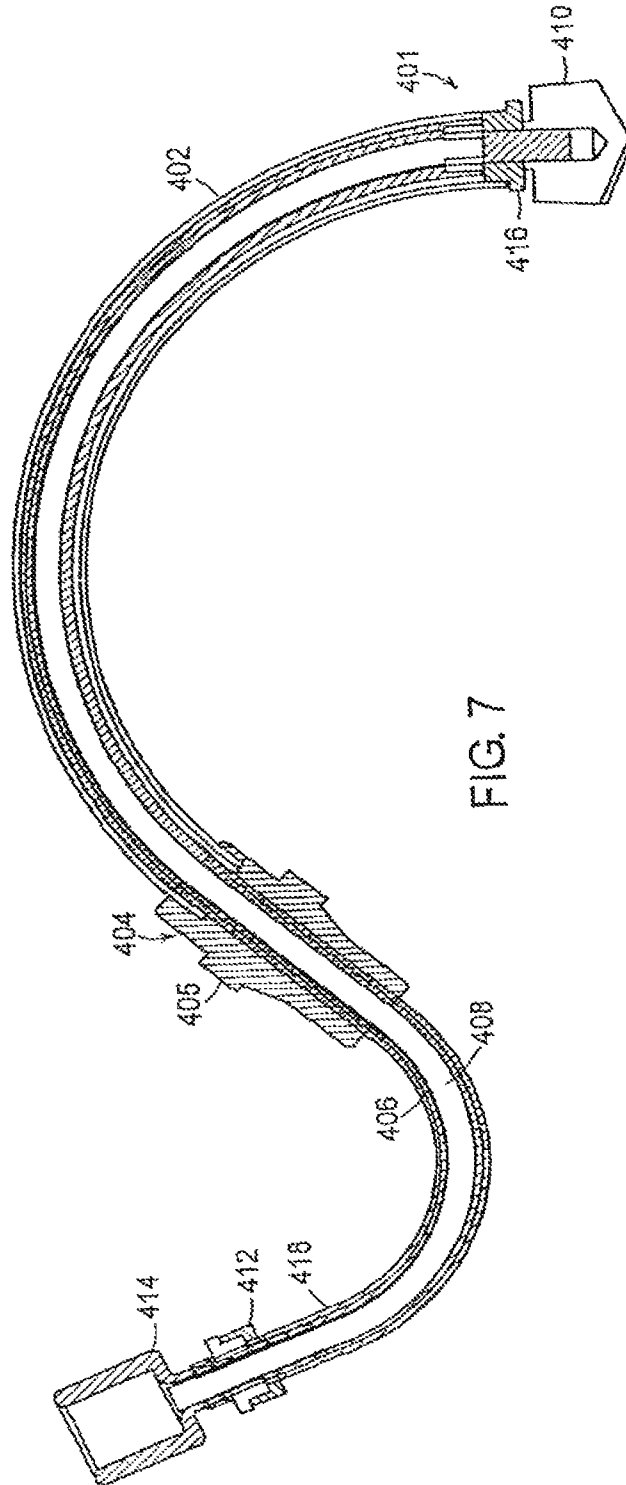


FIG. 7

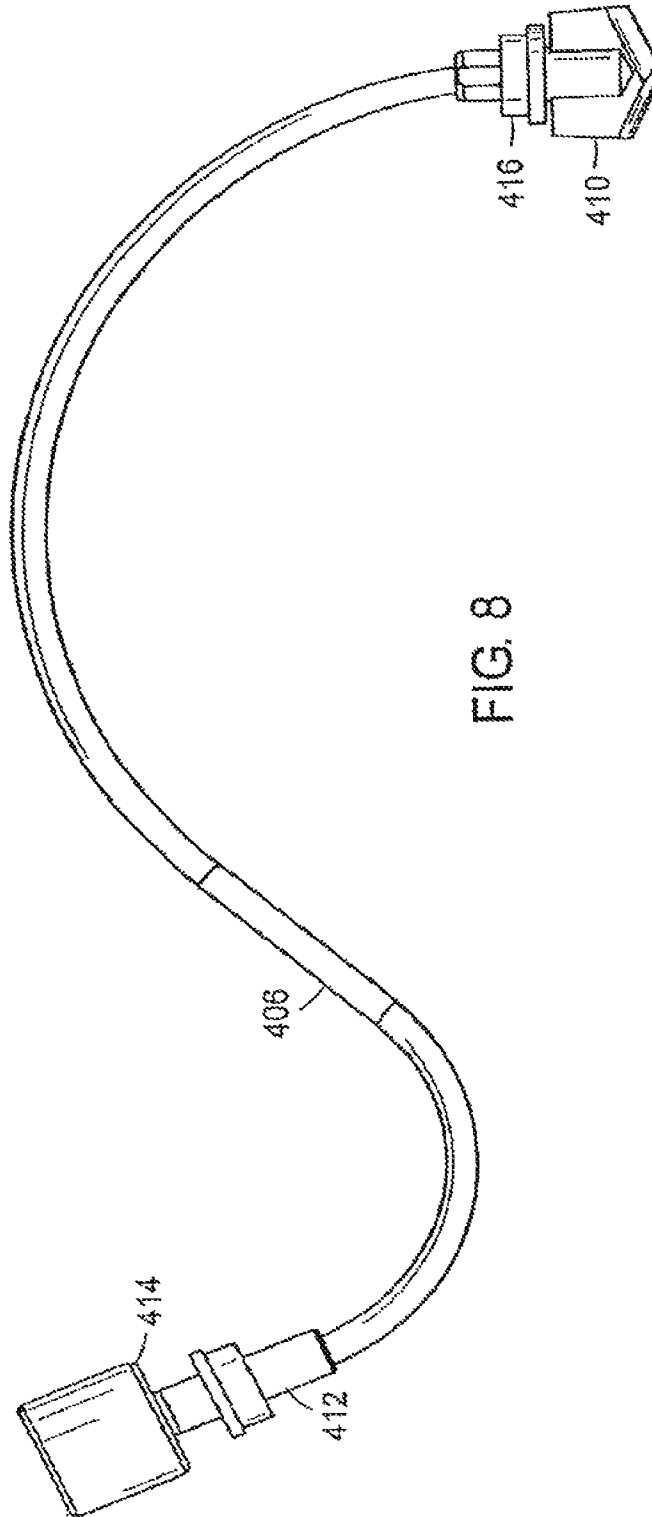
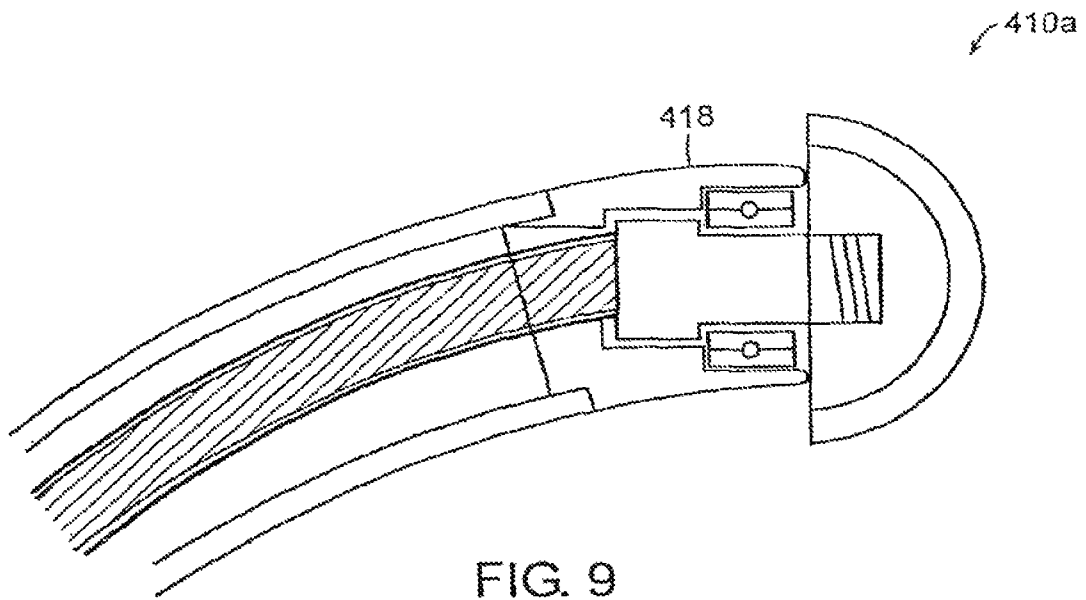


