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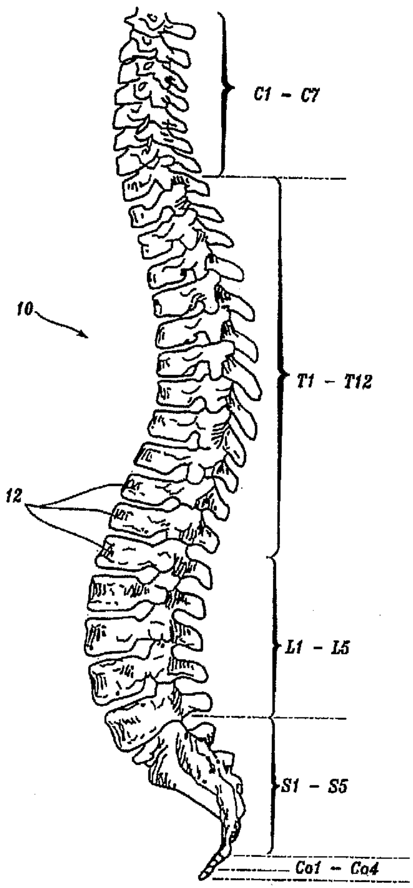
(54) Title: ANTI-ROTATION FIXATION ELEMENT FOR SPINAL PROSTHESES



(57) Abstract: Prostheses, systems, and methods are provided for replacement of natural facet joints between adjacent vertebrae with vertebral prostheses. A portion of the vertebral prosthesis includes anti-rotation and/or anti-pullout elements to prevent or reduce prosthesis fastener rotation or pull out as a result of torques applied to the prosthesis. Various tools and methods aid the process of surgically adding the vertebral prosthesis to a patient's vertebra.

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ANTI-ROTATION FIXATION ELEMENT FOR SPINAL PROSTHESES

FIELD OF THE INVENTION

This invention relates to prostheses, systems, and methods for treating various types of spinal pathologies, and in particular relates to attachment of prostheses to spinal vertebrae.

BACKGROUND OF THE INVENTION

The human spinal column 10, as shown in Figure 1, is comprised of a series of thirty-three stacked vertebrae 12 divided into five regions. The cervical region includes seven vertebrae, known as C1-C7. The thoracic region includes twelve vertebrae, known as T1-T12. The lumbar region contains five vertebrae, known as L1-L5. The sacral region is comprised of five vertebrae, known as S1-S5, while the coccygeal region contains four vertebrae, known as Co1-Co4.

Figure 2 depicts a superior plan view of a normal human lumbar vertebra 12. Although human lumbar vertebrae vary somewhat according to location, they share many common features. Each vertebra 12 includes a vertebral body 14. Two short bones, the pedicles 16, extend backward from each side of the vertebral body 14 to form a vertebral arch 18.

At the posterior end of each pedicle 16, the vertebral arch 18 flares out into broad plates of bone known as the laminae 20. The laminae 20 fuse with each other to form a spinous process 22. The spinous process 22 serves for muscle and ligamentous attachment. A smooth transition from the pedicles 16 to the laminae 20 is interrupted by the formation of a series of processes.

Two transverse processes 24 thrust out laterally on each side from the junction of the pedicle 16 with the lamina 20. The transverse processes 24 serve as levers for the attachment of muscles to the vertebrae 12. Four articular processes, two superior 26 and two inferior 28, also rise from the junctions of the pedicles 16 and the laminae 20. The superior articular processes 26 are sharp oval plates of bone rising upward on each side of the vertebrae, while the inferior processes 28 are oval plates of bone that jut downward on each side.

The superior and inferior articular processes 26 and 28 each have a natural bony structure known as a facet. The superior articular facet 30 faces upward, while the inferior articular facet 31 (see Figure 3) faces downward. When adjacent vertebrae 12 are aligned, the facets 30 and 31, capped with a smooth articular cartilage, interlock to form a facet joint 32, also known as a zygapophyseal joint.

The facet joint 32 is composed of a superior half and an inferior half. The superior half is formed by the vertebral level below the joint 32, and the inferior half is formed by the vertebral level above the joint 32. For example, in the L4-L5 facet joint, the superior half of the joint 32 is formed by bony structure on the L5 vertebra (i.e., a superior articular surface and supporting bone 26 on the L5 vertebra), and the inferior half of the joint 32 is formed by bony structure on the L4 vertebra (i.e., an inferior articular surface and supporting bone 28 on the L4 vertebra).

An intervertebral disc 34 between each adjacent vertebrae 12 permits gliding movement between the vertebrae 12. The structure and alignment of the vertebrae 12 thus permit a range of movement of the vertebrae 12 relative to each other.

Back pain, particularly in the "small of the back" or lumbosacral (L4-S1) region, is a common ailment. In many cases, the pain severely limits a person's functional ability and quality of life. Such pain can result from a variety of spinal pathologies.

Through disease or injury, the laminae, spinous process, articular processes, or facets of one or more vertebral bodies can become damaged, such that the vertebrae no longer articulate or properly align with each other. This can result in an undesired anatomy, loss of mobility, and pain or discomfort.

For example, the vertebral facet joints can be damaged by either traumatic injury or by various disease processes. These disease processes include osteoarthritis, ankylosing spondylolysis, and degenerative spondylolisthesis. The damage to the facet joints often results in pressure on nerves, also called "pinched" nerves, or nerve compression or impingement. The result is pain, misaligned anatomy, and a corresponding loss of mobility. Pressure on nerves can also occur without facet joint pathology, e.g., a herniated disc.

One type of conventional treatment of facet joint pathology is spinal stabilization, also known as intervertebral stabilization. Intervertebral stabilization prevents relative motion between the vertebrae. By preventing movement, pain can be reduced. Stabilization can be accomplished by various methods. One method of stabilization is spinal fusion. Another method of stabilization is fixation of any number of vertebrae to stabilize and prevent movement of the vertebrae.

Another type of conventional treatment is decompressive laminectomy. This procedure involves excision of the laminae to relieve compression of nerves.

These traditional treatments are subject to a variety of limitations and varying success rates. None of the described treatments, however, puts the spine in proper alignment or returns the spine to a desired anatomy or biomechanical functionality. In addition, stabilization techniques hold the vertebrae in a fixed position thereby limiting a person's mobility.

Prostheses, systems, and methods exist which can maintain more spinal biomechanical functionality than the above discussed methods and systems and overcome many of the problems and disadvantages associated with traditional treatments for spine pathologies. One example of such prosthesis is shown in Figure 4. Figure 4 shows an artificial cephalad and caudal facet joint prostheses 36 and 50 for replacing a natural facet joint. Cephalad joint prosthesis 36 replaces the inferior half of a natural facet joint. Cephalad prosthesis 36 has a bearing element 38 with a bearing surface 40. Caudal joint prosthesis 50 replaces the superior half of a natural facet joint. Caudal prosthesis 50 has a bearing element 52 with a bearing surface 54. Conventional fixation elements 56 attach cephalad and caudal facet joint prostheses 36 and 50 to a vertebra in an orientation and position that places bearing surface 40 in approximately the same location as the natural facet joint surface the prosthesis replaces. The prosthesis may also be placed in a location other than the natural facet joint location.

The spinal column permits the following types of movement: flexion, extension, lateral movement, circumduction and rotation. Each movement type represents relative movement between adjacent vertebra or groups of vertebrae. In addition, these relative movements may be simple movements of a single type but it is more likely that a single movement of the spine may result in several movement types or compound movement occurring contemporaneously. In the illustration of Figure 4, this translates into movement between the upper vertebral body 12 attached to the cephalad prosthesis 36 and the lower vertebral body 12 attached to caudal prosthesis 50. The movement of the vertebral bodies 12 can result in large, complex forces being generated and transmitted through the prosthesis. The point or points of contact between the bearing surface 40 of the cephalad prosthesis 36 and the bearing surface 54 of the caudal prosthesis 50 can transmit enormous amounts of force onto both the cephalad and caudal facet joint prostheses 36 and 50. The distance between each conventional fixation element 56 and the point or points of contact serves as a lever arm, thereby applying an enormous amount of axial, lateral and torque forces about each of the conventional fixation elements 56, which act as fulcrums. Thus, cephalad prosthesis 36 experiences a force somewhere on bearing surface 40, which is expressed as axial, lateral and torque forces about the conventional fixation element 56 of the cephalad prosthesis 36; and likewise, caudal prosthesis 50 experiences a force somewhere on bearing surface 54, which is expressed as axial, lateral and torque forces about the conventional fixation element 56 of the caudal prosthesis 50. As a result, enormous amounts of such forces can be generated and must be absorbed by the facet joint prostheses and its anchoring system(s).

The existence of enormous amounts of torque presents significant problems for permanent fixation of facet joint prostheses into vertebra. Over time, this torque can act to loosen conventional fixation elements, ruin the facet joint, and require more surgical intervention to restore the facet joint prostheses in the vertebra.

Thus, what is needed is a solution to the torque problem experienced by facet joints of artificial vertebral prostheses.

SUMMARY OF THE INVENTION

The present invention provides prostheses, systems, and methods designed to replace natural facet joints and possibly part of the lamina at virtually all spinal levels including L1-L2, L2-L3, L3-L4, L4-L5, L5-S1, T11-T12, and T12-L1, using attachment mechanisms for securing the prostheses to the vertebrae. The prostheses, systems, and methods help establish a desired anatomy to a spine and return a desired range of mobility to an individual. The prostheses, systems, and methods also help lessen or alleviate spinal pain by relieving the source nerve compression or impingement.

For the sake of description herein, the prostheses that embody features of the invention are identified as either "cephalad" or "caudal" with relation to the portion of a given natural facet joint they replace. As previously described, a natural facet joint, such as facet joint 32 (Figure 3), has a superior half and an inferior half. In anatomical terms, the superior half of the joint is formed by the vertebral level below the joint, which can thus be called the "caudal" portion of the facet joint because it is closer to the feet of the person. The inferior half of the facet joint is formed by the vertebral level above the joint, which can thus be called the "cephalad" portion of the facet joint because it is closer to the head of the person. Thus, a prosthesis that, in use, replaces the caudal portion of a natural facet joint (i.e., the superior half) will be called a "caudal" prosthesis. Likewise, a prosthesis that, in use, replaces the cephalad portion of a natural facet joint (i.e., the inferior half) will be called a "cephalad" prosthesis.

In one aspect, a vertebral prosthesis includes a first bearing element and a first fixation element coupled to the first bearing element. The first bearing element can be shaped to form a facet joint with a second bearing element. The first fixation element can be inserted into a hole in a vertebra.

The first fixation element can include an anti-rotation element. The anti-rotation element can be coupled to at least a portion of the vertebra. This portion of the vertebra can define the hole in the vertebra. The anti-rotation element can be adapted to resist a rotational force. With no resistance, the rotational force may cause rotation of the first fixation element within the hole in the vertebra.

In some embodiments, the hole in the vertebra may be just one hole. In other embodiments, there may be multiple holes in the vertebra. In the case of multiple holes in the vertebra, the first fixation element can be inserted into just one hole in the vertebra, or into multiple holes in the vertebra. Also in the case of multiple holes in the vertebra, the rotation force may cause rotation of the first fixation element within just one hole in the vertebra, or within multiple holes in the vertebra.

In various embodiments, the second bearing element with which the first bearing element forms a facet joint, can be part of a second prosthesis, or part of a natural vertebra. If the second bearing element is part of a second prosthesis, the second prosthesis can be one of the embodiments discussed herein, or another type of prosthesis.

The fixation element may be secured directly into the vertebral body, or can be attached and/or "fixed" using a supplemental fixation material such as bone cement, allograft tissue, autograft tissue, adhesives, osteo-conductive materials, osteo-inductive materials and/or bone scaffolding materials. In one embodiment, the first fixation element can be enhanced with a bony in-growth surface, such as surfaces created using sintering processes or chemical etching (Tecomet Corporation of Woburn, Mass.) which can help fix the fixation element within a vertebra. The bony in-growth surface can cover a portion or all of the first fixation element.

A width of the prosthesis may be constant, or vary. For example, a width of a proximal end of the first fixation element can exceed a width of a distal end of the first fixation element. A width of a proximal end of the anti-rotation element can exceed a width of a distal end of the anti-rotation element. In an alternate embodiment, a width of a distal end of the first fixation element can exceed a width of a proximal end of the first fixation element

The anti-rotation element can be coupled to the vertebra by being directly connected to the vertebra. The anti-rotation element also can be coupled with at least cement to the vertebra.

In some embodiments, the anti-rotation element includes a wing. The wing can be positioned at a proximal of distal portion of the first fixation element. When the first fixation element is inserted into a first hole or holes in the vertebra, the wing can be inserted into a second hole of the vertebra.

In some embodiments, the anti-rotation element includes a blade. The blade can be positioned at a proximal or distal portion of the first fixation element. When the first fixation element is inserted into a first hole or holes in the vertebra, the blade can also be inserted into the first hole in the vertebra.

In some embodiments, the anti-rotation element includes a paddle. The paddles can be positioned at a distal or proximal portion of the first fixation element. The first fixation element can be straight, or include one or more bends. The anti-rotation element can include one or more grooves positioned distally and/or proximally from the paddle. The anti-rotation element can also include other features, such as one or more wings positioned proximally or distally from the paddle, and/or one or more blades positioned proximally or distally from the paddle.

In some embodiments, the anti-rotation element includes an intersection of three or more projections. The intersection can be positioned at a distal or proximal portion of the first fixation element.

In some embodiments, the anti-rotation element includes a helical projection. The anti-rotation element can include an intersection of two or more helical projections.

In some embodiments, the anti-rotation element includes a longitudinal depression. The longitudinal depression can have a longitudinally varying profile. The longitudinal depressions can be a helical longitudinal depression, a groove, or a flute. The longitudinal depression can help define a spline. The anti-rotation element may further include a perimeter (circumferential) depression. The perimeter depression can be a perimeter undercut.