FIG. 8



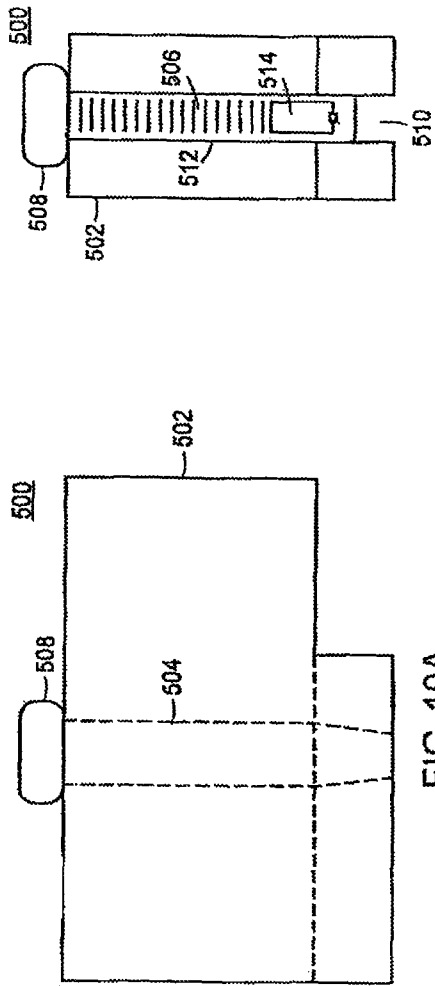


FIG. 10B

FIG. 10A

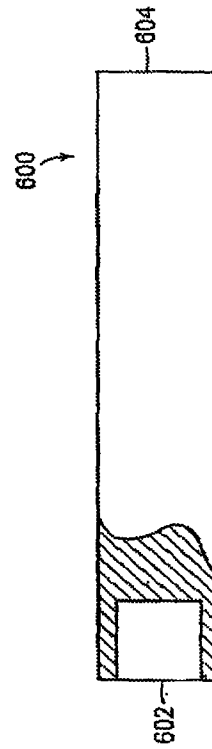


FIG. 12

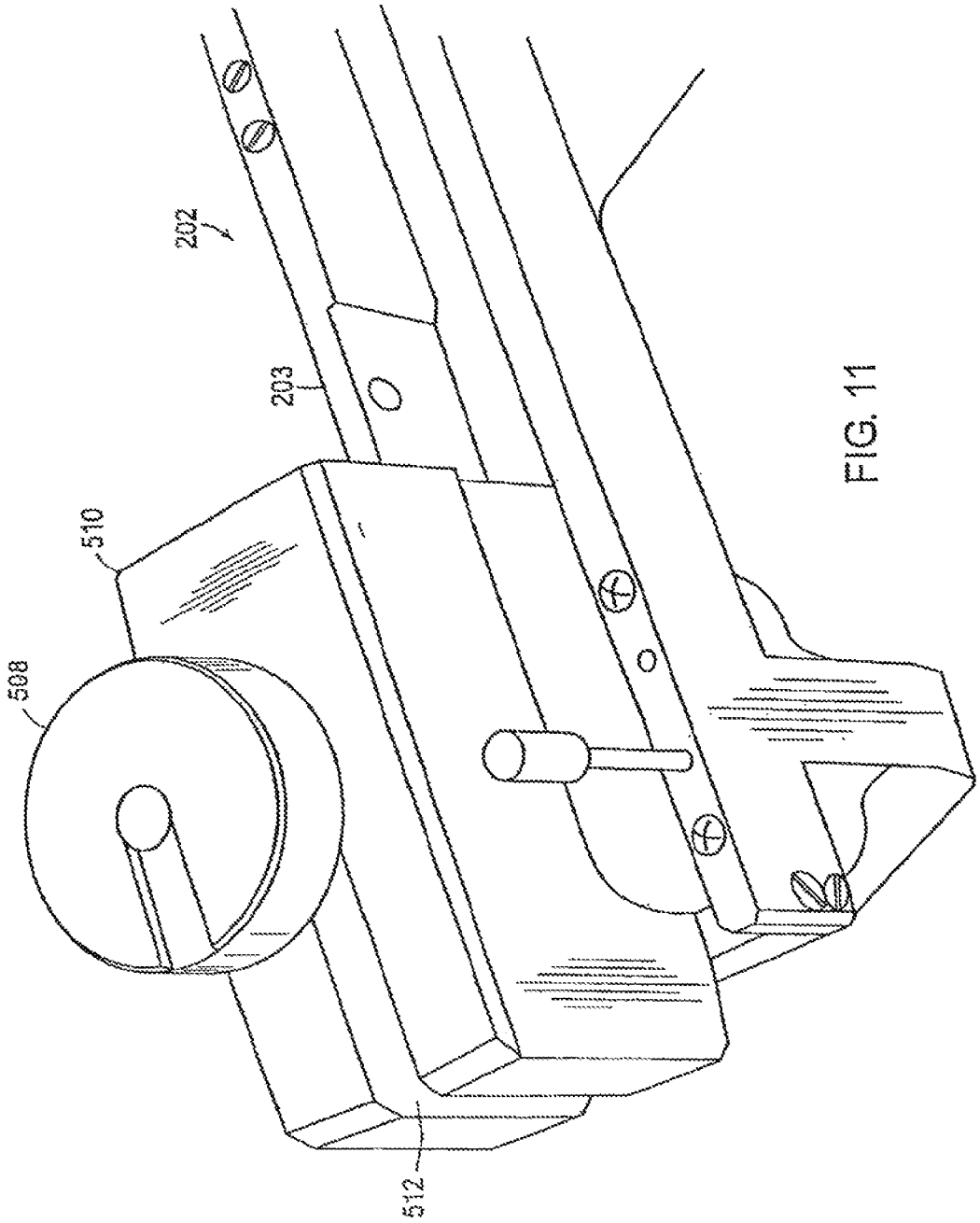


FIG. 11

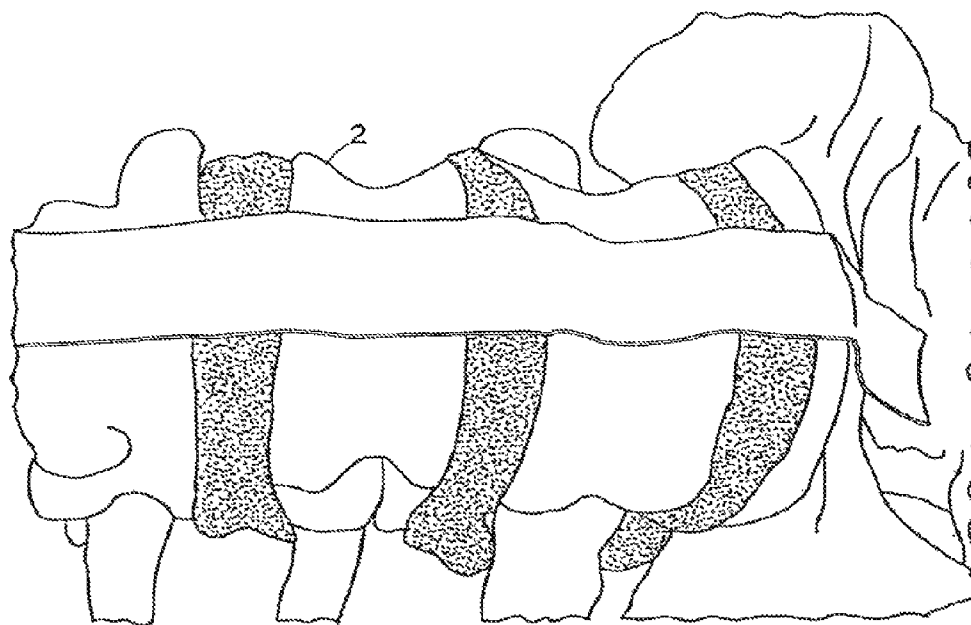


FIG. 13A

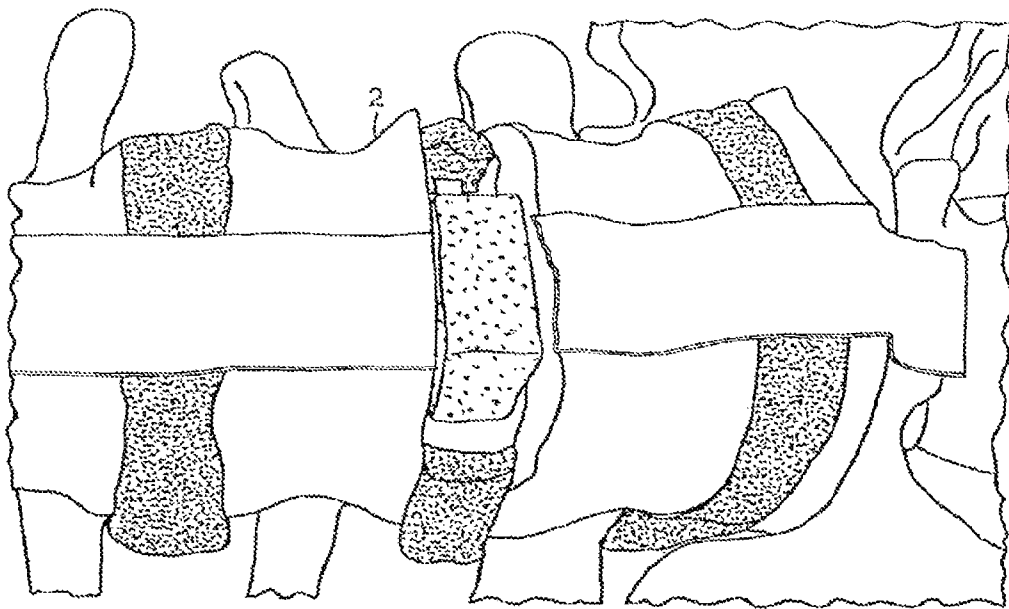


FIG. 13B

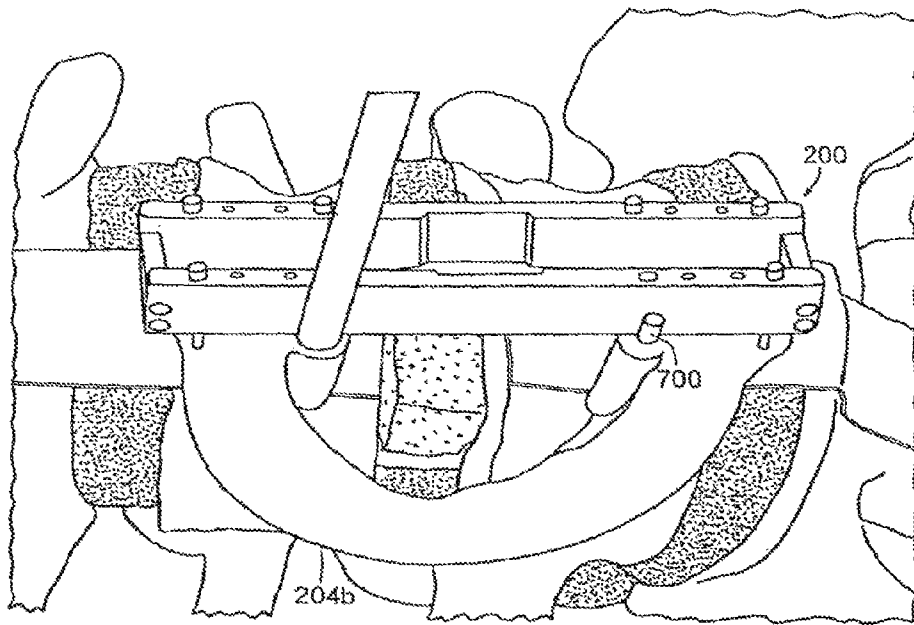


FIG. 13C



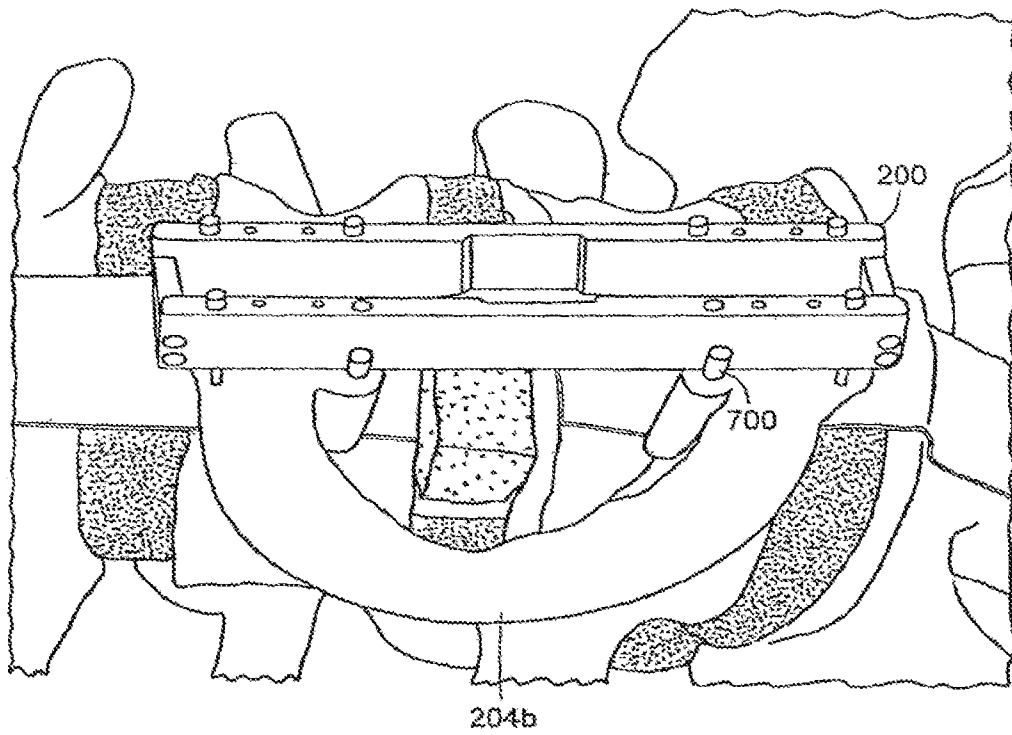


FIG. 13D

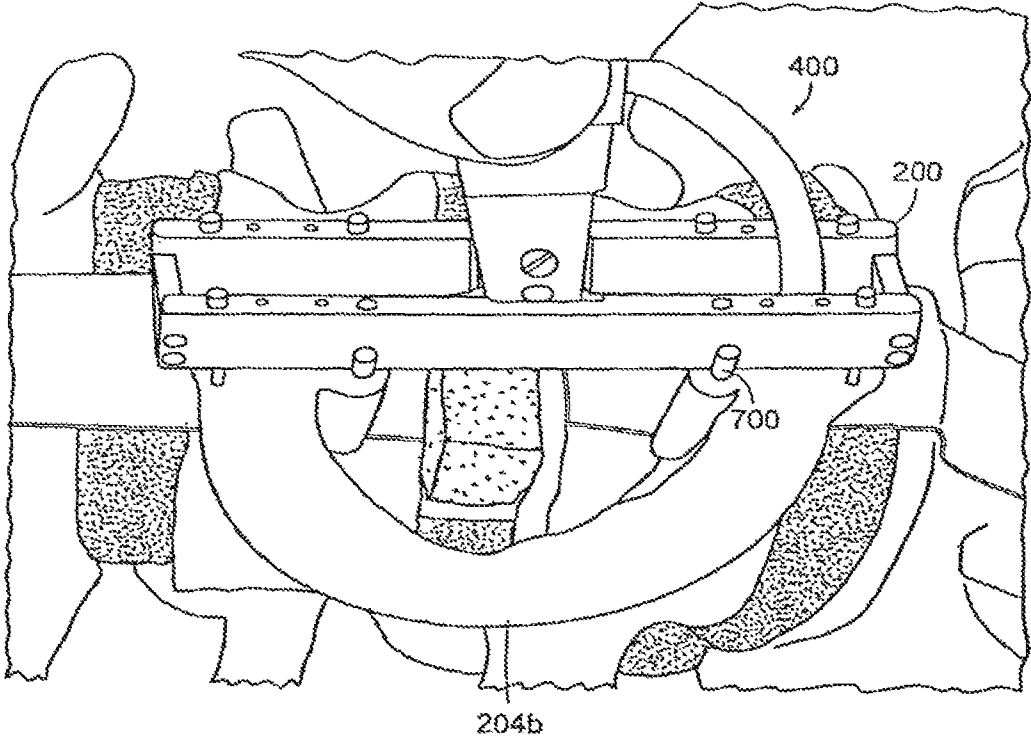


FIG. 13E

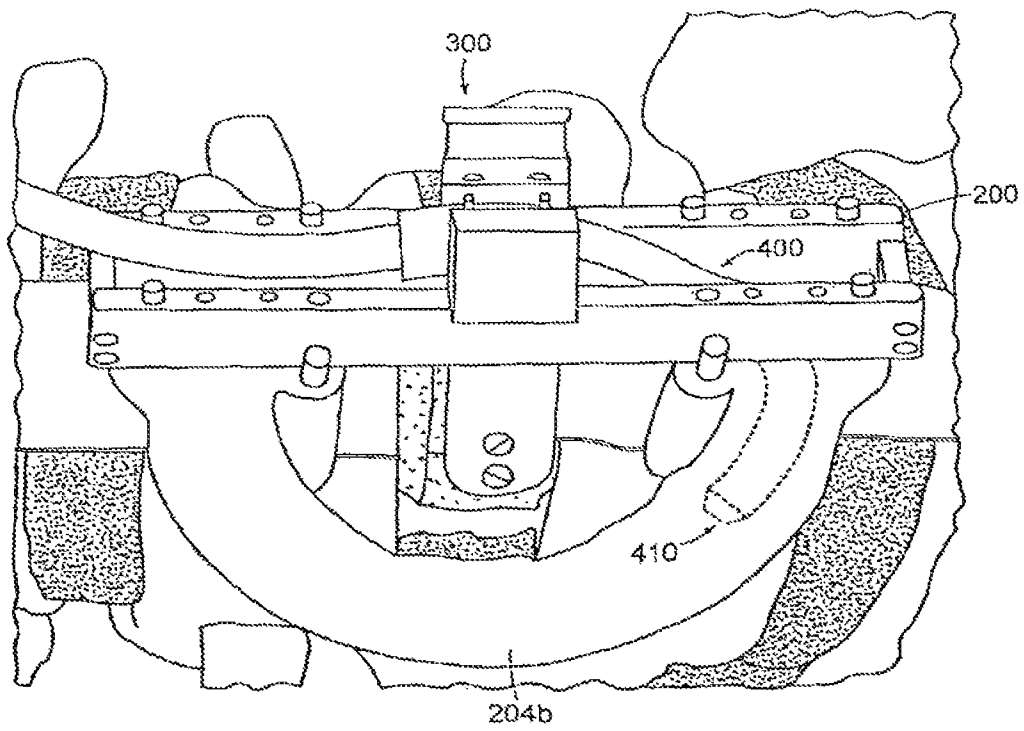


FIG. 13F

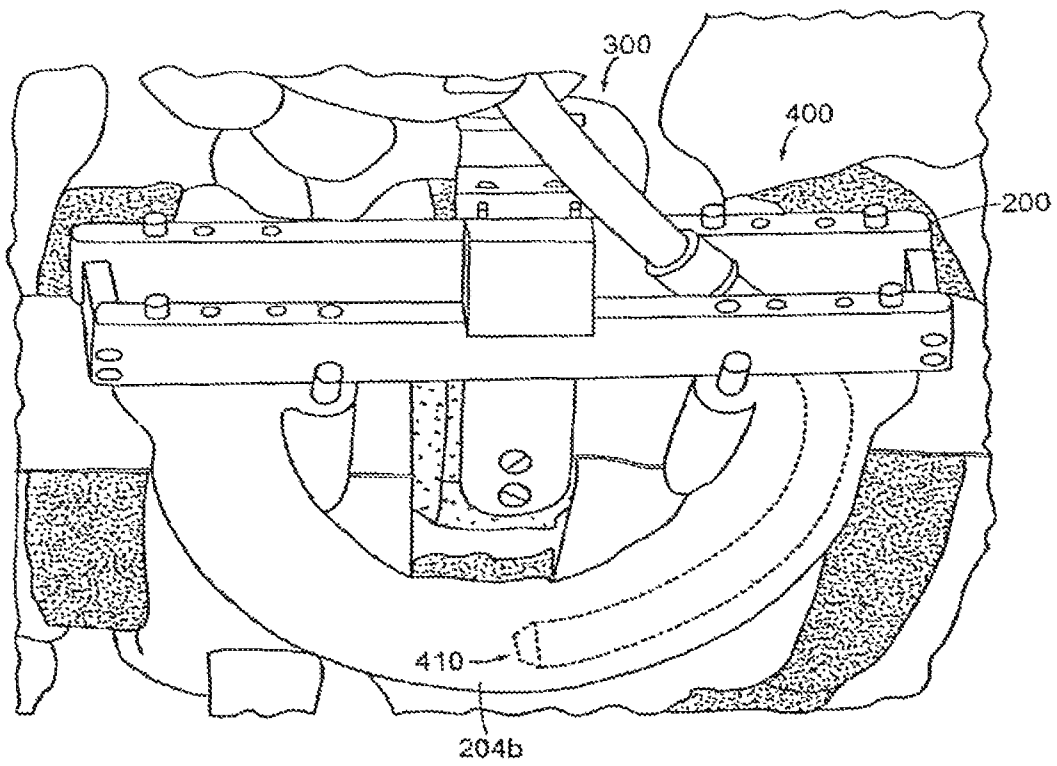


FIG. 13G

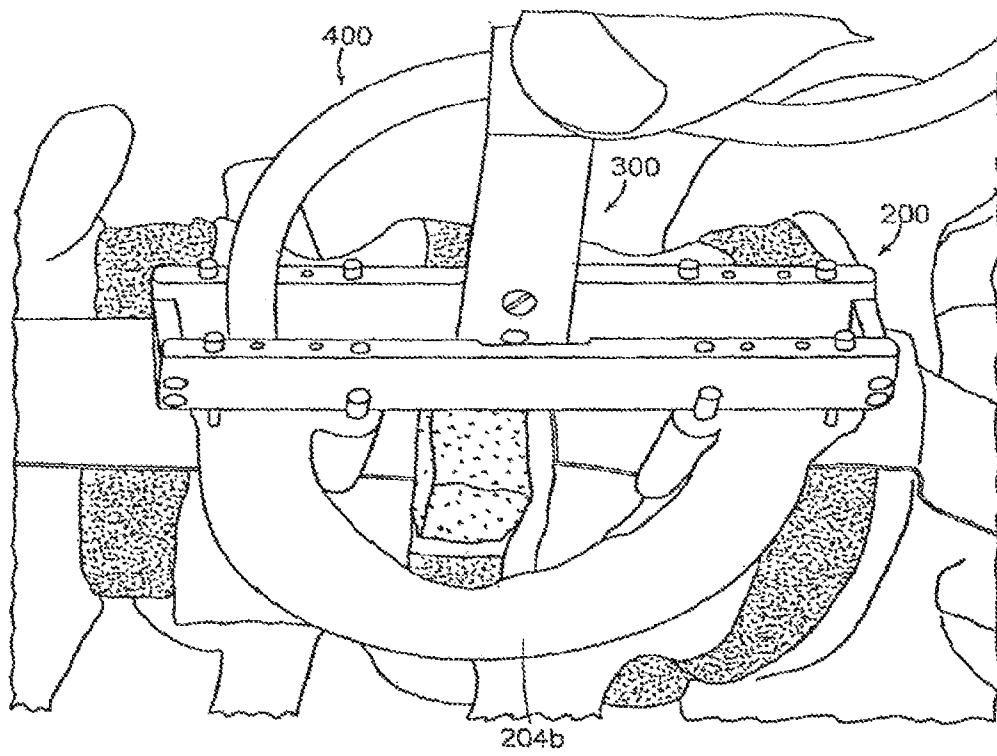


FIG. 13H

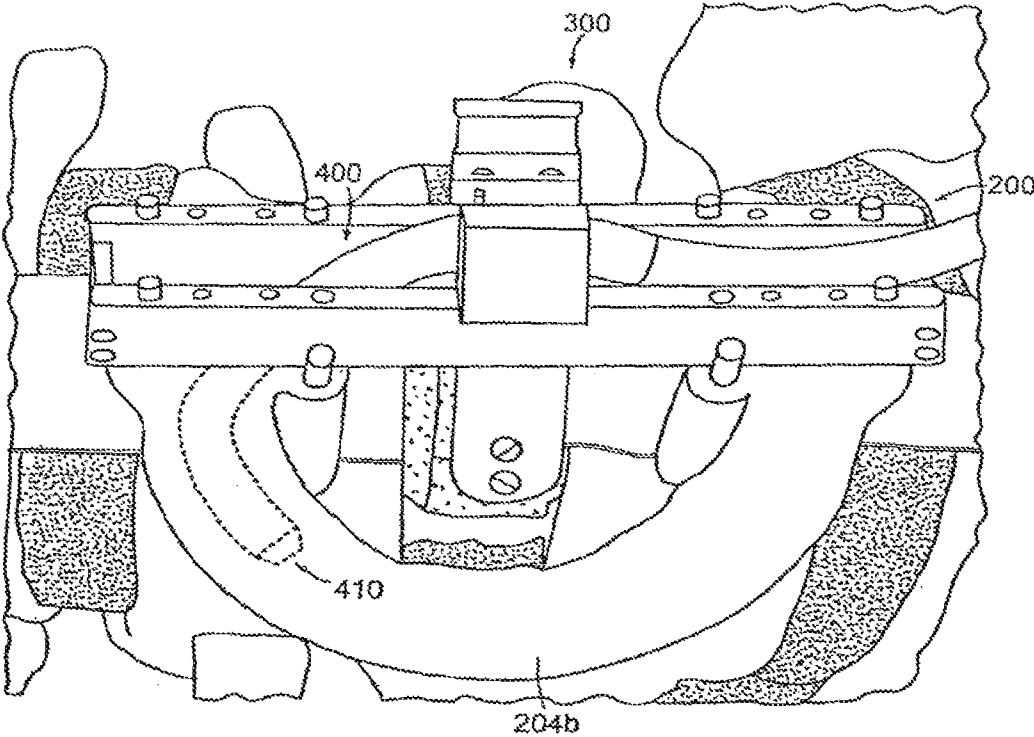


FIG. 13I

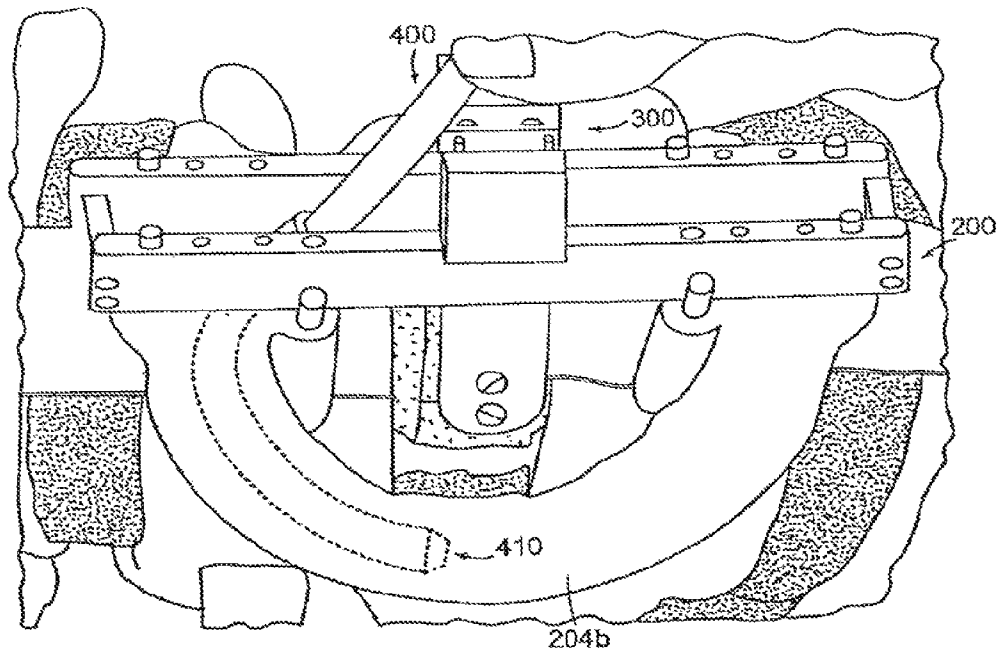


FIG. 13J

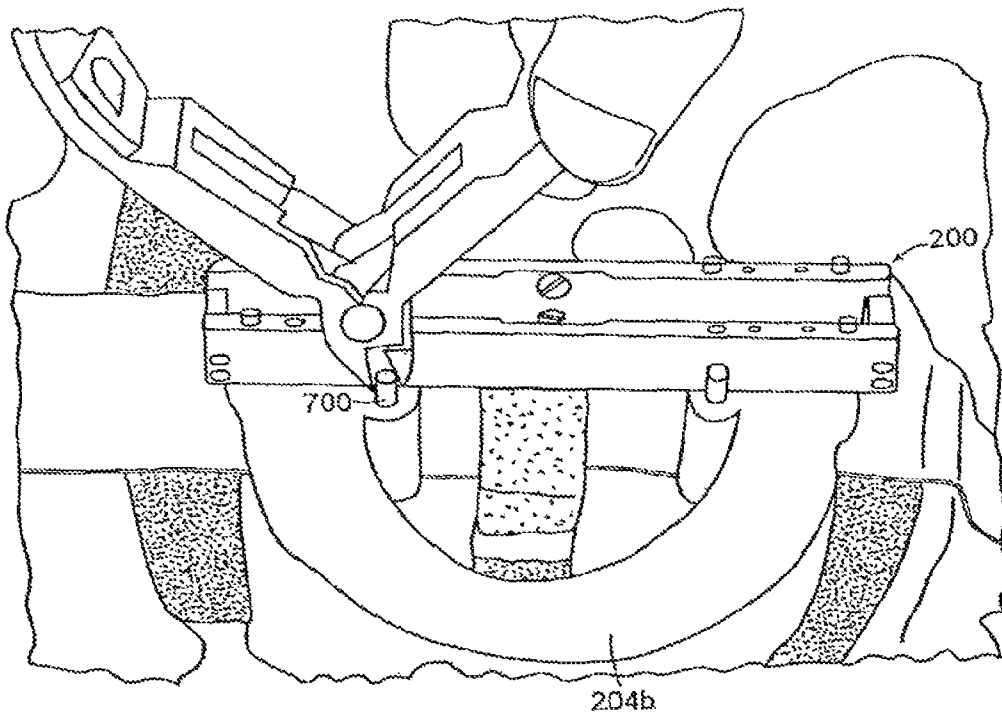


FIG. 13K



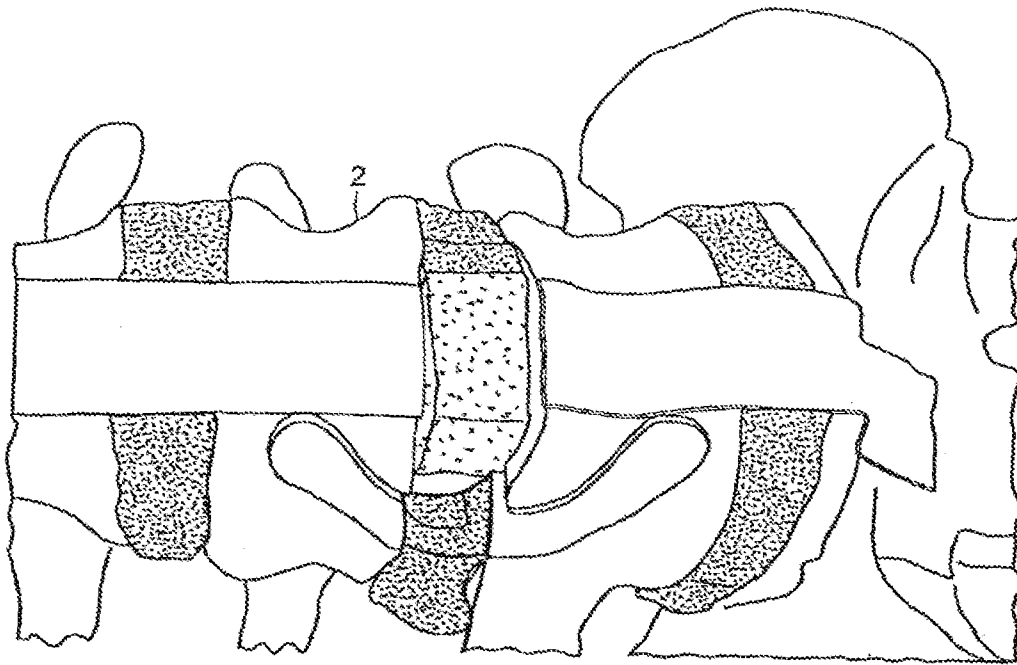


FIG. 13L

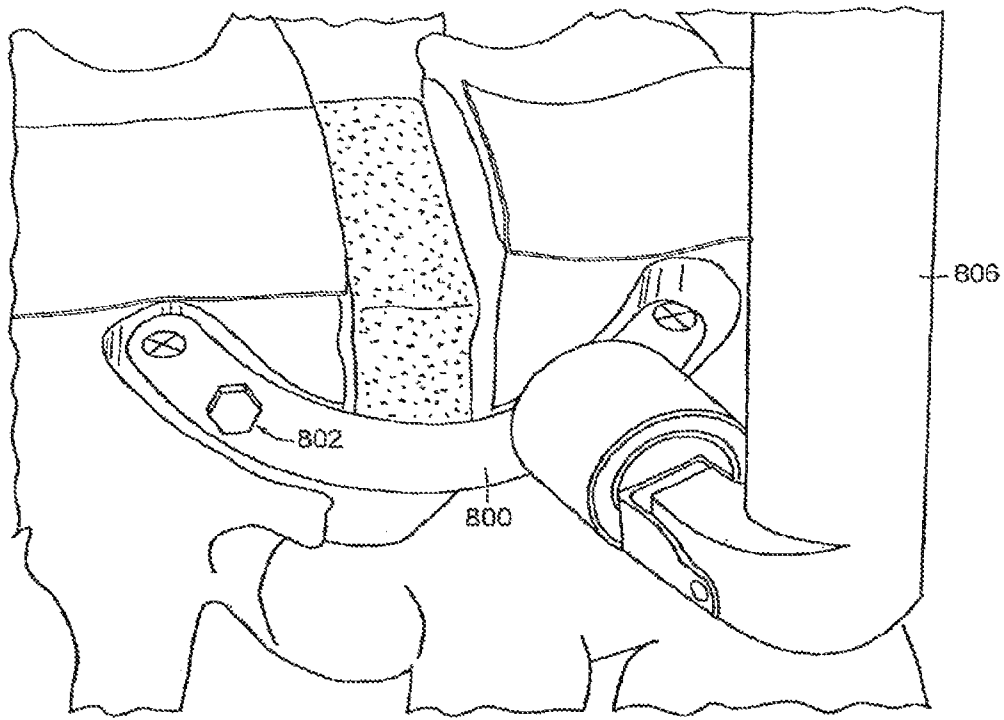


FIG. 14A

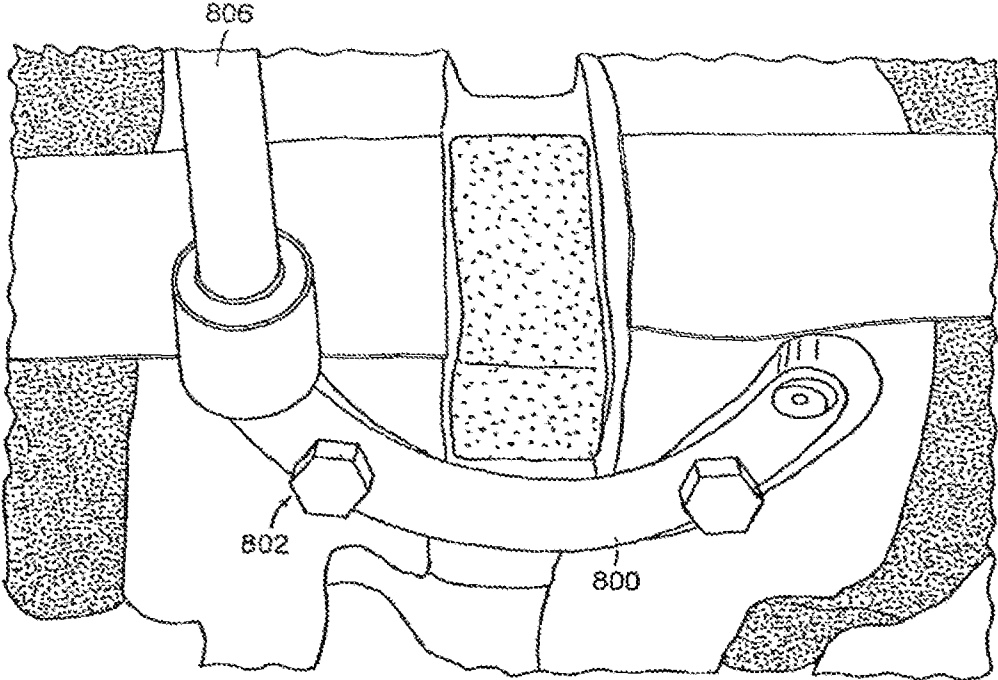


FIG. 14B

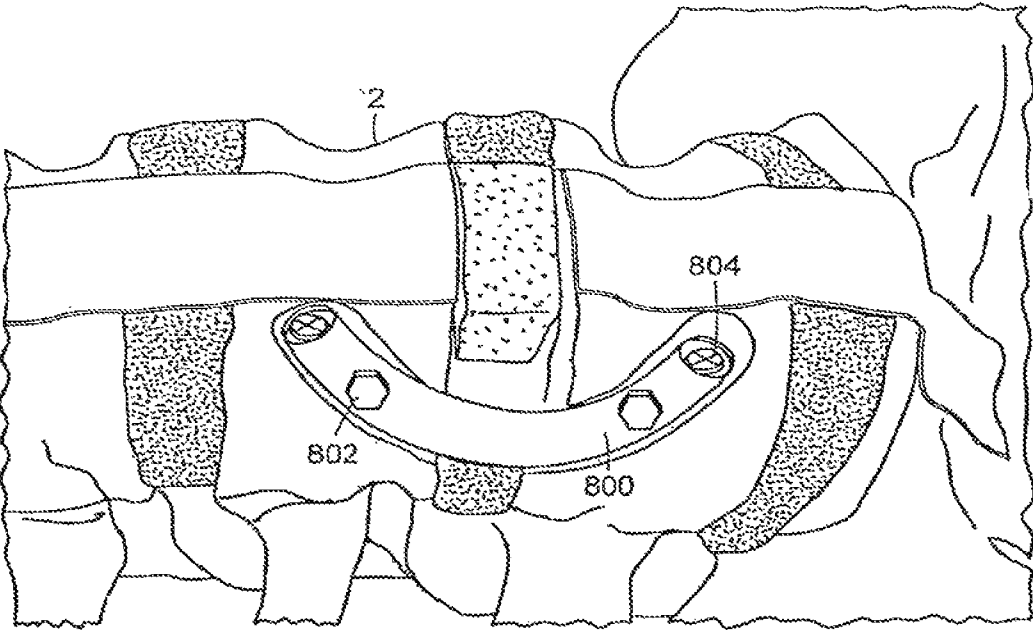


FIG. 14C

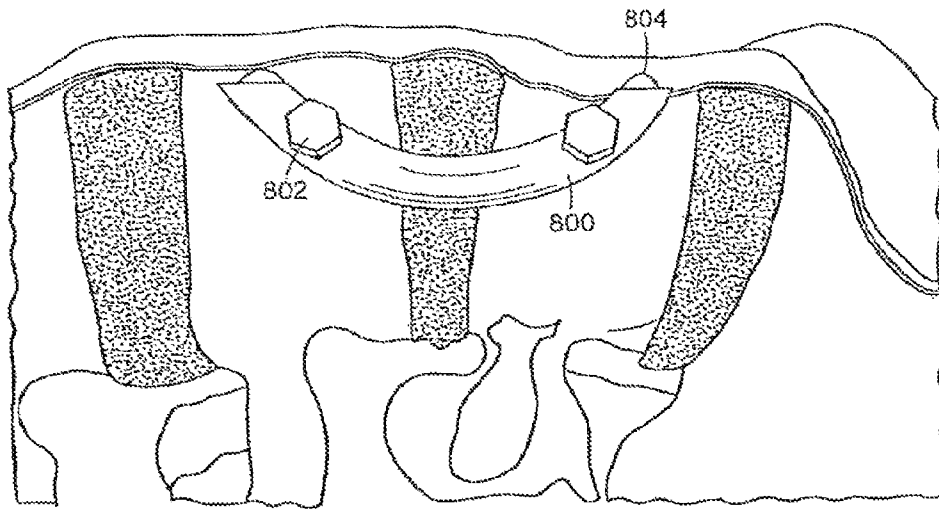


FIG. 14D

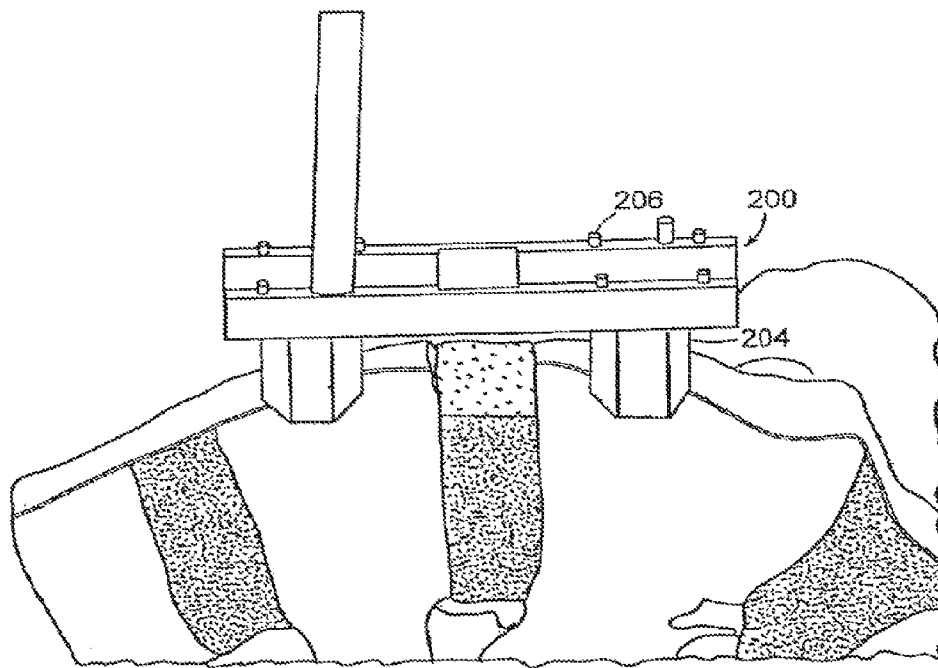


FIG. 15A

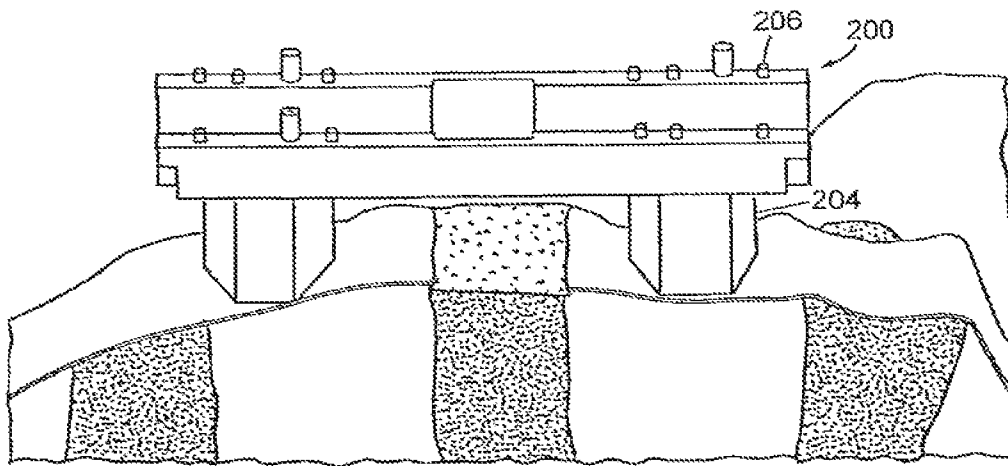


FIG. 15B

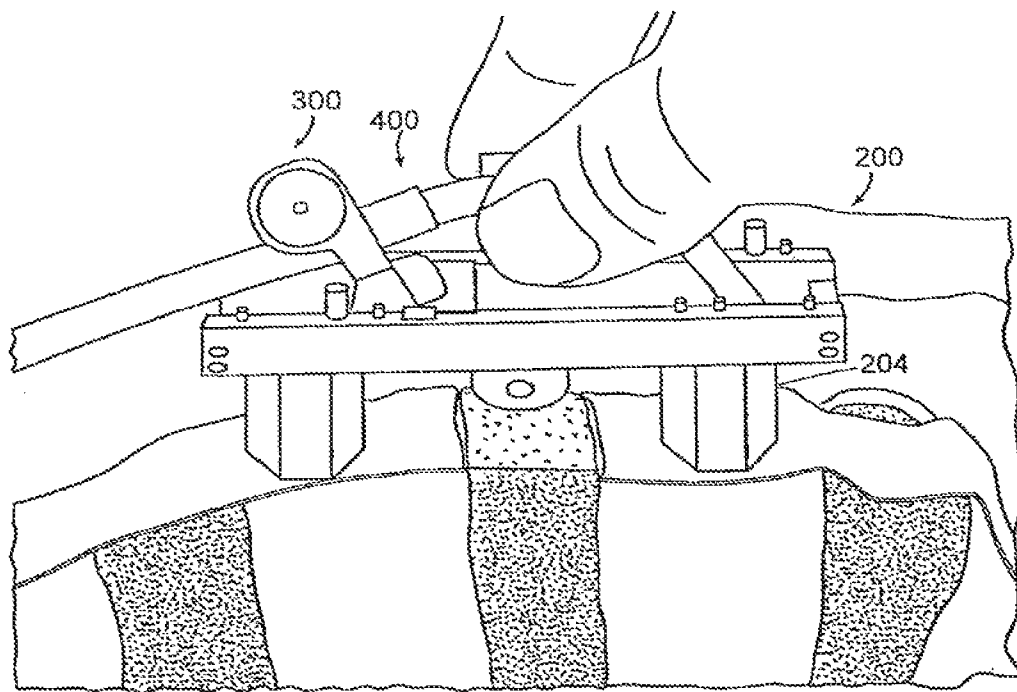


FIG. 15C



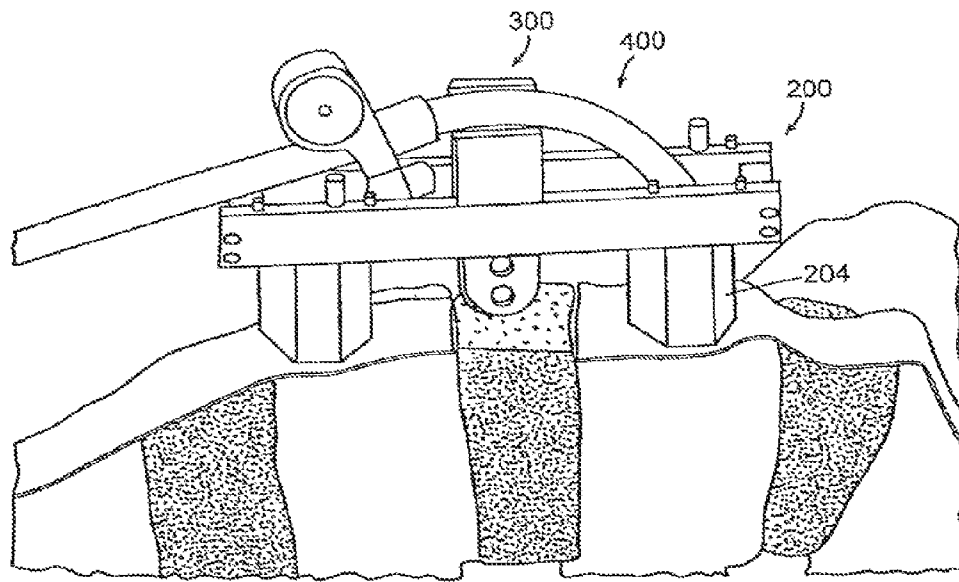


FIG. 15D

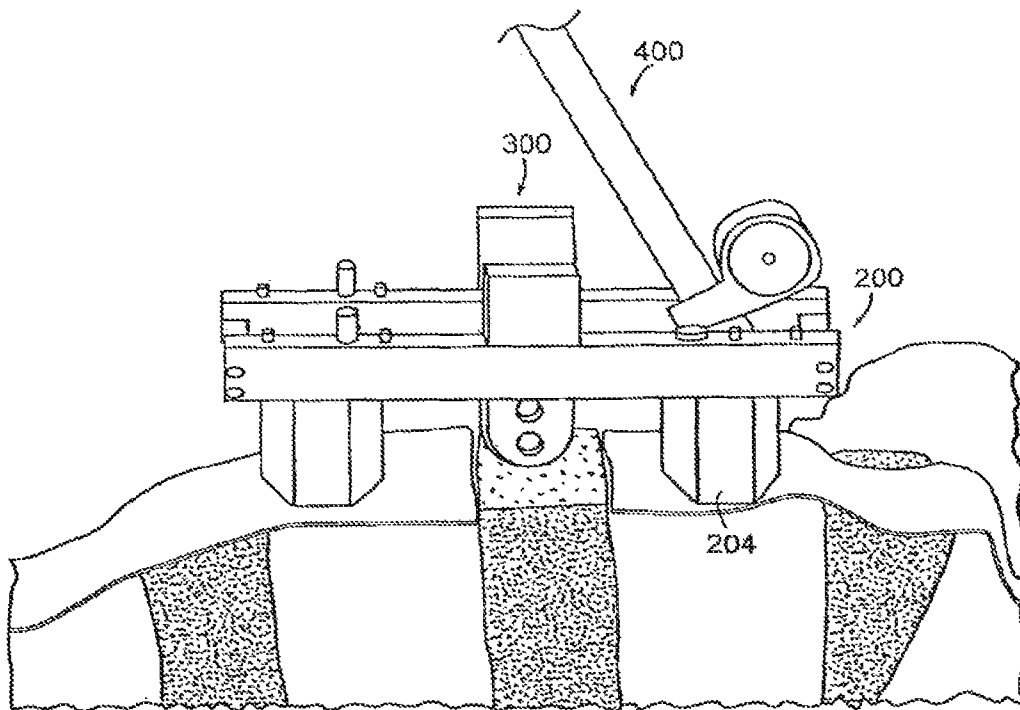


FIG. 15E

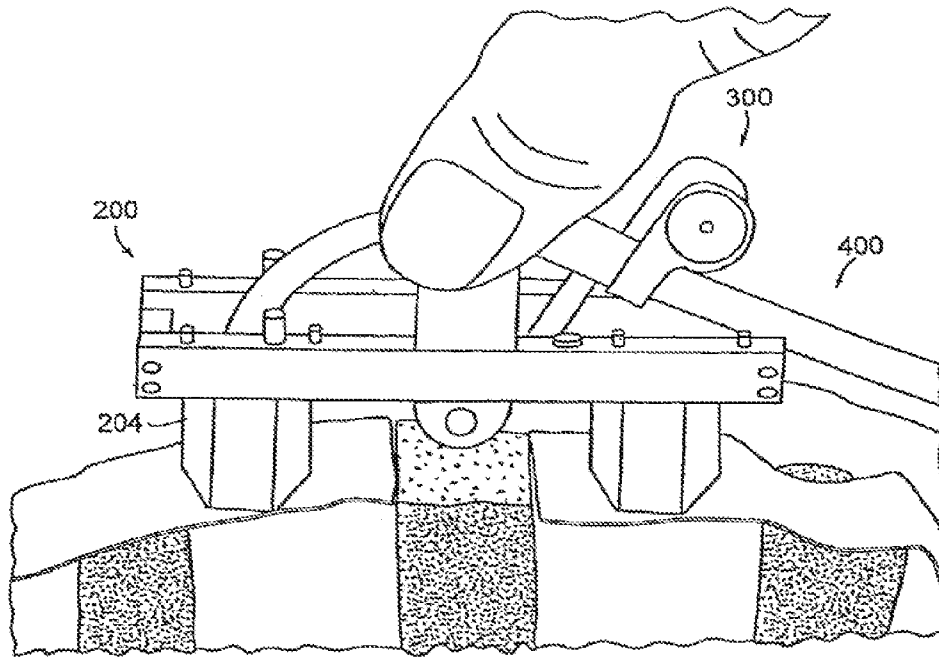


FIG. 15F

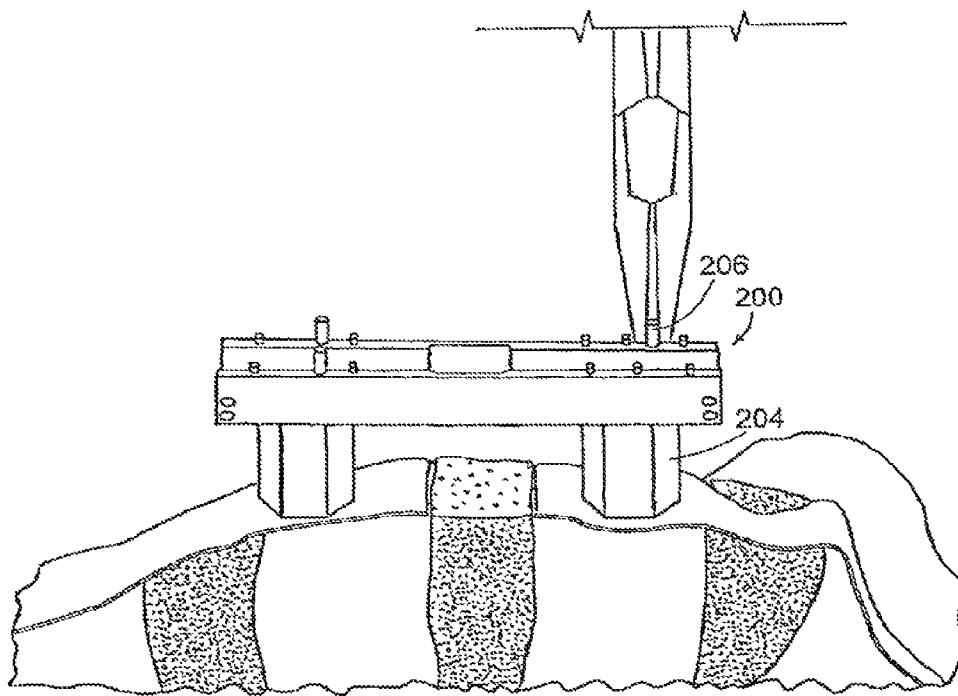


FIG. 15G

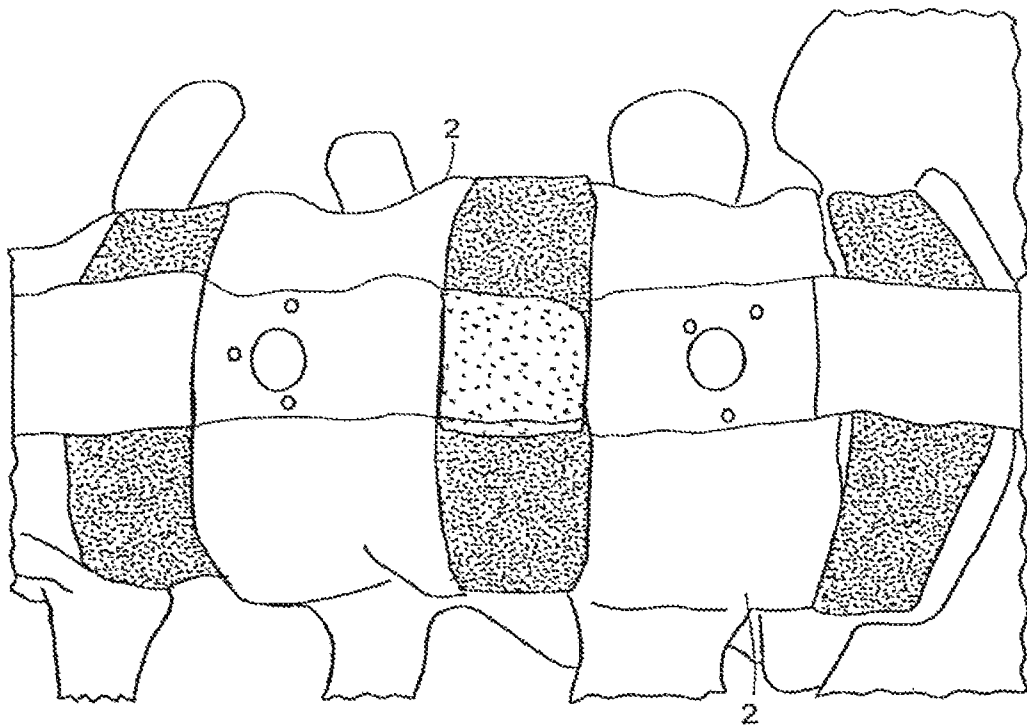


FIG. 15H

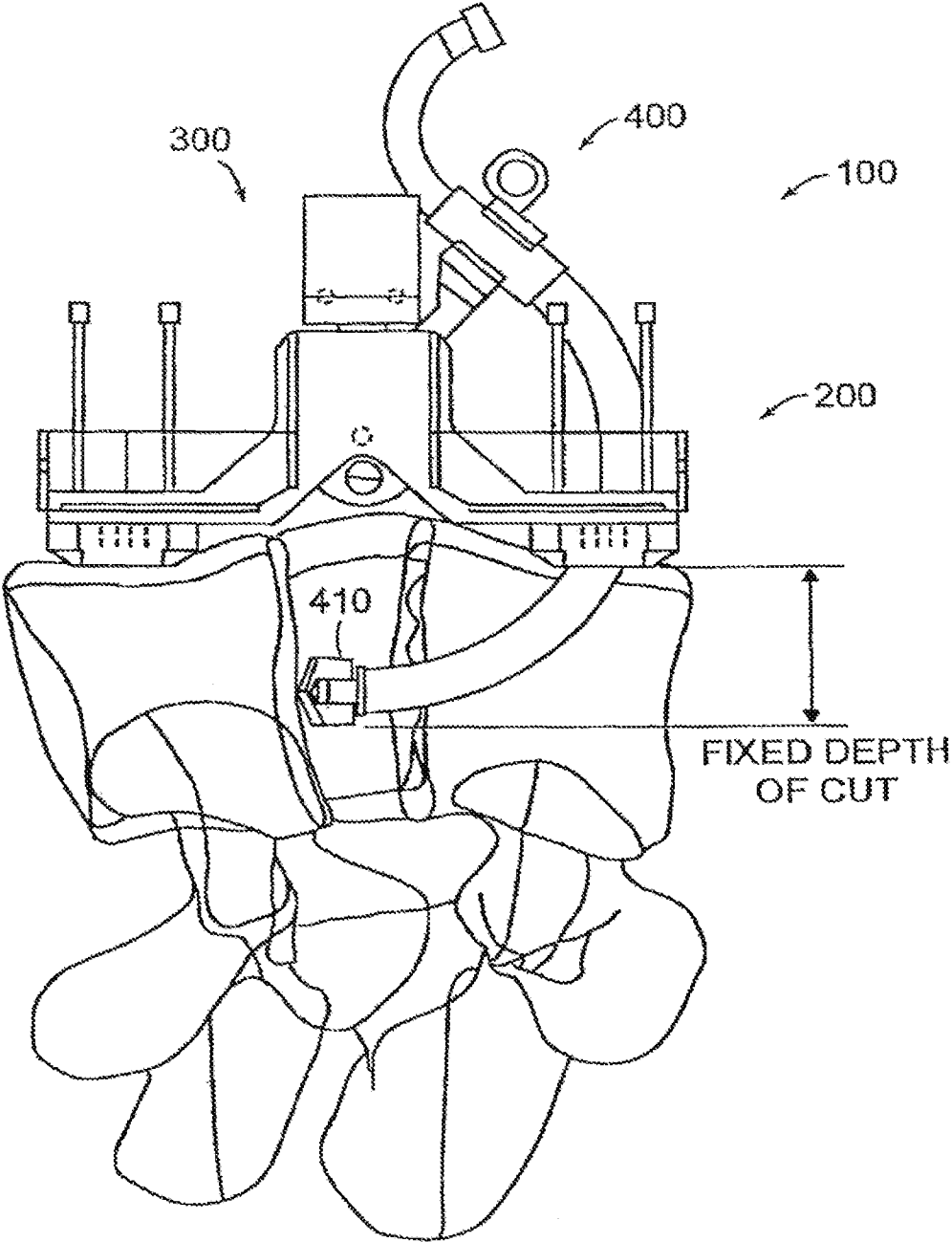


FIG. 15I

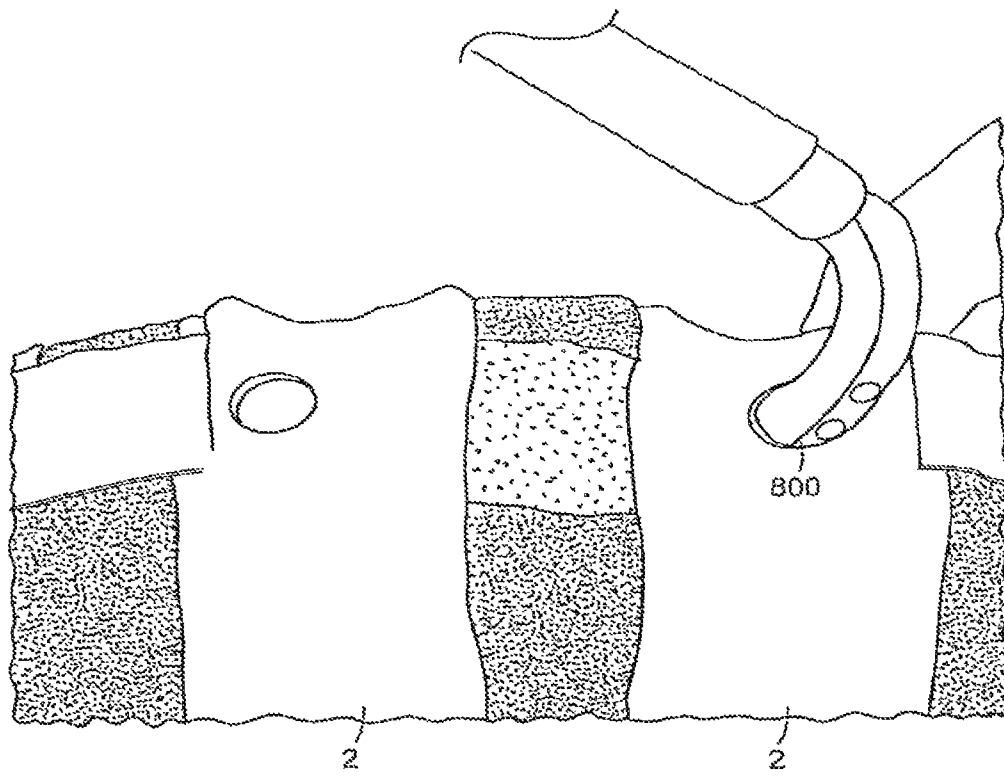


FIG. 16A

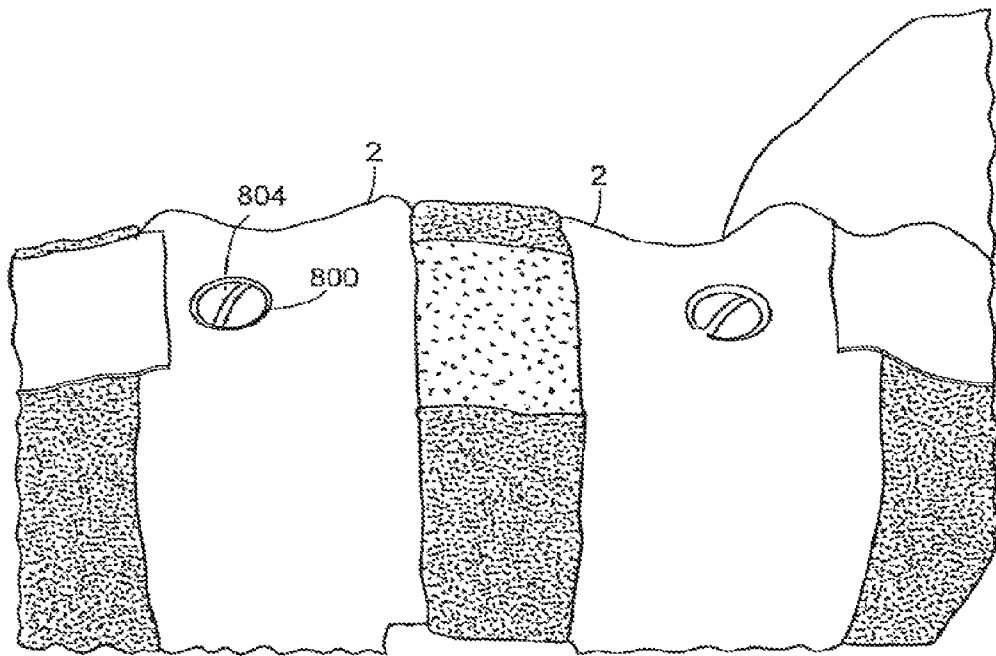


FIG. 16B



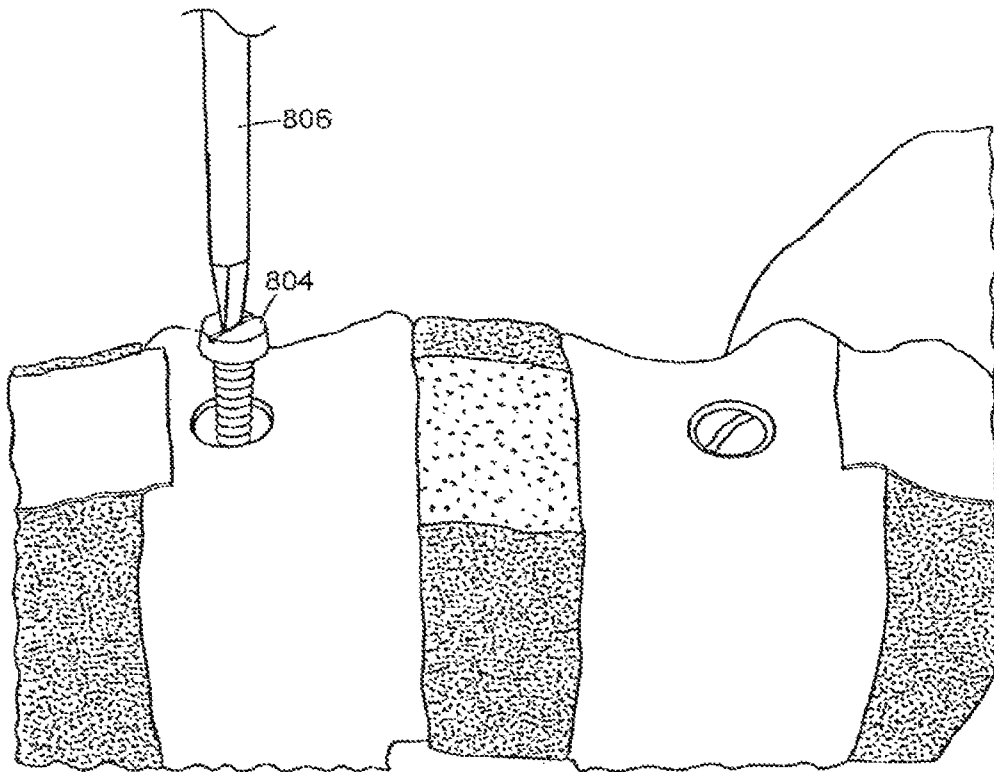


FIG. 16C

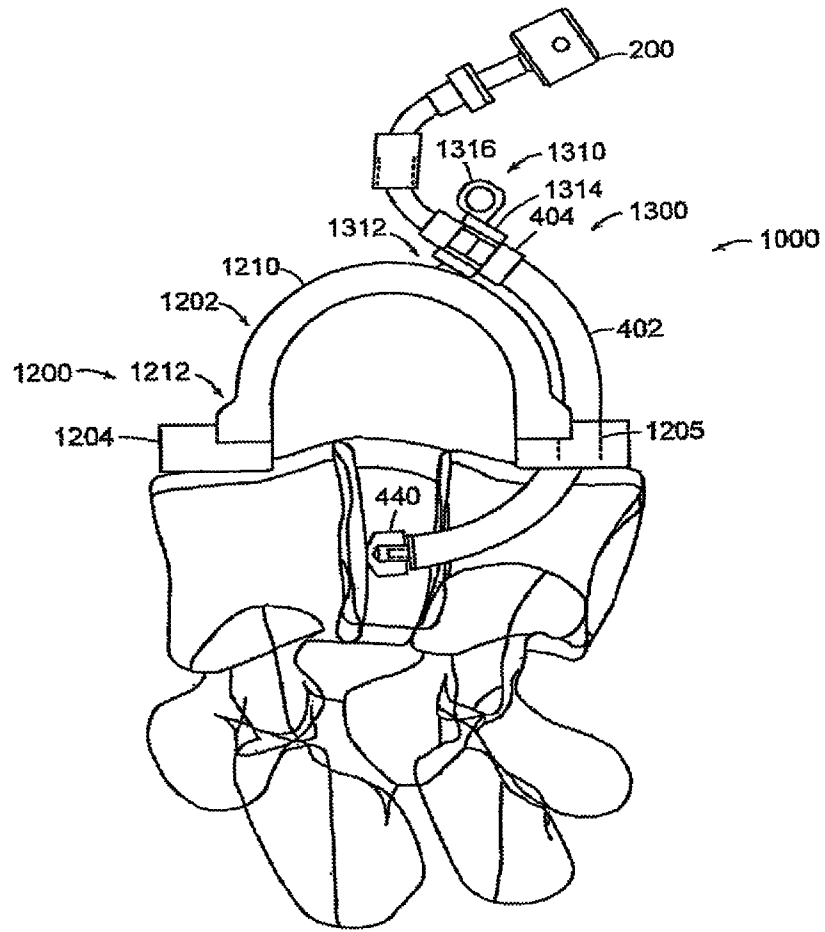


FIG. 17

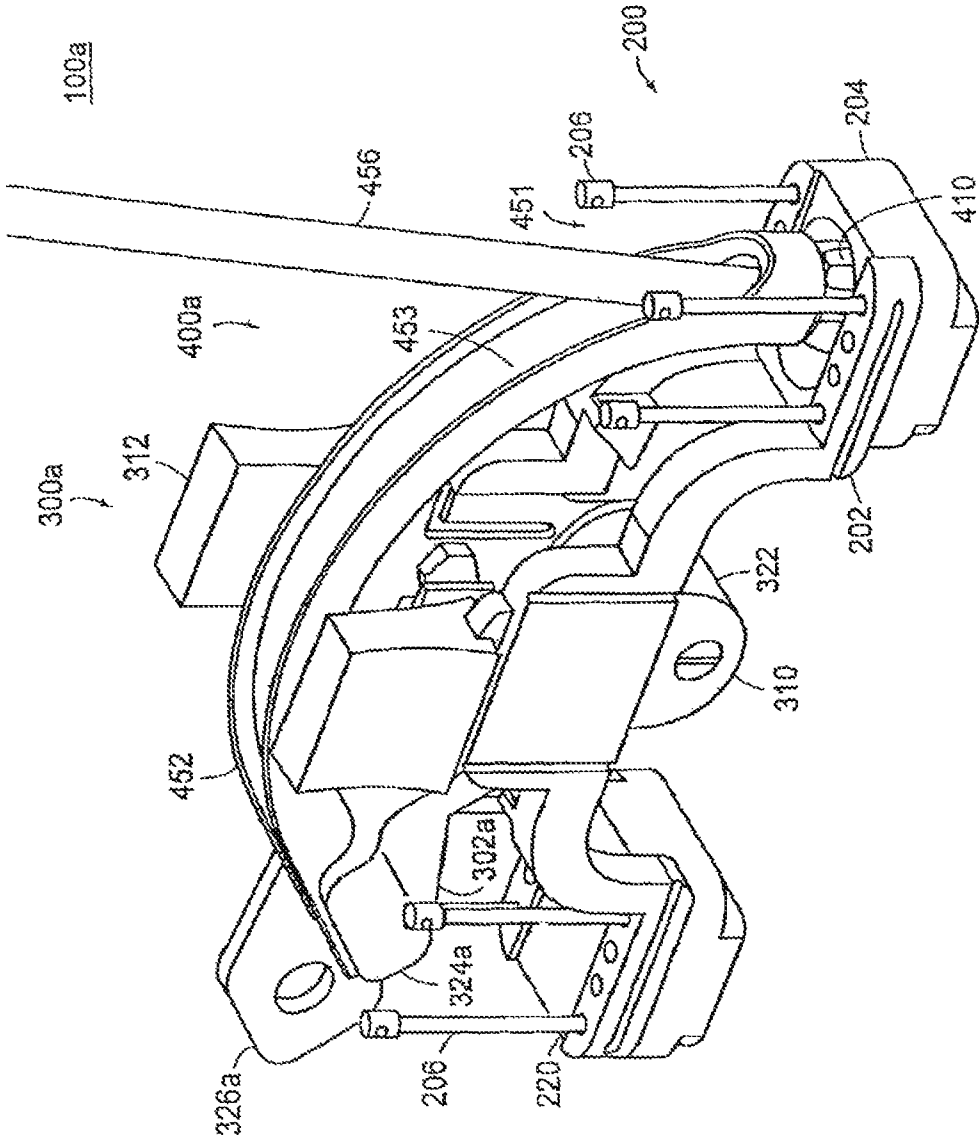


FIG. 18A

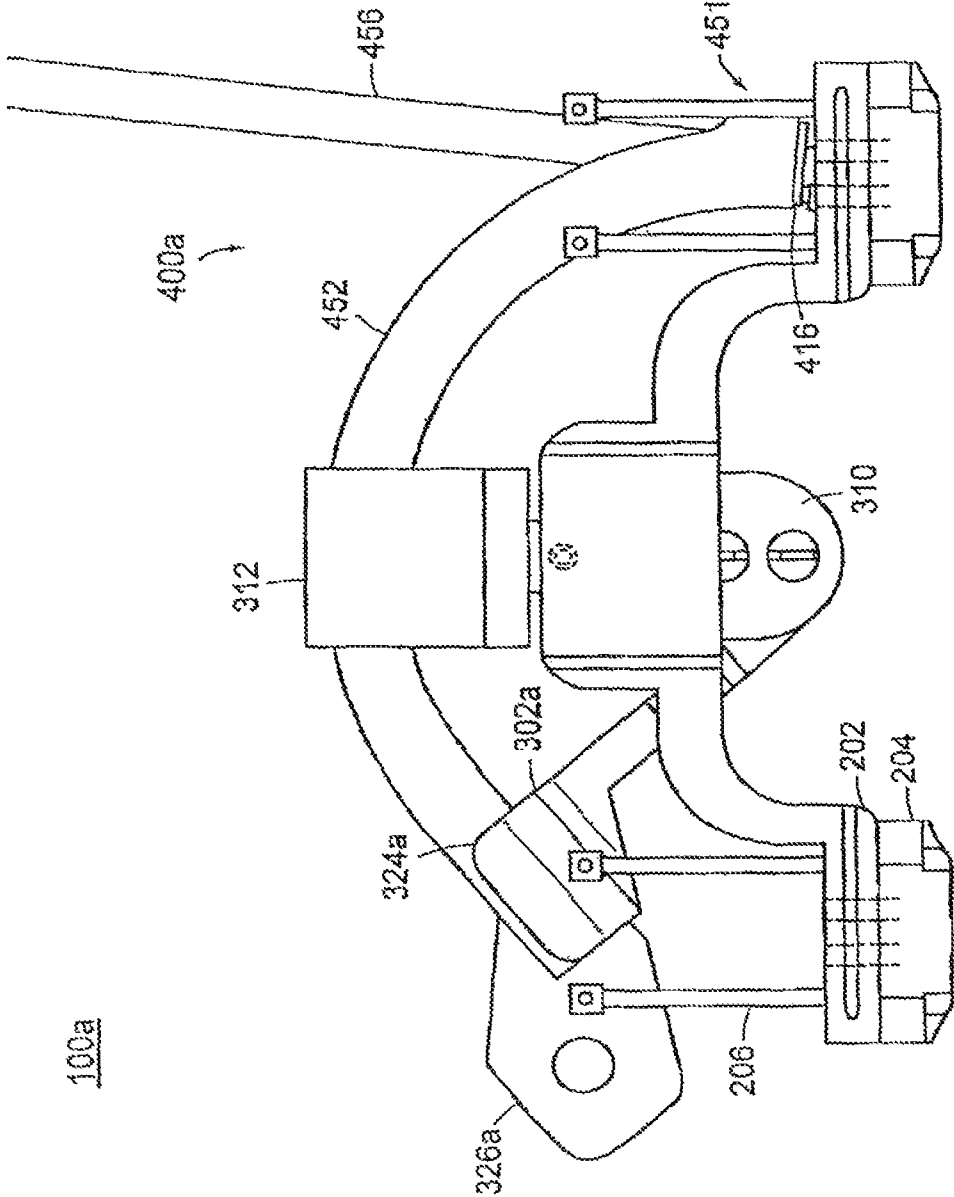


FIG. 18B

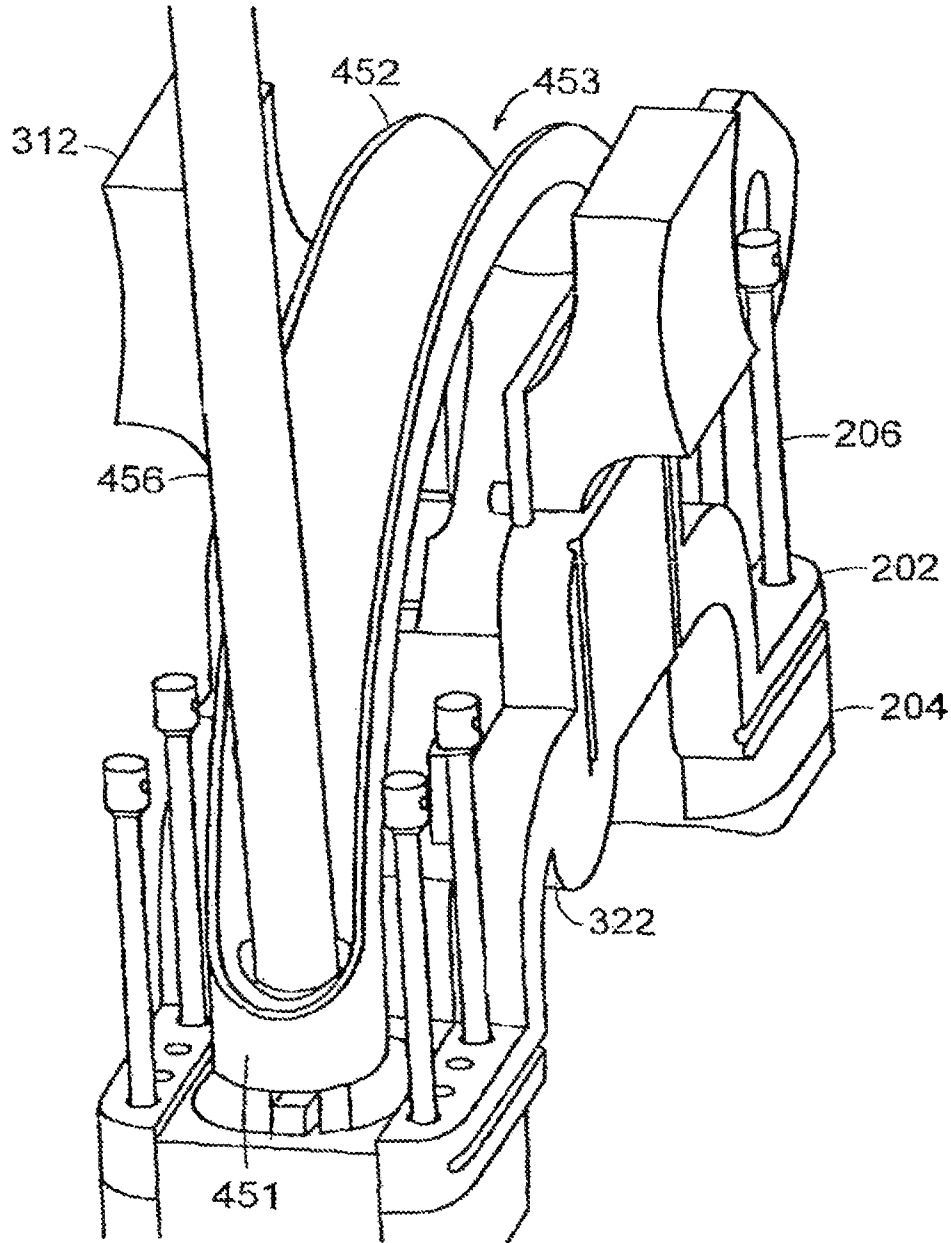


FIG. 18C

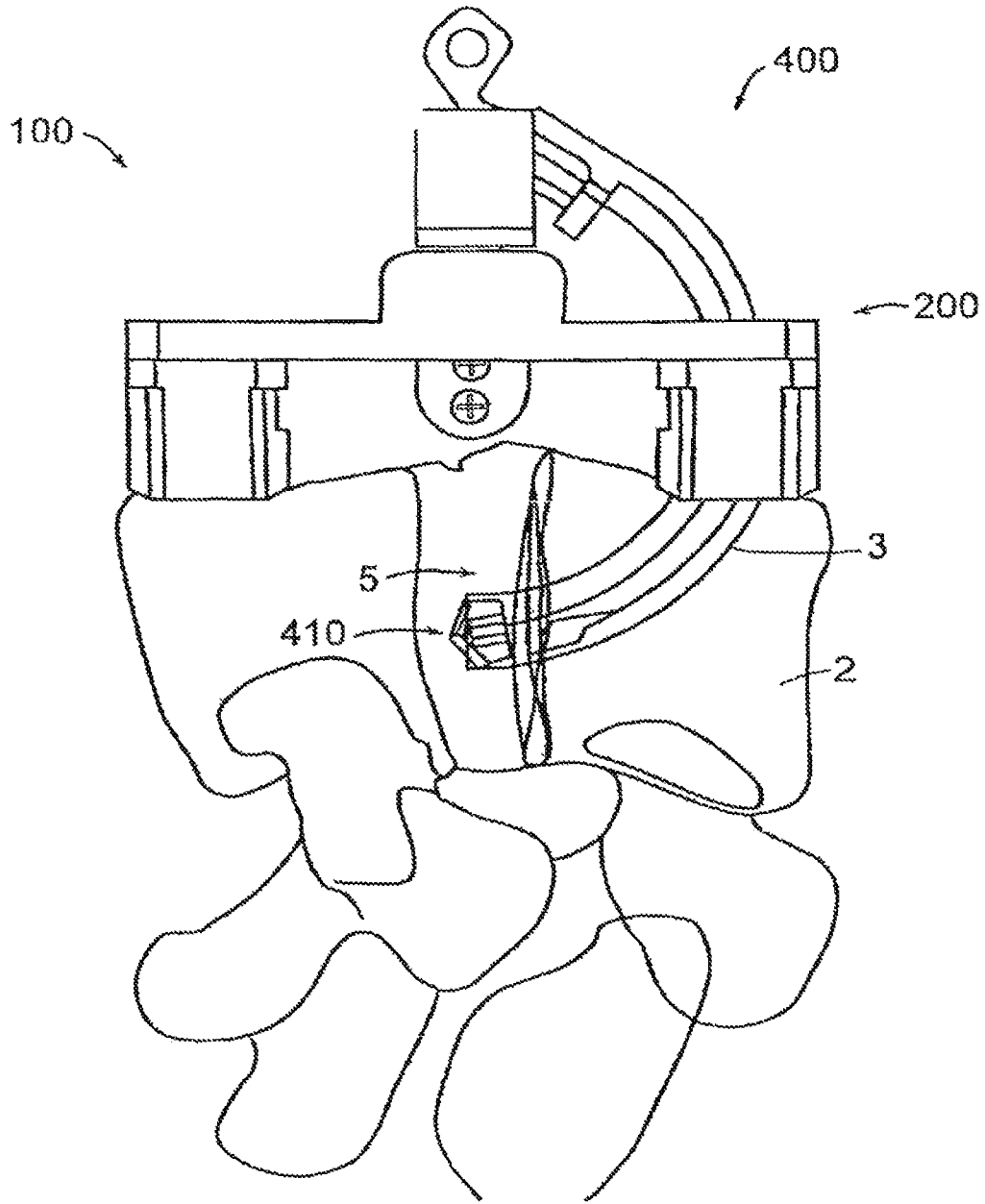


FIG. 19A

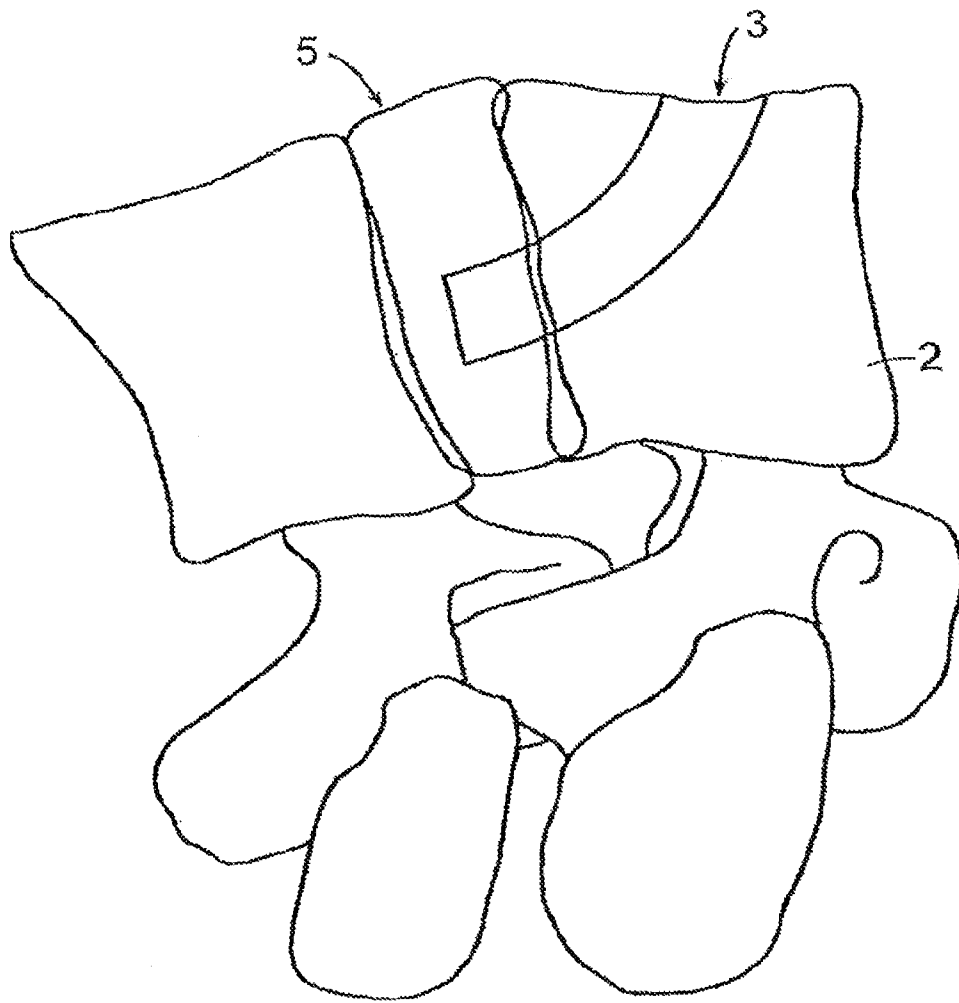


FIG. 19B

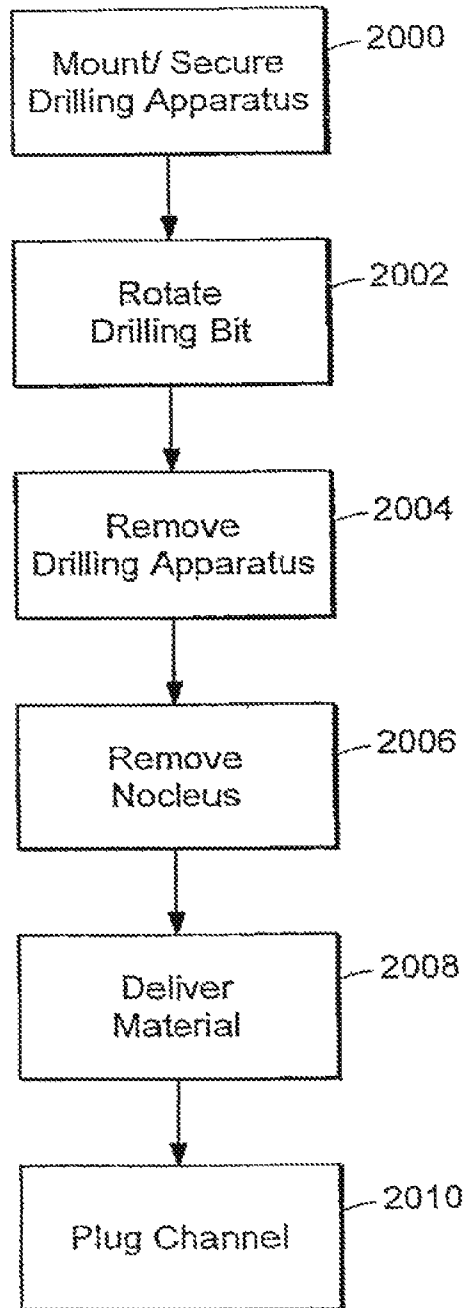
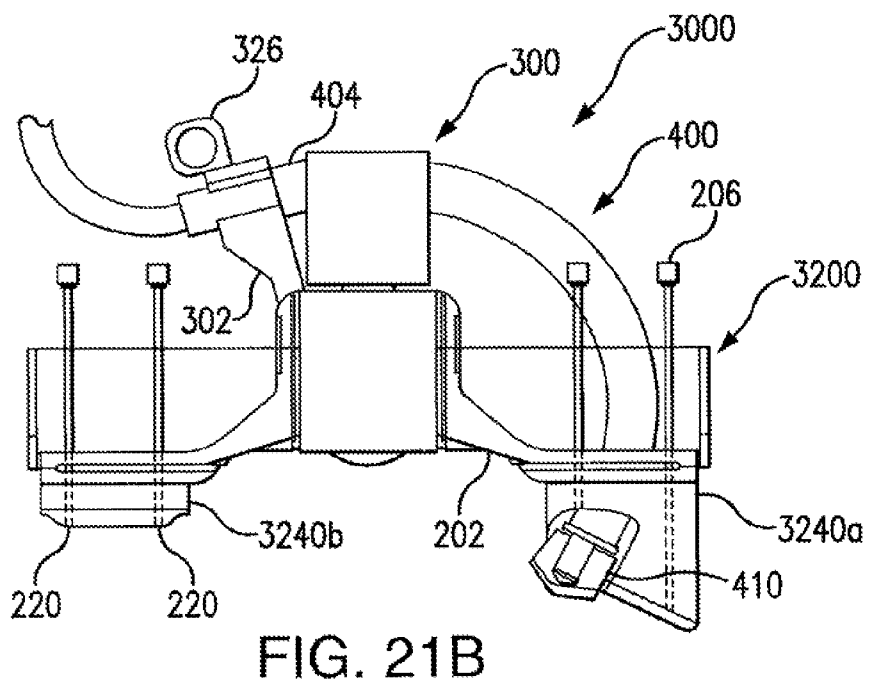
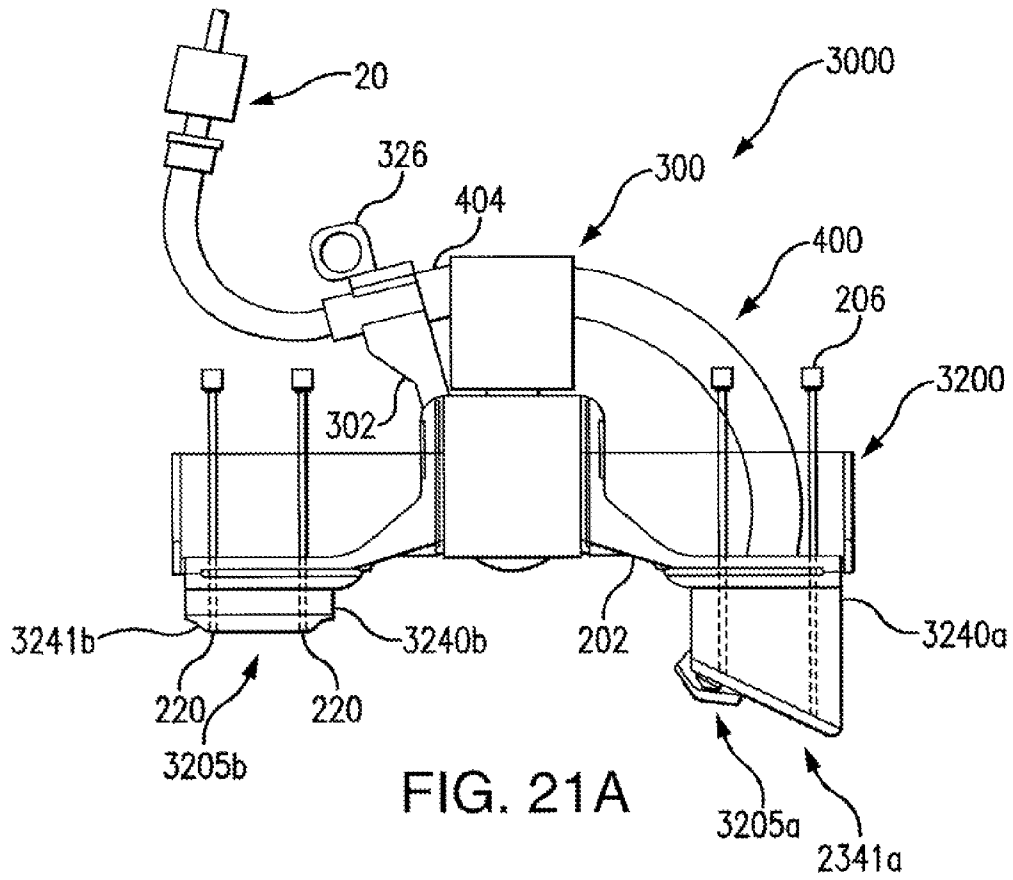