In some embodiments, the anti-rotation element can include separated members. The first fixation element can include a longitudinal hole. A filling element can be inserted into the longitudinal hole and spread the separated members of the anti-rotation element. The separated members can be positioned at a distal portion of the first fixation element.

In various embodiments, the anti-rotation element can define a hole, into which the first fixation element is inserted. Alternatively, the first fixation element can define a hole into which the anti-rotation element is inserted. In various embodiments, the hole can be tapered (using, for example, a tapered broach) and/or the first fixation element can have a taper. The anti-rotation element can have a taper. The anti-rotation element can be coupled to the first fixation element by an interference fit. The anti-rotation element can include a bend, or be straight. The first fixation element can be straight, or include a bend.

In some embodiments, the anti-rotation element includes one or more proximal projections.

In another aspect, a vertebral prosthesis includes a first bearing element and a first fixation element. The first bearing element can be shaped to form a facet joint with a second bearing element. The first fixation element can be coupled to the first bearing element. The first fixation element can be inserted into a hole in the vertebra. The first fixation element can be shaped to resist a rotational force. With no resistance, the rotational force may cause rotation of the first fixation element within the hole in the vertebra.

In various embodiments, the second bearing element with which the first bearing element forms a facet joint, can be part of a second prosthesis, or part of a natural vertebra. If the second bearing element is part of a second prosthesis, the second prosthesis can be one of the embodiments discussed herein, or another type of prosthesis.

The first fixation element can be enhanced with a bony in-growth surface, which can help fix the fixation element within a vertebra. The bony in-growth surface can cover a portion or the entire first fixation element.

A width of the prosthesis may be constant, or vary. For example, a width of a proximal end of the first fixation element can exceed a width of a distal end of the first fixation element. A width of a proximal end of the anti-rotation element can exceed a width of a distal end of the anti-rotation element. In another embodiment, the width of a distal end of the anti-rotation element can exceed a width of a proximal end of the anti-rotation element

The anti-rotation element can be coupled to the vertebra by being directly connected to the vertebra. The anti-rotation element also can be coupled with at least cement to the vertebra.

In some embodiments, the first fixation element can be shaped with a bend. The first fixation element can have a taper.

In another aspect, a vertebral prosthesis method includes coupling a first bearing element to a first fixation element, coupling an anti-rotation element to the first fixation element (as a feature of the component or as a separate component), and inserting the first fixation element into a hole in the vertebra. The first bearing element can be shaped to form a facet joint with a second bearing element. The anti-rotation element can be adapted to resist a rotational force. With no resistance, the rotational force may cause rotation of the first fixation element within the hole in the vertebra.

In another aspect, a vertebral prosthesis preparation method includes perforating a vertebra with at least a first hole, supporting a perforation guide with a guide support, guiding a perforation tool with the perforation guide, and perforating the vertebra with a second hole (or shaped cavity) aligned by the perforation guide. The first hole can be shaped to receive a prosthetic fixation element. The guide support can be positioned by a portion of the vertebra defining a hole. The second hole can be shaped to receive a first prosthetic anti-rotation element.

In some embodiments, the method can include the step of using the perforation tool while at least partly removing the guide support.

Various embodiments include the step of perforating the vertebra with a third hole aligned by the perforation guide. The third hole can be shaped to receive a second prosthetic anti-rotation element.

In some embodiments, the method can include the step of using the perforation tool while least partly removing the guide support.

The guide support can be inserted while perforating the vertebra with the first hole. The guide support can be inserted after perforating the vertebra with the first hole.

In yet another aspect, a vertebral prosthesis tool includes a guide support and a perforation guide.

The guide support can be stabilized by a first hole of the vertebra. The first hole can be shaped to receive a prosthetic fixation element of the vertebral prosthesis. The vertebral prosthesis can form a facet joint with a second vertebral prosthesis.

The perforation guide can be coupled to the guide support. The perforation guide can guide a perforation tool to perforate the vertebra with a second hole aligned by the perforation guide. The second hole can be shaped to receive a prosthetic anti-rotation element of the vertebral prosthesis.

Other features and advantages of the invention are set forth in the following description and drawings, as well as in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a lateral elevation view of a normal human spinal column;

FIG. 2 is a superior plan view of a normal human lumbar vertebra;

FIG. 3 is a lateral elevation view of adjoining normal human lumbar vertebrae L4 and L5;

FIG. 4 is a perspective view of a cephalad prosthesis for replacing the inferior half of a natural facet joint on a superior vertebral body;

FIGS. 5A and **5B** provide a perspective and proximal sectional view, respectively, of a vertebral prosthesis portion with blades;

FIGS. 6A, **6B**, and **6C** provide a side elevation view, another side elevation view, and a perspective view, respectively, of a vertebral prosthesis portion with a paddle;

FIGS. 7A, 7B, 7C, and **7D** provide a side elevation view, plan view, distal sectional view, and perspective view, respectively, of a vertebral prosthesis portion with a fixation element having a bend and a paddle;

FIGS. 8A, 8B, and **8C** provide a side elevation view, plan view, and perspective view, respectively, of a vertebral prosthesis portion with a fixation element having a bend, a paddle, and additional distally located anti-rotation elements;

FIGS. 9A and **9B** provide a perspective views of a vertebral prosthesis portion with a paddle, straight fixation element, and additional anti-rotation elements;

FIGS. 10A and **10B** provide a perspective view and a distal end view, respectively, of a vertebral prosthesis portion with an intersection of multiple projections;

FIGS. 11A, 11B, 11C, and **11D** provide a side view, a perspective view, another side view, and a distal end view, respectively, of a vertebral prosthesis portion with a helical projection;

FIGS. 12A and **12B** provide a perspective view and a distal end view, respectively, of a vertebral prosthesis portion with two helical projections;

FIGS. 13A and **13B** provide a perspective view and a distal end view, respectively, of a vertebral prosthesis portion with longitudinal depressions;

FIGS. 14A and **14B** provide a perspective view and a distal end view, respectively, of a vertebral prosthesis portion with helical longitudinal depressions and a fixation element with a bend;

FIG. 14C provides a perspective view of a pair of vertebral prosthesis, as in **FIG. 14A** and **14B**, connected by a cross-bar member;

FIGS. 15A, 15B, 15C, and **15D** provide, a side view, an isometric view and a distal end view, a sectional view taken along the line shown in the distal end view **FIG. 15C** respectively, of a vertebral prosthesis portion with tapered longitudinal depressions and perimeter depressions;

FIGS. 16A and **16B** provides a perspective view of a vertebral prosthesis portion with separated members;

FIGS. 17A, 17B, and **17C** provide a perspective view, a side view, and a distal end view, respectively, of a vertebral prosthesis portion with wings;

FIGS. 18A through 18F illustrate different steps in a vertebral prosthesis method for the vertebral prosthesis of **FIGS.. 17A through 17C**;

FIG. 19 is a close up view of the vertebral prosthesis tool used in the method of **FIGS. 18A through 18F**;

FIGS. 20A and 20B show a perspective view and a close-up view, respectively, of a vertebral prosthesis tool for a vertebral prosthesis with proximal anti-rotation features;

FIGS. 21A and 21B show a vertebral prosthesis portion with proximal projections, and the insertion of the prosthesis portion into a vertebra following the vertebral prosthesis tool of **FIGS. 20A and 20B**, respectively;

FIG. 22 is a perspective view of an installed vertebral prosthesis according to an embodiment of the invention where a fixation element is inserted into anti-rotation element;

FIG. 23 is a perspective view of an installed vertebral prosthesis according to another embodiment of the invention where a fixation element is inserted into anti-rotation element; and

FIG. 24 is a perspective view of a vertebral prosthesis portion shaped to resist rotational force.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Although the disclosure presented herein provides details to enable those skilled in the art to practice various embodiments of the invention, the physical embodiments disclosed herein merely exemplify the invention, which may be embodied in other specific structure. Accordingly, while preferred embodiments of the invention are described below, details of the preferred embodiments may be altered without departing from the invention. All embodiments that fall within the meaning and scope of the appended claims, and equivalents thereto, are intended to be embraced by the claims.

Embodiments of the present invention may be used, with advantage, on a wide variety of prosthesis devices, particularly spinal prostheses. Some of these prostheses, systems, and methods are discussed in the following applications entitled: "Facet Arthroplasty Devices And Methods", by Mark A. Reiley, Serial No. 09/693,272, filed October 20, 2000, now U.S. Patent No. 6,610,091, issued August 26, 2003; "Prostheses, Tools And Methods For Replacement Of Natural Facet Joints With Artificial Facet Joint", by Lawrence Jones et al., Serial No. 10/438,295, filed May 14, 2003; "Prostheses, Tools And Methods for Replacement Of Natural Facet Joints With Artificial Facet Joint", by Lawrence Jones et al., Serial No. 10/438,294, filed May 14, 2003; "Prostheses, Tools And Methods For Replacement Of

Natural Facet Joints With Artificial Facet Joint", by Lawrence Jones et al., Serial No. 10/615,417, filed July 8, 2003; "Prosthesis For the Replacement of a Posterior Element of a Vertebrae", by T. Wade Fallin et al., U.S. Patent No. 6,419,703; “"Multiple Facet Joint Replacement", by E. Marlowe Goble et al., U.S. Patent No. 6,565,605; “Facet Joint Replacement"; by E. Marlowe Goble et al., U.S. Patent No. 6,579,319; “Method and Apparatus for Spine Joint Replacement"; by E. Marlowe Goble et al., Serial No. 10/090,293, filed March 4, 2002; and “Polyaxial Adjustment Of Facet Joint Prostheses, by “Mark A. Reiley et al., Serial No. 10/737,705, filed December 15, 2003, all of which are hereby incorporated by reference for all purposes.

FIGS. 5A and 5B show one embodiment of a vertebral prosthesis portion **500** with proximally positioned blades **504** that function as anti-rotation elements. The vertebral prosthesis portion **500** has a proximal portion **502** with a pair of blades **504**. The two blades **504** are positioned on opposite sides of the perimeter of the vertebral prosthesis portion **500**, and are thus positioned apart by about 180 degrees. Also shown is a grooved portion **505** having grooves **506** along the periphery of the vertebral prosthesis portion 500. The illustrated grooved portion **505** has grooves **506** that taper in a proximal direction along the vertebral prosthesis portion **500**. Other groove configurations as possible, for example, see **FIGS. 6A, 6B, 6C, and 9A and 9B** discussed in further detail below. Additionally, there may be embodiments having no grooves. In the illustrated embodiment, a transition section **525** separates the proximal portion **502** from the grooved portion **505**. While the illustrated transition section **525** has a uniform, linear transition from the diameter of the proximal portion **502** to the grooved portion **505**, other transition sections are possible depending upon the relative geometry of the grooved portion **505** and the proximal portion **502**. In one embodiment, the transition section **525** can serve as a cement restrictor, preventing and/or inhibiting cement flow out of the vertebral body. In some embodiments, a transition section **525** may not be used.

Alternative embodiments of the vertebral prosthesis portion **500** may have one blade, three blades, or more blades. Alternative embodiments can also employ a different amount of spacing other than 180 degrees between multiple blades for embodiments with multiple blades, and the spacing can be the same or different between the multiple blades. While the embodiment illustrated in **FIGS. 5A and 5B** illustrates blades **504** separated by convex portions **520**, other configurations are possible. For example, the blades **504** may be separated by concave sections as illustrated, for example, in **FIG. 15D** or in combinations of convex and concave portions. Although the illustrated blades **504** have pointed triangular profiles, alternative embodiments can have rounded points, no points, and/or other profiles of other geometries, such as square, rectangular, trapezoidal, arcuate, etc and combinations thereof. In addition, blades **504** have a uniform incline section **514** and decline section **516** and a single height ridge **518**. Other configurations are possible. For example, the incline and decline sections **514, 516** may be different as in, for example, **FIGS. 17A, 17B and 17C**. In one embodiment, the blades **504** are sufficiently small such that the blades **504** can fit into the same vertebral hole that receives the fixation element. It is to be appreciated that embodiments of the proximal anti-rotation elements of vertebral prosthesis portion **500** may be used in combination with other vertebral prosthesis portions described below. In addition, the advantages of the proximal anti-rotation features of vertebral prosthesis portion **500** may be combined with conventional prosthesis fasteners resulting in a hybrid prosthesis fastener having a conventional distal portion and a proximal portion having anti-rotations feature or features of the vertebral prosthesis portion **500**.

FIGS. 6A, 6B, and 6C show an embodiment of a vertebral prosthesis portion **600** with a paddle **604** and grooves as an anti-rotation element. While desiring not to be bound by theory, it is believed that the wide surface area(s) provided by the anti-rotational paddle embodiments of the present invention provide greater resistance to the torque loads applied to the prosthesis and attempted rotation of the paddle within the vertebra. For example, the additional of surface projections and/or pits can significantly increase the total surface are of the prosthesis, thereby increasing the ability of any adhesion between the prosthesis and the surrounding material (such as bone cement, epoxy or in-growing bony material) to secure the prosthesis in position. As another example, the additional of surface projections and pits can interact with the surrounding material to create a geometric or mechanical "interlock" that resists relative motion between the prosthesis and the surrounding material. As such, the paddle embodiments of the present invention described herein act as improved anti-rotational elements. Similarly, other anti-rotation elements described herein are also used to counteract the torque loads developed within and acting upon various portions of vertebral prosthesis.

The vertebral prosthesis portion **600** has a distal end **601** and a proximal end **602**. The proximal end **602** is configured to accept tooling and instruments to secure the vertebral prosthesis portion **600** into the vertebra and/or to provide an attachment point to another vertebral prosthesis component. A distal portion of a fixation element has a paddle **604** configured to act as an anti-rotation element to prevent the rotation of the vertebral prosthesis portion **600** once implanted into a vertebra. Alternative embodiments of the vertebral prosthesis portion **600** can have multiple paddles. Although the illustrated paddle **604** has a rounded profile, alternative embodiments may have different profiles including, for example, one or more corners. Although the illustrated paddle **604** is flat, alternative embodiments can have nonflat contours, with one or more concave and/or convex features.

FIGS. 6A, 6B, and 6C also illustrate an embodiment of an anti-pull out feature of the vertebral prosthesis portion **600**. Embodiments of the vertebral prosthesis portion **600** also include anti-pull out features. As used herein, an anti-pull out feature refers to an element or combination of elements of a prosthesis portion or fastener acting to mitigate, minimize or counteract forces bearing upon the prosthesis portion or fastener to disengage, loosen, advance, pull or otherwise axially translate the fastener relative to a desired position on or within the vertebra. (For purposes of this disclosure, anti-pullout forces can be interpreted to include, but are not limited to, both "pull" and "push" forces which serve to translate the prosthesis along a longitudinal axis outward or inward relative to the targeted vertebral body.) In the illustrated embodiment, the vertebral prosthesis portion **600** includes a proximal grooved portion **605** having proximal grooves **606** and a distal grooved portion **615** having distal grooves **617**. In the illustrated embodiment, proximal grooves **606** have a proximal tip with a width that increases distally and distal grooves **617** have a nearly constant width terminating in a distal tip. A reduced diameter portion **608** separates the proximal grooved portion **605** from the distal grooved portion **615**. The proximal grooves **606**, distal grooves **617** and reduced diameter section **608** act to increase the surface area of the vertebral prosthesis portion **600**. By increasing the surface area of the vertebral prosthesis portion **600** provides greater attachment between the vertebral prosthesis portion **600** and the vertebra. The greater amount of surface area may be used advantageously with bone cement, bone growth compounds or other materials used to bond the external surfaces the vertebral prosthesis portion **600** to the interior of the vertebra. The greater surface area allows, in embodiments where bone fixation cement is used, more cement to be present along the length and a particularly greater amount of cement or fixation material to be present about the reduced diameter section **608**. The increased amount of cement present adjacent the reduced diameter portion **608** produces a section of increased diameter that counteracts pull out forces. Other configurations, arrangements and geometries of the proximal grooved portion **605**, reduced diameter portion **608**, and distal grooved portion **615** are possible. For example, different groove configurations are possible (e.g., **FIGS. 9A, 13A and 15F**), there may be multiple distal or proximate grooved portions (e.g., **FIG. 15 B**), multiple reduced diameter portions (e.g., **FIG. 15B**) or different paddle configurations (e.g., **FIGS. 7A-7D and FIGS. 8A – 8C**).

FIGS. 7A, 7B, 7C, and 7D show an embodiment of a vertebral prosthesis portion **700** with a fixation element having a bend **710**, and a paddle **704** as an anti-rotation element, similar to the vertebral prosthesis portion shown in **FIGS. 6A, 6B, and 6C**. The vertebral prosthesis portion **700** includes a distal end **701** and a proximal end **703**. The proximal end **703** includes a bearing element **715** for engagement to other portions of the vertebral prosthesis. To accommodate a number of different facet joint prosthesis configurations, the fixation element includes a bend **710** connected to a shaft **735** having a paddle **704** attached thereto.

The vertebral prosthesis portion **700** also illustrates an embodiment of a modular prosthesis fastener concept. For example, in some embodiments, the shaft **735** is detachably fastened to the attachment point **740**. The shaft **735** has a length "l" between the attachment point **740** and the proximate end of the paddle **704**. The shaft **735** is detachably coupled to the attachment point **740** to allow for shafts **735** of different lengths to be used with different configurations of the vertebral prosthesis portion **700** thereby providing a modular vertebral prosthesis. As such, in use, the shaft **735** may be detached from the attachment point **740** and replaced with a shaft **735** having a different length "l" as needed until the proper alignment of the vertebral prosthesis is achieved. Modular components can be attached to the prosthesis using one or more attachments methods well known in the art, including threaded screws, morse tapers, adhesives or set screws.

While the modular concept has been described with regard to the vertebral prosthesis **700**, it is to be appreciated that other embodiments of the vertebral prosthesis portions described herein may have a portion or portions that are detachably coupled in furtherance of the modular vertebral prosthesis concept. For an alternative example, the shaft **735** may be of fixed length and permanently attached to the attachment point **740** while the detachable attachment point is positioned between the shaft **735** and the paddle **704** thereby allowing paddles **704** of different lengths to be used. In yet another alternative, both the shaft and the paddle may have detachable attachment points thereby allowing various shaft lengths and configurations and paddle lengths and configurations to be used in furtherance of the modular vertebral prosthesis concepts described herein. It is to be appreciated that the detachable attachment point may be positioned between any portion or portions of the embodiments of the vertebral prosthesis portions described herein and elsewhere in this patent application.

In an alternate embodiment, one or more sections of the vertebral prosthesis may be made of a deformable or shape-memory material (such as Nitinol or similar materials), which permits the physician to make adjustments to the prosthesis geometry to "form-fit" the implant to the patient's specific anatomy. In the case of Nitinol, the material can be heated or cooled away from the body temperature (depending upon the type of material and it's martensitic/austenitic properties), be deformed to a desired shaped, and then held in the deformed position and allowed to return to the body temperature, thereby "hardening" into the desired shape or form. Such an embodiment would facilitate a reduction in the number of sections or "modules" required for a modular prosthesis, as each module could assume a variety of desired positions.

While the angle of the illustrated bend **710** is acute, other embodiments of the vertebral prosthesis portion **700** can have bend **710** having a right angle or an obtuse angle. Alternative embodiments of the vertebral prosthesis portion **700** may include two, three, or more bends **710**. In the illustrated embodiment, the paddle **704** has a flat surface **720** and a proximal end having a transition portion **730**. The flat surface **720** is illustrated in the same plane in which the fixation element has the bend **710**. In other embodiments, the paddle **704** has a flat surface **720** in another plane, and/or a nonflat contour, with one or more concave and/or convex features or have paddle shapes similar to the distal portions illustrated in **FIGS. 10A, 10B, 13A and 13B**. The transition portion **730** has a width that decreases linearly in a proximal direction. Other configurations of the transition portion **730** are possible for transitioning from the paddle **704** to the shaft **735** of the vertebral prosthesis portion **700**. The alternative shapes of the transition portion include, for example, a non-linear decreasing proximal width, asymmetric portions, curved portions or compound portions.

FIGS. 8A, 8B, and 8C show an embodiment of a vertebral prosthesis portion **800** with a fixation element having a bend **810**, and compound anti-rotational elements included in the paddle **804**. A proximal socket element **807** is attached to the bend **810** by a proximal shaft **850**. A distal shaft **860** couples the bend **810** to the paddle **804**. While the illustrated bend **810** has only a single, acute angle, it is to be appreciated that in other embodiments the bend **810** may have a have a right angle or an obtuse angle and may include two, three, or more bends. Further to the modular and configurable vertebral prosthesis concepts described herein, one or more detachable connections may exist between the various elements of the vertebral prosthesis portion **800**. In addition, elements of different lengths (e.g., shafts **850, 860**), size (e.g., socket **807** and paddle **804**) or angular orientation (e.g., bend **810**, paddle **804**) may be advantageously employed in furtherance of the modular vertebral prosthesis concept.

Embodiments of the vertebral prosthesis portion **800** may have paddle **804** embodiments similar to the paddle embodiments shown and described with regard to vertebral prosthesis portion **700** (see e.g., **FIGS. 7A, 7B, 7C, and 7D**). The paddle **804** may include a flat face similar to face **720** described above, however, other configurations are possible. As illustrated, paddle **804** has a non-flat face **820** that may be convex, concave or have portions that are combinations of convex, concave or flat. Alternatively, the paddle surface **820** may be a flat surface in another plane, and/or a nonflat contour, with one or more concave and/or convex features. As illustrated, the paddle surface **820** is in the same plane in as the bend **810**. In other embodiments, the paddle surface(s) **820** may not be in plane with the bend **810**.

In addition to having paddle surfaces **820** of varying shape than earlier described paddle embodiments, embodiments of the paddle **804** also include compound or more than one anti-rotation elements. As discussed above, the paddle surfaces generally provide an anti-rotation or rotation-resistant component to the vertebral prosthesis. Additionally, embodiments of paddle **804** include other anti-rotational elements such as the enlarged distal tip **812** having grooves **815** and projections **819**. The enlarged distal tip **812** may have one or more grooves **815** positioned distally from the paddle **804**. In some embodiments, the grooves occur in the same plane as the plane of the paddle **804**. In other embodiments, grooves can occur in multiple planes and/or planes that are different from the plane of the paddle **804**. Similarly, the distal tip may have projections **819** in the same or different plane with the faces of paddle **804**. While the illustrated projections **819** appear identical in shape and size and are arranged parallel to the axis of the proximal shaft **860**, it is to be appreciated that the projections **819** may have different configurations. The projections **819** may not all be the same size or have the same overall shape, have an asymmetrical orientation relative to the paddle **804** or be positioned in a non-parallel arrangement with regard to the axis of the proximal shaft **860**.

FIGS. 9A and 9B illustrate an alternative embodiment of a vertebral prosthesis portion having anti-rotation and anti-pullout elements. The paddle **955** and proximal ridges **925, 927** act as anti-rotation elements. The reduced diameter section **940**, grooved sections **930, 945** and reduced shank diameter **920, 922** act as anti-pullout elements. The vertebral prosthesis portions **900** and **990** are similar in many regards to vertebral prosthesis portion **600** if **FIGS. 6A, 6B and 6C**. However, several differences are important. Paddle **955** has a flat face **960** but a rounded, tapered distal end **965** instead of a flat distal edge found on paddle **604** (see **FIG. 6B**). Proximal grooves **935** have a constant width instead of a tapered width (see **FIG. 6A** grooves **606**). Distal grooves **950** have a uniform width and a rounded distal end instead of a distal tip (grooves **617** of **FIG. 6B**).

One notable difference between the prosthesis potions **900, 990** and the prosthesis portion **600** is the addition of the proximal anti-rotation sections **920, 922**. The proximal anti-rotation sections **920, 922** include a shank having a diameter less than the shank **915** and a plurality (two in the illustrated embodiments) of ridges that act as proximal anti-rotation elements. Vertebral prosthesis portion **900** has a proximal anti-rotation portion **920** and ridges **925** having an overall height h_1. Vertebral prosthesis portion **990** has a proximal anti-rotation portion **922** and ridges **927** having an overall height h_2. These embodiments advantageously provide reduced shank sizes thereby allowing for increased cement mantle (if cement is desired), while still providing a mechanical "interlock" with the surrounding tissue that resists prosthesis rotation (In various embodiments, the ridges can desirably engage surrounding cortical bone at the pedicle entry point, which is often stronger than the cancellous bone contained within the vertebral body, although the ridges' engagement with either or both types of bone will serve to resist rotation to varying degrees). In a specific embodiment of the prosthesis portion **900** the height h_1 is 8.25mm and the proximal anti-rotation section diameter is 6.5mm but still maintains a moment of inertia (I_y) equal to that of a 7mm rod. In a specific embodiment if the prosthesis portion **990**, the overall ridge height h_2 is 8.75mm and the proximal anti-rotation section diameter is 6.0mm but the embodiment still maintains a moment of inertia (I_y) equal to that of a 7mm rod.

It is to be appreciated that the vertebral prosthesis portions **900 and 990** may differ from the illustrated embodiments. For example, there may be one or more ridges present in the proximal anti-rotation sections (as opposed to the pair of ridges disclosed above). The additional ridges need not have uniform cross sections or be uniformly spaced about the perimeter of the proximal anti-rotation section. The paddle face **960** may have a different face such as convex, concave or other compound shape or combinations thereof.

FIGS. 10A and 10B show an embodiment of a vertebral prosthesis portion **1000** with an intersection of multiple projections as an anti-rotation element. The distal portion of the fixation element has three projections **1018**. The three projections **1018** meet at an intersection 1020 of the projections. The three projections **1018** meet at the center, as viewed from the distal end. In alternative embodiments multiple projections can meet at an off-center position as viewed from the distal end. The three projections **1018** are positioned equidistantly about the perimeter of the fixation element, and are thus positioned apart by about 120 degrees. Alternative embodiments can have one projection, two projections, four projections, or more projections. Alternative embodiments can also employ a different amount of spacing other than 120 degrees between multiple projections, and the spacing can be the same or different between the multiple projections. Although the illustrated projections **1018** have a trapezoidal profile as viewed from the side of the prosthesis portion, alternative embodiments can have other profiles of other geometries, such as square, rectangular, triangular, etc.

FIGS. 11A, 11B, 11C and 11D illustrate another embodiment of a vertebrae prosthesis portion having a helical projection that acts as an anti-rotation element. **FIGS. 11A, 11B** are right and left side views of a vertebral prosthesis portion **1100**. The vertebral prosthesis portion **1100** has a distal tip **1105** and a proximal fitting **1110**. The proximal fitting **1110** is attached to a shank **1115** and a tapered shaft **1120**. A single step transition section **1130** is used to change diameters from the shank **1115** to the proximal end of the tapered shaft **1120**. A rounded profile ridge **1122** spirals proximally from the distal tip **1105** to the transition section **1130**. While the illustrated embodiment shows the ridge **1122** beginning at the distant tip **1105** and spiraling continuously to the transition section **1130**, other configurations are possible where, for example, the ridge begins at a position proximate to the distal tip **1105** or ends distal to the transition section **1130**. Moreover, the ridge **1122** need not be continuous but may be segmented into a plurality of sections have the same or different lengths. (If desired, the interrupted ridge could additionally act as a "self-locking" feature to resist undesired removal of the prosthesis.) The ridge **1122** need not be of uniform height but may have various heights that increase or decrease in a proximal direction or alternate such as in a sinusoidal pattern. **FIG. 11C** illustrates a view of the vertebral prosthesis **1100** viewed proximally from the distal tip **1105**. The ridge **1122** has a pitch of about one revolution meaning that as the ridge **1122** spirals along the tapered shaft **1120** it traces a path that traverses a single rotation absent the tapered shaft. In alternative embodiments, the ridge **1122** may traverse the tapered shaft **1122** at an increased pitch (more than one revolution) or a decreased pitch (less than one revolution, see e.g. **FIG. 11D**). In addition to changing the pitch, the ridge **1122** may have other cross-sectioned shapes other than rounded such as, for example, a sharp edge or triangular cross section as in **FIG. 11D**.