FIG. 20





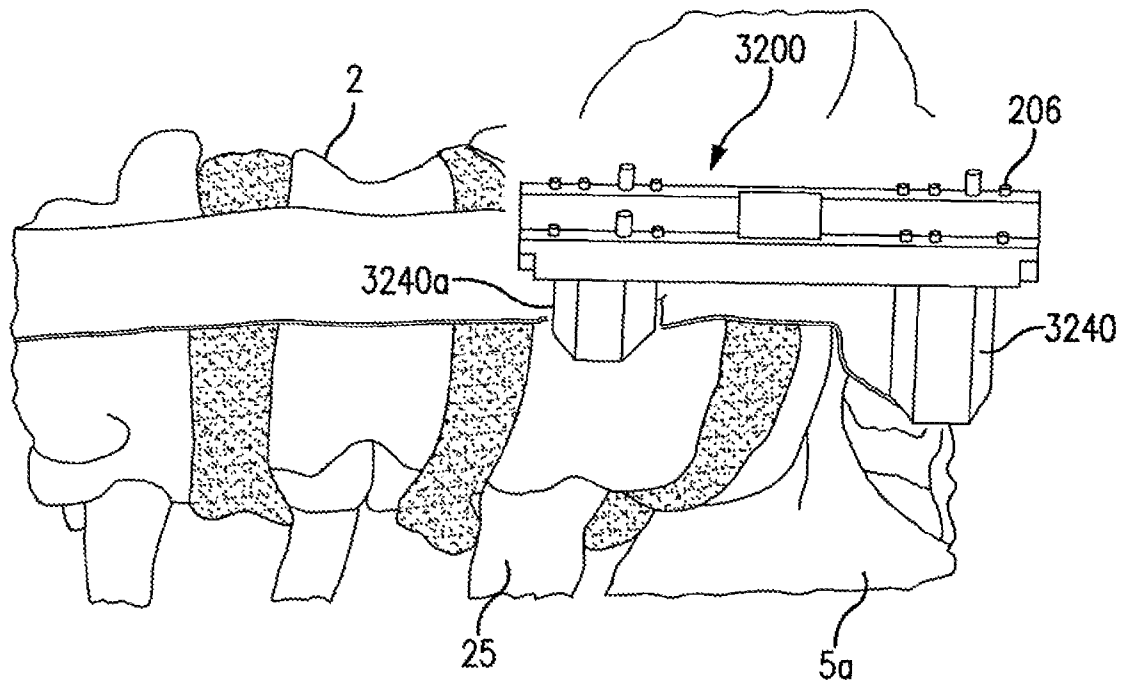


FIG. 21C

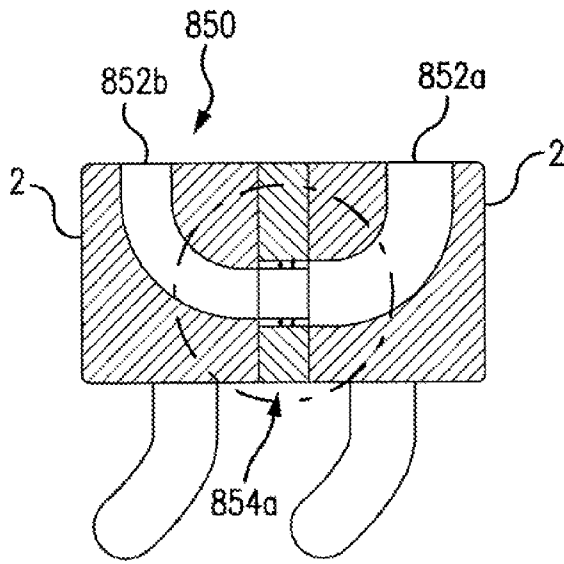


FIG. 22A

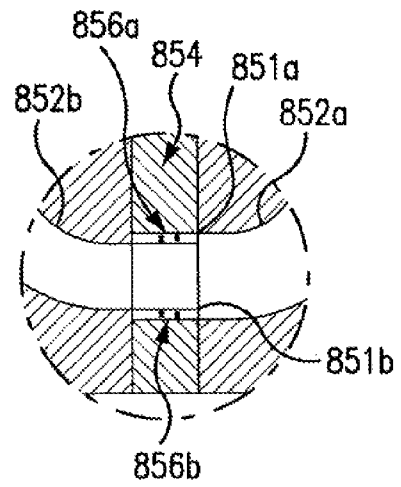


FIG. 22B

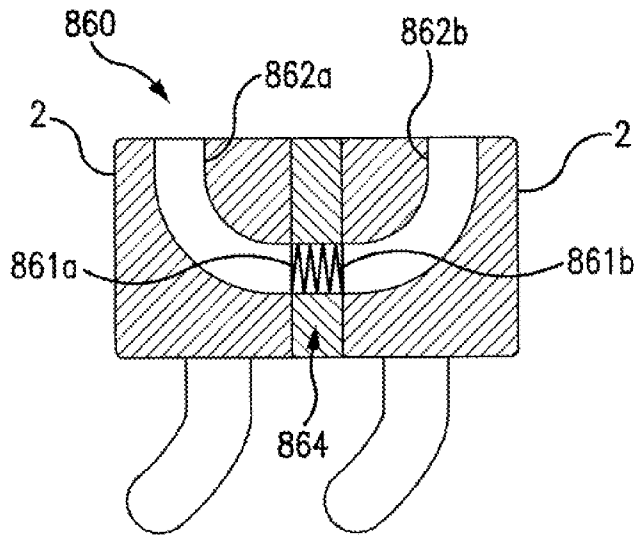


FIG. 23A

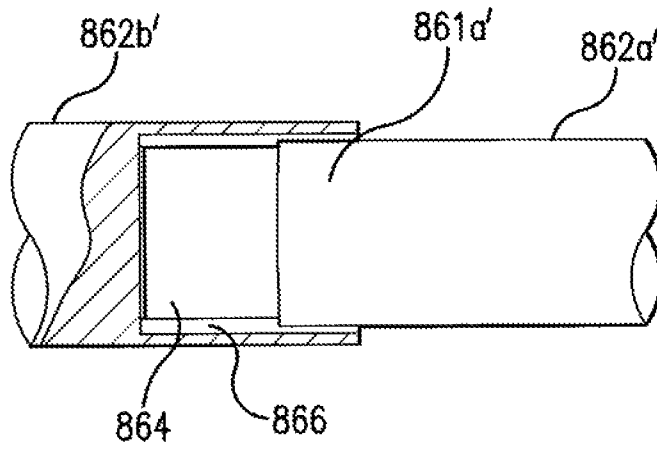


FIG. 23B

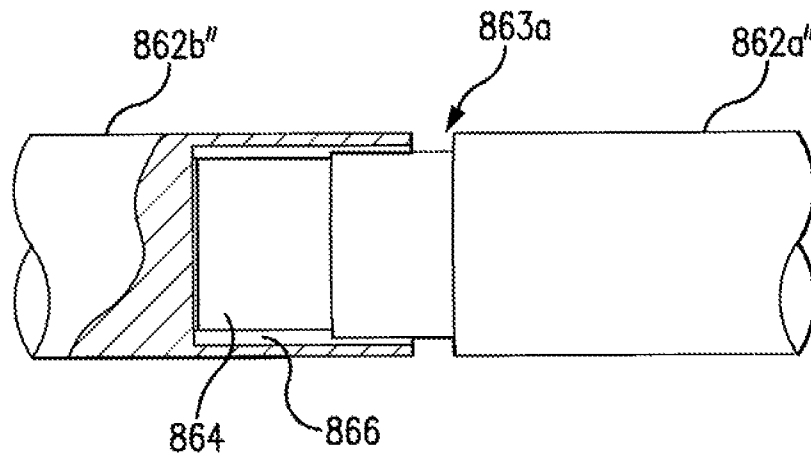


FIG. 23C

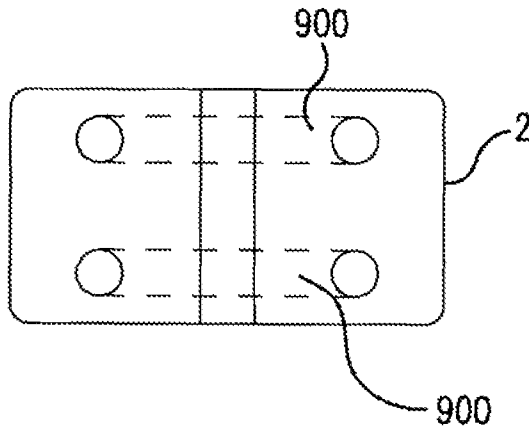


FIG. 24A

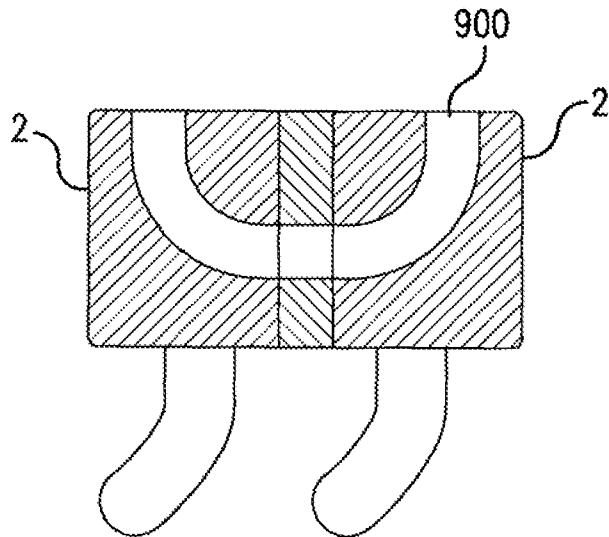


FIG. 24B

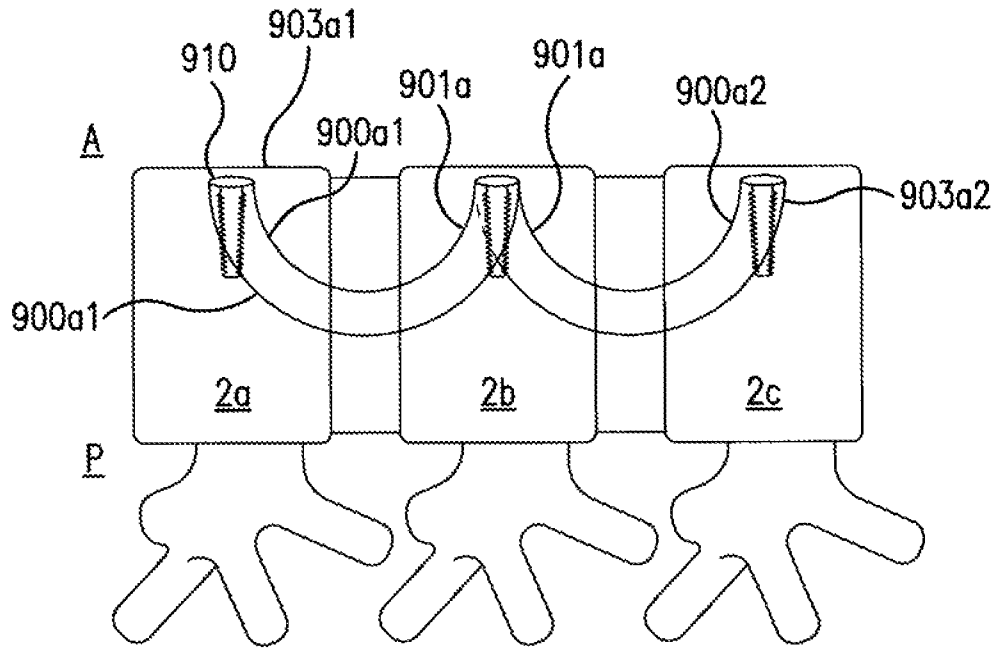


FIG. 24C

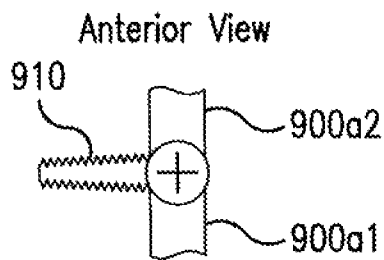


FIG. 24D

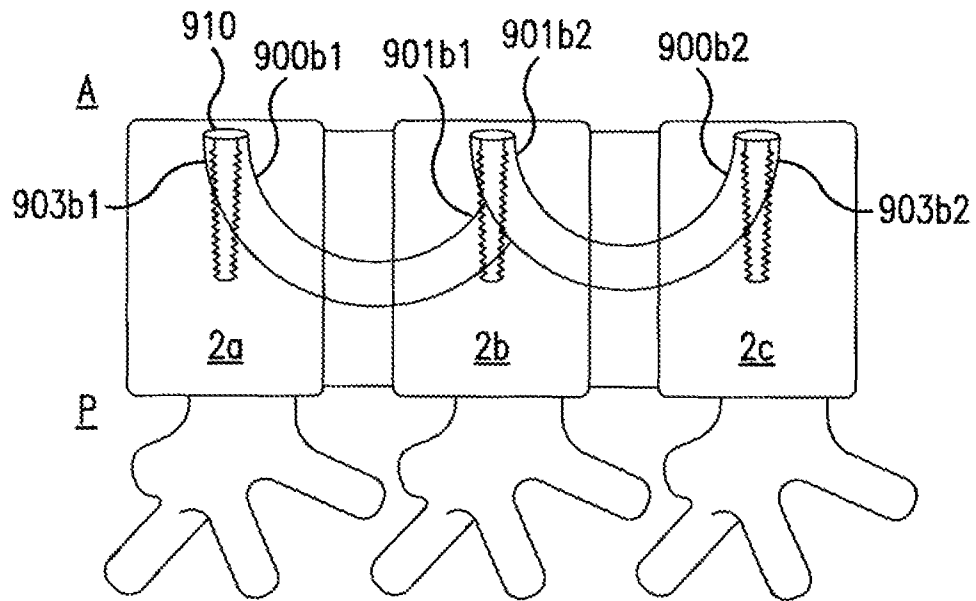


FIG. 24E

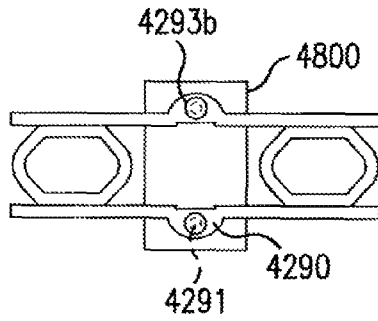


FIG. 25A

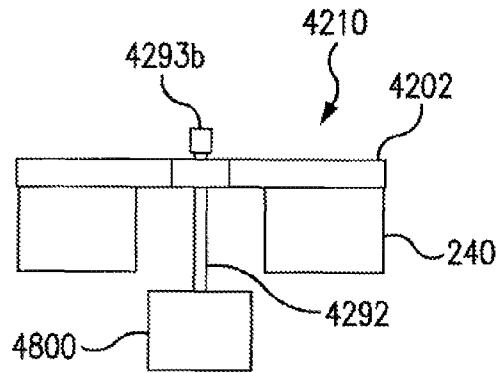


FIG. 25B

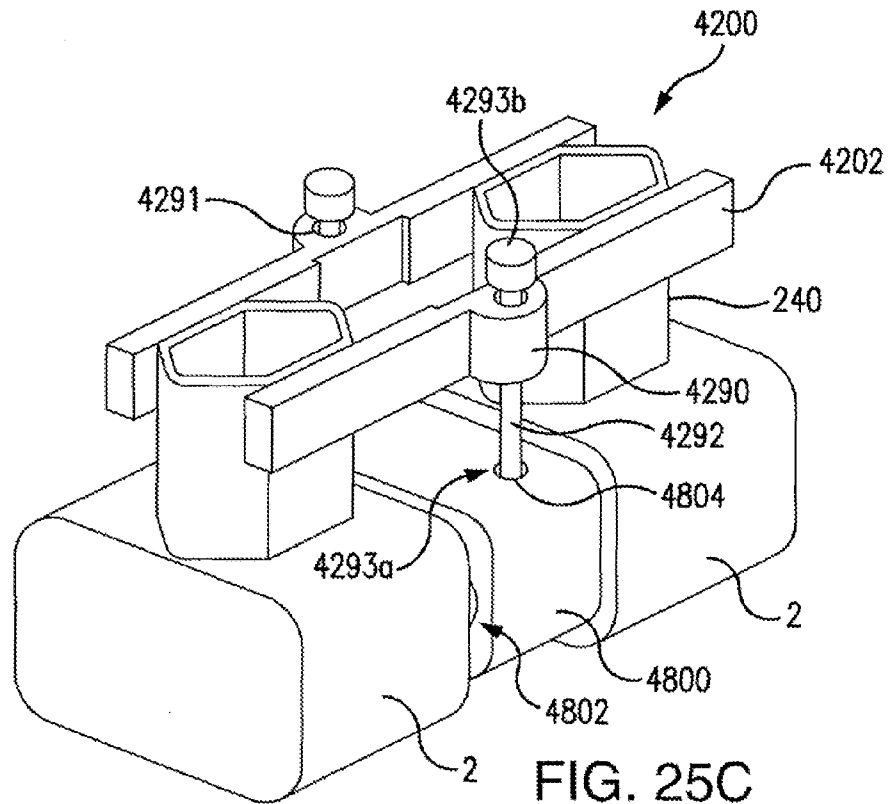


FIG. 25C



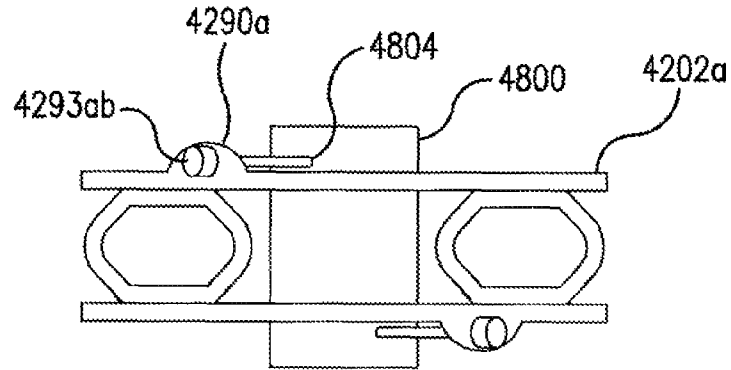


FIG. 26A

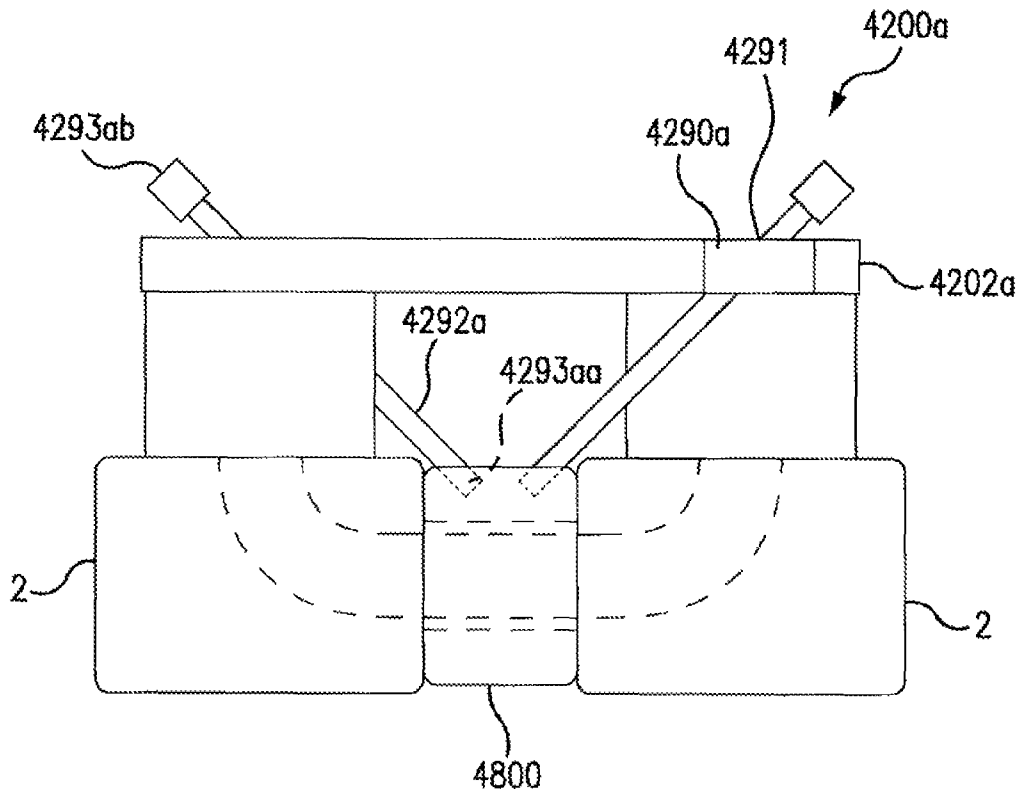


FIG. 26B

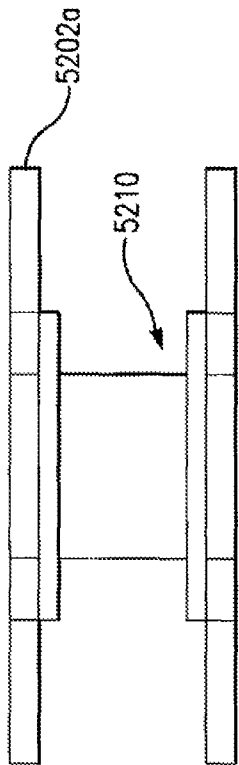


FIG. 27A

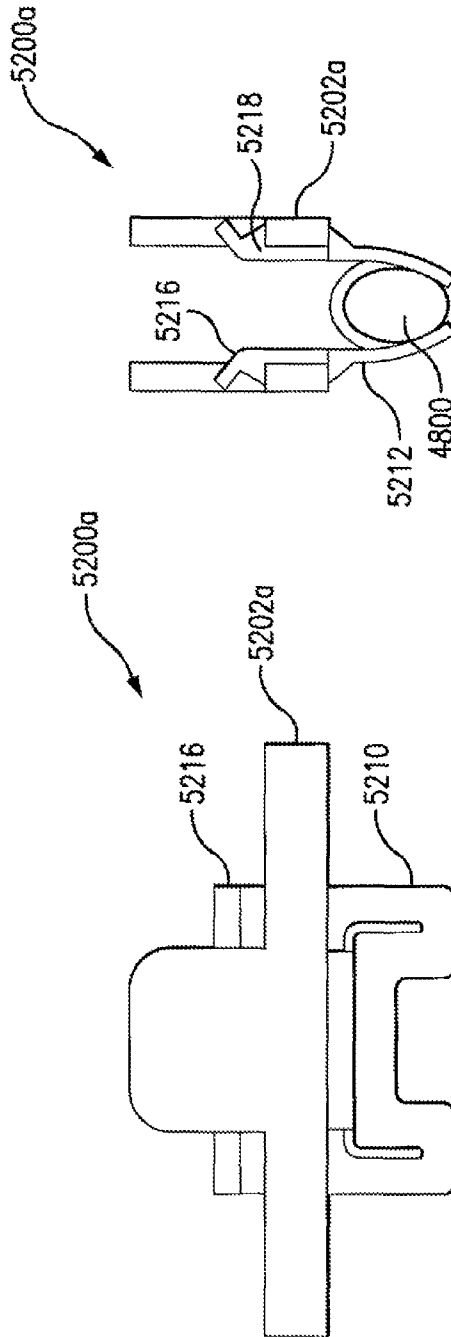


FIG. 27B

FIG. 27C

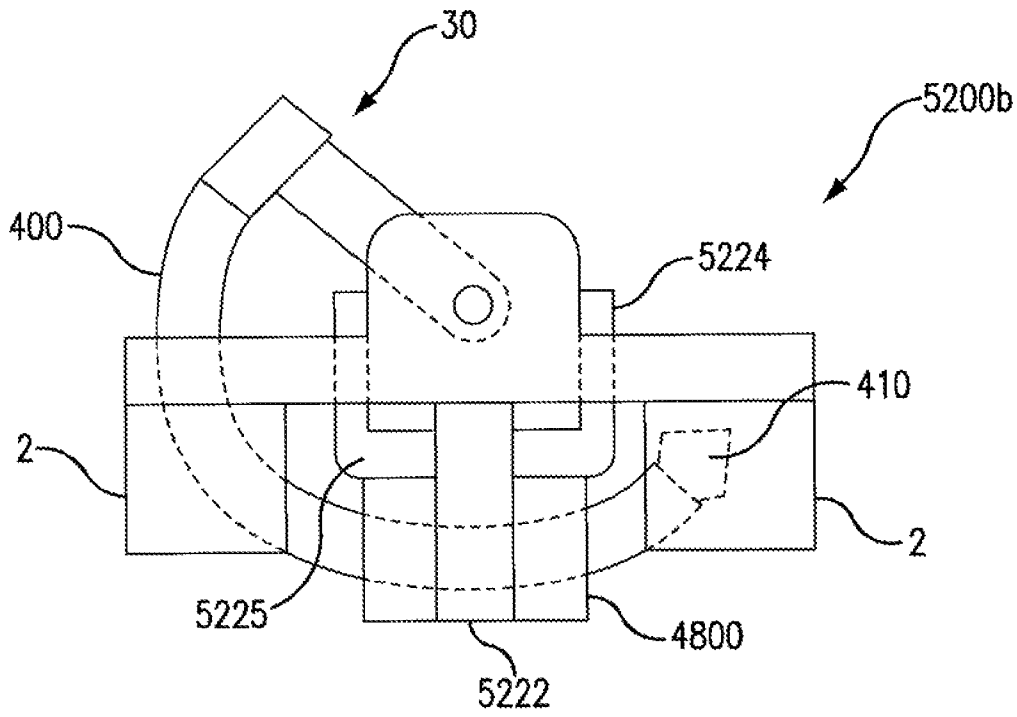


FIG. 28A

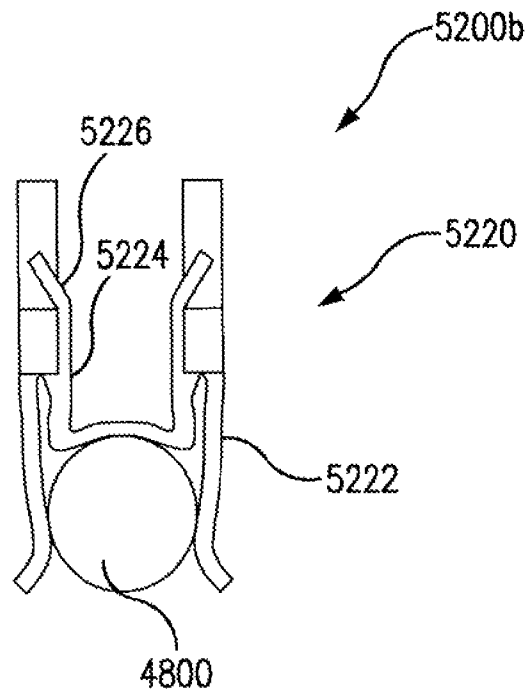


FIG. 28B

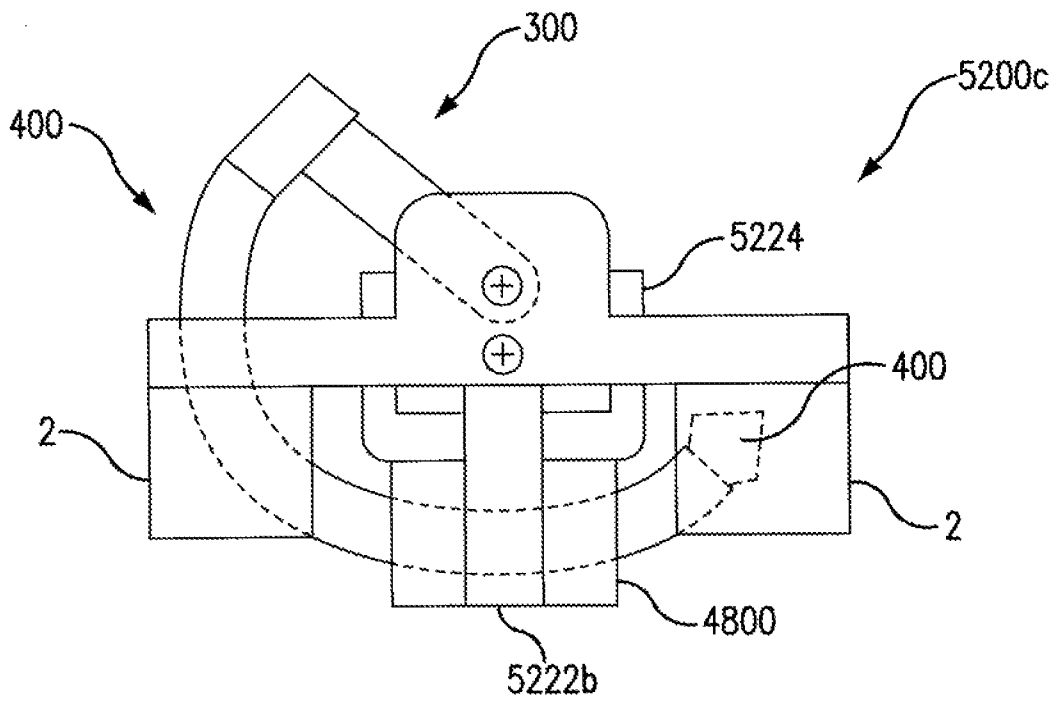


FIG. 29A

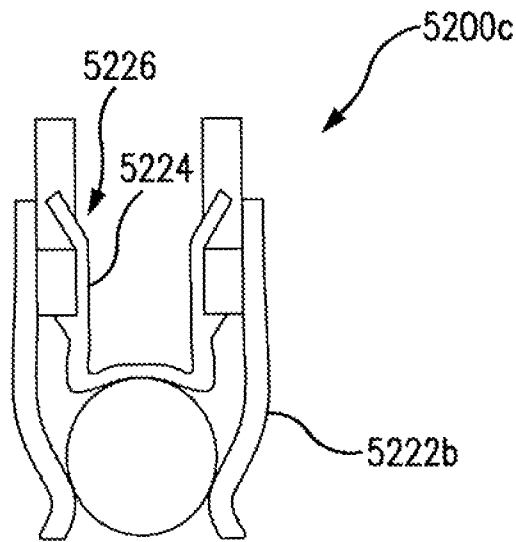


FIG. 29B

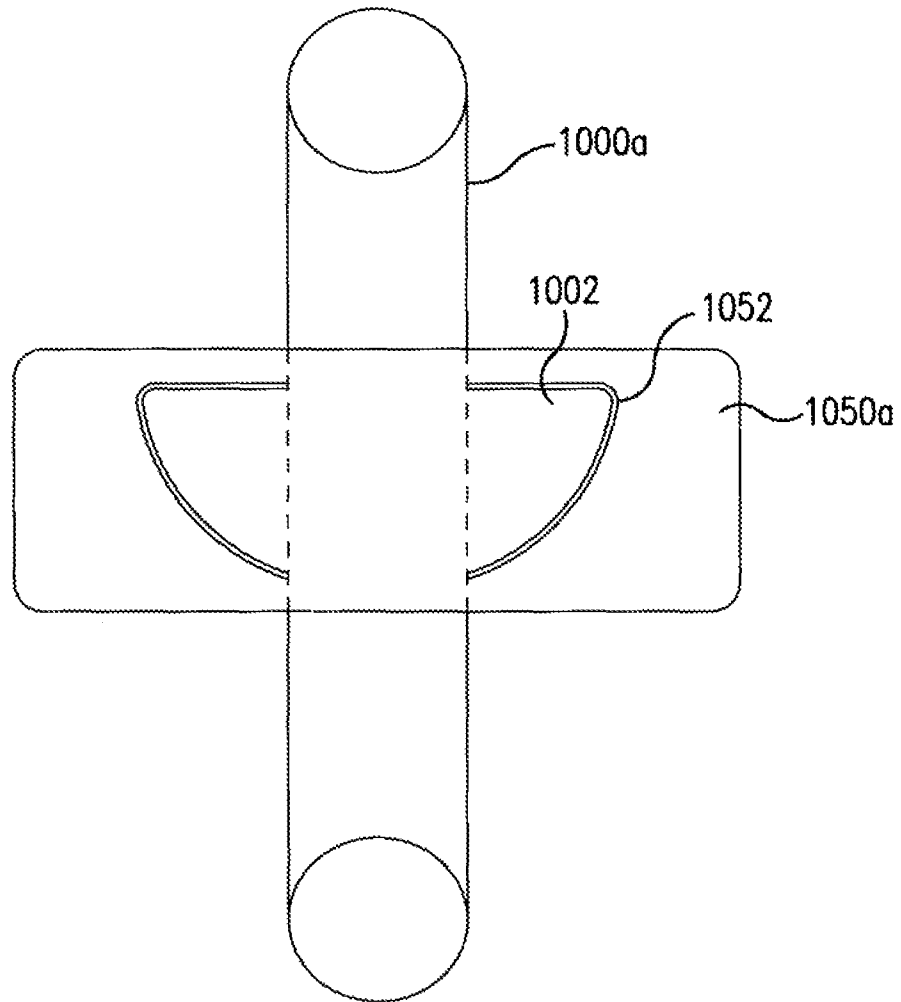


FIG. 30A

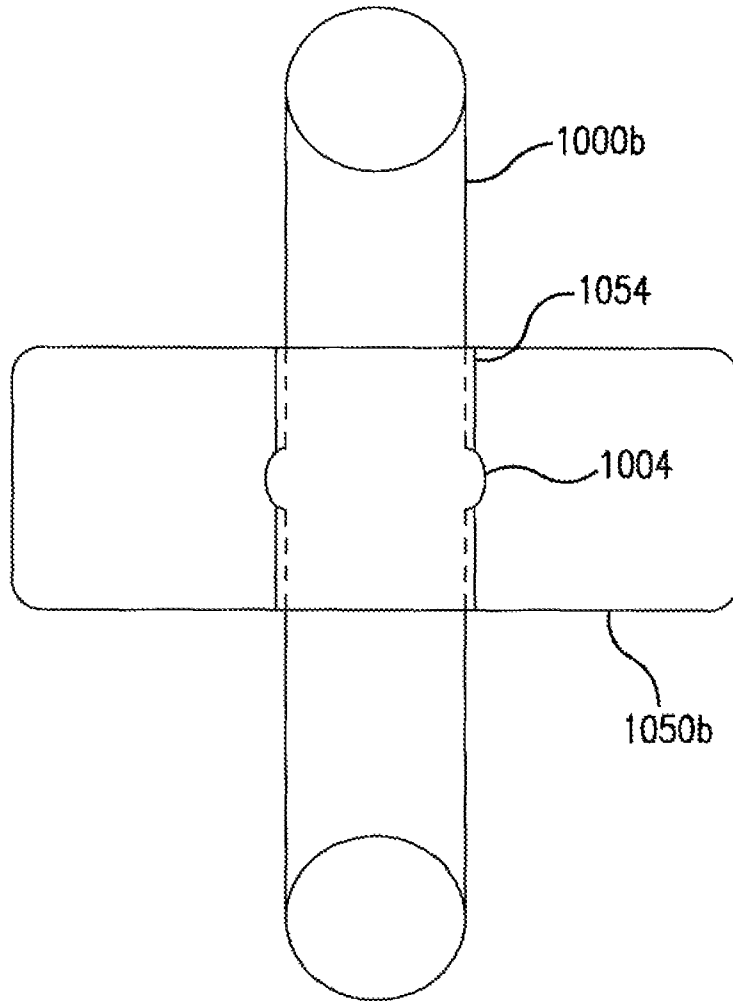


FIG. 30B

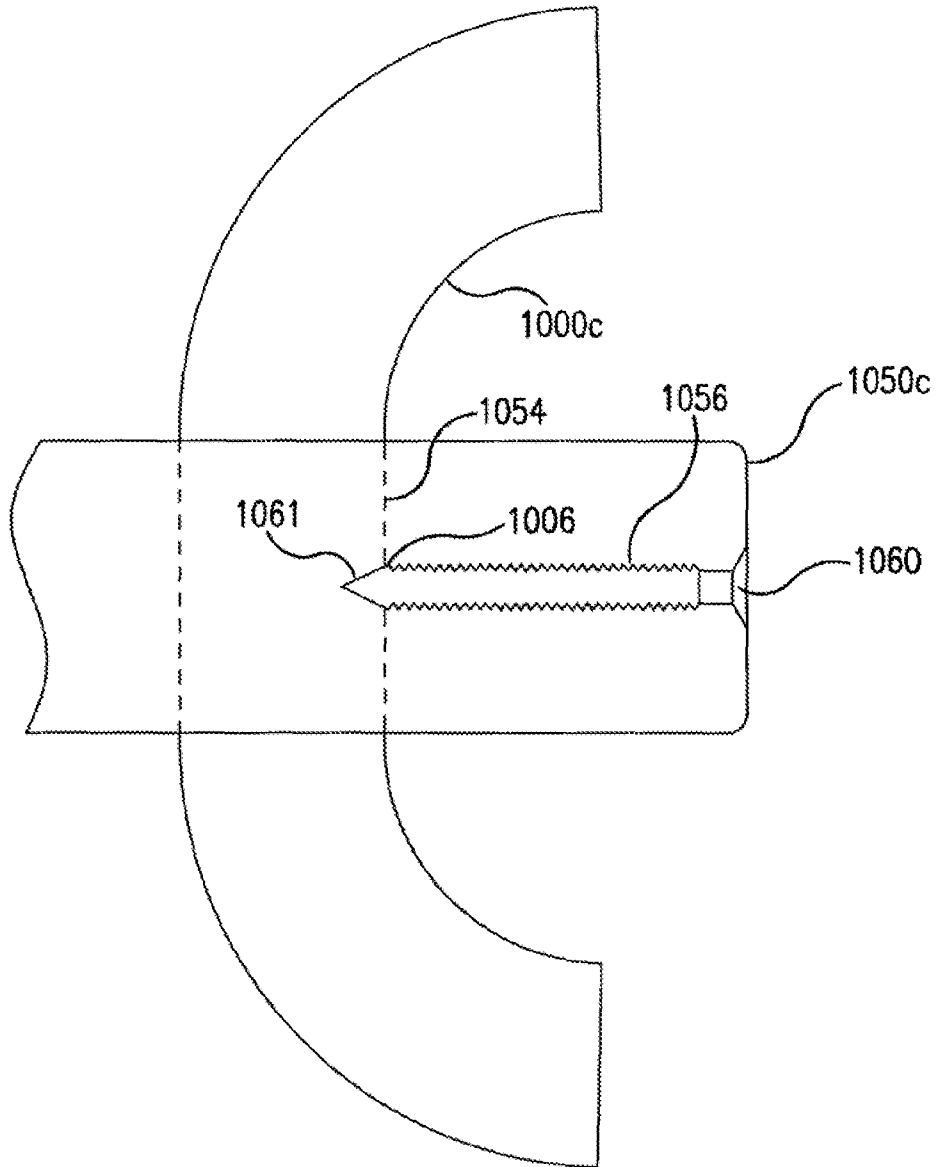


FIG. 30C

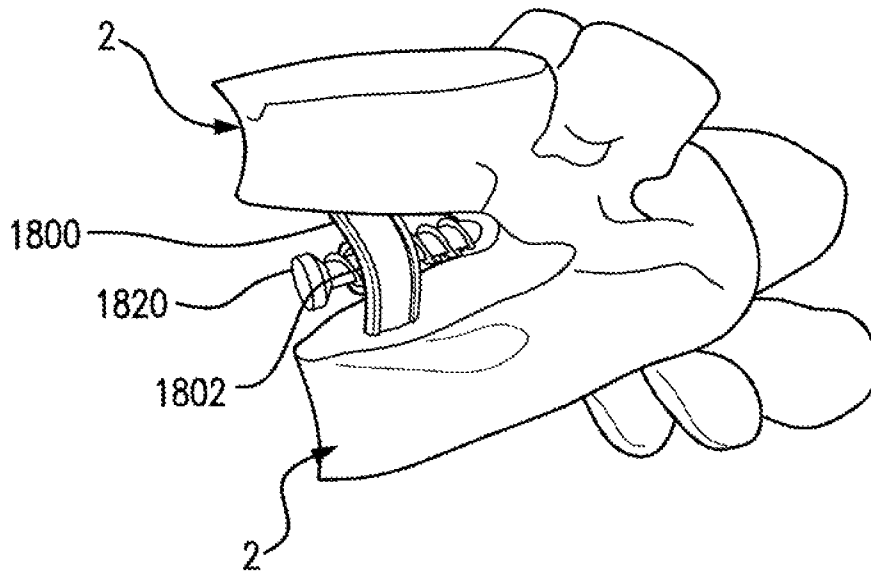


FIG. 31



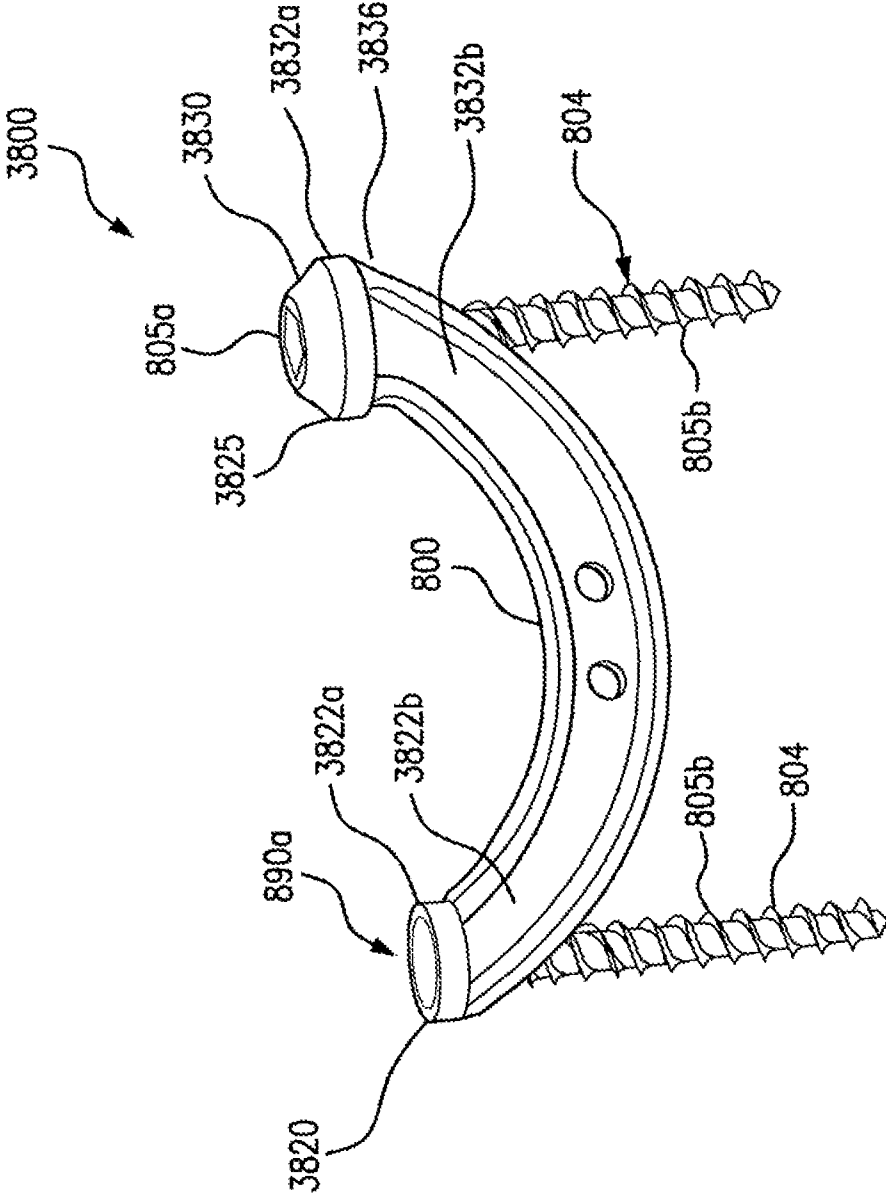


FIG. 32A

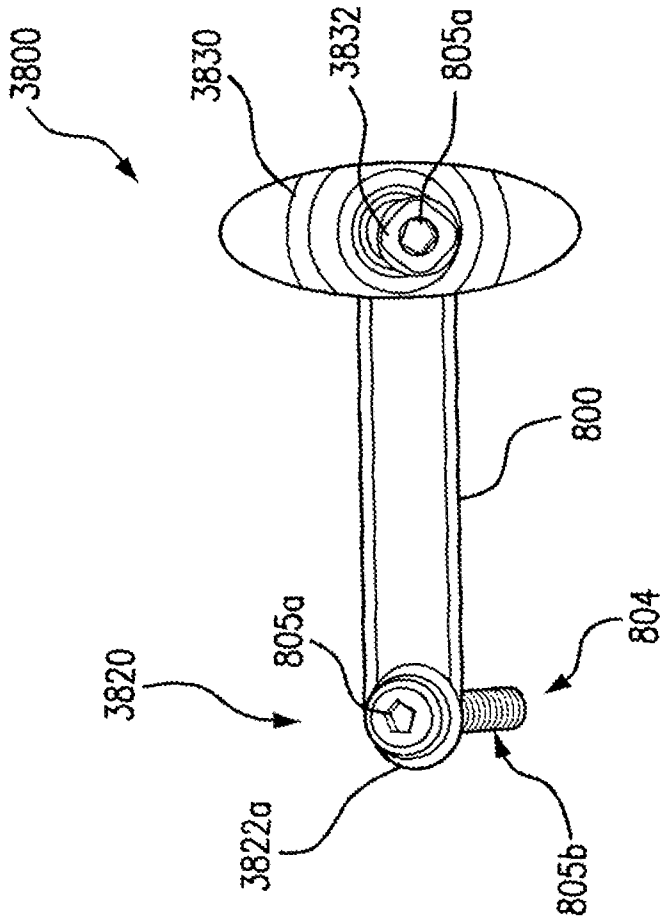


FIG. 32B

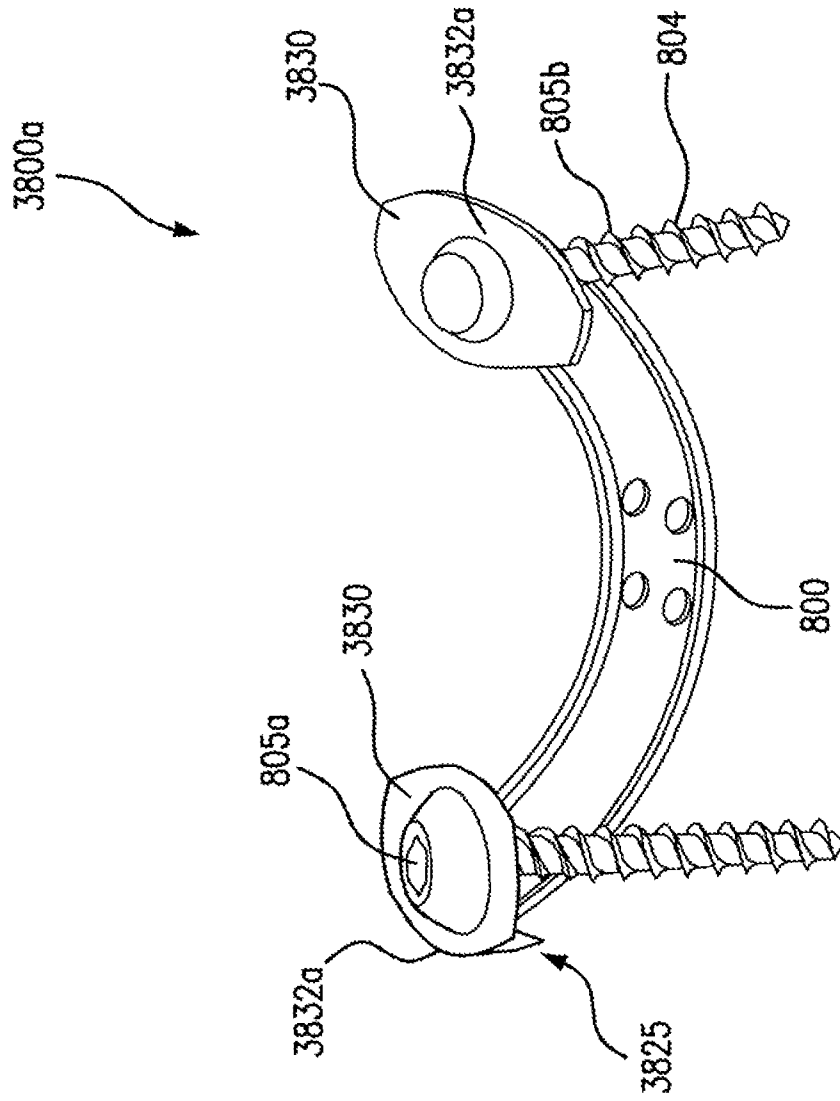


FIG. 32C

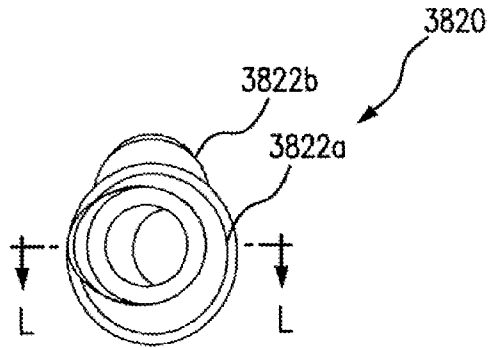


FIG. 33A

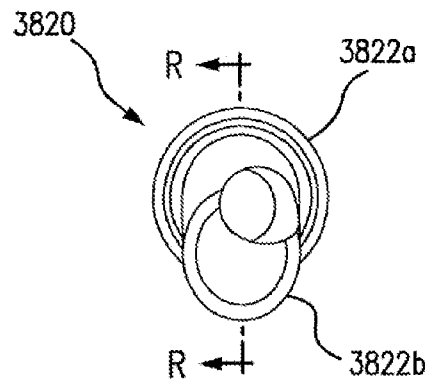


FIG. 33B

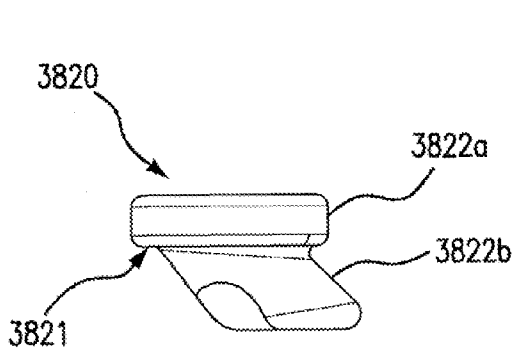


FIG. 33C

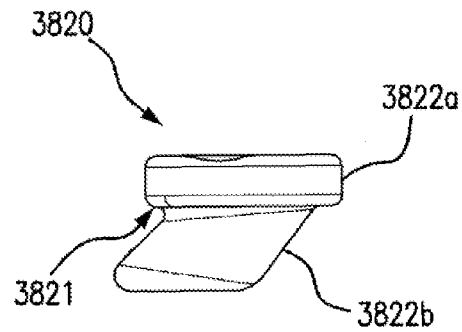


FIG. 33D

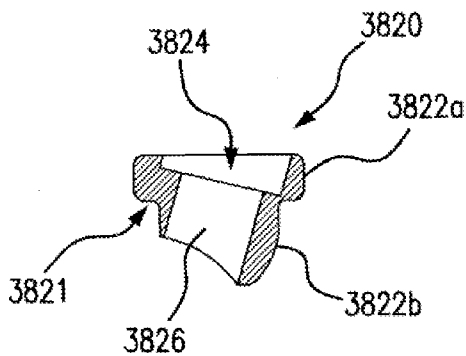


FIG. 33E

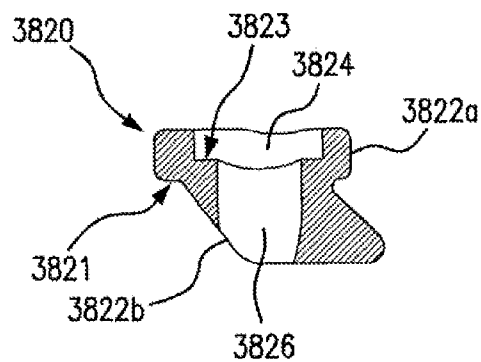


FIG. 33F

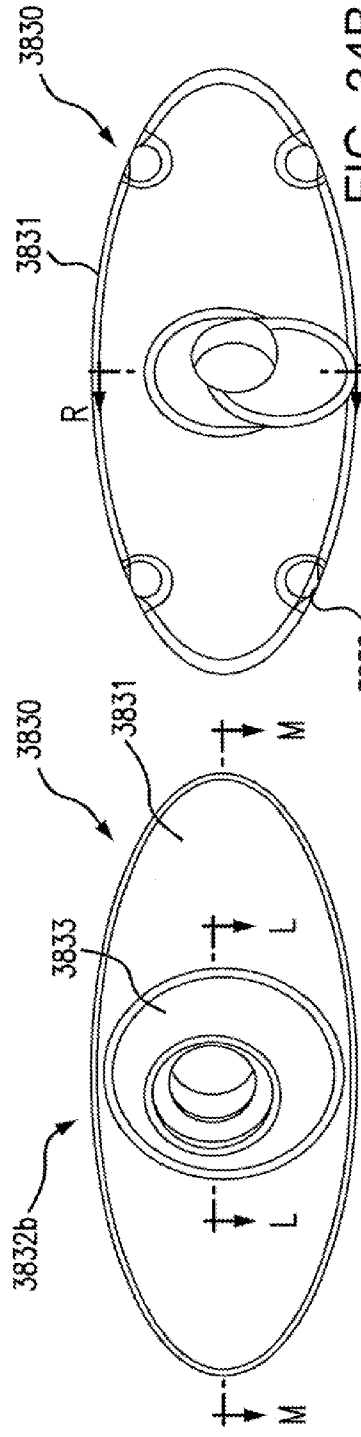


FIG. 34A

FIG. 34B

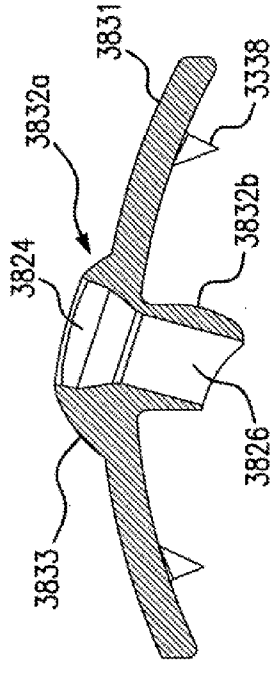


FIG. 34C

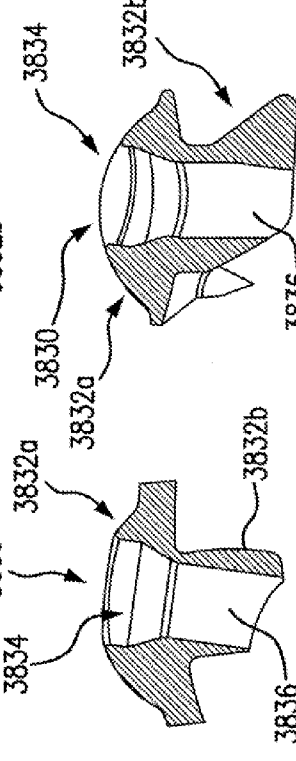


FIG. 34D

FIG. 34E

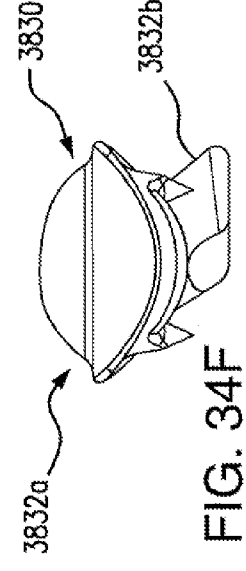


FIG. 34F

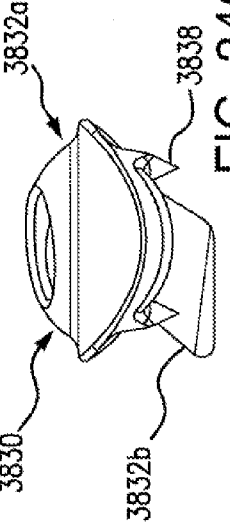


FIG. 34G

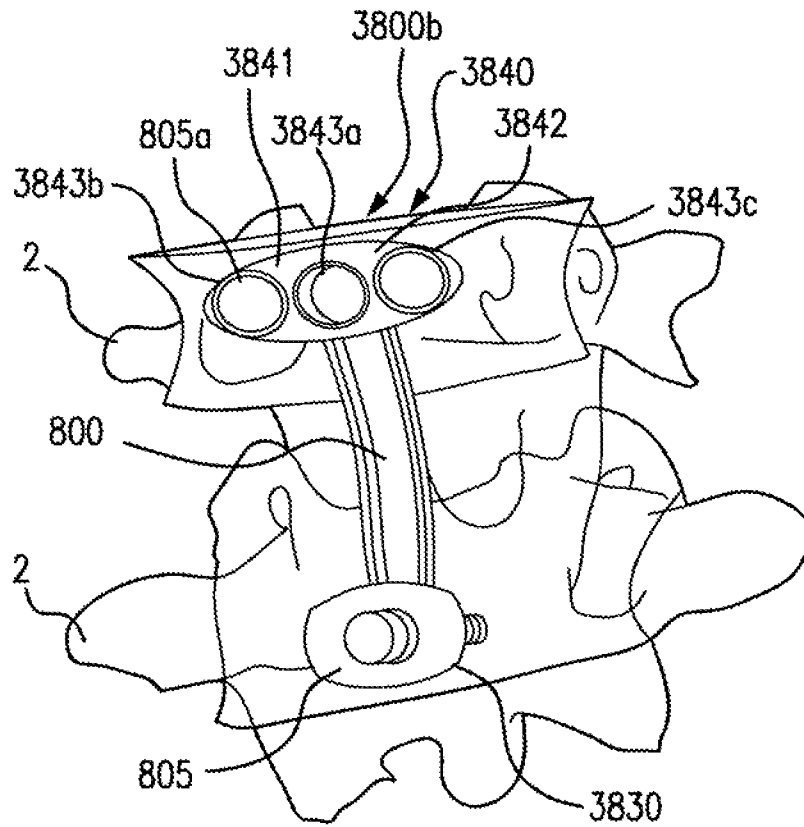


FIG. 35A

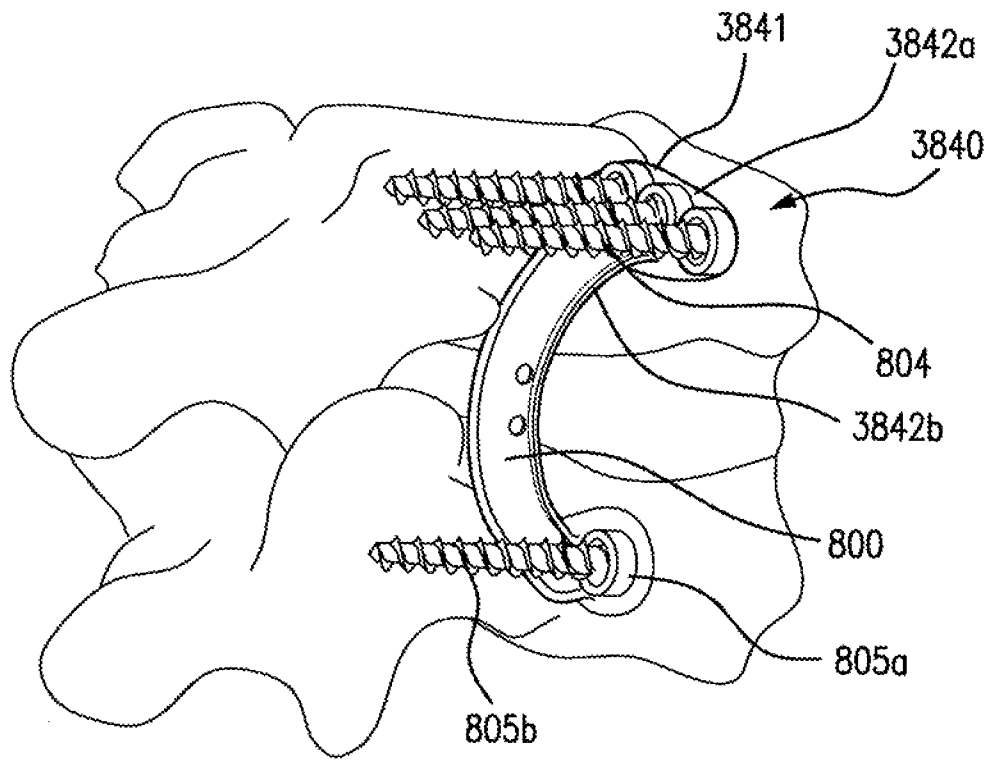


FIG. 35B

**SYSTEMS, DEVICES AND APPARATUSES  
FOR BONY FIXATION AND DISK REPAIR  
AND REPLACEMENT METHODS RELATED  
THERE TO**

This application is a continuation of U.S. patent application Ser. No. 13/928,027 filed on Jun. 26, 2013, which is a divisional of U.S. patent application Ser. No. 12/087,912 filed on Jun. 2, 2010 (U.S. Pat. No. 8,486,078), which is a National Stage Entry of PCT/US2007/001402 filed on Jan. 17, 2007, which claims the benefit of U.S. Provisional Application Ser. No. 60/759,718 filed Jan. 17, 2006.

Ser. No. 12/087,912 application is a continuation-in-part of U.S. application Ser. No. 10/968,867 filed Oct. 18, 2004, which application claims the benefit of U.S. Provisional Application Ser. No. 60/512,134 filed Oct. 17, 2003. Ser. No. 12/087,912 application also is a continuation-in-part of U.S. application Ser. No. 10/601,014 filed Jun. 20, 2003 (U.S. Pat. No. 8,021,401), which is a continuation of U.S. application Ser. No. 09/536,732 filed Mar. 28, 2000 (U.S. Pat. No. 6,607,530), which claims the benefit of U.S. Provisional Application Ser. No. 60/133,356 filed May 10, 1999. The teachings of all of the foregoing are incorporated herein by reference.

FIELD OF INVENTION

The present invention generally relates to methods, systems and apparatuses for bony fixation and more particularly to methods, systems and apparatuses adapted for fixing the bones of the spine. The present invention also generally relates to methods, systems and devices for augmenting, repairing or replacing the nucleus and/or annulus of an intervertebral disk of a spine, such as the spine of a mammalian body.

BACKGROUND OF THE INVENTION

Fixation or fusion of vertebral columns with bone or material, rods or plates is a common, long practiced surgical method for treating a variety of conditions. Many of the existing procedures involve the use of components that protrude outwardly, which may contact and damage a body part, such as the aorta, the vena cava, the sympathetic nerves, the lungs, the esophagus, the intestine and the ureter. Also, many constructions involve components that may loosen and cause undesirable problems, often-necessitating further surgical intervention. Additionally, limiting the success of these procedures are the biomechanical features of the spine itself, whose structure must simultaneously provide support to regions of the body, protect the vertebral nervous system and permit motion in multiple planes.

As indicated above, spinal surgery for spine fusion generally involves using implants and instrumentation to provide support to the affected area of the spine while allowing the bones thereof to fuse. The technology initially evolved using bone chips around and on top of an area of the spine that had been roughened to simulate a fracture in its consistency. The area, having encountered the bone chips, would then proceed to heal like a fracture, incorporating the bone chips. However, surgical procedures dealing with the spine present notable challenges. For example, bioengineers have been required to identify the various elements of the complex motions that the spine performs, and the components of the complex forces it bears. This complexity has made it difficult to achieve adequate stability and effective healing in surgical procedures directed to the spine.

One surgical technique provided by Cloward, involves cutting a dowel type hole with a saw across or through the moveable intervertebral disc and replacing it with a bone graft that was harvested from the hip bone. This procedure results in a fusion of the adjacent vertebral bodies and limits motion and mobility. However, as a result of the complex motions of the spine, it is often difficult to secure the dowel from displacing. Further, it has become apparent over time, however, that this particular technique does not always yield a secure fusion.

Other techniques have been developed that involve the placement of various hardware elements, including rods and hooks, rods and screws and plates and screws. The dowel technique also has advanced over the past five years or so, with dowels being fabricated from cadaver bone or metals such as titanium or stainless steel. These techniques, whether using hardware, dowels or some combination thereof, have a common goal to enhance stability by diminishing movement, thereby resulting in or enhancing the potential of a fusion of adjacent vertebral bones. For example, in one of these other techniques, the disc is removed and adjacent vertebrae are positioned in a stable position by placing a plate against and traversing them, which plate is secured or anchored to each by means of screws.

In another procedure, cages in the form of two parallel circular or rectangular devices are made out of a material such as titanium or stainless steel and these devices are fenestrated. Bone is packed in the center of the devices that will heal to adjacent bone through each fenestration. In this procedure, the disc space is distracted so all ligamentous structures are taut and the bones are held in their normal maximal position of distraction. Because the cages are implanted in spongy bone, they are more likely to collapse the surrounding bone, thus resulting in loss of distraction and subsequently cage dislodgment.

U.S. Pat. No. 5,591,235 reports a certain spinal fixation device and technique for stabilizing vertebrae. In this technique, a hollow screw is inserted into a hole, preferably a hole saw recess, in each adjoining vertebrae. A channel is cut into the vertebrae, which is lined up with corresponding axial slots in the screw. A rod is inserted into the channel and so as to pass through the axial slots in the screw. The rod is secured to each of the screws by means of a locking cap. The rod also is arranged so as to provide a bridge between the hollow screws in the adjoining vertebrae. Certain disadvantages have been surmised using such a device and technique. For example, it has become apparent that the trough in the vertebral bodies destabilizes some of the cortex of the vertebrae body wall, which is the strongest component.

In addition to fixation or fusion of vertebral columns, the prior art also describes methods or other spinal repair procedures, such as discectomy wherein an artificial disc or prosthetic device is placed within the vertebrae of the spine. For such prior art methods and related devices, there have been short comings such as having difficulty in securing the prostheses within the vertebral space or resulting in significant modification or damage to the load bearing surfaces of the vertebrae in an effort to secure the prosthesis.

Another method or other spinal repair technique involves augmentation of the nucleus of an intervertebral disk of the spine. The intervertebral disk is a flexible cartilaginous structure that is disposed between adjacent vertebrae. These disks form joints between the bodies of the vertebrae, which serve to unite adjacent vertebrae and to permit movement between them. These disks also play a role as shock absorbers when force is transmitted along the vertebral column during standing and movement.



Each disk is formed of two parts, a central mass called the nucleus pulposus (herein the nucleus) and a surrounding fibrous layer, the annulus fibrosus (herein the annulus). The nucleus has a semi-gelatinous consistency, which allows it to become deformed when pressure is placed upon it, enabling the disk to change shape as the vertebral column moves.

There is described in U.S. Pat. Nos. 5,047,055; 5,824,093 6,264,695; the teachings of which are incorporated herein by references, various techniques and/or prosthetics for use in replacing or augmenting a spinal disc nucleus. Given the structure of the disk and its location between adjacent vertebrae, it is not a simple task to access the nucleus for the insertion of such prosthetics or materials to augment the nucleus. One technique for accessing the nucleus contemplates using the defect in the annulus, however, in practice the defect usually needs to be enlarged to allow the insertion of the prosthetic. Another technique contemplates having the surgeon drill through one of the adjacent bodies using a lateral approach. This another technique relies heavily on the skill and dexterity of the surgeon not to damage surrounding tissues, nerves and blood vessels. Also, the hole formed by such drilling is not easily sealed because of its shape and configuration.

Conventional techniques relating to fixation of the spine and bony structure rely in great part on the skill and dexterity of the surgeon to control the devices and instrumentalities being used to protect surrounding tissues, muscles, nerves and blood vessels from damage during the procedure. This is so because the devices and/or instrumentalities that the surgeon uses during such techniques, themselves do not provide the surgeon with a mechanism to protect the tissues, muscles, nerves and blood vessels surrounding the treatment or target area within the body from coming into contact with the device or instrumentality during the procedure. Consequently, the surgeon must use surgical techniques to relocate tissues, muscles, nerves and blood vessels from the surgical field, if that is possible, and for those which it is not possible, the surgeon must take care in the use of the device or instrumentality to prevent injury. It should be recognized that the surgeon while inserting and retracting or removing the device or instrumentality from the bony structure or spine must exercise such care to prevent injury.

Thus, it would be desirable to provide a new apparatus, system and methods for bony fixation that enhances healing of the bone while providing structural support therefore. It would be particularly desirable to provide such an apparatus, system and method that would involve the use of open surgical or minimally invasive surgical techniques as well as a technique in which the implant burrows in the structure of the bone; more particularly a technique in which the implant burrows in the bone spine, traverses across the disk space, and ends in an adjacent or neighboring vertebrae or vertebrae, providing limited or no protrusions. It also would be desirable to provide such an apparatus, system and method where the implant is retained within the bone without requiring external fixation including contour-varying external vertebral wall fixation as compared to conventional devices, as such a device would avoid many of the problems associated with conventional devices such as blood vessel injury, erosion into organs, as well as placement near nerves. It also would be desirable for such apparatuses and systems to be adaptable for use in a wide range of procedures and techniques, including but not limited to augmentation of the nucleus such as by use of prosthetics.

#### SUMMARY OF THE INVENTION

The present invention features new methods, apparatuses and devices for fixing adjacent bone segments, segments of a

bony structure and adjacent vertebrae of a spine. The methods, apparatuses and devices utilize a new apparatus for forming a channel in a surface of the bone or bony structure segments or adjacent vertebra or a channel submerged within the bone or bony structure segments or adjacent vertebra. In more particular embodiments such apparatuses and methods include forming an arcuate channel. Also the channel formed can receive therein a curved rod or implant member, which also preferably is arcuate, and avoids the associated problems with prior cage or straight rod and screw systems. Also featured are devices used in connection with such apparatuses and methods.

According to an aspect of the present invention there is featured a method for forming a channel, an arcuate channel in adjacent bone segments, adjacent segments of a bony structure or adjacent vertebra of a spine, the bone segments, bony structure and spine more particularly being those of a mammalian body (e.g., human body). Such a method includes positioning a frame assembly proximal the treatment or surgical site, securing the frame assembly to the adjacent segments of the bone or bony structure or adjacent vertebra and rotating a drill bit in fixed relation to the frame assembly to form the channel in the surface or sub-surface of the bone, bony structure or vertebra. In further embodiments, the method further includes mechanically engaging a securing mechanism to the frame assembly so that the frame is maintained in fixed relation by such mechanical engagement alone or in combination with the lateral stiffness of the securing mechanism.

In more specific embodiments, the frame assembly includes a frame having a plurality of through apertures, each through aperture including a constricted portion and a plurality of securing members. Each of the plurality of securing members are driven through the through apertures and the constricted portion and into the bone, bony structure or vertebra at the site such that the frame is secured in fixed relation to the bone, bony segments or vertebra by the engagement of the constricted portion with the securing member and by the lateral stiffness of the securing members.

In further embodiments, the method further includes attaching a drill assembly to the frame assembly so a drill bit of the drill assembly follows a predetermined path, more particularly a predetermined circular path, in fixed relation with respect to the frame and moving the drill bit through the predetermined path while the drill bit is rotating so as to cut the channel. In more particular embodiments, the method further includes providing a pivot arm assembly having a pivot arm that rotates in fixed relation to the frame, securing a portion of the drill assembly including the drill bit to the pivot arm assembly and rotating the drill bit using the pivot arm assembly so the drill bit traverses the predetermined path, more specifically the predetermined circular path.