Vertebral prosthesis portion **1150** illustrates and alternative embodiment of the helical ridge anti-rotation element (**FIG. 11D**). Vertebral prosthesis portion **1150** is similar in many respects to vertebral prosthesis portion **1100** and similar reference numbers have been used for like components. Vertebral prosthesis portion **1150** has a multiple step transition section **1155** between the shank **1115** and the tapered shaft **1160**. The tapered shaft **1160** has a more gradual taper than the taper in tapered shaft **1120**. The ridge **1170** has a sharp edge and a pitch of less than one revolution. Desirably, the transition in the shaft will reduce and/or eliminate the stress concentration or "stress riser" inherent in the diameter transition.

In an alternative embodiment to the single ridge anti-rotation element (**FIGS. 11A-11D**), a vertebral prosthesis portion **1200** may have more than one ridge anti-rotation element (**FIGS. 12A, 12B**). The vertebral prosthesis portion **1200** has a distal tip **1205** and a proximal end **1210**. A shank **1215** is attached to the proximal end **1210** and a stepped transition section **1255**. A tapered shaft **1260** extends from the stepped transition section **1255** to the distal tip **1205**. Two ridges **1222, 1224** project outwardly from the tapered shaft **1260**. Using the orientation at the distal tip **1205** (**FIG. 12B**), the upper ridge **1222** has a rounded top surface and is wider than the lower ridge **1224** that is narrower with a more pronounced or sharper ridge top surface. In the illustrated embodiment, ridges **1222, 1224** have the same pitch of less than one revolution. It is to be appreciated that the ridges **1222, 1224** could have a pitch greater than one or each ridge could have a different pitch or more than two ridges could traverse tapered shaft **1260**. Other alternative ridge configurations as described above with regard to ridges **1122** and **1170** (e.g., **FIGS. 11A, 11D**) are applicable to ridges **1222, 1224**. The ridges **1222, 1224** project from opposite sides of the tapered shaft **1260** and are evenly spaced apart by a separation angle of about 180 degrees. Alternative embodiments can have three ridge or helical projections, four helical projections, or more helical projections. Alternative embodiments and the illustrated embodiment may also employ a separation angle or angles of other than 180 degrees between helical projections and the spacing can be uniform between all projections or be variable and/or different between projections. As described above, the ridges or helical projections may begin at a location on the tapered shaft **1260** proximal to the distal tip **1205** and may end distal to the stepped transition section **1255**.

FIGS. 13A and 13B illustrate an embodiment of a vertebral prosthesis portion **1300** have longitudinal grooves as anti-rotation elements. The vertebral prosthesis portion **1300** has a distal end **1305** and a proximate end **1310** attached to a shank **1320**. A transition section **1325** separates the shank **1320** from the proximal grooved section **1330** having grooves **1335** formed therein. A reduced diameter section **1340** separates the proximal grooved section **1330** from the distal grooved section **1345**. The distal grooved section **1345** has grooves **1350** formed therein. As can be seen more clearly in distal end view of **FIG. 13B**, there are four grooves **1350** in the illustrated embodiment. The groove configuration of vertebral prosthesis portion **1300** differs from earlier described grooves **506**

(**FIG. 5A**), grooves **945**, grooves **935** (**FIG. 9A, 9B**) in a number of ways. The grooves **1350** are much wider and there are fewer of them than in previous embodiments. The grooves **1350** are wider distally and taper proximally to the reduced diameter section **1340**. The grooves **1350** are evenly spaced about the distal grooved section **1345** and have the same rounded cross section (see **FIG. 13B**). However, in alternative embodiments, the grooves **1350** have different spacings and different cross-sectioned shapes.

It is to be appreciated that each of the longitudinal grooves or depressions 1350 has a longitudinally varying profile, narrowing as the groove extends proximally. In alternative embodiments, the longitudinally varying profile can widen or remain constant as the longitudinal depression or groove extends proximally (if desired, they can change in depth as they narrow in width). Although in the illustrated embodiment, all of the longitudinal depressions or grooves **1350** are identical, in other embodiments, the multiple longitudinal depressions can differ, for example by having different profiles, lengths, starting and/or ending points, etc. Alternative embodiments can have one longitudinal depression, two longitudinal depressions, three longitudinal depressions, five longitudinal depressions, or more longitudinal depressions. Alternative embodiments can also employ a different amount of spacing other than 90 degrees between multiple longitudinal depressions for embodiments with multiple longitudinal depressions, and the spacing can be the same or different between the longitudinal depressions.

The proximal grooved section 1330 has fewer grooves 1335 than previously described proximal grooved sections (e.g. **FIG. 5A, 9A and 9B**). There are two grooves **1335** in the proximal grooved section **1330**, although only one is visible in **FIG. 13A**. Grooves **1335** align with a distal groove **1350** in the illustrated embodiment. The grooves **1335** have a groove profile that is wider distally and tapering proximally to a tip at transition section **1325**. It is to be appreciated that alternative embodiments may have one or more grooves **1335** to align one for one with grooves **1350**. In another alternative embodiment, there may be the same number of grooves **1335** as grooves **1350** however, grooves **1335** may be offset radically so as not to align axially with grooves **1350** as illustrated. Both grooves **1350, 1335** need not be parallel to the longitudinal axis if the vertebral prosthesis portion **1300** but may instead be arranged in non-parallel configurations with respect to the longitudinal axis of the vertebral prosthesis portion **1300**.

FIGS. 14A and 14B show an embodiment of a vertebral prosthesis portion **1400** with helical longitudinal depressions as anti-rotation elements and a fixation element with a bend. The illustrated embodiment of the vertebral prosthesis portion **1400** has a distal tip **1404** and a proximal end **1402**. The proximal end **1402** includes a socket element **1407** for further attachment to a vertebral prosthesis. (Alternatively, the element **1407** could comprise a bearing surface for slidably engaging a corresponding bearing surface (not shown) of a caudal portion of a vertebral prosthesis). Proximal shaft **1415** is attached to the socket element **1407** and the bend **1410**. The tapered section **1430** transitions from the proximal shaft **1415** to the distal shaft **1417** [as the proximal shaft **1415** is a different diameter than the distal shaft **1417**.] Other transitions are possible such as a stepped transition (e.g. section 740 of **FIG. 7B**) or no transition if the diameter of the shafts **1415** and **1417** are the same.

The distal shaft **1417** includes a plurality of longitudinal depressions **1423** extending from the distal end **1404** to a point beyond the tapered section **1430**. The proximal end of the longitudinal depressions **1423** has a bulbed section **1460**. The distal shaft **1417** also includes a reduced diameter section **1440**. The reduced diameter section **1440**, longitudinal grooves **1423** and bulbed section **1460** may be used to increase the surface area of the vertebral prosthesis portion **1440** that is, when implanted, within a vertebra of the spine. The increased surface area allows for more area to support the cement mantle for applications using cement or, bony ingrowth for applications using bone ingrowth. It is to be appreciated that the longitudinal grooves **1423** may also be varied as described elsewhere with regard to other grooves and, for example, as described with regard to **FIGS. 13A, 13B, 6A, 6B, 6C and 5A**. In addition, alternative embodiments of bend **1410** are possible as described with regard to **FIGS. 7A-7D** and **FIGS. 8A-8C**.

It is to be appreciated that each of the longitudinal depressions **1423** has a longitudinally varying profile, narrowing as the longitudinal depression extends proximally. In alternative embodiments, the longitudinally varying profile can widen or remain constant as the longitudinal depression extends proximally. Although in the illustrated embodiment all of the longitudinal depressions are identical, in other embodiments, the multiple longitudinal depressions can differ, for example by having different profiles, lengths, starting and/or ending points, etc. Alternative embodiments can have one longitudinal depression, two longitudinal depressions, four longitudinal depressions, five longitudinal depressions, or more longitudinal depressions.

FIG. 14C depicts an alternate embodiment of the vertebral prosthesis of **FIGS. 14A, 14B** in which a pair of prosthesis **1400** are connected by a cross-bar **1405**. Cross-bar **1405** can be a cylindrical member fitting into openings **1409** in each of the shafts **1415** of the prosthesis **1400** (or can be virtually any rigid or semi-rigid member secured between the two prosthesis), and the cross-bar **1405** desirably reduces or prevents rotation of the prosthesis

1400 relative to each other. When both of the prosthesis are secured into a targeted vertebral body through the pedicles (not shown), any torsional loads experienced by an individual prosthesis **1400** will be transferred to the shaft **1415** of the opposing prosthesis by the cross-bar **1405**, which will convert the torsional load to a transverse load acting on the opposing prosthesis. Desirably, the newly loaded prosthesis can resist this transverse force, thereby maintaining the entire structure in a desired position. In this embodiment, the cross-bar therefore "shares" and redistributes the torsional loading experienced by an individual prosthesis, significantly reducing the tendency for an individual prosthesis to rotate.

FIGS. 15A-15D illustrate a vertebral prosthesis portion **1500** having a plurality of grooved portions and reduced diameter portions as anti-rotation elements and anti-pullout elements. The vertebral prosthesis portion **1500** includes a proximal end **1505** and a distal end **1510**. A shank **1515** is connected to the proximal end **1505**. A diameter transition section **1520** is used to step down the diameter from the shank **1515** to the distal grooved section. The transition section **1520** desirably limits or eliminates potential stress concentrations or "risers" which can occur due to this geometry change. Moreover, the transition section **1520** desirably will form a tight fit with the opening formed in the bone, sealing the opening (not shown) and facilitating pressurization of cement or other supplemental fixation material within the bone without cement exiting the opening – thereby ensuring the prosthesis is well-anchored in the fixation material, if used. The vertebrae prosthesis portion **1500** includes three grooved sections: the proximal grooved section **1525** having proximal grooves **1530**, the middle grooved section **1540** having middle grooves **1545** and the distal grooved section having distal grooves **1560**. Additionally, there is provided a proximal reduced diameter section **1535** between the proximal grooved section **1525** and the middle grooved section **1540** and a distal reduced diameter section **1550** between the middle grooved section **1540** and the distal grooved section **1555**.

In the illustrated embodiment, the grooves **1530, 1545** and **1560** are of similar size, shape and orientation. The grooves have a rounded cross section profile best seen in **FIG. 15D** and pronounced or sharp ridges **1565** between adjacent grooves. In addition, middle grooves **1545** and proximal grooves **1530** have a tapered width that decreases proximally. Other groove and reduced diameter configurations, cross section profile and angular orientations are possible and are described above with regard to other grooves and reduced diameter portions in other embodiments as well as described with regard to **FIGS. 6A, 6B, 6C, 14A, 14B, 13A, 13B, 9A and 9B**.

FIGS. 16A and 16B show an embodiment of a vertebral prosthesis fixation element **1600** having separable members **1625** that, when deployed as in **FIG. 16B**, act as anti-rotation and anti-pullout elements to compensate for forces, including torque, applied to the fixation element **1600** when used to secure intervertebral implants. The vertebral prosthesis fixation element **1600** has at least two configurations, stowed **1605** (**FIG. 16A**) and deployed **1610** (**FIG. 16B**). Vertebral prosthesis fixation element **1605** illustrates the separable members **1625** in a stowed configuration and vertebral prosthesis fixation element **1610** illustrates the separable members **1625** in a deployed configuration. The stowed configuration **1605** simplifies the transportation of the vertebral prosthesis fixation element **1600** to the implantation site by maintaining the separable members **1625** in close proximity thereby reducing the overall fixation element size. Inside of the vertebral implantation site, the separable members **1625** are placed into a deployed configuration whereby the separable member ridges **1635** are urged into contact with the surrounding vertebra. The ridges **1635** may be arranged in any orientation relative to the separable member **1625**. Advantageously, when the separable members **1625** are urged into a deployed configuration **1610** and into contact with the surrounding vertebra, the size, shape, and orientation of the ridges **1635** along the separable members **1625** "dig into" or press against the surrounding material and secure the vertebral prosthesis fixation element **1600** into position. More importantly, the size, shape and orientation of the ridges 1635 provide anti-rotation and/or anti-pullout stability to the vertebral prosthesis fixation element **1600**.

In the illustrated embodiments, the distal portion of the vertebral prosthesis fixation element **1600** has four separable members **1625** separated by the longitudinal hole **1626**. The longitudinal hole **1626** permits a filling member **1628** to be inserted from the proximal end of the vertebral prosthesis fixation element **1600**, causing the separable members **1625** to spread apart into the deployed configuration (i.e., vertebral prosthesis fixation element **1610**) with deployed spacing **1640** separating adjacent separable members **1625**. The exterior surface of each separable member **1625** has a plurality of continuous ridges **1635**. Continuous ridges are single ridges that extend along the surface of a separable member from one spacing **1640** to the next adjacent spacing **1640**. It is to be appreciated that the ridges may be segmented ridges meaning more than one ridge between adjacent spacings **1640**. The ridges **1635** in the illustrated embodiment are all continuous and the ridges **1635** on each separable member **1625** are similarly oriented relative to the separable members. It is to be appreciated that other ridge configurations are possible, such as for example, combinations of continuous and segmented ridges on a single separable member, as well as different ridge orientations on the same separable member or different ridge orientations on different separable members. In addition, alternative embodiments can have more or fewer ridges than the illustrated embodiment, or be at least partly smooth.

Additionally, other embodiments of the vertebral prosthesis fixation element **1600** can have two, three, five, or more separable members **1625**. The filling member can be a smooth peg as shown, or alternatively a bar, a wire, or any other shape that, upon insertion into the longitudinal hole **1626**, causes the separable members **1625** to move from a stowed configuration **1605** to a deployed configuration **1610**.