Such a method further includes determining if the rotation of the drill bit in a first direction formed a complete channel or a partial channel and in the case where it is determined that a partial channel was formed, reconfiguring the drill assembly so as to be rotatable in a second rotational direction that is different from the first direction and rotating the drill bit in the second rotational direction to form the complete channel.

Such methods further include locating and attaching an implant in the channel so formed and securing the implant therein using any of a number of techniques known to those skilled in the art. In more particular embodiments, such a method include securing the implant to the bone, bony structure or vertebra using a plurality or more of securing devices, more specifically using a plurality of threaded members.

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Such methods further include forming a plurality or more channels in one or more surfaces of the bone or bony structure segments or adjacent vertebra or a channel submerged within the bone or bony structure segments or adjacent vertebra. In particular embodiments, two channels are formed submerged within the bone or bony structure segments or adjacent vertebra. In further embodiments, such methods include locating an implant in each of the plurality or more channels so formed and securing the implant therein using any of a number of techniques known to those skilled in the art. In more particular embodiments, such methods include securing the implant to the bone, bony structure or vertebra using a plurality or more of securing devices, more specifically using a plurality of threaded members. It should be noted that the term adjacent vertebrae includes the sacrum.

In further embodiments, such implants include a sliding implant device comprising two implant members, one of which is disposed in sliding relation with respect to the other. Thus, such methods further include implanting the sliding implant device such that one member is securably retained to, or within, one of the adjacent vertebrae; such that the other member is securably retained to, or within, the other of the adjacent vertebrae; and such that the sliding interconnection between the two members is located in the intravertebral space between the adjacent vertebrae.

In further embodiments, the two implant members also are configured so as to include stops, elements or surface artifacts in opposing surfaces of the two members that cooperate so as to restrain further relative movement between the two members. More particularly, such stops, elements or surface artifacts are arranged so as to prevent the two members from being displaced in a direction that would allow the said one member to slide out an end of said other member, thereby breaking the sliding interconnection between the two members. In illustrative embodiments, each such stop comprises a vertically extending member that extends upwardly from each of the opposing surfaces and which extends at least partially about the circumference of each member.

In further embodiments, such implants include a dynamized implant device comprising two implant members and a compressive segment compressibly interconnecting the two implant members. Thus, such methods further include implanting the dynamized implant device such that one member is securably retained to, or within, one of the adjacent vertebrae; such that the other member is securably retained to, or within, the other of the adjacent vertebrae; and such that the compressive segment is located in the intravertebral space between the adjacent vertebrae. In particular embodiments, the compressive segment further includes a resilient element or feature (e.g., spring or compressible material) that in effect controls or limits the amount of compression or movement between the two members.

According to further aspects of the present invention there is featured a method for forming a channel, an arcuate channel in adjacent vertebra of a lower portion of the spine, more particularly between the lumbar vertebrae and more specifically, between the lowest lumbar vertebrae (L-5) and the sacrum. Such a method includes positioning a frame assembly proximal the treatment or surgical site, securing the frame assembly to the adjacent segments of the adjacent vertebra including the lumbar vertebrae L-5 and the sacrum and rotating a drill bit in fixed relation to the frame assembly to form the channel in the surface or sub-surface of the bone, bony structure or vertebra. In further embodiments, the method further includes mechanically engaging a securing mechanism to the frame assembly so that the frame is maintained in

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fixed relation by such mechanical engagement alone or in combination with the lateral stiffness of the securing mechanism.

In further embodiments, the provided frame assembly is configured to accommodate relative differences in the surface and the height or elevation between the adjacent vertebrae including the lumbar vertebrae L-5 and the sacrum so the channel being formed follows a desired path through the adjacent vertebrae. In more particular embodiments, a portion of the frame assembly is configured so the pivot point of the rotating drill point is in fixed relation with respect to the desired path.

According to further aspects, such methods further includes removably attaching a spacer element to the frame assembly so as to maintain alignment of the spacer with respect to the frame as well as with respect to the channel being formed in adjacent vertebrae and releasing the spacer element from the frame assembly following forming of the channel in the adjacent vertebrae using any of the methods described herein. In one embodiment, the spacer element includes a preformed aperture and said attaching includes attaching the spacer element to the frame assembly so as to maintain alignment of the preformed aperture with respect to the frame as well as with respect to the channel being formed in adjacent vertebrae. In another embodiment, said method includes forming an aperture in the spacer element, preferably when forming the channel in the adjacent vertebrae. Such spacers can be formed from any of a number of materials, including bone, metal, allograft or autologous as well as using any of a number of techniques known to those skilled in the art. It also is contemplated that such spacers remain in the intervertebral disc space following the procedure being performed that embodies the methodologies of the present invention as well as devices, apparatuses and systems of the present invention.

Also featured is a system or apparatus embodying the frame, pivot arm assembly and drill assembly herein described. In addition there is featured devices or tools for use with such systems, apparatuses and methods to drive the securing members or to remove the securing members after the channel has been formed in the surface or sub-surface of the bone, bony structure or adjacent vertebrae.

In further aspects of the present invention, there are featured systems, apparatuses and methods for augmenting, repairing or replacing the nucleus and/or the annulus that embody the frame, pivot arm assembly and drill assembly herein described as well as other such systems and apparatuses described in U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265 (the teachings of which are incorporated herein by reference). In such systems, apparatuses and methods, the drill is rotated as described herein to form a channel or passage through one of the vertebrae that is adjacent to the disk to be repaired so that the nucleus of the disk can be accessed through the vertebral end plate. The size of the channel or passage formed can be controlled so as to provide the desired or needed amount of access for the surgeon to insert for example, the material or prosthetic into the nucleus as well as other devices or mechanisms (e.g., a patch) that can be used to form a seal or closure at the defect on the annulus. Such control is achieved for example, by adjusting the size of the drill bit to fit a given application. Such a disk repair procedure also can include sealing of the channel, passage or hole formed in the vertebrae using any of a number of techniques known to those skilled in the art, such as for example, inserting bone or bony material into the channel.

It should be recognized that the drilling apparatus, methods and systems of the present invention can be used anteriorly

or posteriorly and so that the drill bit of such systems or apparatuses can penetrate or enter the vertebral body through the pedicles.

Other aspects and embodiments of the invention are discussed below.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and desired objects of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference character denote corresponding parts throughout the several views and wherein:

FIG. 1 is a side view of a drilling apparatus according to an aspect of the present invention;

FIG. 2 is one perspective view of the drilling apparatus of FIG. 1;

FIG. 3 is another perspective view of the drilling apparatus of FIG. 1;

FIGS. 4A,B are various perspective views of the pivot arm assembly of the drilling apparatus of FIG. 1;

FIG. 5 is a perspective view of the pivot arm of the pivot arm assembly;

FIG. 6 is a perspective view of the drill assembly of the drilling apparatus and a drive motor connected thereto;

FIG. 7 is a cross-sectional side view of the drill assembly of FIG. 6;

FIG. 8 is a side view of the bit, bearing and drive cable sub-assembly of the drill assembly;

FIG. 9 is a cross-sectional view of the drill assembly end including the bit, illustrating another exemplary bit;

FIG. 10A is a side view of a nail removal tool according to one embodiment of the present invention;

FIG. 10B is an end view of the nail removal tool;

FIG. 11 is a perspective view of the nail removal tool mounted on the platform assembly of the drilling apparatus;

FIG. 12 is a side view with a partial cut away of a nail drive tool according to an embodiment of the present invention;

FIGS. 13A-L are illustrations of the process for forming a recess in adjacent vertebral bodies;

FIGS. 14A-D are illustrations of the process for implanting or attaching a curved rod across the adjacent vertebrae;

FIGS. 15A-H are illustrations of the process for forming a through aperture in adjacent vertebral bodies;

FIG. 15I is an illustrative view of adjacent vertebral bodies illustrating the fixed cutting depth aspect yielded by the drilling apparatus of the present invention;

FIGS. 16A-C are illustrations of the process for implanting or attaching a curved rod in the through aperture and across the adjacent vertebrae;

FIG. 17 is a side view of a drilling apparatus according to another aspect of the present invention illustrated disposed upon adjacent vertebral bodies;

FIG. 18A is a perspective view of drilling apparatus according to yet another aspect of the present invention;

FIG. 18B is side view of the drilling apparatus of FIG. 18A;

FIG. 18C is another perspective view from a different perspective of the drilling apparatus of FIG. 18A;

FIG. 19A is a perspective view of a portion of a spine on which is mounted a drilling apparatus of the present invention for creating a channel, passage or hole for a disk repair procedure;

FIG. 19B is a perspective view of the portion of the spine illustrating the channel, passage or hole through an adjacent vertebrae allowing access to the nucleus;

FIG. 20 is a flow diagram briefly describing a disk repair procedure according to the present invention;

FIGS. 21A,B are side views of a drilling apparatus according to another aspect of the present invention where FIG. 21B includes a partial cutaway;

FIG. 21C is a perspective view of a lower portion of a spine including the sacrum on which is mounted a drilling apparatus of FIG. 21A,B;

FIG. 22A is a cross-sectional side view that illustrates implanting or attaching a sliding implant device in the through apertures and across the adjacent vertebrae;

FIG. 22B is a detailed view of sliding connection of the sliding implant device of FIG. 23A;

FIG. 23A is a cross-sectional side view that illustrates implanting or attaching a compressible implant device of the present invention in the through apertures and across the adjacent vertebrae;

FIGS. 23B-C are illustrations of embodiments of the compressive segment for a compressible implant device of the present invention;

FIG. 24A illustrates implanting or attaching two curved implants in the through apertures and across the adjacent vertebrae;

FIG. 24B is a cross-sectional side view of the implants within and across the adjacent vertebrae of FIG. 22A;

FIG. 24C is a lateral view of the spine showing an illustrative embodiment of stacked overlaid implant devices or arcuate rods in multiple adjacent vertebrae;

FIG. 24D is an anterior view of the crossing point of adjacent implant devices;

FIG. 24E is a lateral view of the spine showing another illustrative embodiment of stacked overlaid implant devices or arcuate rods in multiple adjacent vertebrae;

FIGS. 25A,B are top and side views respectively of an illustrative frame according to another aspect of the present invention;

FIG. 25C is a perspective view of a portion of a spine on which is mounted the illustrative frame of FIGS. 25A,B;

FIG. 26A is a top view of an embodiment of the illustrative frame according to said another aspect of the present invention;

FIG. 26B is a perspective view of a portion of a spine on which is mounted the illustrative frame of FIG. 26A;

FIGS. 27A-C are top, side and cross-sectional end views respectively of another embodiment of the illustrative frame according to said another aspect of the present invention;

FIG. 28A is an illustrative view of a drilling apparatus including another embodiment of the illustrative frame according to another aspect of the present invention when mounted upon adjacent vertebral bodies;

FIG. 28B is a cross-sectional end view of the illustrative frame of FIG. 28A;

FIG. 29A is an illustrative view of another drilling apparatus including another embodiment of the illustrative frame according to another aspect of the present invention when mounted upon adjacent vertebral bodies;

FIG. 29B is a cross-sectional end view of the illustrative frame of FIG. 29A; and

FIGS. 30A-C are views of various illustrative embodiments of securing an arcuate rod or implant device within a spacer;

FIG. 31 is an illustrative view of adjacent vertebral bodies illustrating an implanted arcuate rod or implant device and pinning member to secure an intervertebral spacer or cage (not shown) to and between the adjacent vertebral bodies;

FIGS. 32A,B are various illustrative views of an arcuate rod or implant device, cap and screw assembly according to

one illustrative embodiment of the present invention, where the arcuate rod or implant device is shown in cross-section;

FIG. 32C is an illustrative view of an arcuate rod or implant device, cap and screw assembly according to another illustrative embodiment of the present invention, where the arcuate rod or implant device is shown in cross-section;

FIGS. 33A-D are top, bottom and side views respectively of one illustrative embodiment of a cap according to the present invention;

FIG. 33E is a cross-section view along section L-L of FIG. 33A;

FIG. 33F is a cross-section view along section R-R of FIG. 33B;

FIGS. 34A-B and F-G are top, bottom and side views respectively of second illustrative embodiment of a cap according to the present invention;

FIG. 34C is a cross-section view along section M-M of FIG. 33A;

FIG. 34D is a cross-section view along section L-L of FIG. 34A;

FIG. 34E is a cross-section view along section R-R of FIG. 34B; and

FIGS. 35A-B are various illustrative axonometric views of adjacent vertebral bodies illustrating yet an arcuate rod or implant device, cap and screw assembly according to yet another illustrative embodiment of the present invention, where the arcuate rod or implant device is shown in cross-section.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in FIGS. 1-3 various views of a drilling apparatus 100 according to an aspect of the present invention that is generally comprised of a platform assembly 200, a pivot arm assembly 300 and drill assembly 400. As hereinafter described in more detail, the pivot arm assembly 300 is removably secured to the platform assembly 200 and the platform assembly is removably secured to the bone or bony structure so as to maintain the pivot point of the pivot arm assembly in general fixed relation to the bone or bony structure. The drill assembly 400 is removably secured to the pivot arm assembly 300 so as to maintain the end of the drill assembly including the bit 410 or drill end in fixed relation with respect to the pivot arm 302 of the pivot arm assembly. Consequently, as the pivot arm 302 is rotated about the pivot point, the bit 410 follows a predetermined arcuate, curved or circular path in the bone or bony structure as defined by the length of the pivot arm.

For purposes of illustrating the drilling apparatus 100 of the present invention, reference hereinafter is generally made to the structure and structural features or elements of a mammalian spine (e.g., human spine), however, this shall not be construed as limiting the use and application of the drilling apparatus of the present invention to these applications. It is contemplated and as such within the scope of the present invention to adapt the drilling apparatus of the present invention and the methods related thereto so the drilling apparatus is used so as to form grooves or arcuate passages in bones or bony structures of the mammalian body in which grooves is received a curved rod or other member as is hereinafter described thereby stabilizing and/supporting the bone or bony structure.

The platform assembly 200 includes a frame 202, a plurality of first path guards 204 and a mechanism for securing the

frame to the bone or bony structure. In the illustrated embodiment, the securing mechanism comprises a plurality of nail members 206 that each pass respectively through each of the frame 202 and the first path guards and so as to be disposed in the bone or bony structure as herein described. In further embodiments, and as hereinafter described, the platform assembly 200 can further include a second path guard 204b, in cases where the drilling apparatus 100 is used to form a groove or recess in an outer surface of the bone or bony structure thereby providing a protective structure between the moving and rotating drill bit 410 and the tissues or other structures or features of the mammalian body (e.g., nerves, blood vessels) that are proximal the bone or bony structure outer surface.

The frame 202 is configured and arranged so as to form an essentially rigid structure and frame work to which the pivot arm assembly 300 is removably attached and at least one and more particularly two through passages 210 that communicate with a corresponding passage in the first path guards 204. The through passages 210 and the corresponding passage in the first path guards 204 are each configured and arranged so as to allow the outer tube member 402 of the drill assembly to pass there through as the pivot arm 302 is being rotated or pivoted about the pivot point. The frame 202 is composed of any one of number of materials known to those skilled in the art that is appropriate for the intended use and the anticipated structural loads that can be imposed during use. In an exemplary embodiment, the frame 202 is made from stainless steel such as a stainless steel bar stock.

The first path guards 204 are secured to the frame 202 so as to extend downwardly from a bottom surface 210b therefrom. Each of the first path guards 204 are arranged so as to include a generally centrally located through passage, through which the outer tube member 402 and the drill bit 410 or burr of the drill assembly 400 are passed. In addition, each of the first path guards 204 are configured and arranged so as to include a plurality of through passages 220, one for each of the nail members 206. Each of the nail member through passages 220 also are preferably formed in the first guard member so as to present constricted holes that firmly grab the nail member within the corresponding through passage. In this way, the gripping action of the through passages and the lateral stiffness of the nail members 206 provides a mechanism for supporting and fixing the frame 202, and in turn the pivot point's relation with respect to the bone, bony structure or spine. In use, each of the nail members 206 are passed through the through aperture 208 in the frame 202 and driven through the through passage 220 of the first path guard 204.

In more particular embodiments, each through passage 220 is configured and arranged so that the passages are over sized with respect to the diameter of the nail members 206 and a portion of the through passage forms a land or raised region comprising a constriction region. More particularly, the constricted region is located above or from the lower end of the through passage such that the pointed ends of each nail member 206 are not exposed when the nail members 206 are initially pressed into the platform assembly 200. In this way, each of the nail members 206 are confined within the first path guard 204 prior to positioning of the platform assembly 200 in the surgical field amidst vital structures or features of the mammalian body.

The first path guards 204 are constructed from any of a number of materials known to those skilled in the art that are appropriate for the intended use and so as to provide a medium that can form a protective barrier between the drill path and the tissues including nerves and blood vessels that are proximal the site of the bone, bony structure or spine to be

drilled. In exemplary embodiments, the first path guards **204** are made from a plastic material such as, but not limited to, polycarbonate. In further embodiments, the end of the first path guard **204** proximal the bone, bony structure or spine is configured and arranged so as to include a soft conformal region that contact and seal against the surface of the bone, bony structure or spine. Alternatively, a conformable material may be disposed in the space, if any, between the base or bottom surface of each first path guard **204** and the opposing surface of the bone, bony structure or spine (e.g., vertebral cortex).

The nail members **206** are configured and arranged so that each extends from a top surface **210a** of the frame **200**, through the frame and the first path guard **204** and a sufficient distance into the bone, bony structure or spine to fix and secure the frame thereto. In addition, each of the nail members **206** also is configured and arranged so at least a portion thereof has a diameter that is set so that this portion of the nail member is gripped within the constricted region of the through passage **220** of the first path guards **204** as herein described.

Each of the nail members **206** includes a head portion **230** and a shaft portion **232** one end of which is mechanically coupled to the head portion using any of a number of techniques known to those skilled in the art that yields a nail member that is capable of being driven into the bone, bony structure or spine and removed therefrom. In further embodiments, the nail member **206** is formed such that the head portion **230** is integral with the shaft portion **232**. In particular embodiments, the head portion **230** is configured and arranged so as to allow the nail member **206** to be driven through and into the bone, bony structure or spine and later removed therefrom. In further embodiments, the head portion **230** is further configured so as to include a through aperture or hole extending generally laterally or radially through the head portion, the through aperture being configured to receive one or more suture lines therein for interoperative locating.

The other end of the shaft portion **232** is configured so as to form a pointed end that is appropriately configured and shaped for insertion into the bone, bony structure or spine and for securing the pointed end and a portion of the shaft member in such bone, bony structure or spine. In illustrative embodiments, the pointed end is configured to form a non-cutting pencil point end that wedges the end into the bone, bony structure or spine.

In the illustrated embodiment, four nail members **206** are driven through each of the first guard members **204** and into the bone or bony structure or spine. This shall not be construed as a limitation as the number and placement of the nail members is not so particularly limited as each end of the frame **202** can be secured to the bone or bony structure using one or more and more particularly two or more nail members **206**. It also should be recognized that other mechanisms known to those skilled in the art, such as screws or threaded devices, are contemplated for use with the present invention.

Each of the nail members **206** is composed of any one of number of materials known to those skilled in the art that is appropriate for the intended use and the anticipated structural loads that can be imposed during use. In an exemplary embodiment, the nail member **206** is made from a metal such as stainless steel.

Referring now also to FIGS. 4-5, the pivot arm assembly **300** includes a radial arm or pivot arm **302**, a pivot pin bracket **304** and a pivot pin **306**. The pivot pin bracket **304** includes side plates **310** and finger pads **312** that are secured to the side plates, where the pivot pin extends between the side plates.

The pivot pin **306** is received within an aperture **320** in the pivot arm such that the pivot arm can rotate about a pivot axis **321**.

The pivot pin bracket **304**, more particularly the side plates **310** thereof, is generally configured and arranged so as to secure the pivot arm assembly **300** to the platform assembly **200** so as to prevent the disengagement of the pivot arm assembly and correspondingly the drill assembly **400** from the platform assembly when it is being rotated from the fully retracted position of the pivot arm. More particularly, the side plates thereof are configured and arranged such that the bracket can be removed from the platform assembly **200** when the pivot arm is in the fully retracted position.

In particular embodiments, the side plates **310** are configured so as to form spring members that can slide in mating grooves provided on opposing inside surfaces of the platform assembly frame **202**. In addition, the side plates **310** further include binding head screws that engage complimentary holes within the mating grooves to lock the pivot pin bracket **304** in place. A finger pad **312** is secured to an end of each side plate so as to facilitate placement and removal of the pivot pin bracket **304** in the platform assembly. In illustrative embodiments, the finger pads **312** are configured so as to include concavities **313** that the fingertips of the user can engage to thereby facilitate placement and removal of the pivot pin bracket **304**.

The pivot arm **302** is configured and arranged so an end **322** thereof includes an aperture **320** so the pivot arm can be mounted upon the pivot pin **306** such that it can rotate or swing about the pivot pin **306**. The pivot arm **302** also is configured and arranged so as to include a mating portion **324** that receives therein and mates with a feature of the drill assembly **400** so as to removably secure the drill assembly to the pivot arm. The mating portion **324** is located distal from the end **322** of the pivot arm **302** that is mounted upon the pivot pin **306**. Also, the length of the pivot arm **302**, more particularly the distance between the pivot axis **321** and the mating portion **324**, establishes or controls the radius of curvature of the hole or recess being formed in the bone, bony structure or spine by the rotation of the pivot arm. It should be noted that this radius of curvature or diameter is different from the diameter of the hole or recess formed by the rotating drill bit **410** or bur. As such, it is contemplated that pivot arms **302** will be provided that have lengths set that are appropriate for the given geometry and physical make-up of the mammalian body.

The platform assembly **200** and pivot arm assembly **300** of the present invention advantageously creates a mechanism that allows tissue, muscle, blood vessels (e.g., aorta) and nerves to pass under and around the platform assembly and also to localize the drilling elements of the drill assembly **400** within the structure of the platform assembly. In addition, the pivot arm assembly **300** in combination with the platform assembly provides a mechanism to control the radial movement or radial motion of the drilling elements of the drill assembly **400** from their insertion into the bone or bony structure as well as the retraction from the bone or bony structure such that the drilling elements traverse a specific radius of curvature during such insertion and retraction. In this way, the drilling apparatus of the present invention also controls the maximum depth within the bone or bony structure the drilling elements can attain during use. Thus, and in contrast to conventional techniques, devices and instrumentalities, the drilling apparatus **100** of the present invention provides a mechanism that protects tissues, blood vessels and nerves from damage while the drilling elements of the drill assembly **400** are being inserted into and withdrawn from the

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bone or bony structure as well as assuring that the drilling elements will follow a generally fixed path such that the drilling elements do not come into contact with nor damage the tissues, blood vessels and nerves proximal to and surrounding the bone or bony structure while the hole or recess is being formed in the bone or bony structure. Consequently, the drilling apparatus **100** of the present invention minimizes the potential for damage without having to rely solely on the dexterity or skill of the surgeon, as is done with conventional techniques and devices.

In further embodiments, at least a segment or a part of the mating portion **324** is configured and arranged so as to complement the shape of the drive assembly feature being received therein. For example, and as illustrated, a portion or part of the key **404** of the drill assembly is configured so as to be polygonal in shape and the mating portion **324** is configured so as to include a polygonal shaped recess for receiving therein the hexagonal surfaces of the key. Such polygonal shapes includes but are not limited to a square, triangular, rectangular or hexagonal shapes.

In yet further embodiments, the pivot arm **302** is configured and arranged so as to include a finger grip **326** at or proximal and end of the pivot arm that is opposite to the end **322** mounted upon the pivot pin **306**. The finger grip **326** presents a structural element or feature that is configured to allow the thumb and/or fingers of the user to grasp the finger grip so as to thereby control rotation of the pivot arm and to also control the drilling pressure (i.e., pressure being exerted by the drill bit **410** on the bone or bony structure while drilling the hole or recess therein). In illustrated embodiments, the finger grip **326** presents a small tab having bilateral concavities that allow the finger tips to grasp it or a through aperture.

Each of the pivot arm **302**, pivot pin **306**, side plates **310** and finger pads **312** is composed of any one of number of materials known to those skilled in the art that is appropriate for the intended use and the anticipated structural loads that can be imposed during use. In an exemplary embodiment, any one or more of the foregoing elements of the pivot arm assembly **300** is made from a metal such as stainless steel.

Referring now also to FIGS. 6-7 there is shown a perspective view and a cross-sectional view of drill assembly **400** of the present invention. There also are shown in FIGS. 8-9 various views of portions or segments of such a drill assembly and/or embodiments thereof. The drill assembly **400** generally forms a curved structure, more particularly a curved tubular structure, that is attached to the pivot arm **302** as herein described and which thus swings around the pivot point or pivot axis **321**. In use, the drill bit **410** rotates about its axis while this axis is held tangent to and swept along an arc of constant radius as defined by the distance between the mating portion **324** of the pivot arm **302** and the pivot axis **321**. This movement results in or yields a toroidal hole.

The drill assembly includes an outer tube member **402**, a key **404**, a flexible inner housing **406**, a drive cable **408**, a drill bit **410** or burr, a barbed fitting **412**, a drive adapter **414**. In further embodiments, the drill assembly includes a distal drive cable bearing **416** and a proximal drive cable bearing **418**. Any one of a number of motors **20** or motor drive assemblies as is known in the art having sufficient power (e.g., torque) and rotational speed are coupled to the drive adapter **414** including but not limited to the Micro100 (Linvatech/Hall Surgical 5053-009) or Blachmax (Anspach Blackmax-KT-0). The drive adapter **414** is a swage-type of fitting that is configured and arranged so it can be swaged upon one end of the drive cable **408**. The drive adapter **414** also is configured and arranged so as to provide an input end arrangement that

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can be mechanically coupled to the output end of a variety of motors or motor drive assemblies or drills including those identified herein.

The outer tube member **402** is curved to a predetermined radius of curvature so that the centerline thereof is a set distance from the pivot axis **321** of the pivot arm **302**. The key **404** and the distal cable bearing **416** are secured to the outer tube using any of a number of techniques known to those skilled in the art that is appropriate for the materials comprising these elements or features. In exemplary embodiments, the key **404** and the distal cable bearing **416** are secured to the outer tube member by brazing or soldering. In more particular embodiments, the distal drive cable bearing **416** is secured to the outer tube member **402** such that the outer edge of the outer race of the bearing lies in a radial plane from the pivot point, whereby the axis of the drill bit **410** or burr is arranged so as to tangent to the centerline of the arc of the outer tube member.

The key **404** is generally cylindrical in construction and serves to align and anchor the outer tube member **401** to the pivot arm assembly **300**, more particularly the pivot arm **302**. As indicated herein, a portion **405** of the key **404** is configured so as to provide a surface feature, artifact or contour that complements at least a part of the mating portion **324** of the pivot arm. In the illustrated embodiment, the portion **405** of the key **404** forms an external polygonal feature that mates to the internal polygonal feature provided in the pivot arm mating portion. The key **404** also is configured and arranged so as to be secured to the mating portion using any of a number of techniques known to those skilled in the art. In an exemplary embodiment, a portion of the key is configured so as to include an external thread and a part of the mating portion **324** is configured so as to include a complementary threaded element or feature in an aperture thereof. In use, the key is articulated so as to threadably secure or lock the key **404** to the pivot arm **302**. Other techniques for securing, such as brazing, soldering and adhesives are contemplated for use with the present invention.

The key **404** includes a through aperture that is coupled to the inner region or area of the outer tube member **402**. The diameter of the key through aperture and the outer tube member are set so as to at least allow the flexible inner housing **406** and the drive cable **408** to pass there through. The flexible inner housing **406** extends from the distal end **401** of the outer tube member **402** to the barbed fitting **412**. The flexible inner housing **406** is a generally tubular member of flexible construction, such as Teflon for example, for housing the drive cable **408**. In particular embodiments, the flexible inner housing **406** is a small diameter tubular member (i.e., smaller than the inner diameter of the outer tube member) and is secured to the key **404** using any of a number of techniques known to those skilled in the art, which are appropriate for the materials of use. In an exemplary embodiment, the flexible inner housing is secured to the key **404** using an adhesive, such as a medical grade adhesive.

The barbed fitting **412** is secured to the end of the flexible inner housing that is opposite to the drill bit **410** using any of a number of techniques known to those skilled in the art, which are appropriate for the materials of use. The end of the barbed fitting **412** being secured to the flexible inner housing **406** also is received within the flexible inner housing. In particular embodiments, the barbed fitting **412** is configured and arranged so the end being received in the flexible inner housing **406** is secured thereto by an interference fit. In further exemplary embodiments, the interference fit is augmented by use of an adhesive, such as a medical grade adhesive.

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The proximal drive cable bearing **418** is disposed within the barbed fitting **412** in which is received the drive cable **408**. In particular embodiments, the proximal drive cable bearing **418** is retained within the barbed fitting **412** using any of a number of techniques known to those skilled in the art. In an exemplary embodiment, the proximal drive cable bearing is secured to the barbed fitting using one of soldering, brazing or adhesives.

The distal and proximal drive cable bearings **416**, **418** are any of a number of bearing assemblies known to those skilled in the art and appropriate for the intended use. In particular embodiments, the distal and proximal drive cable bearing **416**, **418** are miniature ball bearing assemblies as is known to those skilled in the art (e.g., SR133zz MSC 35380799, 0.9375" bore, 0.1875" OD, 0.0937" width, double shielded).

In an alternative embodiment, the inner housing is a double curved inner tube of a fixed non-flexible construction. The double curved inner tube has two radii of curvature, the first radius of curvature involves all but the most distal section of the inner tube and the second radius of curvature involves a smaller portion of the inner tube. The second radius of curvature is set so as to bring the path of the drive cable **408** around so as to enter the proximal end of the distal drive cable bearing **416** in the correct direction. In this way, the fixed inner tube can be configured and arranged so as to swing wide and make a turn to enter essentially parallel to the axis of an end fitting being swaged to the end of the inner tube. In this way, fatiguing of the drive cable **408** can be minimized and misalignment of the drive cable and the inner tube proximal the end of the inner tube can be minimized.

Although specific embodiments are described herein for the outer tube member **402** and the inner tube member or flexible inner housing **406** this shall not be considered as particularly limiting. The present invention contemplates adapting the present invention using any of a number of techniques known to those skilled in the art whereby a cable is generally turned through a protected series of rigid or flexible cannulas or tubes such that a bit operably coupled to one end of the cable can turn at an end of the outer tube or cannula.

The drill bit **410** or burr is any of a number of cutting tools or implements known to those skilled in the art and appropriate for the intended use, speed and power developed by the drive motor **20** and the material to be drilled. In particular illustrative embodiments, the drill bit **410** or burr is a spade bit such as that shown in FIGS. **6-8**, alternatively and with reference to FIG. **9**, the drill bit is a hemispherical bit **410a**.

The drive cable **408** is a flexible cable that is more particularly comprised of a large number of smaller strands of an appropriate material, including but not limited to steel, stainless steel, and titanium, that are compound wound using any of a number of techniques known to those skilled in the art so as to yield a flexible cable having the desired width, length, flexibility and strength characteristics. In a particularly illustrative embodiment, the drive cable **408** is a custom wound 1.8 mm (0.072 in.) diameter 7×19 left regular lay strand wound cable. In more particular aspects, the drive cable **408** is manufactured so as to be capable of being rotated or turned at a high rate of speed or revolution while maintaining its flexibility and such that right hand turning of the cable should not result in the unwinding or loosening of construction.

In particular embodiments, the length ("Ldc") of the drive cable **408** shall be controlled so as to maintain a relationship with the length of the portion of the drive cable ("Ldci") that is disposed within the outer cannula or outer tube **402** or correspondingly the arc length of the outer tube. In more particular embodiments, the relationship between the length

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of the drive cable **408** and the length of the portion of the drive cable within the outer tube **402** satisfies the following relationship  $Ldc \leq 4 \times Ldci$ ; more particularly satisfies the relationship  $Ldc \leq 3 \times Ldci$ , and more specifically satisfies the relationship  $Ldc \leq 2 \times Ldci$ . In more specific embodiments, the length of the drive cable **408** is set based on the particular application or material to be drilled. For example, the overall cable length is shortened or lengthened based on the relative hardness of the material in which the channel or opening is to be formed in the bone or bony structure. In further embodiments, the flexible inner housing **406** is configured and arranged so as to have a length that satisfies the foregoing relationships.

Referring now to FIG. **17** there is shown a side view of a drilling apparatus **1000** according to another aspect of the present invention that is illustrated being disposed upon adjacent vertebral bodies. Reference shall be made to FIGS. **1-3** and **6-9** and the discussion related thereto for features and functions not provided in the following discussion. Such a drilling apparatus **1000** includes a platform assembly **1200** and a drill assembly **1300**.

The platform assembly **1200** includes a frame member **1202** and a plurality of path guard members **1204** and a mechanism for securing the frame to the bone or bony structure. As with the drilling apparatus illustrated in FIG. **1**, the securing mechanism comprises a plurality of nail members **206** that each pass respectively through each of the path guard members **1204** so as to be disposed in the bone or bony structure as herein described. In further embodiments, and as hereinafter described, the platform assembly **1200** can further include a second path guard **205**, in cases where the drilling apparatus **1000** is used to form a groove or recess in an outer surface of the bone or bony structure thereby providing a protective structure between the moving and rotating drill bit **410** and the tissues or other structures or features of the mammalian body (e.g., nerves, blood vessels) that are proximal the bone or bony structure outer surface.

The frame member **1202** and the first guard members **1204** are configured and arranged so as to form an essentially rigid structure and frame work to which the drill assembly **1300** is removable attached and at least one and more particularly two through passages **1205**. Each of the through passages **1205** are configured and arranged so as to allow the outer tube member **402** of the drill assembly **1300** to pass there through as drill bit **410** is being rotated or pivoted about the pivot point. The frame member **1202** is composed of any one of number of materials known to those skilled in the art that is appropriate for the intended use and the anticipated structural loads that can be imposed during use. In an exemplary embodiment, the frame member **1202** is made from stainless steel such as a stainless steel bar stock.

The first path guard members **1204** are secured to the frame member **1202** using any of a number of techniques known to those skilled in the art so that the through aperture **1205** extends downwardly towards a bottom surface thereof. As indicated above, the through passage **1205** in each of the first path guard members **1204** are arranged so the outer tube member **402** and the drill bit **410** or burr of the drill assembly **1300** are passed there through. In addition, each of the first path guard members **1204** are configured and arranged so as to include a plurality of through passages, one for each of the nail members. Reference shall be made to the foregoing discussion for the nail member through passages **220** of FIG. **1** for further detail and characteristics of these nail member through apertures.

The frame member **1202** also is configured and arranged so as to provide a mechanism for guiding the drill assembly **1300** such that the drill bit **410** thereof follows a predetermined arc



or radius of rotation. In illustrative embodiments, the frame member **1202** is configured so as to include a web portion **1210** that extends width wise along the circumferential length of the frame member. In further embodiments, the frame member **1202** is configured and arranged so as to form a step region or a discontinuous radial region **1212** at the ends of the frame member proximal the first guard members **1204** so as to form in effect a radial stop.

The drill assembly **1300** generally forms a curved structure, more particularly a curved tubular structure, that is coupled to the frame member **1202** as herein described and which thus swings around a pivot point or pivot axis that is defined by the frame member **1202**. In use, the drill bit **410** rotates about its axis while this axis is held tangent to and swept along an arc of constant radius as defined by the pivot pint. This movement results in or yields a toroidal hole in the bone or bony structure.

The drill assembly includes an outer tube member **402**, a key **404**, a flexible inner housing **406**, a drive cable **408**, a drill bit **410** or burr, a barbed fitting **412**, a drive adapter **414** and moveable mount member **1310**. In further embodiments, the drill assembly includes a distal drive cable bearing **416** and a proximal drive cable bearing **418**. As indicated above reference shall be made to FIGS. **1-3** and **6-9** for details and characteristics of the drill assembly **1000** not otherwise shown in FIG. **17** or described hereinafter.

The moveable mount member **1310** includes a frame member mounting portion **1312** and a drill assembly mating portion **1314** that form an integral structure. The frame member mounting portion **1312** is configured and arranged so as to be slidably mounted upon the frame member **1202**, more specifically the web portion **1210** thereof. Thus, motion of the frame member mounting portion **1312** along the circumference of the frame member **1202** causes the drill bit **410** to in effect rotate about a fixed point, the pivot point defined by the arcuate portion of the frame member.

As with the mating portion **324** of the pivot arm **302**, the drill assembly member mating portion **1314** is configured and arranged so as to receive therein the drill assembly key **404**. Reference shall be made to the discussion herein for the pivot arm mating portion **324** and the drill assembly key **404** for further details and characteristics of the drill assembly mating portion **1314**.

In further embodiments, the moveable mount member **1310** is configured and arranged so as to include a finger grip **1316** at or proximal an end of the mount member **1310** that is opposite to the end frame member **1302**. The finger grip **1316** presents a structural element or feature that is configured to allow the thumb and/or fingers of the user to grasp the finger grip so as to thereby control movement of the moveable mount member **1310**, rotation of the drill bit **410** and to also control the drilling pressure (i.e., pressure being exerted by the drill bit **410** on the bone or bony structure while drilling the hole or recess therein. In illustrated embodiments, the finger grip **1316** presents a small tab having bilateral concavities that allow the finger tips to grasp it or a through aperture.

In an alternative embodiment, the frame member **1202** is configured and arranged so as to comprise two sub-members being spaced from each other. The two sub-members further include a slot or other feature in opposing surfaces of the sub-members, which slot or other feature extends in the circumferential direction. In this embodiment, the frame mounting portion **1312** of the movable mount member **1310** is configured and arranged so as to be received in and slide within the slot in each of the opposing surfaces. In this way, the drill bit **410** can be rotated about a fixed point defined by the circumferentially arranged slots in the two sub-members.

The foregoing is illustrative of a couple of techniques for configuring the frame member **1302** and the frame member mount portion **1312** so the drill bit **410** can be rotated about a fixed point being defined by the structure of the frame member, however, the foregoing shall not be considered limiting as it is within the scope of the present invention to adapt the drilling apparatus of the present inventions so as to provide a mechanism by which the drill bit can be rotated about a fixed point and/or such that the drill bit follows a fixed path during the drilling process.

Referring now to FIGS. **18A-C** there are shown various views of a drilling apparatus **100a** according to yet another aspect of the present invention that is generally comprised of a platform assembly **200**, a pivot arm assembly **300a** and a drill assembly **400a**. Reference shall be made to FIGS. **1-9** and the discussion related thereto for features and functions in common with the above-described drilling apparatus **100** shown thereon and not more particularly provided in the following discussion or shown in FIGS. **18A-C**. Reference also shall be made to FIGS. **1-9** and the discussion related thereto for details concerning the removably attachment of the pivot arm **300a** to the platform assembly **200** and the removable securing of the platform assembly **200** to the bone or bony structure.

The pivot arm assembly **302a** includes a radial arm or pivot arm **302a**, a pivot pin bracket **304** and a pivot pin **306**. The pivot pin bracket **304** includes side plates **310** and finger pads **312** that are secured to the side plates, where the pivot pin extends between the side plates. The pivot pin **306** is received within an aperture **320** in the pivot arm **302a** such that the pivot arm can rotate about a pivot axis **321**. The pivot arm **302a** is configured and arranged so as to include a mating portion **324a** that is distal from the end **322** of the pivot arm that is mounted upon the pivot pin. In further embodiments, the pivot arm includes a finger grip **326a**. Reference shall be made to the foregoing discussion for FIGS. **1-9** for further details of the pivot pin bracket **304**, the pivot pin **306**, and certain features of the pivot arm **302a** not described further below. Reference also shall be made to the discussion above for the pivot arm **302** and the finger grip **326** for further details regarding the construction other characteristics for the pivot arm **302a** and finger grip **326** features not expressly described below or shown in FIGS. **18A-C**.

The drill assembly includes a curved or arcuate member **452**, a drive cable **456**, a drill bit **410** or burr, a drive adapter **414** and a distal drive cable bearing **416**. Reference shall be made to the foregoing discussion for FIGS. **1-9** for further details of the drill bit **410**, the drive adapter **414** and the distal drive cable bearing **416** not otherwise provided below or shown on FIGS. **18A-C**. Reference also shall be made to the discussion above for the drive cable **408** for further details regarding the construction, width and other features not expressly described below.

As indicated herein any one of a number of motors **20** or motor drive assemblies as is known in the art having sufficient power (e.g., torque) and rotational speed are coupled to the drive adapter **414** including but not limited to the Micro100 (Linvatech/Hall Surgical 5053-009) or Blachmax (Anspach Blackmax-KT-0). The drive adapter **414** is a swage-type of fitting that is configured and arranged so it can be swaged upon one end of the drive cable **456**. The drive adapter **414** also is configured and arranged so as to provide an input end arrangement that can be mechanically coupled to the output end of a variety of motors or motor drive assemblies or drills including those identified herein.

The pivot arm mating portion **324a** is secured to a portion of the drill assembly curved or arcuate member **452** using any



of a number of techniques known to those skilled in the art that are appropriate for the use and materials used in the construction of these features. In a specific embodiment, the arcuate member **452** is removably secured to the pivot arm-mating portion **324a** (e.g., mechanical fasteners, adhesives) and in other embodiment the arcuate member is secured to the pivot arm-mating portion (e.g., adhesives, soldering, brazing) so as to form an integral structure. In further embodiments, at least a segment or portion of the pivot arm-mating portion **324a** is configured and arranged so as to complement the shape of the portion of the arcuate member **452** being received therein. For example and as illustrated in FIGS. **18A-B**, the arcuate member **324** also has a curved or arcuate cross-section. Thus, the pivot arm mating portion **324a** is configured so as to receive therein a curved member having a curved or arcuate cross section. This shall not be considered limiting as the arcuate member **452** can be configured and arranged so as to have any of a number of external cross-sectional shapes.

As indicated above, the arcuate member **452** forms a curved structure that is attached to the pivot arm **302a** as herein described and which thus swings around the pivot point or pivot axis **321**. In use, the drill bit **410** rotates about its axis while this axis is held tangent to and swept along an arc of constant radius as defined by the distance between the mating portion **324a** of the pivot arm **302a** and the pivot axis **321**. This movement results in or yields a toroidal hole.

The arcuate member **452** is curved to a predetermined radius of curvature so that the centerline thereof is a set distance from the pivot axis **321** of the pivot arm **302a**. In further embodiments, the arcuate member **452** is a tubular like member having a portion of the tubular structure removed so the arcuate member **452** includes a dished area or depressed region **453** in which is received the drive cable **456** as hereinafter described. In an illustrative embodiment, the dished area or depressed region **453** is generally curved or circular in cross-section as more clearly illustrated in FIGS. **18A, C**. This, however, shall not be limiting as other geometric shapes are within the scope of the present invention that do not unduly impair the rotational capability of the drive cable **456** when received in the depressed region **453**. In further embodiments, the dished area or depressed region **453** of the arcuate member **452** is sized and arranged so as to be capable of removably receiving therein the drive cable **456** and, more particularly so external surfaces of the drive cable are within an envelope or boundary defined by the depressed region **453** of the arcuate member.

The distal end **451** of the arcuate member **452** provides a structure in which the distal distal cable bearing **416** can be secured therein using any of a number of techniques known to those skilled in the art that is appropriate for the materials comprising these elements or features. In exemplary embodiments, the distal cable bearing **416** is secured within the arcuate member distal end **451** by brazing or soldering. Such a structure also provides a fixed point of attachment for the drive cable **456** such that that end of the drive cable and the drill bit **410** moves with the rotation of the arcuate member about the pivot axis **321**. In more particular embodiments, the distal drive cable bearing **416** is secured within the arcuate member **452** such that the outer edge of the outer race of the bearing lies in a radial plane from the pivot point, whereby the axis of the drill bit **410** or burr is arranged so as to be tangent to the centerline of the arc of the arcuate member.

When drilling of an aperture or hole in the bone or bony structure is desired, the surgeon or medical personnel applies a force to the finger portion **326a** so as to cause the arcuate member **452** to rotate about the pivot axis **321** and so as to

cause the distal end **451** of the arcuate member to also rotate about the pivot axis. As the arcuate member distal end **451** rotates through the platform assembly **200**, the drive cable **456** also is drawn along with the distal end and also is received in the depressed region **453** of the arcuate member (e.g., as the cable passes below the platform assembly **200**). In this way, the rotating drive cable **456** is caused to lie within the depressed region **453** while the drive cable **456** is disposed within the bone or bony structure as the channel or aperture is being formed in the bone or bony structure as hereinafter described.

The arcuate member **452** according to this aspect of the present invention minimizes stress on the drive cable and reduces the amount of access required by the surgeon to perform the surgical procedure. The arrangement, however, also yields an apparatus that advantageously creates a mechanism that allows tissue, muscle, blood vessels (e.g., aorta) and nerves to pass under and around the platform assembly **200** and also to localize the drilling elements of the drill assembly **400a** within the structure of the platform assembly. In addition, the pivot arm assembly **300a** in combination with the platform assembly **200** provides a mechanism to control the radial movement radius or motion of the drilling elements of the drill assembly **400a** from their insertion into the bone or bony structure as well as the retraction from the bone or bony structure such that the drilling elements traverse a specific radius of curvature during such insertion and retraction. In this way, the drilling apparatus **100a** according to this aspect of the present invention also controls the maximum depth within the bone or bony structure the drilling elements can attain during use. Thus, and in contrast to conventional techniques, devices and instrumentalities, the drilling apparatus **100a** of the present invention provides a mechanism that protects tissues, blood vessels and nerves from damage while the drilling elements of the drill assembly **400a** are being inserted into and withdrawn from the bone or bony structure as well as assuring that the drilling elements will follow a generally fixed path such that the drilling elements do not come into contact with nor damage the tissues, blood vessels and nerves proximal to and surrounding the bone or bony structure while the hole or recess is being formed in the bone or bony structure. Consequently, the drilling apparatus **100a** of the present invention minimizes the potential for damage without having to rely solely on the dexterity or skill of the surgeon as is done with conventional techniques and devices.

In general, the drilling path follows a desired path through the adjacent vertebrae or bony segments because the drilling apparatus, in particular the frame assembly thereof, is maintained in fixed relation with respect to the adjacent vertebral bodies or bony segments. However, the physical structure of the bony segments or the adjacent vertebral bodies in some cases creates a configuration in which the drilling assembly needs to be adapted to suit the particulars of the physical structure (e.g., the surface of the sacrum is at an angle with respect to the surface of the L-5 vertebrae).

Referring now to FIGS. **21A-B** there is shown a side view of a drilling apparatus **3000** according to another aspect of the present invention and in FIG. **23C** there is shown a perspective view that illustrates the frame assembly **3200** thereof being disposed upon adjacent vertebral bodies **2**. Such a drilling apparatus **3000** includes a platform assembly **3200**, a pivot arm assembly **300** and a drill assembly **400**. It should be recognized that the frame assembly **3200** is illustrative and that it is contemplated that any of the other frame assemblies herein described are adaptable so as to embody the specifics of the platform assembly of this aspect of the present invention. Such a drilling apparatus **3000** is particularly adaptable

to accommodate the physical structure and so as to allow channels to be formed in adjacent bony segments or adjacent vertebral bodies while minimizing the risk of injury or damage to nearby nerves, tissues, muscles and/or blood vessels. Reference shall be made to FIGS. 1-9 and 17-18 and the discussion related thereto for features and functions in common with the below-described drilling apparatus 3000 shown thereon and not more particularly provided in the following discussion or shown in FIGS. 21A-B.

The platform assembly 3200 includes a frame member 202 and a plurality of path guard members 3204a,b and a mechanism for securing the frame to the bone or bony structure. As with the drilling apparatus illustrated in FIG. 1, the securing mechanism comprises a plurality of nail members 206 that each pass respectively through each of the first path guard members 3204a,b so as to be disposed in the bone or bony structure as herein described. In further embodiments, and as hereinafter described, the platform assembly 3200 can further include a second path guard 205, in cases where the drilling apparatus 3000 is used to form a groove or recess in an outer surface of the bone or bony structure thereby providing a protective structure between the moving and rotating drill bit 410 and the tissues or other structures or features of the mammalian body (e.g., nerves, blood vessels) that are proximal the bone or bony structure outer surface.

The frame member 202 and the first guard members 3204a,b are configured and arranged so as to form an essentially rigid structure and frame work to which the drill assembly 300 is removably attached and at least one and more particularly two through passages 3205a,b. Each of the through passages 3205a,b are configured and arranged so as to allow the outer tube member of the drill assembly 300 to pass there through as drill bit 410 is being rotated or pivoted about the pivot point. The frame member 202 is composed of any one of number of materials known to those skilled in the art that is appropriate for the intended use and the anticipated structural loads that can be imposed during use. In an exemplary embodiment, the frame member 202 is made from stainless steel such as a stainless steel bar stock.

The first path guard members 3204a,b are each configured and arranged so the frame assembly 3200 is maintained in a desired orientation with respect to the adjacent bony segments or adjacent vertebral bodies for formation of the channel. In particular embodiments, the bottom surface 3241a,b of each first path guard members is configured and arranged so as to correspond generally to the opposing surface of the adjacent bony segment or vertebrae. In an illustrative exemplary embodiment, a bottom surface 3241a for one first path guard member 3240a is formed at an angle with respect to a longitudinal axis of the first path guard member when the opposing surface is at an angle with respect to the desired orientation of the frame assembly (e.g., the angled surface of the sacrum) such as illustrated in FIG. 23C. In further embodiments, the length of each first path guard member is adjusted so as to compensate for differences in relative heights between the frame assembly attachment point of one adjacent bony segment or vertebral body and the frame assembly attachment point of the other adjacent bony segment or vertebral body. In an illustrative exemplary embodiment, one first path guard member 3240a is made longer than the other first path guard member 3240b so the frame 202 is maintained in a particular orientation with respect to the target are such as illustrated in FIG. 23C. In this way, the frame 202 is oriented so that the channel formed by the rotation of the drill bit 410 is along the desired path in the adjacent vertebrae.

The foregoing is illustrative of a couple techniques for maintaining the frame assembly 3200 at a desired orientation with respect to the adjacent bony segments or adjacent vertebral bodies. However, this shall not be construed as limiting as other techniques can be utilized to address the described angular and length as well as other differences that may arise because of the physical structure (e.g., adjusting for surfaces being at angles with respect to more than one axis).

The first path guard members 3204a,b are secured to the frame member 202 using any of a number of techniques known to those skilled in the art so that the through apertures 3205a,b in the first path guard members 3204a,b extend generally downwardly towards a bottom surface 3241a,b thereof. In further embodiments, particularly when a first path guard member 3240b has a different length than the other first path guard member 3240a as well as having a bottom surface 3241a that is at angle with respect to a longitudinal axis of the guard member, the through aperture 3205b may comprise an opening through a side of such a first path guard member 3204b or such an opening that extends through the side and into the bottom surface. These openings are generally established based on the geometry between the frame assembly 3200 when it is secured to the adjacent bony segments or adjacent vertebral bodies and the pivot point for forming the desired channel.

As indicated above, the though passage 3205a,b in each of the first path guard members 3204 are arranged so the outer tube member 402 and the drill bit 410 or burr of the drill assembly 300 are passed there through. In addition, each of the first path guard members 3204a,b are configured and arranged so as to include a plurality of through passages, one for each of the nail members. Reference shall be made to the foregoing discussion for the nail member through passages 220 of FIG. 1 for further detail and characteristics of these nail member through apertures.

The arrangement of the drilling apparatus 3000 yields an apparatus that advantageously creates a mechanism that allows tissue, muscle, blood vessels (e.g., aorta) and nerves to pass under and around the platform assembly 3200, to localize the drilling elements of the drill assembly 400 within the structure of the platform assembly and to provide a mechanism to compensate for any differences between the adjacent bony structure or adjacent vertebrae. In addition, the pivot arm assembly 300 in combination with the platform assembly 3200 provides a mechanism to control the radial movement radius or motion of the drilling elements of the drill assembly 400 from their insertion into the bone or bony structure as well as the retraction from the bone or bony structure such that the drilling elements traverse a specific radius of curvature during such insertion and retraction. In this way, the drilling apparatus 3200 according to this aspect of the present invention also controls the maximum depth within the bone or bony structure the drilling elements can attain during use. Thus, and in contrast to conventional techniques, devices and instrumentalities, the drilling apparatus 3200 of the present invention provides a mechanism that protects tissues, blood vessels and nerves from damage while the drilling elements of the drill assembly 400 are being inserted into and withdrawn from the bone or bony structure as well as assuring that the drilling elements will follow a generally fixed path such that the drilling elements do not come into contact with nor damage the tissues, blood vessels and nerves proximal to and surrounding the bone or bony structure while the hole or recess is being formed in the bone or bony structure. Consequently, the drilling apparatus 3200 of the present invention minimizes the potential for damage without having to rely

solely on the dexterity or skill of the surgeon as is done with conventional techniques and devices.

Upon completion of the procedure involving use of the drill assembly **100** of the present invention, and as described herein, the nail members **206** are acted upon so as to remove each of the nail members from the bone or bony structure or spine. This removal can be accomplished using any of a number of techniques or devices known those skilled in the art. In particular embodiments of the present invention, and with reference to FIGS. **10A,B**, there is shown a side view and an end view respectively of a nail member removal device **500** according to the present invention. Reference also should be made to FIG. **11**, which illustrates the removal technique using such a nail member removal device **500**.

The nail member removal device **500** includes a block member **502** and a knurled screw member **506**. The block member **502** includes a through passage that extends lengthwise in the block member so as to form a saddle structure that can straddle and slide along side rails **203** of the frame **202**. In further embodiments, the block member **502** includes a slotted passage **512** that extends from a bottom surface to a top surface of the block member and extends partially lengthwise to a surface of the through aperture **504** or hole that is formed in the block member. The slotted passage **512** also is generally sized so to allow the block member to slide past the head portion **230** that is sticking up above the top surface **210a** of the frame, more particularly the side rails thereof.

The threaded aperture **504** or hole is positioned within the block member **502** so that it can be centered over one of the head portions **230** of the nail members **206**. In use, the nail members **206** are typically driven into the bone or bony structure such that a bottom surface of the head portion **230** is proud of or above the frame top surface **210a**. As such a lower portion of the knurled screw member **506** is machined so as to include a side pocket **514** therein. The side pocket **514** is made in the screw member **506** so as to have sufficient depth (e.g., width) and length to accommodate the head portion coaxially therein. The bottom segment of the screw member **506** also includes a notch that extends generally radially to allow the nail member shaft portion **232** to be received therein and so as to be also coaxial with the screw member.

In particular embodiments, when the screw member **506** is rotated in one direction (e.g., clockwise) the side pocket **514** can be aligned with the slotted through passage **512** and thus be ready to receive therein a nail member head portion **230**. The block member **502** is slide along the frame side rail **203** until the head portion is contained within the side pocket **514**. After the head portion is disposed in the side pocket, the screw is rotated in the opposite direction (e.g., counterclockwise) thereby causing the screw to rotate in an upwardly direction drawing the notched bottom surface of the side pocket into contact with the bottom surface of the head portion. When the notched bottom surface of the side pocket **514** engages the bottom surface of the head portion, continued rotation of the screw member **506** also causes the head portion to be moved upwardly. In this way, the pointed end of the shaft portion is withdrawn from the bone or bony structure.

In more particular embodiments, the block member **502** and the slotted passage **512** therein are formed such that a portion of the block member is disposed over an end portion of the end rail of the frame **203**. This establishes a configuration whereby the pulling load is applied between two support points, thereby minimizing the potential for tipping of the nail member removal device **500** due to unbalanced force couples.

As indicated herein, prior to use of the drilling capabilities of the drilling assembly **100** of the present invention, the nail

members are driven into contact with the constricted regions of the first path guards **204** and into engagement with the bone or bony structure or spine. This driving of the nail members can be accomplished using any of a number of techniques or devices known those skilled in the art. In particular embodiments of the present invention, and with reference to FIG. **12** there is shown a side view with a partial cut-away of a nail member drive tool **600** according to the present invention.

The drive tool **600** is a generally cylindrical member having a blind hole **602** or aperture in one end thereof. The blind hole **602** is sized so as to receive therein a head portion **230** of a nail member **206**. The drive tool **600** is constructed so that an impact load, such as that imparted by a hammer, at the opposite end **604** thereof drives the nail member **206** disposed in the blind hole **602**. In further embodiments, the blind hole **602** also is sized so as to generally prevent the tool from slipping off the head portion. In yet further embodiments, the depth of the blind hole **602** is set so that the bottom surface of the head portion **230** remains a predetermined distance above the frame top surface **210a** so as to allow the head portion to be later received in the side pocket of the screw member **506** of the nail member removal device **500**.

As indicated herein the drilling apparatus **100** of the present invention is adaptable for use for forming recesses or holes in bones, bony structures or the spine of a mammalian body. The following describes the use of the drilling apparatus in connection with two different techniques (i.e., anterior approach and medial approach) for forming a recess or an aperture in adjacent vertebral bodies of a spine. Although the following discussion specifically refers to the drilling apparatus **100** shown in FIG. **1** it shall be understood that the below described techniques can be used in conjunction with the drilling apparatus **1000**, **100a** shown in FIGS. **17-18** as well as other embodiments of such apparatuses **100**, **100a**, **1000**. Referring now to FIGS. **13A-L** there is shown a series of views illustrating the process for the anterior approach. Reference shall also be made to FIGS. **1-11** and **17-18** and the discussion related thereto for features and functions not provided in the following discussion.

The area of concern is exposed by a surgeon using one of a transperitoneal or retroperitoneal approach, as shown in FIG. **13A** and a discectomy is performed at the level to be instrumented and immobilized. After placing a support (e.g., a femoral ring allograft) in the disc space, lateral stabilization is performed (see FIG. **13B**).

The drilling apparatus frame **202** is aligned such that it is vertical in an anteroposterior orientation and placed as far lateral as possible on the anterolateral aspect of the vertebrae across the operative level. Temporary placement pins **700** are driven into the vertebral cortex to hold the frame **202** in place while creating the channel or recess. In addition, the present invention contemplates the addition of a second path guard **204b** that extends between the first path guards **204**. The second path guard **204b** is arcuate or curved having a radius that generally corresponds to the path of the drill bit **410**. The second path guide **204b** also is configured so as to extend outwardly from the vertebral cortex so as to provide a barrier between the drill bit travel path and tissues, nerves and blood vessels proximal the site. The second path guard **204b** is constructed of similar materials as the first path guards **204**. See FIGS. **13D-E**.

When the frame **202** is positioned in the intended fashion, the pivot arm assembly **300** is located and secured within the frame **202**, thereby also securing the drill assembly **200** in the frame. See FIG. **13E**. The drive motor **20** or drive motor assembly is then secured to the adapter **414**. The pivot arm

**302** is then positioned so the drill assembly/drill bit is in the starting position so the channel or recess can be cut. See FIG. 13F.

The drill motor **20** is started so as to cause the drill bit **410** to rotate at the desired speed and power, and the pivot arm **302** is rotated about the pivot point thereby causing the drill bit **410** to rotate in a predetermined direction in a downward, circular path as dictated by the frame and the pivot arm. The resulting cut should be made immediately adjacent to the lateral vertebral surface. This cut is complete when the drill bit **410** reaches the disc space as shown in FIG. 13G.

Once the first half of the channel is cut, and with the drive motor **20** turned off and/or disconnected from the adapter **414**, the pivot arm is rotated in the opposite direction to return it to the starting position, where the pivot arm assembly **300** can be removed from the frame **202**. After removing the pivot arm assembly **300** from the frame **202**, the pivot arm assembly is flipped to the opposite side of the frame and reconnected to the frame. In this way, a matching channel can be cut into the other vertebra adjacent to the operative level. See FIG. 13H. As with the first cut, the drive motor **20** is turned on and the pivot arm rotated so the drill bit **410** follows a downward, circular path. After the second half of the channel has been cut, the pivot arm is returned to the starting position and the pivot arm assembly **300** is removed from the frame **202**. See FIGS. 13I-J.

The temporary placement pins **700** are removed from the vertebral bodies and the frame **202** is removed from the operative site (see FIG. 13K) and a standard osteotome chisel can be used to remove any remaining bone from the channel edges so that the channel is open to receive or accept the curved rod.

Now with reference with FIGS. 14A-D there is shown the process for placing, positioning and attaching or implanting a curved rod **800**, including those described in any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265, the teachings of which are incorporated herein by reference. The curved rod **800** is positioned in the channel and secured to the vertebral bodies using interlocking screws **802**, **804** that traverse the rod and penetrate the vertebra at an angle that will avoid sensitive neurologic structures. The screws hold the curved rod **800** in place and stabilize the motion segment to facilitate healing of the bone within the disc space.

Two lateral screws **802** pass through the lateral holes of the curved rod and set on the lateral surface of the implant. The two end screws **804** are passed through the open ends of the curved rod and each is inserted until the screw head is contained within the hollow of the implant. The lateral and end screws are inserted using for example a Cardan screwdriver **806**. As shown in FIGS. 14C-D the curved rod is now securely in place in either the recess (FIG. 14C) or a surface-mounted configuration (FIG. 14D).

Referring now to FIGS. 15A-H there is shown a series of views illustrating the process for the medial approach. Reference shall also be made to FIGS. 1-11 and 17-18 and the discussion related thereto as well as for FIGS. 13-14 for features and functions not provided in the following discussion. As above, the area of concern is exposed by a surgeon using the appropriate technique and the drilling apparatus frame **202** is aligned such that it is vertical in an anteroposterior orientation and placed as far midline as possible on the anterior aspect of the vertebrae across the operative level. The pointed ends of the nail members **206** are then driven through the platform frame **202** and the first path guards **204** so as to be driven into the vertebral cortex to hold the frame in place while cutting the channel or through aperture. See FIG. 15A-B.

The pivot arm assembly **300** is then secured to the frame **202** and thereby also securing the drill assembly to the frame. The drive motor **20** also is coupled to the drill assembly **300** via the adapter **414** See FIG. 15C. The pivot arm **302** is then rotated until the drill bit **410** and the pivot arm are in the start position, whereat the drill motor **20** is started. See FIG. 15D. The pivot arm is rotated so as to cause the drill bit to travel in a downward circular path thereby making cuts in the vertebral body. In the case where, the first cut does not cut a complete channel or through aperture, the pivot arm assembly is detached from the frame, flipped, reconnected to the frame and the cutting process described above is repeated until the rest of the channel or through aperture has been cut. See FIGS. 15D-F.

There is shown in FIG. 15I, a illustrative view of adjacent vertebral bodies with the drilling apparatus **100** of the present invention mounted thereon. As illustrated, the arrangement of the drilling apparatus **100** of the present invention is such that the drilling bit follows a fixed path established by the configuration of the drilling apparatus **100**. In this way, a maximum or fixed cutting depth also is set or established by the configuration of the drilling apparatus **100**.

After the complete channel or through aperture is cut in the adjacent vertebral bodies, the pivot arm assembly **300** and the drill assembly **400** are detached from the frame **202** and the nail members **206** are removed from the vertebral bodies and the frame or platform assembly **200** is removed from the operative site. As indicated herein, removal of the nail members **206** can be accomplished using the nail member removal device **500** of the present invention. The above process yields a channel opening or through aperture in both vertebral bodies that can accept the curved rod **800**. See FIGS. 15G-H.

It should be recognized that it is within the scope of the present invention to cut a channel through or partially through one of the vertebral bodies. Thus, the foregoing process is adaptable for accomplishing this by limiting rotational movement such that a channel is not cut completely through one of the vertebral bodies.

Now with reference to FIGS. 16A-C there is shown the process for placing, positioning and attaching or implanting a curved rod **800**, including those described in any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265, the teachings of which are incorporated herein by reference. The curved rod **800** is inserted into the channel and manipulated so that the curved rod is submerged along the midline of the vertebra (see FIGS. 16A-B). The curved rod **800** is now secured to the vertebral bodies using interlocking screws **804** that traverse the rod and penetrate the vertebra at an angle that will avoid sensitive neurologic structures. The screws hold the curved rod **800** in place and stabilize the motion segment to facilitate healing of the bone within the disc space.

Two end screws **804** are passed through the open ends of the curved rod and each is inserted until the screw head is contained within the hollow of the implant. The screws are inserted using for example a Cardan screwdriver **806**.

It should be recognized, and as taught in any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265, the teachings of which are incorporated herein by reference, the curved rods **800** can be configured so as to include fenestration or surface artifacts that secure the curved rod within the channel without the retaining screws **804** are described above or in addition to such retaining screws.

In addition to the foregoing teachings of any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265 as to the type and form of rod or implant that can be placed, positioned, attached and/or implanted, there are shown in FIGS. 22-24 other implants that are contemplated for use with the methodology,

devices and/or apparatuses of the present invention as well as for use in combination with any of a number of other methodologies, devices and/or apparatuses described in U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265. Now with reference to FIGS. 23A,B there is shown a sliding implant device **850** or a dynamized implant device that includes first and second members that are configured and arranged so as to form a sliding interconnection **854** there between. Such a sliding implant device **850** provides a mechanism to provide stability to the spine while preserving at least some ability of motion in the spine. Such a device provides dynamic stabilization to a patient who needs stability but necessarily fusion of adjacent vertebrae.

In a particular embodiment, the sliding interconnection **854** is formed by having an end **851a** of the first member **852a** being slidably disposed with an end **851b** of the second member **852b**. As illustrated in FIG. 22B, in the inner diameter of at least the end **851a** of the first member **852a** is larger than the outer diameter of the end of the second end **851b** of the second member **852b**. This can be achieved using any of a number of techniques known to those skilled in the art. As illustration, in one case the first member end **851a** is machined or processed so that this end is expanded radially outwardly so as to form a socket for receiving the second member end **851b**. In another case, the second member **852b** is formed so the end **851b** has an outer diameter that is set so as to slidably received within the first member end **851a**. In yet another case, the first member **852a** is formed so that the end **851a** includes a pocket therein and the second member **852b** is formed so the end **851b** has an outer diameter that is set so as to slidably received within the pocket of the first member end **851a**.

In further embodiments, the first member **852a** is a solid member and the end **851a** is formed so as to create a pocket or socket within the first member and the second member **852b** is a solid member and the end **851a** thereof is formed so as to have a reduced diameter so as to form a plug type end that can be slidably received within the socket/pocket of the first member **852a**. In this way, the shoulder of the plug end and the lip of the first member end cooperate to stop further relative motion between the first and second members **852a,b**. In further embodiments, the first and second members **852a,b** have respective different outer diameters such that the outer diameter of the second member **852b** is less than the inner diameter of the first member or the pocket/socket on the end **851a** thereof.

In further particular embodiments, and with reference to FIG. 22B, the respective ends **851a,b** of the first and second members **852a,b** also are arranged so as to include stop members **856a,b** that cooperate to restrict relative movement between the first and second members as well as restrict relative movement between the adjacent vertebrae **2**. In exemplary embodiment, the stop members **856a,b** extend outwardly from opposing surfaces of the first and second members **852a,b**. The stop members **856a,b** also are arranged such that when the first and second members are secured within the adjacent vertebrae **2**, the stop members are opposed to each other and spaced from each other corresponding to a given spacing between the adjacent vertebrae.

Thus, when the spacing between the adjacent vertebrae changes responsive to relative movement of the adjacent vertebrae (e.g., compression), such relative movement also causes the stop members **856a,b** to also move with respect to each other. When the stop members **856a,b** contact each other, however, further relative movement between the first and second members **852a,b** as well as between the adjacent vertebrae is restrained. Thus, the spacing between the stop members in effects sets the dynamic range of movement for

the adjacent vertebrae. In further embodiments, the spacing between the stop members **856a,b** is adjusted so as to provide different dynamic ranges of movement.

In further exemplary embodiments, each of the stop members **856a,b** comprise a plurality or more of segments, each segment extending around part of the circumference of the respective first and second members so as to form channels between the adjacent segments of a respective first or second member. These channels form paths through which the stop member segments of the other of the first and second member can pass axially when forming the sliding interconnection. When the first and second members **852a,b** are assembled to form the sliding interconnection, the stop member segments are rotated with respect to each other so that they are orientated opposed to each other.

In further exemplary embodiments, the stop members **856a,b** and the stop member segments, are formed integral with the respective first and second members **852a,b**. In alternative embodiments, the stop members **856a,b** and the stop member segments, are coupled or secured to the respective first and second members **852a,b** using any of a number of techniques known to those skilled in the art (e.g., adhesives, welding, brazing, ultrasonic welding, laser welding, or other mechanical connections) and appropriate for the structure forming the first and second members **852a,b** of the implant device.

Referring now to FIGS. 23A-C there is shown another embodiment of a dynamized implant device **860** that includes first and second members **862a,b** members, that are configured and arranged so as to form a sliding or piston-like interconnection between opposing ends of the respective first and second members, and a compressive device **864** that is disposed between opposing ends of the respective first and second members. Such a dynamized implant device **860** provides a mechanism to provide stability to the spine while preserving at least some ability of motion in the spine. Such a device provides dynamic stabilization to a patient who needs stability but necessarily fusion of adjacent vertebrae.

The compressive device **864** comprises a spring, a compressive material, for example a bio-compatible foam material or other resilient or compressive material as is known to those skilled in art. In exemplary embodiments, the compressive device is operably coupled or secured to one of the opposing ends and in more particular embodiments is operably coupled to both opposing ends. For example, when a spring comprises the compressive device **864** one end of the spring is secured to the end **861a** of the first member **862a** and the other end of the spring is secured to the end **861b** of the first member **862a**.

In a further exemplary embodiment, and with reference to FIG. 23B, the ends **861a',b'** of the respective first and second members **862a',b'** are arranged so the first member end **861a'** is slidably disposed within a pocket **866** in the end **861b'** of the second member **b'**. Also, the compressive device **864** is disposed within the pocket and between the ends **861a',b'** of the first and second members.

In another further exemplary embodiment, and with reference to FIG. 23C, the end **861a''** of the first member **862a''** is configured so its cross-section or outer diameter is reduced with respect to that of the rest of the first member so as to form a plug **863a** or piston-like member. In this arrangement, the plug like member **863**, is slidably disposed within a pocket **866** in the end **861b** of the second member **862b''**. Also, the compressive device **864** is disposed within the pocket and between the ends **861a'',b''** of the respective first and second members.