In one embodiment, a vertebral prosthesis fixation element **1600** is used to secure a vertebral prosthesis implanted between two vertebrae to provide restoration of movement between the vertebrae. Features of the vertebral prosthesis fixation element **1600**, such as the shape, size and orientation of the ridges **1635**, advantageously secure the implanted vertebral prosthesis while providing anti-rotation capability for the torques generated within the implanted prosthesis and applied to the vertebral prosthesis fixation element **1600**. In another embodiment, a vertebral prosthesis fixation element **1600** is used to secure at least a portion of a vertebral prosthesis connecting two adjoining vertebrae to restore movement between the adjoining vertebrae. In this embodiment, when the separable members are in a deployed configuration, at least a portion of the ridges on at least one separable member engages the surrounding vertebrae and counteracts the forces generated by relative motion between the adjoined vertebrae, and/or the forces generated between the vertebral prosthesis and the vertebrae attached to the vertebral prosthesis.

FIGS. 17A, 17B, and 17C show an embodiment of a vertebral prosthesis portion with wings as anti-rotation elements. The two wings **1730** are positioned on opposite sides of the perimeter of the fixation element, and are thus positioned apart by about 180 degrees. Alternative embodiments can have one wing, three wings, or more wings. Alternative embodiments can also employ a different amount of spacing other than 180 degrees between multiple wings for embodiments with multiple wings, and the spacing can be the same or different between the multiple wings. Although the illustrated wings **1730** have pointed triangular profiles, alternative embodiments can have rounded points, no points, and/or other profiles of other geometries, such as square, rectangular, trapezoidal, etc. In one embodiment, the wings **1730** can be sufficiently large such that the blades **1730** could fit into laterally extending slots (not shown) extending outward from to the vertebral hole that receives the fixation element.

FIGS. 18A through 18F illustrate an embodiment of a vertebral prosthesis placement method for the vertebral prosthesis of **FIGS. 17A** through **17C**. In **FIG. 18A**, the vertebra **1832** is perforated with a perforation tool **1831** to make a hole. The hole is large enough to receive a fixation element of a vertebral prosthesis. Although a drill is shown as the perforation tool, other perforation tools can be used, such as an auger, a laser, a broach, etc. **FIG. 18B** shows guide supports **1834** and **1835** of various lengths which can be chosen depending on the depth of the hole made by the perforation tool. The guide supports **1834** and **1835** are sized large enough such that the vertebra hole stabilizes the particular guide support that is inserted into the vertebra hole. For example, guide supports **1834** and **1835** can include increased-diameter sections **1830** which optimize centering in the vertebra hole. In alternative embodiments, the guide support and perforation tool can be the same, such that the perforation tool does not have to be removed after perforating the vertebra and the perforation tool also can be used as a guide support. **FIG. 18C** shows the guide support **1834** inserted into the hole made by the perforation tool. A perforation guide **1836** and a handle **1838** are attached to the guide support **1834**. **FIG. 18D** shows a perforation tool **1831** guided by the perforation guide **1836**. Guided by the perforation guide **1836**, the vertebra **1832** is perforated with another hole. The perforation stop **1839** on the perforation tool **1831** strikes the perforation guide **1836**, thereby stopping the perforation and defining the depth of that hole. **FIG. 18E** shows another perforation process aided by the perforation guide **1836**. **FIG. 18F** shows that as the assembly of the handle **1838**, perforation guide **1836**, and guide support **1834** is removed from the vertebra, the perforation tool **1831** can be used to remove the remainder of bone from the vertebra. This can be repeated for each of the holes.

FIG. 19 is a close up view of the embodiment of the vertebral prosthesis tool used in the method of **FIGS. 18A** through **18F**. Perforation guide **1936** has an anti-rotation flat **1944** to ensure alignment of the perforation tools **1931**. Locking hex nuts **1942** allow the physician to adjust the depth of the perforation tools if necessary.

FIG. 20A and **20B** show an embodiment of a vertebral prosthesis tool for the vertebral prosthesis with proximal projections as anti-rotation elements. Perforation guide **2036** is attached to guide support **2034**. In this embodiment, the guide support **2034** includes a perforation tool **2031**. In alternative embodiments, the guide support and perforation tool can be distinct, such that the perforation tool is removed after perforating the vertebra, and replaced with a guide support.

FIG. 21A shows an embodiment of a vertebral prosthesis portion with proximal projections. In alternative embodiments, the projections can be blades and/or wings.

Alternative embodiments can have one projection, three projections, or more projections. The two proximal projections **2116** are positioned on opposite sides of the perimeter of the proximal portion of the fixation element, and are thus positioned apart by about 180 degrees. Alternative embodiments can also employ a different amount of spacing other than 180 degrees between multiple proximal projections for embodiments with multiple proximal projections, and the spacing can be the same or different between the multiple proximal projections. **FIG. 21B** shows the insertion of the prosthesis portion of **FIG. 21A** into a vertebra following the use of the vertebral prosthesis tool of **FIGS. 20A and 20B**.

FIG. 22 is a perspective view of an installed vertebral prosthesis according to an embodiment of the invention where a fixation element is inserted into an anti-rotation element. The anti-rotation element **2241** defines a hole, into which the fixation element **2243**, shown as a screw, is inserted into. Both the hole defined by the anti-rotation element **2241** and the fixation element **2243** have a taper **2245**, which can be a Morse taper, if desired. The anti-rotation element **2241** and the fixation element **2243** can thereby couple together with an interference fit when the fixation element **2243** is inserted into the anti-rotation element **2241**. In various embodiments, the anti-rotation element can include a bend, or be straight; and the first fixation element can be straight, or include a bend. The bend can be sharp or gradual. In alternative embodiments, the first fixation element can define a hole into which the anti-rotation element is inserted.

FIG. 23 is a perspective view of an installed vertebral prosthesis according to another embodiment of the invention where a fixation element is inserted into anti-rotation element, similar to the embodiment of **FIG. 22**. The fixation element **2343** is a stem. In other embodiments, the fixation element and the anti-rotation element can be a corkscrew, wire, staple, adhesive, bone, and other materials known in the prosthetic arts.

FIG. 24 is a perspective view of a vertebral prosthesis portion shaped to primarily resist rotational force. The shape of the fixation element **2400** has a bend. Also shown is a longitudinal depression **2423** and proximal projections **2416**. Alternative embodiments can have neither the longitudinal depression **2423** nor the proximal projections **2416**. Some alternative embodiments include limited anti-rotation elements, relying primarily on the non-uniform shape of the fixation element to resist rotation. Other embodiments can include anti-rotation elements other than longitudinal depressions and proximal projections.

For purposes of illustration and explanation of the anti-rotation and/or anti-pullout advantages of embodiments of the present invention, vertebral prosthesis portions have been illustrated and described in axial shaft configurations (e.g., **FIGS.. 6A-6C, 9A-9B, 10A, 11A-**

13B) and curved shaft configurations (e.g., **FIGS. 7A-8C, 14A-14B, and 22-24**). It is to be appreciated that the anti-rotation and anti-pull out embodiments described in each are not limited to only the illustrated and described embodiments but are applicable to other different embodiments, as a substitute to or combination with the described and illustrated embodiment. For clarity, the various embodiments of the invention have been referred to as portions of a vertebral prosthesis having anti-rotation and/or anti-pull out elements. It is to be appreciated that while these elements provide the additional advantages described herein, these elements are also fasteners that act generally to secure the various loading elements and components of the prosthesis to the spine.

While preferred embodiments of the invention have been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

CLAIMS

What is claimed is:

1. A vertebral prosthesis, comprising:

a first bearing element shaped to form a facet joint with a second bearing element; and

a first fixation element adapted to be coupled to the first bearing element, the first fixation element adapted to be inserted into one or more holes in a vertebra, the first fixation element including:

an anti-rotation element coupled to at least a portion of the vertebra defining the one or more holes in the vertebra, the anti-rotation element being adapted to resist a rotational force from causing rotation of the first fixation element within a hole in the vertebra.

2. The prosthesis of claim 1, wherein the second bearing element is part of a second prosthesis.

3. The prosthesis of claim 1, wherein the second bearing element is part of a natural vertebra.

4. The prosthesis of claim 1, further comprising:

a bony in-growth surface on at least part of the first fixation element.

5. The prosthesis of claim 1, wherein a width of a proximal end of the first fixation element exceeds a width of a distal end of the first fixation element.

6. The prosthesis of claim 1, wherein a width of a proximal end of the anti-rotation element exceeds a width of a distal end of the anti-rotation element.

7. The prosthesis of claim 1, wherein the anti-rotation element is directly connected to at least the portion of the vertebra defining the one or more holes in the vertebra.

8. The prosthesis of claim 1, wherein the anti-rotation element is coupled with at least cement to at least the portion of the vertebra defining the one or more holes in the vertebra.

9. The prosthesis of claim 1, wherein the anti-rotation element includes one or more wings.

10. The prosthesis of claim 9, wherein at least one of the one or more wings is positioned at a proximal portion of the first fixation element.

11. The prosthesis of claim 9, wherein the first fixation element is inserted into a first hole of the one or more holes in the vertebra, and at least one of the one or more wings is inserted into at least a second hole of the one or more holes in the vertebra.

12. The prosthesis of claim 1, wherein the anti-rotation element includes one or more blades.

13. The prosthesis of claim 12, wherein at least one of the one or more blades is positioned at a proximal portion of the first fixation element.

14. The prosthesis of claim 12, wherein the first fixation element is inserted into a first hole of the one or more holes in the vertebra, and at least one of the one or more blades is inserted into at least the first hole of the one or more holes in the vertebra.

15. The prosthesis of claim 1, wherein the anti-rotation element includes one or more paddles.

16. The prosthesis of claim 15, wherein at least one of the one or more paddles is positioned at a distal portion of the first fixation element.

17. The prosthesis of claim 15, wherein the first fixation element is straight.

18. The prosthesis of claim 15, wherein the first fixation element includes one or more bends.

19. The prosthesis of claim 15, wherein the anti-rotation element includes one or more grooves positioned distally from at least one of the one or more paddles.

20. The prosthesis of claim 15, wherein the anti-rotation element includes one or more grooves positioned proximally from at least one of the one or more paddles.

21. The prosthesis of claim 15, the anti-rotation element includes one or more wings positioned proximally from at least one of the one or more paddles

22. The prosthesis of claim 15, the anti-rotation element includes one or more blades positioned proximally from at least one of the one or more paddles

23. The prosthesis of claim 1, wherein the anti-rotation element includes one or more intersections of three or more projections.

24. The prosthesis of claim 23, wherein at least one of the one or more intersections is positioned at a distal portion of the first fixation element.

25. The prosthesis of claim 1, wherein the anti-rotation element includes one or more helical projections.

26. The prosthesis of claim 25, wherein the anti-rotation element includes one or more intersections of two or more helical projections.

27. The prosthesis of claim 1, wherein the anti-rotation element includes one or more longitudinal depressions.

28. The prosthesis of claim 27, wherein at least one of the one or more longitudinal depressions has a longitudinally varying profile.

29. The prosthesis of claim 27, wherein at least one of the one or more longitudinal depressions is a helical longitudinal depression.

30. The prosthesis of claim 27, wherein the anti-rotation element includes one or more perimeter depressions.

31. The prosthesis of claim 30, wherein at least one of the one or more perimeter depressions is a perimeter undercut.

32. The prosthesis of claim 27, wherein at least one of the one or more longitudinal depressions is a groove.

33. The prosthesis of claim 27, wherein the one or more longitudinal depressions defines one or more splines.

34. The prosthesis of claim 27, wherein at least one of the one or more longitudinal depressions is a flute.

35. The prosthesis of claim 1, wherein the anti-rotation element includes a plurality of separated members.

36. The prosthesis of claim 35, wherein the first fixation element includes a longitudinal hole.

37. The prosthesis of claim 36, further comprising:
a filling element inserted into the longitudinal hole and spreading the plurality of separated members of the anti-rotation element.

38. The prosthesis of claim 37, wherein the plurality of separated members is positioned at a distal portion of the first fixation element

39. The prosthesis of claim 1, wherein the anti-rotation element includes one or more proximal projections.

40. The prosthesis of claim 1, wherein the anti-rotation element defines one or more holes, and the first fixation element is inserted into at least one of the one or more holes defined by the anti-rotation element.

41. The prosthesis of claim 1, wherein the first fixation element defines one or more holes, and the anti-rotation element is inserted into at least one of the one or more holes defined by the first fixation element.

42. The prosthesis of claim 1, wherein at least part of the first fixation element has a taper.

43. The prosthesis of claim 1, wherein at least part of the anti-rotation element has a taper.

44. The prosthesis of claim 1, wherein the anti-rotation element is coupled to the first fixation element by at least an interference fit.

45. The prosthesis of claim 1, wherein the anti-rotation element includes one or more bends.

46. The prosthesis of claim 1, wherein the anti-rotation element is straight.

47. The prosthesis of claim 1, wherein the first fixation element is straight.

48. The prosthesis of claim 1, wherein the first fixation element includes one or more bends.

49. A vertebral prosthesis, comprising:

a first bearing element shaped to form a facet joint with a second bearing element; and

a first fixation element coupled to the first bearing element, the first fixation element inserted into one or more holes in a vertebra, the first fixation element shaped to resist a rotational force from causing rotation of the first fixation element within at least one of the one or more holes in the vertebra.

50. The prosthesis of claim 49, wherein the second bearing element is part of a second prosthesis.

51. The prosthesis of claim 49, wherein the second bearing element is part of a natural vertebra.

52. The prosthesis of claim 49, further comprising:

a bony in-growth surface on at least part of the first fixation element.

53. The prosthesis of claim 49, wherein a width of a proximal end of the first fixation element exceeds a width of a distal end of the first fixation element.

54. The prosthesis of claim 49, wherein the anti-rotation element is directly connected to at least the portion of the vertebra defining the one or more holes in the vertebra.

55. The prosthesis of claim 49, wherein the anti-rotation element is coupled with at least cement to at least the portion of the vertebra defining the one or more holes in the vertebra.

56. The prosthesis of claim 49, wherein the first fixation element is shaped with one or more bends.

57. The prosthesis of claim 49, wherein at least part of the first fixation element has a taper.

58. A vertebral prosthesis method, comprising:

coupling a first bearing element to a first fixation element, the first bearing element shaped to form a facet joint with a second bearing element;

coupling an anti-rotation element to the first fixation element, the anti-rotation element being adapted to resist a rotational force from causing rotation of the first fixation element within at least one of the one or more holes in the vertebra; and inserting the first fixation element at least partly into one or more holes in a vertebra.

59. A vertebral prosthesis tool, comprising:

a guide support stabilized at least partly by a portion of a vertebra defining at least a first hole shaped to receive a prosthetic fixation element of a vertebral prosthesis, the vertebral prosthesis forming a facet joint with a second vertebral prosthesis; and

a perforation guide coupled to the guide support, the perforation guide guiding a perforation tool to perforate the vertebra with at least a second hole aligned by the perforation guide, the second hole shaped to receive a prosthetic anti-rotation element of the vertebral prosthesis.

60. A vertebral prosthesis fastener for securing at least a portion of prosthesis to one of adjoining vertebrae, comprising:

a body having a distal end that includes at least one separable member, the at least one separable member positionable between a stowed configuration and a deployed configuration;

at least one ridge formed along the surface of the at least one separable member, the at least one ridge being adapted to engage with a vertebrae so as to counteract a force generated by the relative movement between the adjoining vertebrae.

61. A vertebral prosthesis fastener according to claim 60 wherein the at least one ridge is adapted to engage with a vertebrae so as to counteract a force comprising torque that is generated by the relative movement between the adjoining vertebrae.

62. A vertebral prosthesis fastener according to claim 60 wherein the at least one ridge is adapted to engage with a vertebrae so as to counteract a force comprising a rotational element that is generated by the relative movement between the adjoining vertebrae.

63. A vertebral prosthesis fastener according to claim 60 wherein the at least one ridge is a continuous ridge.

64. A vertebral prosthesis fastener according to claim 60 wherein the at least one ridge is a segmented ridge.

65. A vertebral prosthesis, comprising:

a first bearing element shaped to form a facet joint with a second bearing element; and

a first fixation element coupled to the first bearing element, the first fixation element adapted for insertion into a hole formed in a vertebra, the first fixation element including an anti-rotation element adapted to engage with at least a portion of the vertebra when disposed within a hole formed in a vertebra and to resist a rotational force from causing rotation of the first fixation element relative to the vertebra.

66. A vertebral prosthesis according to claim 65 wherein the vertebral prosthesis is implanted between adjoined vertebrae.

67. A vertebral prosthesis according to claim 66 wherein the rotational force results from relative movement between the adjoined vertebrae.

68. A vertebral prosthesis according to claim 65 wherein the anti-rotational element comprises one or more wings.

69. A vertebral prosthesis according to claim 65 wherein the anti-rotational element comprises one or more paddles.

70. A vertebral prosthesis according to claim 65 wherein the anti-rotational element comprises one or more bends.

71. A vertebral prosthesis according to claim 65 wherein the anti-rotational element comprises one or more helical projections.

72. A vertebral prosthesis, comprising:

a first bearing element shaped to form a facet joint with a second bearing element; and

a first fixation element adapted to be coupled to the first bearing element, the first fixation element adapted to be inserted into one or more holes in a vertebra and having a moment arm perpendicular to the axis of the fixation element, the first fixation element including:

an anti-rotation element coupled to at least a portion of the vertebra defining the one or more holes in the vertebra, the anti-rotation element being adapted to resist a rotational force generated by the moment arm from causing rotation of the first fixation element relative to the vertebra.

73. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a paddle.

74. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a longitudinal groove.

75. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a plurality of projections.

76. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a distal paddle and a proximal ridge.

77. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a plurality of paddles.

78. A vertebral prosthesis according to claim 72 wherein the anti-rotation element comprises a curved shaft and a helical longitudinal groove.

79. A vertebral prosthesis according to any of clams 73 to 78 further comprising an anti-pull out element.

80. A vertebral prosthesis according to claim 79 wherein the anti-pull out element is a reduced diameter portion of the fixation element.

81. A vertebral prosthesis according to claim 79 wherein the anti-pull out element is groove formed along the surface of the fixation element.

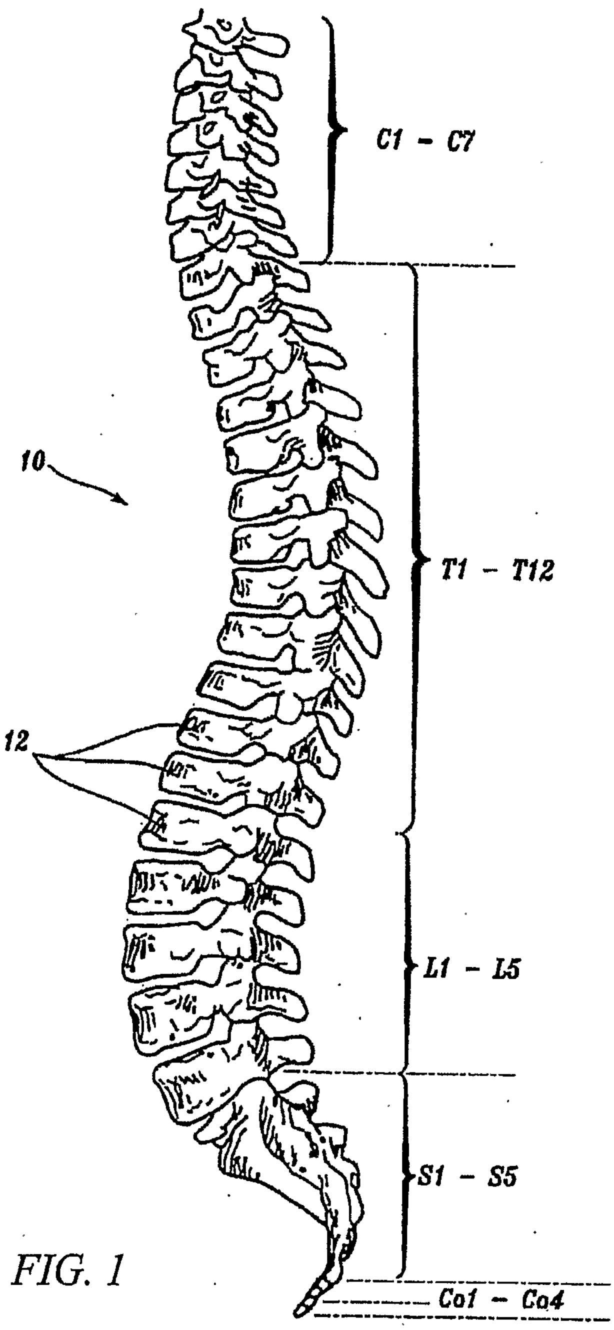

FIG. 1

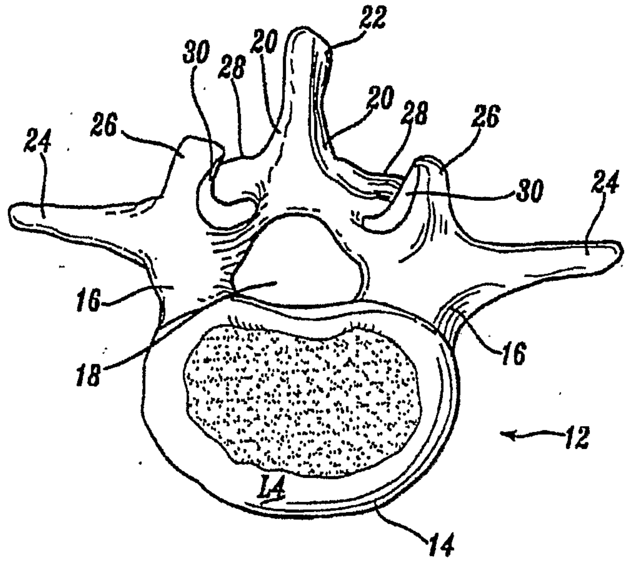
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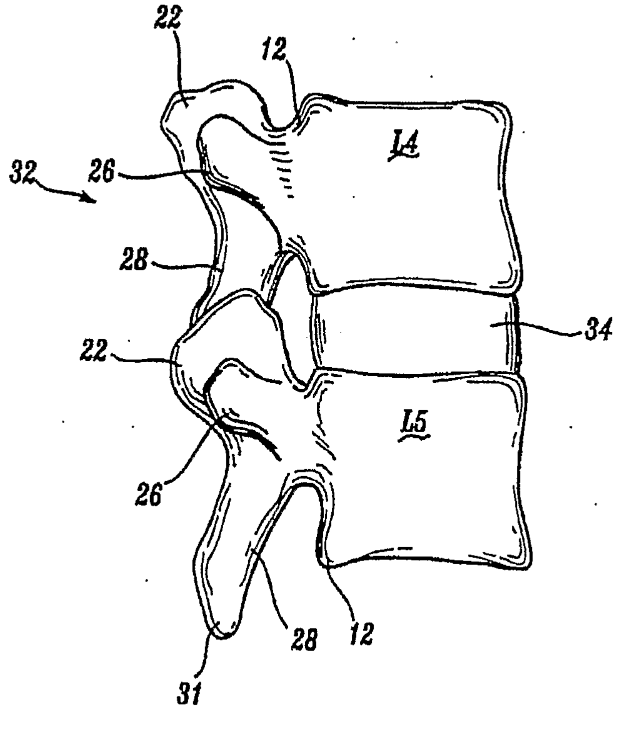
FIG. 2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L5
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31

FIG. 3

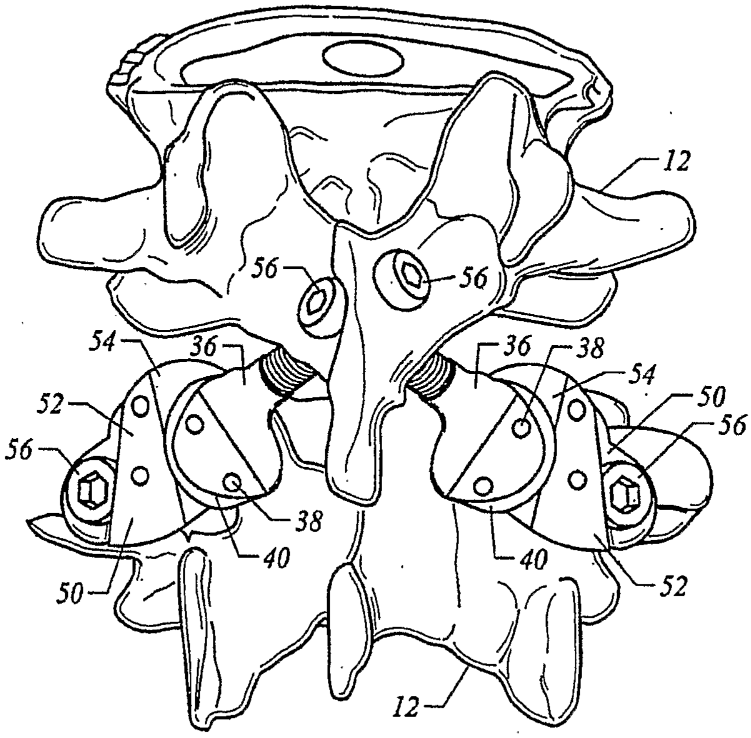

FIG. 4

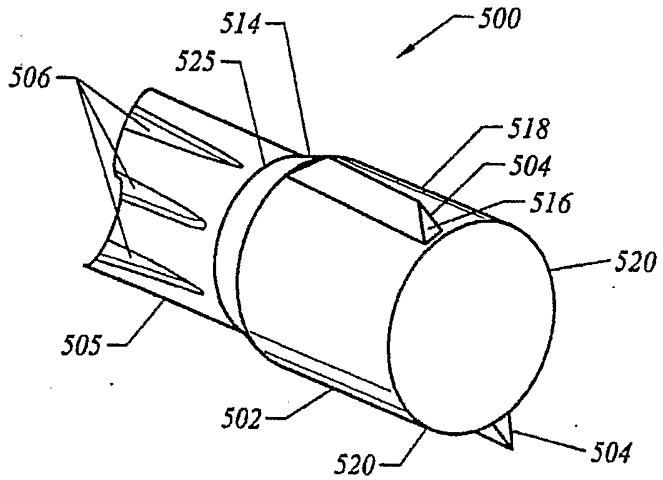
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FIG. 5A

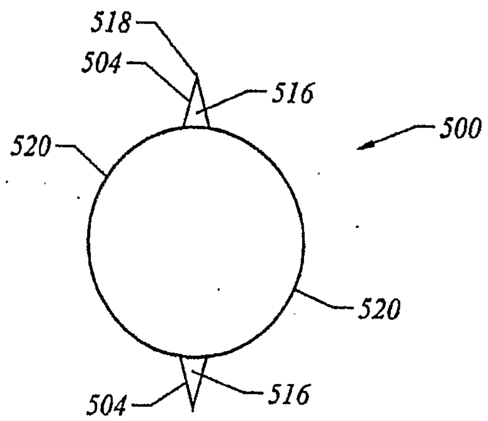
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FIG. 5B