Although the foregoing discussion, has generally described the present invention in terms of implanting one arcuate rod or implant device between bony segments such as between adjacent vertebrae, this shall not be construed as a limitation as it is contemplated and thus within the scope of the present invention for a plurality or more of implant devices **900** (FIGS. **24A,B**) to be positioned and secured between adjacent bony segments including adjacent vertebrae. In further embodiments, the plurality or more of implant devices **900** can both have the same general makeup or constitution or the plurality or more of implant devices **900** can be different. Thus, and in addition to the foregoing teachings of any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265 as well as that described hereinabove, the methods of the present invention can further include placing, positioning and attaching or implanting a plurality of implants **900**.

In addition to securing a plurality of implant devices in adjacent vertebrae is also contemplated and thus within the scope of the present invention to position and secure one or more arcuate rods or implant devices in three or more adjacent vertebrae. Referring now to FIG. **24C**, there is shown an illustrative embodiment in which two or more arcuate rods or implant devices **900a1,a2** are stacked or overlaid so that there is an implant device **900a1** extending between adjacent vertebrae **2a,b** and another implant device **900a2** extending between adjacent vertebrae **2b,2c**. In this illustrative embodiment, an end **901a1,901a2** of each implant device **900a1,900a2** is located and secured in the same vertebrae **2b** by a screw **910** or other type of device known to those skilled in the art. The other end **903a1,903a2** is secured in the respective vertebrae **2a,2c** by a screw **910**. In particular embodiments, and with reference to the anterior view shown in FIG. **24D**, the ends **901a1,901a2** being secured in the middle vertebrae **2b** are configured and arranged so that one end **901a2** is configured so as to be disposed about the other end **901a1**.

Referring now to FIG. **24E** there is shown another illustrative embodiment, in which the one arcuate rod or implant device **900b1** is configured so as to be shorter than the other implant device **900b2**. As with the embodiment described above, one end **903b1,903b2** of each implant device **900b1,900b2** is secured in the respective vertebrae **2a,2c** by a screw **910**. The shorter implant device **900b1** is configured so an end **901b1** thereof is disposed about a portion of the longer implant device **900b2** that is proximal to the end **901b2** that is to be secured in the middle vertebrae **2b** by the screw **910**. The end **901b1** of the shorter implant device also is configured so that the screw **910** exiting from the longer implant device **900b2** also passes through the end **901b1** so as to secure both ends **901b1,b2** in the middle vertebrae **2b**.

As indicated herein, the drilling apparatus of the present invention is adaptable for use in a wide range of spinal repair procedures including but not limited to a repair procedure for an intervertebral disk **5** (FIG. **19A,B**). Although the following discussion refers to the drilling apparatus **100** according to one aspect/embodiment of the present invention, it is contemplated that any of the drilling apparatuses herein described are adaptable for use to perform such a disk repair procedure. Also, it is contemplated that a disk repair procedure according to the present invention also can be accomplished using any of the devices, apparatuses or mechanisms described in and as taught in any of U.S. Pat. No. 6,607,530 and U.S. Ser. No. 10/019,265.

Referring now to FIGS. **19A-B**, there is shown a drilling apparatus **100** mounted/secured upon a spine, more specifically adjacent vertebrae **2**, Step **2000**. Such mounting and securing is accomplished using the methods and techniques for doing so as described herein. Reference shall be made to

FIGS. **1-9** and the discussion related thereto, for further details of the drilling apparatus not provided below. Reference also should be made to the process flow diagram illustrated in FIG. **20**.

In further embodiments, the drill bit **410** of the drilling apparatus **100** and related components are selected so that the channel, passage or hole **3** in the adjacent vertebrae **2** is sized so as to provide a desired access to the nucleus for carrying out the repair procedure. For example, the hole **3** may be one size if a fluid or gel is to be injected into the nucleus, whereas it may be made larger if a prosthetic or device is to be inserted through the hole so as to reside in the area within the annulus for the disk nucleus.

After the drilling apparatus **100** is so mounted, the surgeon would manipulate the drill bit so as to cause it to rotate and create a curved or arcuate hole **3** in the adjacent vertebrae and into the disk **5**, Step **2002**. Such a drilling operation advantageously minimizes penetration of the vertebral endplates. Also, the drill as it follows the predetermined curved or arcuate path penetrates the vertebral end plates at essentially a right angle, thereby creating a circular defect. In contrast, the straight drill used in conventional techniques would penetrate the end plate at an angle thereby causing a larger elliptical shaped defect. The near perpendicular access created by the drilling apparatus of the present invention also minimizes trauma and/or disruption to the natural nucleus material. In contrast, a straight drill would need to penetrate more deeply into the disc space to complete the access hole.

In this regard it should be noted that while it is desirable to penetrate the nucleus of the disk, it should be recognized that it is possible that a portion of the annulus also may be drilled during the drilling procedure. Such an occurrence, however, shall not be construed as being unacceptable or outside the scope of the present invention.

Following creating of the hole, the drill bit **410** is extracted or removed from the hole **3** thereby allowing the surgeon access to the hole and thus the nucleus of the disk to be repaired. In particular embodiments, the surgeon would remove the drilling apparatus **100** so as to provide clear access to the opening formed by the hole **3**, Step **2004**. Thereafter, the surgeon would perform the particulars of the disk repair/replacing/augmentation procedure, such as but not limited to removing nucleus material (Step **2006**), delivery of the nucleus augmentation material, artificial disk and/or artificial nucleus (Step **2008**) and plugging of the channel, passage or hole **3** made in the adjacent vertebrae **2** (Step **2010**). The nucleus material can be removed using any of a number of techniques known to those skilled in the art including but not limited to water jets, chemical agents such as Chymopapain chemonucleolysis, rongers and emulsification technology.

Such augmentation material includes but is not limited to the devices, mechanisms and materials described in U.S. Pat. Nos. 5,824,093, 6,264,695 and 5,047,055 the teachings of which are herein incorporated by reference. Also, such delivery of the nucleus augmentation material, as well as such repair procedures, can include delivery and positioning of an annulus closure mechanism or device to seal or retain the artificial disc, nucleus and/or nucleus augmentation material or provide a closure for a defect in the annulus (such as but not limited to the devices described in U.S. Pat. Nos. 6,425,919 and 6,593,625, the teaching of which are incorporated herein by reference). As is known to those skilled in the art, when the annulus becomes damaged a defect is formed in the annulus that allows the nucleus for example, to cause the disk to bulge in a given direction. In addition, to delivery of nucleus or annulus repair and augmentation materials, it also is contem-

plated that drugs, medicaments, or other treatment materials can be delivered to the disk **5**, vertebrae **2** or other element of the body.

The plugging of the hole **3** is accomplished using any of a number of techniques known to those skilled in the art, including but not limited to the use of bone/bone graft material. It also is contemplated that an arcuate rod as herein described also can be used to plug the hole **3**. Thus, the plugging of the hole **3** becomes a relatively straightforward procedure. Also, the plugging should advantageously create a relatively smooth surface at the end plate and the load forces on the vertebral end plate will be perpendicular to the access hole. Such plugging is particularly advantageous as compared to some conventional techniques as defects in the annulus do not heal; whereas defects in the bone (e.g., the vertebral body) can be plugged with bone, metal, etc. and the bone heals around the plug.

Referring now to FIGS. **25-29** there is shown exemplary frame assemblies for a drilling assembly according to another aspect of the present invention, in which an intervertebral spacer or spacer element is removably secured to and extends from the frame assembly so as to be maintained in a fixed relation to the frame assembly as the channel is being formed in the adjacent bony segments or adjacent vertebral bodies. In particular embodiments, the intervertebral spacer is secured to the frame assembly so as to prevent rotational motion of the intervertebral spacer with respect to the channel. Such an arrangement provides a mechanism thereby also provides a mechanism for maintaining alignment of the spacer to the channel as well as to the position of the drill. The intervertebral spacer also allows the surgeon to maintain extremely accurate disk spacing and also protects the spinal cord.

In further embodiments, the intervertebral spacer is formed so that the drill bit **410** as it is being rotated to form the channel passes through the spacer thereby also forming an aperture in the spacer that has corresponds characteristics as the channel formed in the adjacent bony structure/vertebral bodies (e.g., same curvature, diameter). In another embodiment, the intervertebral spacer is formed so as to include a pre-formed aperture; through which the drill bit **410** passes as the drill bit is being rotated to form the channel in the adjacent bony structure or adjacent vertebral bodies. In yet another embodiment, the intervertebral spacer is formed so as to include a pre-formed aperture smaller than the channel to be formed. The drill bit **410** passes through the portion of the spacer including the pre-formed aperture as the drill bit is being rotated, thereby forming the channel in the adjacent bony structure or adjacent vertebral bodies. Such intervertebral spacers can be made using any of a number of techniques and materials known to those skilled in the art and in particular embodiments, the spacer design is suitably based on a construction that facilitates the selected technique for creating an arcuate aperture. In more particular embodiments, the intervertebral spacers are bone, metal, allograft, autologous, plastic (e.g., PEK) or other material appropriate for the intended use.

In further embodiments, the surgical personnel select an intervertebral spacer that is appropriately sized, so it can accommodate the distended disc space. In yet further embodiments, the mechanism securing the intervertebral spacer to the frame assembly is disengaged thereby releasing the spacer from the drilling apparatus following the drilling or forming of the channel in the adjacent bony segments or vertebral bodies. In this way, the intervertebral spacer remains disposed in the intervertebral disc space. In yet further embodiments, the implant or arcuate rod is inserted into

and through the through aperture in the spacer so as to thereby secure the spacer between the intervertebral bodies.

Referring now to FIGS. **25A-C** there is shown one embodiment of an exemplary frame assembly **4200** according to this aspect of the present invention, in which the frame **4202** includes a plurality of side protrusions **4290** that are positioned at about the mid-point of the frame and on either side of the frame. Each of the side protrusions includes a through aperture **4291**. The exemplary frame assembly **4200** also included a plurality of posts **4292** or connectors; each of which are disposed in one of the protrusion through apertures **4291**. The posts **4292** are generally arranged so that an end **4293a** thereof is generally directed towards the intervertebral space between the vertebral bodies **2**.

In particular embodiments, this end **4293a** of the posts **4292** is configured so the post or connector is releasably secured to the intervertebral spacer **4800**. In illustrative exemplary embodiments, an aperture **4804** provided in the spacer **4800** and the end **4293a** of the posts **4292** are threaded, whereby the spacer is threadably secured to the posts. In further embodiments, the other end **4293b** of the posts **4292** is configured so has to have a head or other feature that prevents the post from passing through the protrusion through aperture **4291**. In yet further embodiments, the length of each post is established such that when the intervertebral spacer **4800** is so secured to the frame assembly the spacer is appropriately positioned with respect to the travel path of the drill bit **410** as it is being rotated to form the channel. In particular embodiments, the intervertebral spacer **4800** is secured to the frame assembly so the pre-formed aperture **4802** in the spacer is appropriately positioned and so as to be congruent with the travel path of the drill bit **410** as it is being rotated to form the channel.

Referring now to FIGS. **26A-B** there is shown another embodiment of an exemplary frame assembly **4200a** according to this aspect of the present invention, in which the frame **4202a** includes a plurality of side protrusions **4290a** that are positioned away from the mid-point of the frame and on either side of the frame. Each of the side protrusions includes a through aperture **4291**. The exemplary frame assembly **4200a** also included a plurality of posts **4292a** or connectors; each of which are disposed in one of the protrusion through apertures **4291**. The posts **4292** are generally arranged so that they extend at an angle from each protrusion and so that an end **4293aa** thereof is generally directed towards the intervertebral space between the vertebral bodies **2**.

In particular embodiments, this end **4293aa** of the posts **4292a** is configured so the post or connector is releasably secured to the intervertebral spacer **4800**. In illustrative exemplary embodiments, an aperture **4804** provided in the spacer **4800** and the end **4293aa** of the posts **4292a** are threaded, whereby the spacer is threadably secured to the posts. In further embodiments, the other end **4293ab** of the posts **4292** is configured so has to have a head or other feature that prevents the post from passing through the protrusion through aperture **4291**. The other end **4293ab** also is configured so the surface contacting the frame **4202a** complements the angle of the posts. In yet further embodiments, the length of each post **4292aa** is established such that when the intervertebral spacer **4800** is so secured to the frame assembly the spacer is appropriately positioned with respect to the travel path of the drill bit **410** as it is being rotated to form the channel. In particular embodiments, the intervertebral spacer **4800** is secured to the frame assembly so the pre-formed aperture **4802** in the spacer is appropriately positioned and so as to be congruent with the travel path of the drill bit **410** as it is being rotated to form the channel.



Referring now to FIGS. 27A-C there is shown another embodiment of an exemplary frame assembly **5200a** according to this aspect of the present invention that includes a frame **5202** and a clip mechanism **5210**. The clip mechanism **5210** is attached or secured to the frame **5202** using any of a number of techniques known to those skilled in the art so that manipulation of the clip mechanism by a clinician or other medical personnel does not result in the detachment of the clip mechanism. In an illustrative exemplary embodiment, the clip mechanism **5210** includes a recessed portion **5218** in which is received portions of the frame **5202**. In more particular embodiments, the clip mechanism **5210** is attached on the interior of the frame **5202** so that the clip portion **5212** thereof extends downwardly through the frame.

The clip mechanism **5210** is made of any of a number of bio-compatible materials, such as stainless steel and/or plastic, that are appropriate for the intended use (e.g., compatible with the material of the frame) and which can be attached or secured to the frame **5202**.

The clip portion **5212** of the clip mechanism **5210** is configured so as to releasably hold the intervertebral spacer **4800** in the interior space **5214** of the clip portion. In use the surgeon manipulates the lever arms **5216** thereby causing the clip portion **5212** to release the intervertebral spacer. In particular embodiments, the manipulation of the lever arms **5216** causes the opposing arm segments of the clip portion **5212** to move away from each other so the spacer can pass out of the interior space **5214**.

In further embodiments, the clip portion **5212** is configured so as to include a plurality of pairs of arm segments that are spaced from each other along the length of the frame **5202**, where each pair of arm segments releasably holds the intervertebral spacer **4800**. For example and as illustrated in FIG. 27B, one pair of arm segments can be located forward of the midpoint of the frame and the other pair of arm segments can be located rearward of the frame midpoint. In addition, there also is provided a plurality of pairs of lever arms **5216**. In further embodiments, at least one pair of lever arms **5216** is provided for each pair of arm segments of the clip portion **5212** or at least one pair of lever arms segments is provided for a plurality or more of pairs of arm segments of the clip portion. Such an arrangement provides sufficient gripping area and force to hold the intervertebral spacer **4800** to the frame at least during formation of the channel and but allows the clinician to relatively easily open up the arms segments to release the spacer.

In further embodiments, the methods of the present invention further include securing the frame assembly **5200a** to adjacent vertebral bodies **2** (FIG. 23C) so that the intervertebral spacer **4800** is disposed in the distended intervertebral space. Such methods further included manipulating the lever arms, for example following drilling or forming of the channel, so the intervertebral spacer **4800** remains disposed in the distended intervertebral space after the frame assembly is removed.

Referring now to FIGS. 28A-B there is shown another embodiment of an exemplary frame assembly **5200b** according to this aspect of the present invention that includes a frame **5202** and a spring clip mechanism **5220**. The clip mechanism **5220** includes arm segments **5222** and a manipulating device **5224**. The arm segments **5222** are each attached or secured to the frame **5202** on opposing sides of the frame so as to oppose each other using any of a number of techniques known to those skilled in the art so that manipulation of the clip mechanism by a clinician or other medical personnel does not result in the detachment of the clip mechanism. Also, the arm segments **5222** are attached or secured to the frame **5202** using

any of a number of techniques known to those skilled in the art so that the process for forming the channel, including drilling of such a channel in the intervertebral spacer **4800**, does not result in the detachment of the clip mechanism or release of the intervertebral spacer. The arm segments **5222** are made of any of a number of bio-compatible materials, such as stainless steel and/or plastic, that are appropriate for the intended use (e.g., compatible with the material of the frame) and can be attached or secured to the frame **5202**.

The manipulating device **5224** is removably attached to the frame **5202**, more particularly the interior of the frame. In addition, when removably attached to the frame, the manipulating device **5224** is disposed proximal to and above the intervertebral spacer and extending between the arm segments. In use the surgeon manipulates the lever arms **5226** thereby causing the arm segments **5222** to move away from each other and thereby release the intervertebral spacer **4800**.

In particular embodiments, a lateral segment **5225** extends between a plurality of pairs of lever arms **5226** and the manipulation of the lever arms **5226** causes the manipulation device lateral segment **5225** to urge the arm segments outwardly.

In further embodiments, the clinician or other medical personnel also can manipulate the manipulation device **5224** to detach the manipulation device from the frame. In this way, the intervertebral spacer **4800** can be inserted through the frame interior and secured in place when the manipulation device **5224** is thereafter inserted and secured to the frame.

Such an arrangement provides sufficient gripping area and force to hold the intervertebral spacer **4800** to the frame at least during formation of the channel and but allows the clinician to relatively easily open up the arms segments **5222** to release the intervertebral spacer. Also, as the arms segments **5222** and the manipulation device **5224** are removably attached or secured to the frame, a clinician can select arm segments and manipulations devices that are appropriate sized for locating a spacer in the intervertebral space for a given target site and a patient's particular physiology.

In further embodiments, the methods of the present invention further include securing the frame assembly **5200b** to adjacent vertebral bodies **2** so that the intervertebral spacer **4800** is disposed in the distended intervertebral space. Such methods further included manipulating the lever arms **5226**, for example following drilling or forming of the channel, so the intervertebral spacer **4800** remains disposed in the distended intervertebral space after the frame assembly is removed.

Referring now to FIGS. 29A-B there is shown another embodiment of an exemplary frame assembly **5200b** according to this aspect of the present invention that includes a frame **5202** and a spring clip mechanism **5220**. The clip mechanism **5220** includes arm segments **5222b** and a manipulating device **5224**. Reference shall be made to the discussion regarding FIGS. 28A-B for details of features in common with this embodiment and not otherwise provided below.

The arm segments **5222b** are each removably attached or secured to the frame **5202** on opposing sides of the frame so as to oppose each other using any of a number of techniques known to those skilled in the art so that manipulation of the clip mechanism by a clinician or other medical personnel does not result in the detachment of the clip mechanism. The arm segments **5222b** also are each removably attached or secured to the frame **5202** using any of a number of techniques known to those skilled in the art so that the process for forming the channel, including drilling of such a channel in the intervertebral spacer **4800**, does not result in the detachment of the clip mechanism or of the intervertebral spacer.



The arm segments **5222b** are made of any of a number of bio-compatible materials, such as stainless steel and/or plastic, that are appropriate for the intended use (e.g., compatible with the material of the frame) and can be attached or secured to the frame **5202**.

The manipulating device **5224** is removably attached to the frame **5202**, more particularly the interior of the frame. In addition, when removably attached to the frame, the manipulating device **5224** is disposed proximal to and above the intervertebral spacer and extending between the arm segments **5222b**. In use the surgeon manipulates the lever arms **5226** thereby causing the arm segments **5222b** to move away from each other and thereby release the intervertebral spacer **4800**. In particular embodiments, a lateral segment **5225** extends between a plurality of pairs of lever arms **5226** and the manipulation of the lever arms **5226** causes the manipulation device lateral segment **5225** to urge the arm segments **5222b** outwardly.

In further embodiments, the clinician or other medical personnel also can manipulate the manipulation device **5224** to detach the manipulation device from the frame. In this way, the intervertebral spacer **4800** can be inserted through the frame interior and secured in place when the manipulation device **5224** is thereafter inserted and secured to the frame.

Such an arrangement provides sufficient gripping area and force to hold the intervertebral spacer **4800** to the frame at least during formation of the channel and but allows the clinician to relatively easily open up the arms segments **5222b** to release the intervertebral spacer. Also, as the arms segments **5222b** and the manipulation device **5224** are removably attached or secured to the frame, a clinician can select arm segments and manipulations devices that are appropriate sized for locating a spacer in the intervertebral space for a given target site and a patient's particular physiology.

In further embodiments, the methods of the present invention further include securing the frame assembly **5200b** to adjacent vertebral bodies **2** so that the intervertebral spacer **4800** is disposed in the distended intervertebral space. Such methods further included manipulating the lever arms **5226**, for example following drilling or forming of the channel, so the intervertebral spacer **4800** remains disposed in the distended intervertebral space after the frame assembly is removed.

It should be recognized that the drilling apparatus, methods and systems of the present invention can be used anteriorly or posteriorly and so that the drill bit of such systems or apparatuses can penetrate or enter the vertebral body through the pedicles.

In addition to securing one or both ends of an arcuate rod or implant device in a vertebrae **2** it also is contemplated and thus within the scope of the present invention to secure the arcuate rod within a spacer that is disposed between adjacent vertebrae. Such securing can be done as an alternative to securing one or both ends of the implant device or in addition to such securing of the ends.

Additionally, and referring now also to FIG. **31**, an arcuate rod or implant device **1800** is additionally configured to include one or more receiving apertures **1802** that is/are located so as to be positioned between the adjacent vertebral bodies **2** when the arcuate rod or implant device is disposed in the adjacent vertebral bodies. The one or more receiving apertures **1802** also are arranged to receive therein a pinning member **1820** and also so as to engage the pinning member so as to thereby secure the pinning member relatively to the arcuate member **1800**. Such mechanically engaging includes, but is not limited to threaded connections, snap-fit type of con-

nections or any other connections known to those skilled in the art and otherwise appropriate for the intended use.

In use, after the arcuate member or implant device **1800** is disposed in the adjacent vertebral bodies and the intervertebral spacer **4800** is disposed in the intervertebral space, the pinning member **1820** is inserted through the intervertebral spacer and secured to the arcuate member or implant device. It is contemplated and thus within the scope of the present invention to provide or form a preformed aperture in the intervertebral spacer **4800** through which the pinning member **1820** passes. In this way, the pinning member **1820** in combination with the arcuate rod or implant device **1800** secures the intervertebral spacer **4800** between, and to, the adjacent vertebral bodies **2**. Although the foregoing refers to an intervertebral spacer, it is within the scope of the present invention, for the pinning member **1820** and arcuate rod or implant device **1800** to be used with any of a number of cages, spacers or other devices known to those in the art or hereinafter developed that is/are disposed between adjacent vertebral bodies **2**.

Referring now to FIG. **30A**, there is shown one illustrative embodiment in which an arcuate rod or implant device **1000a** that is configured so as to include one or more re-positional elements or wings **1002** and a spacer **1050a** including one or more recesses or pockets **1052** that is configured to receive each of the one or more wings **1002** therein. The implant device **1002** also is configured such that the wings **1002** are moveably disposed within the implant device such that the wings do not generally extend beyond the outer circumference of the implant device thereby allowing the implant device to be inserted into the arcuate passages formed in the adjacent vertebrae. The wings **1002** and the implant device also are configured such that when the wings are disposed within the pocket(s) **1052** in the spacer **1050a**, the wings extend outwardly from the implant device and into the pocket(s). In an exemplary embodiment, the wings **1002** are pivotably secured to the implant device and are acted upon by a resilient member (e.g., a spring like element) to cause the wings to be displaced outwardly. In this way the wings **1002** become secured in the pocket(s) **1052** and thereby secured within the spacer **1050a**.

Referring now to FIG. **30B**, there is shown another illustrative embodiment in which an arcuate rod or implant device **1000b** that is configured so as to include one or more dimples, bumps **1004** or other surface artifacts and a spacer **1050b** including one or more recesses or pockets **1052**. In particular embodiments, the implant devices **1000b** includes a plurality or 3 or more such bumps **1004** that are arranged about the circumference of the implant device. The one or more bumps **1004** also are configured and arranged so that the bumps are in interference fit with the inner wall **154** of the passage through the spacer **1050b**. In alternative embodiments, the inner wall **154** further includes one or more depressions in the inner wall in which are received a bump **1004**.

Referring now to FIG. **30C** there is shown another illustrative embodiment in which an arcuate rod or implant device **1000c** is secured within a spacer **1050c** by means of a screw or other device. In use, after the implant device **1000c** is positioned within the spacer and adjacent vertebrae, the clinician would screw the screw **1060** through the spacer such that at least the tip **1061** or a portion proximal the tip is received in the implant device. In particular embodiments, the spacer **1050c** includes a passage **1056** extending from the exterior to the inner wall **1054** of the spacer, the passage can be threaded to receive the screw **1060** or be a smooth bore. In further particular embodiments, the implant device includes an opening or depression **1006** in which is received the tip **1061**. Although a screw with a pointed tip is illustrated, this is

not limiting as other types of screws or bolts are contemplated for use with the spacer **1050c** and implant device **1000c**.

Referring now to FIGS. **32A-B** there are shown various views of an arcuate rod or implant device, cap and screw assembly **3800** according to one illustrative embodiment of the present invention, where the arcuate rod or implant device **800** is shown in cross-section. Reference also should be made to the foregoing discussion regarding FIGS. **15-16** for features having common reference numerals (e.g., the arcuate rod or implant device **800** and the screw **804**). In the illustrated embodiment, a cap member **3820, 3830** is provided at each end of the arcuate rod or implant device **800**, which in combination with the screw **804** secures that end and thereby the arcuate rod or implant device to a vertebral body.

In the illustrated embodiment, two different type of cap members **3820,3830** are shown; however, this shall not be considered as a limitation. For example and as shown in FIG. **32C**, an arcuate rod or implant device, cap and screw assembly **3800a** according to another embodiment is arranged so the same type of cap member **3830** is provided at each end of the arcuate rod or implant device **800**. Thus, it is contemplated and within the scope of the present invention for different type cap members or the same type of cap member to be provided at each end of the arcuate rod or implant device **800**.

Referring now to FIGS. **33A-F**, there is shown one of the illustrated cap members, cap member **3820**. The cap number **3820** includes an upper portion **3822a** and a lower portion **3822b** which is secured to, or formed with, the upper portion so as to extend along an arcuate path from the first portion. This arcuate path is such that the curvature of the lower portion essentially matches that of the arcuate rod or implant device **800** so that the lower portion can be received in the lumen of the arcuate rod or implant device. As shown in FIGS. **33C-D**, the lower portion **3822b** also is curved to match the left or right hand direction of the arcuate rod or implant device. In particular embodiments the lower portion **3822b** is sized so as to limit or substantially prevent lateral movement of the lower portion in then lumen.

The upper portion **3822a** is generally sized and arranged so as to form a flange like structure **3821** that extends outwardly so the flange like structure at least rests upon the end of the arcuate rod or implant device **800**. In further embodiments, the radius of the flange like structure **3821** such that the upper portion does not generally extend beyond the region defined by the end of the arcuate rod or implant device.

The upper portion **3822a** includes a stepped through aperture **3824** that is coupled to and communicates with a through aperture **3826** provided in the lower portion **3824b**. The stepped through aperture **3824** and lower portion through aperture **3826** are arranged so the threaded portion **805b** of the screw **804** extends downwardly and in a direction that allows the threaded portion to exit from the arcuate rod or implant device **800** and thereby be secured to the vertebral body **2** (e.g., such as that shown in FIG. **24C**). The stepped through aperture **3824** also is formed so that the head **805a** of the screw **804** should contact a contact surface **3823**; thus limiting the motion of the screw. In further embodiments, the stepped through aperture **3824** including the contact surface **3823** are arranged so as to compliment the shape of the head **805a** of the screw **804**. For example, the stepped through aperture and contact surface form a dish shaped structure such as that illustrated in FIG. **34D**.

Referring now to FIGS. **34A-G**, there is shown another illustrated cap members **3830**. The cap member **3830** includes an upper portion **3832a** and a lower portion **3832b** that is secured to, or formed with, the upper portion so as to

extend along an arcuate path from the first portion. See also the discussion above regarding the lower portion of **3822b** for further details.

The upper portion **3832a** includes a flange like structure **3831** and a raised section **3833** that extends outwardly from a surface of the flange like structure. The flange like structure **3831** is generally sized and arranged so it extends outwardly so at least a portion of the flange like structure extends beyond the end of the arcuate rod or implant device **800** and extends over, and thus adjoins or rests upon, a surface of the vertebral body (such as for example that illustrated in FIGS. **35A,B**). In further embodiments, the flange like structure **3831** forms an elliptical shape, whose long or major axis is arranged so as to be at a predetermined angle with respect to the arcuate rod or implant device. The predetermined angle is such that the portion of the flange like structure along the long or major axis of the elliptical structure is positioned so the one or more downwardly extending spikes **3838** are in a desired location with respect to the vertebral body **2**. In exemplary embodiments the flange like structure **3831** is arranged so the major or long axis is substantially perpendicular to the arcuate rod or implant device **800**.

The raised section **3833** of the upper portion **3832a** is generally arranged to receive the screw **804**, in particular the head **805a** thereof. The upper portion **3832a** including the raised portion **3833** and the flange like structure are arranged so as to include a stepped through aperture **3834** that is coupled to and communicates with a through aperture **3836** provided in the lower portion **3832b**. The stepped through aperture **3834** and lower portion through aperture **3832b** are arranged so the threaded portion **805b** of the screw **804** extends downwardly and in a direction that allows the threaded portion to exit from the arcuate rod or implant device **800** and thereby be secured to the vertebral body **2** (e.g., such as that shown in FIG. **24C**). The stepped through aperture **3834** also is formed so that the head **805a** of the screw **804** should contact a contact surface **3833**; thus limiting the motion of the screw. In further embodiments, the stepped through aperture **3834** including the contact surface **3833** are arranged so as to compliment the shape of the head **805a** of the screw **804**. For example, the stepped through aperture and contact surface can form a dish shaped structure such as that illustrated in FIG. **34D**.

As indicated above, one or more spikes **3838** extend downwardly from the flange like structure **3831** from a surface there of that opposes the vertebral body **2**. The spikes **3838** are sized and arranged so as to engage at least the hard bony structure of the vertebral body **2** (e.g., cortical bone of the vertebral body). In this way, the engagement of the spikes **3838** with the cortical bone also fixes the rod with respect to the vertebrae. In more particular embodiments, a plurality of spikes extend downwardly. In exemplary embodiments, four spikes extend downwardly from the flange like structure, the spikes being arranged so that there are two spikes along each of the ends of the flange like structure and spaced from each other such as shown in FIG. **34B**.

Although the spikes **3038** are illustrated as cylinders with a pointed end, this is not limiting as the spikes may comprise any other structure known in the art that provides a similar effect or function. Without being bound by any particular theory, the above described cap member **3820, 3830** when secured to the vertebral body **2** as described above is expected to create a structure that prevents the screw **804** from rotating or creating a windshield wiper effect within the cancellous bone of a vertebral body **2**.

Referring now to FIGS. **35A-B** there is shown various illustrative axonometric views of adjacent vertebral bodies **2**

that illustrates yet another arcuate rod or implant device, cap and screw assembly **3800b** according to yet another illustrative embodiment of the present invention, where the arcuate rod or implant device is shown in cross-section. The arcuate rod or implant device, cap and screw assembly **3800b** according to this embodiment includes a cap member **3840** which is provided at one end of the arcuate rod or implant device **800**, although it is within the scope of the present invention for such a cap member to be provided at both ends of the arcuate rod or implant device.

Such a cap member **3840** includes an upper portion **3842a** and a lower portion **3842b**. The upper portion **3842a** includes a flange like structure **3831** and a plurality of raised sections **3843a-c** that extend outwardly from a surface of the flange like structure. The flange like structure **3841** extends substantially in one direction at an angle with respect to the arcuate rod or implant device **800**.

The raise sections **3843a-c** are arranged on the flange like structure so that a first raised section **3843a**, the flange like structure **3841** and the lower portion **3842b** cooperate as described above in regards to the discussion for FIGS. **34A-G** so that a screw **804** passes therethrough and through the arcuate rod or implant device. Thus, reference shall be made to the foregoing discussion of FIGS. **34A-G** for further details.

Each of the other of the plurality of raised sections **3843b,c** and the flange like structure **3841** are configured so as to provide a stepped through aperture to receive a screw **804** therein. Reference shall be made to the foregoing discussion for FIGS. **34A-G** as to the details of such a stepped through aperture. Also, each of the other of the plurality of raise sections **3843a,b** are spaced from the first raised section **3843**. In particular embodiments, these other raised sections **3843b,c** are laterally disposed with respect to, and on opposite sides of, the first raised section **3843a**. In use, a screw **804** is passed through the stepped aperture in each of these other raised sections **3843b,c** and is screwed into the vertebral body **2** until the head **805a** of the screw **804** contacts the contact surface of the stepped through aperture. In this way, each of these laterally disposed screws as well as the screw passing through and secured to the first raised section **3843a** thereby further fixates the cap member **3840** and thus the arcuate rod and implant device **800** to the vertebral body.

Although a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

It should be clear that the methods, systems, and devices of the invention are not limited to securing a pair of vertebrae, but rather any combination of multiple vertebrae segments. It also should be clear that the methods, systems, and devices of the present invention are in no way limited to vertebrae segments. In particular, the invention enables securing any solid substrates, particularly bone substrates, without use of protruding screws or plates. It also should be understood that the invention is applicable to a wide variety of fixation configura-

tions, including bone-to-bone with a gap; bone-to-bone without a gap; bone-to-bone with bony spacers; and bone-to-bone with a non-bony spacer such as a metal, polymer, or a biodegradable material.

#### INCORPORATION BY REFERENCE

All patents, published patent applications, US patent application and other references disclosed herein are hereby expressly incorporated by reference in their entireties by reference.

#### EQUIVALENTS

Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents of the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

What is claimed is:

1. A method for stabilizing adjacent vertebrae of a spine, comprising the steps of:
  - providing a frame assembly to which is a spacer is removably secured;
  - securing the frame assembly with respect to the adjacent vertebrae such that the spacer element is disposed in the intervertebral space between the adjacent vertebrae; and
  - rotating a drill bit in fixed relation to the frame assembly to form an arcuate channel in the surface or sub-surface of the bone, bony structure or vertebra, wherein the spacer is removably secured to the frame assembly so that the drill bit passes through a desired part of the spacer as the drill bit is being rotated to form the arcuate channel.
2. The method of claim 1, wherein said rotating includes forming a passage through the spacer when rotating said drill bit, the passage being generally congruent with the formed arcuate channel.
3. The method of claim 1, wherein the spacer includes a pre-formed aperture and wherein the spacer is removably secured to the frame assembly so that the drill bit passes through the pre-formed aperture as the drill bit is being rotated to form the arcuate channel.
4. The method of claim 1, further comprising the steps of: providing a frame assembly including a plurality of connectors that extend a predetermined distance from the frame assembly, and connecting each of the plurality of connectors to the spacer so as to maintain the spacer in fixed relation to the frame assembly.
5. The method of claim 1, further comprising the steps of: providing a frame assembly and a clip mechanism coupled to the frame assembly and extending a predetermined distance from the frame assembly, and removably securing the spacer within the clip mechanism so as to maintain the spacer in fixed relation to the frame assembly.

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