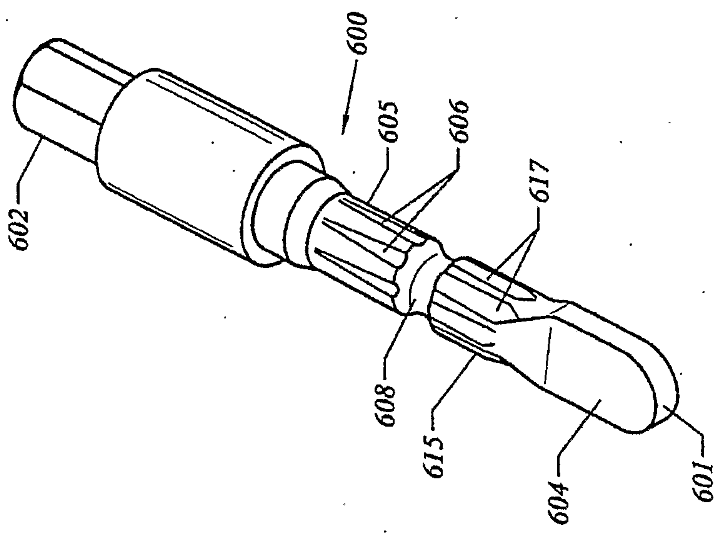

FIG. 6C

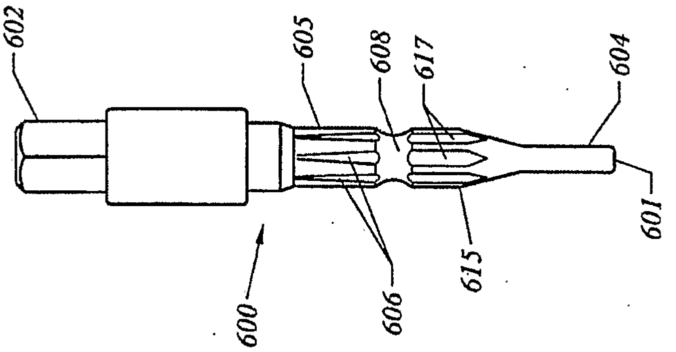

FIG. 6B

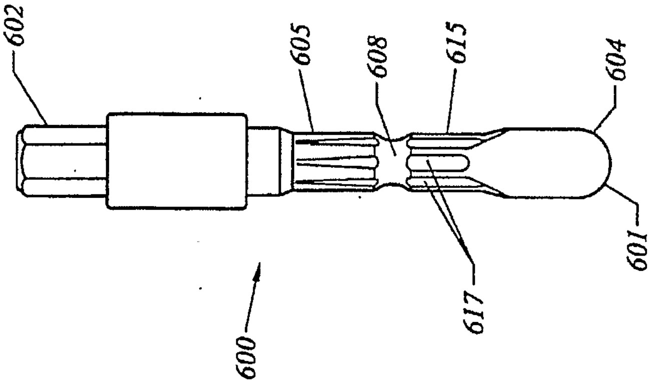

FIG. 6A

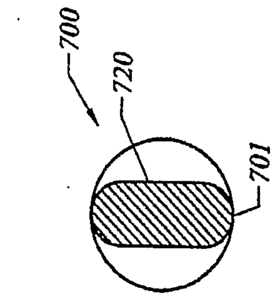

FIG. 7C

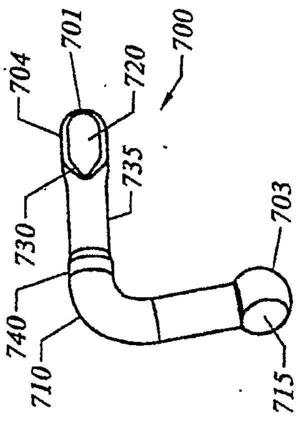

FIG. 7D

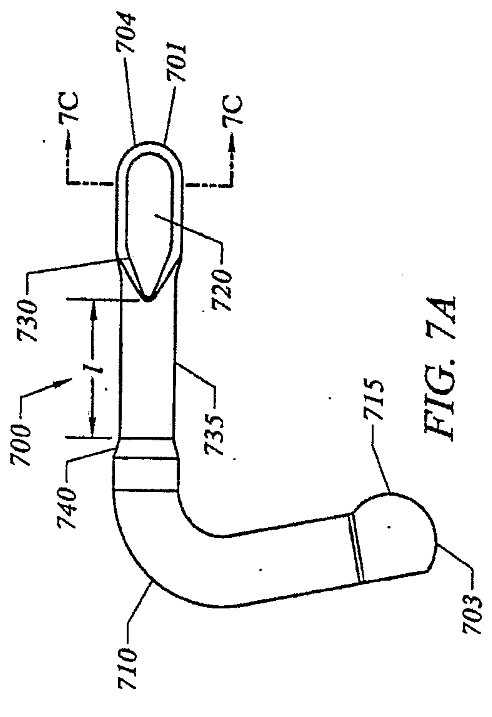

FIG. 7A

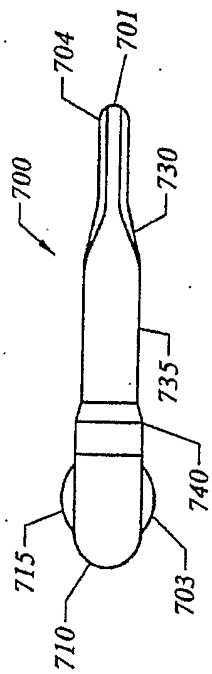

FIG. 7B

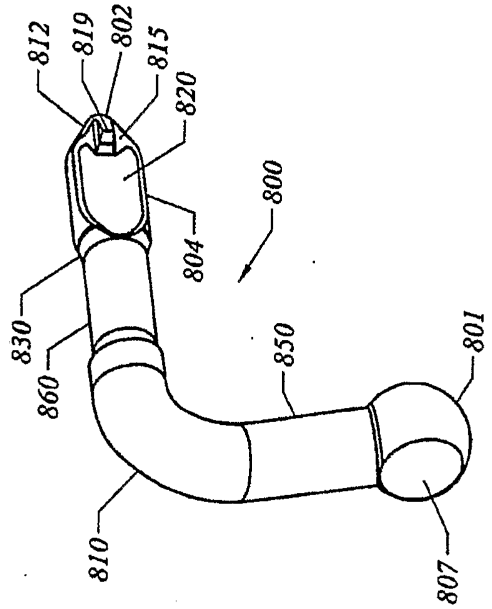

FIG. 8C

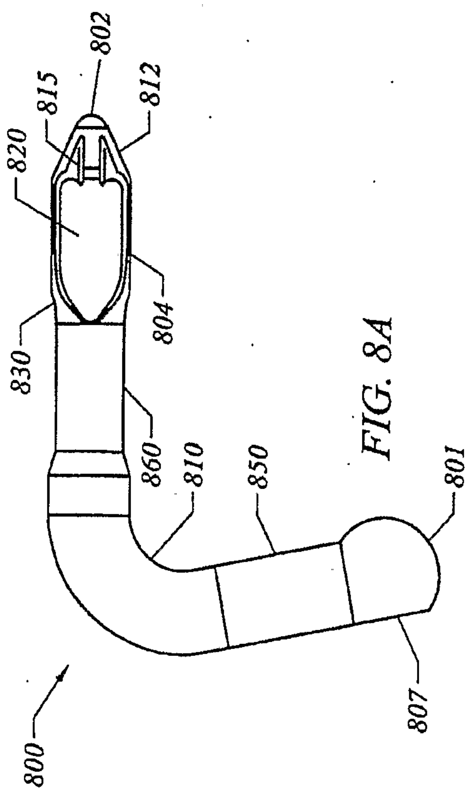

FIG. 8A

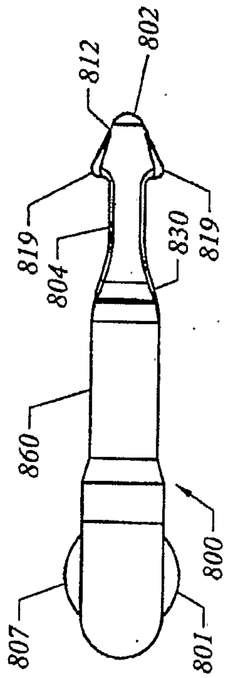

FIG. 8B

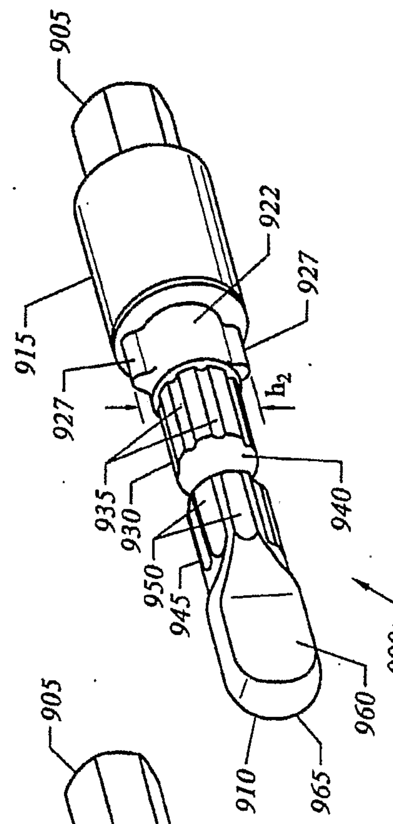
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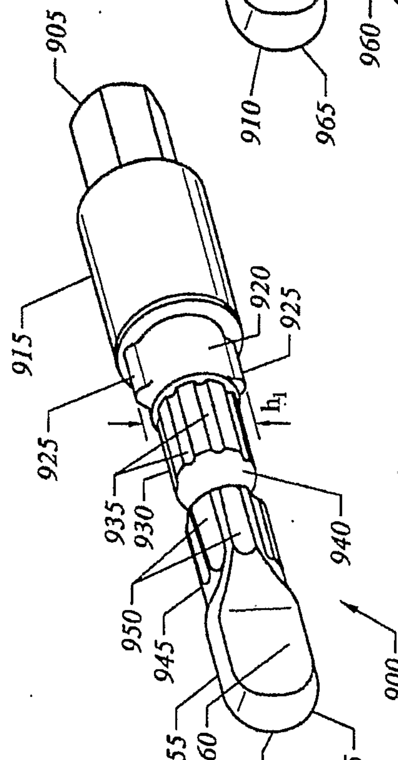
FIG. 9B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945
900
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910
965

FIG. 9A

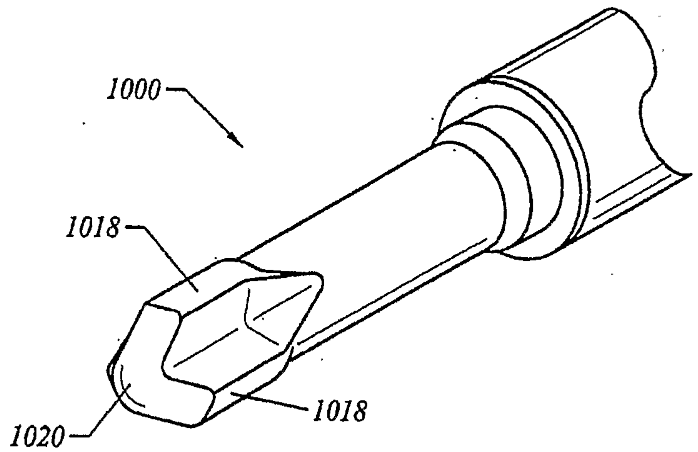

FIG. 10A

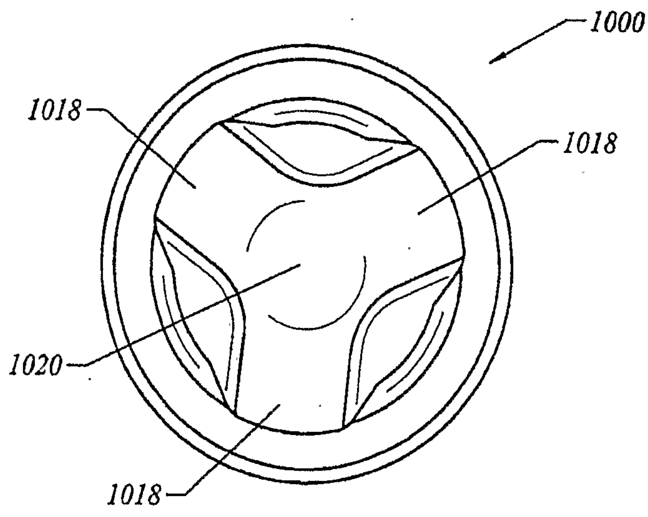

FIG. 10B

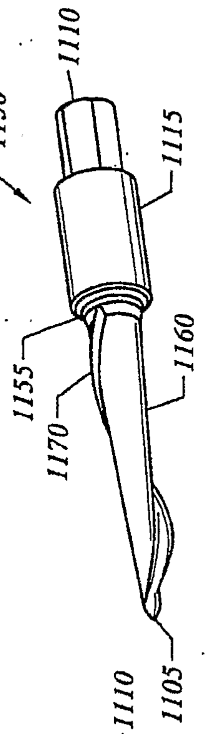

FIG. 11D

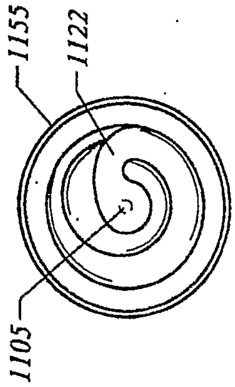

FIG. 11C

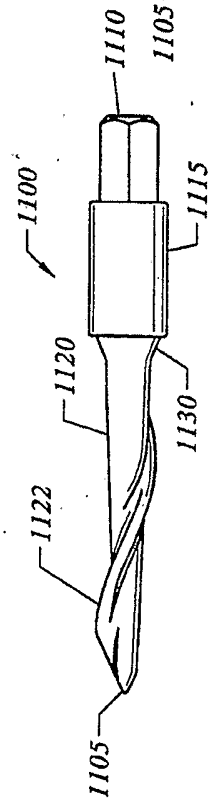

FIG. 11A

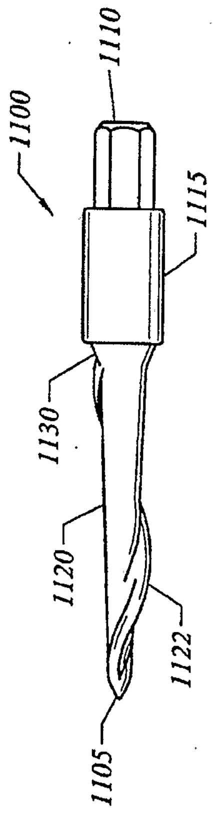

FIG. 11B

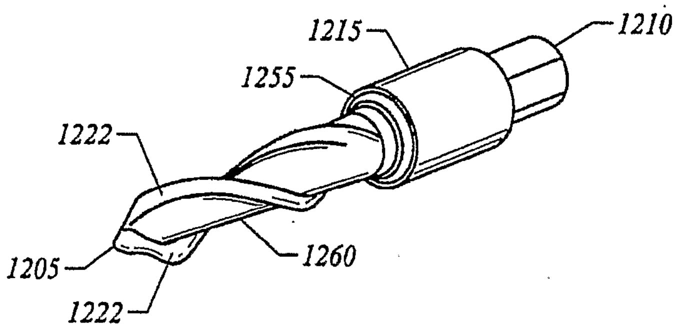

FIG. 12A

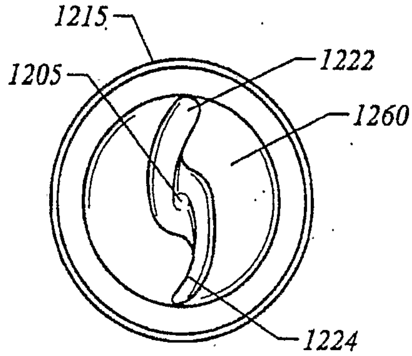

FIG. 12B

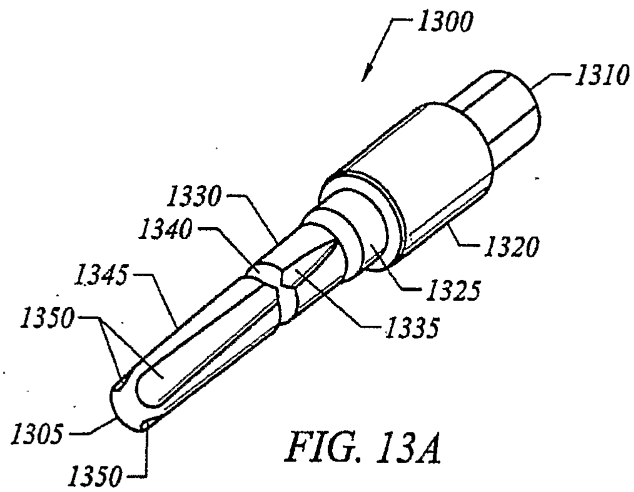

FIG. 13A

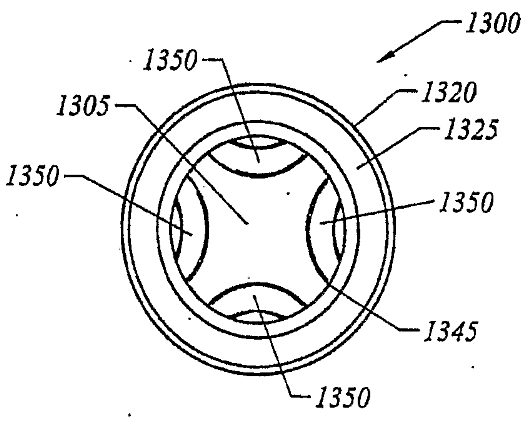

FIG. 13B

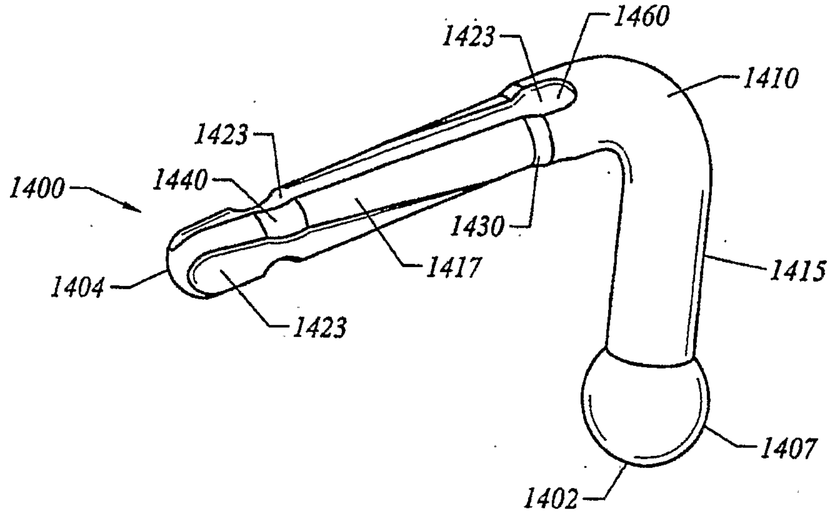

FIG. 14A

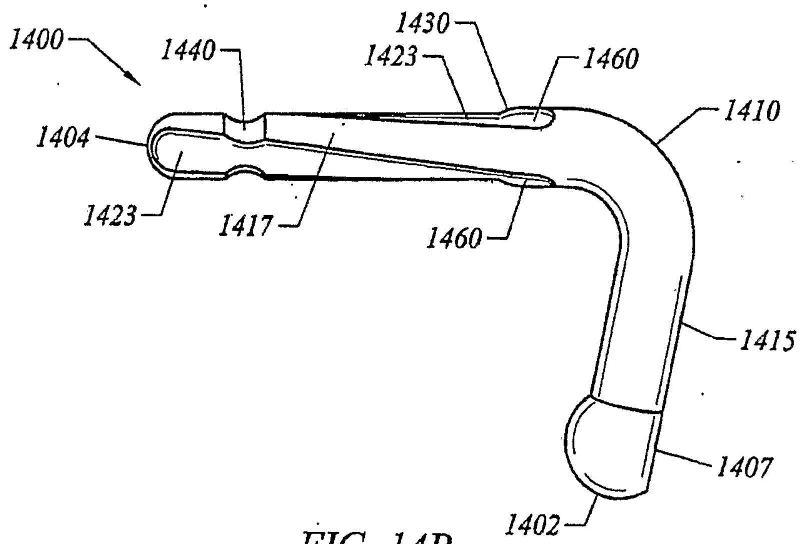

FIG. 14B

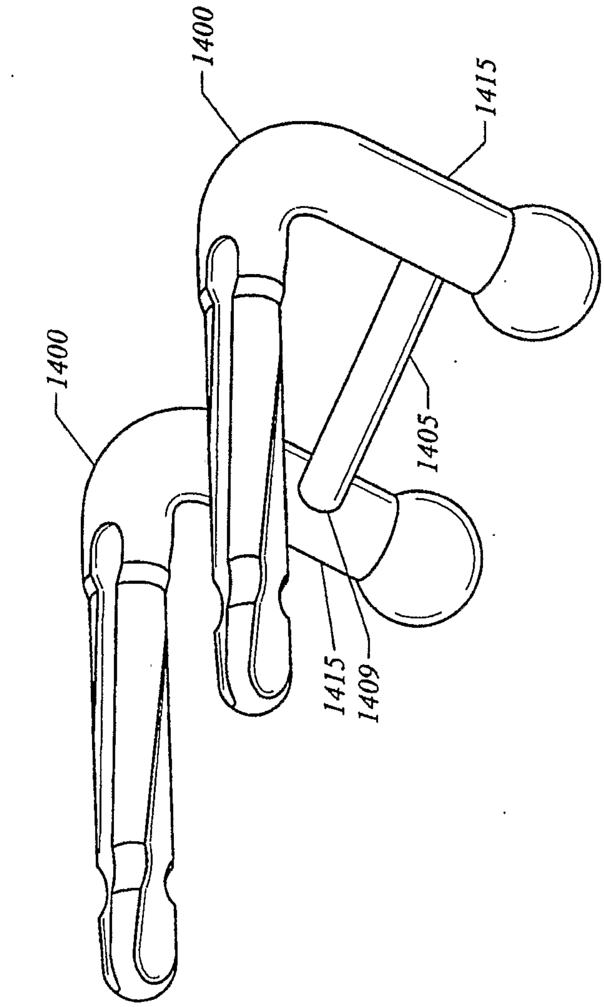

FIG. 14C

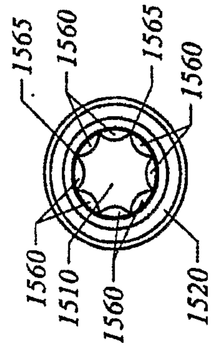

FIG. 15C

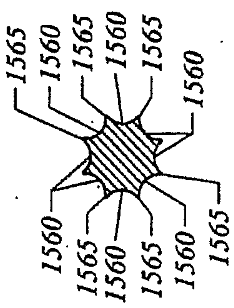

FIG. 15D

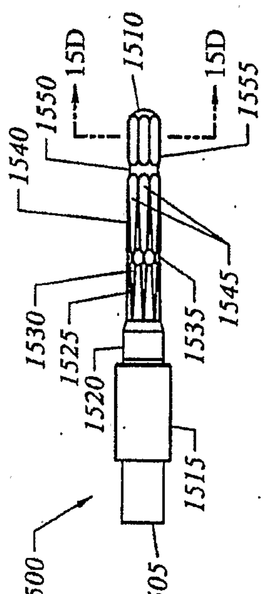

FIG. 15A

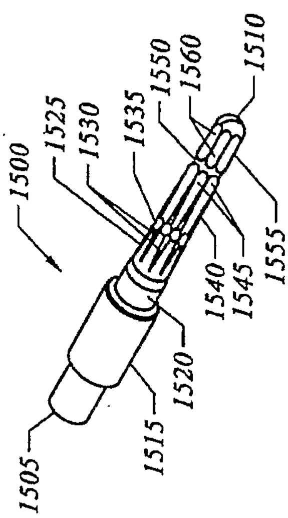

FIG. 15B

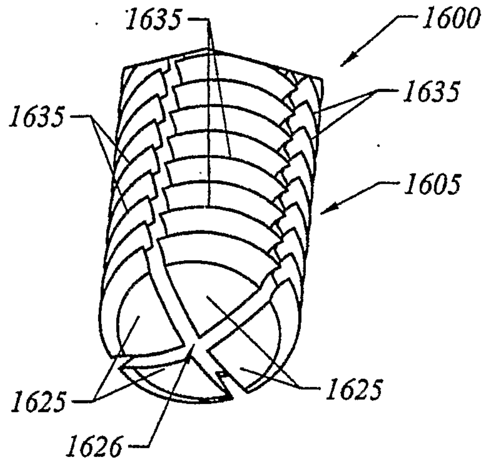

FIG. 16A

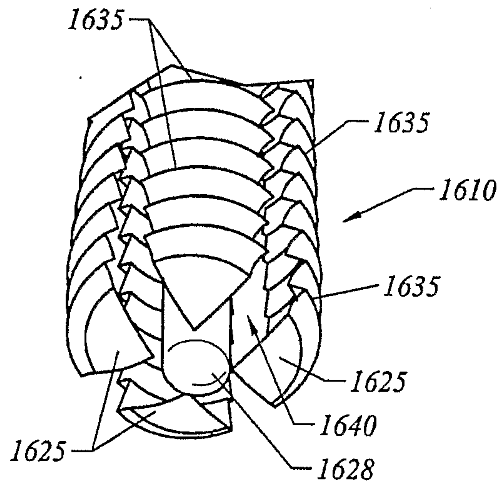

FIG. 16B

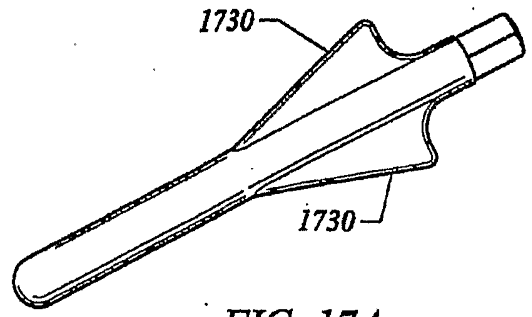

FIG. 17A

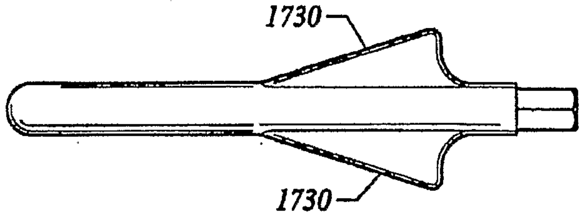

FIG. 17B

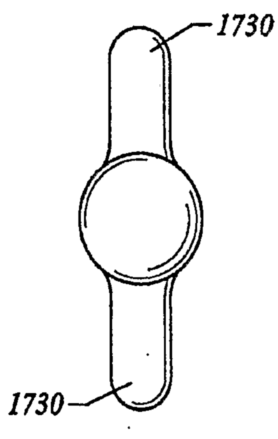

FIG. 17C

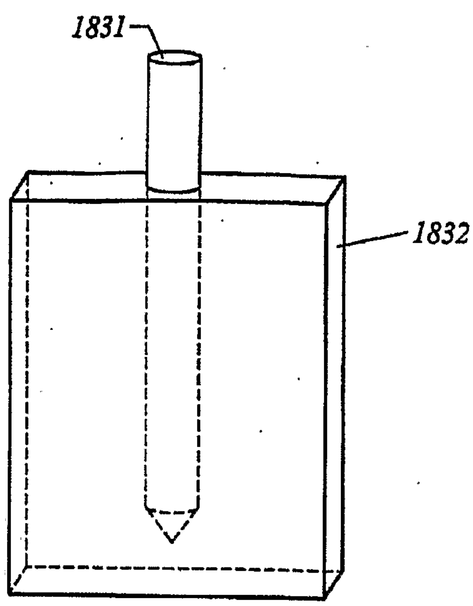

FIG. 18A

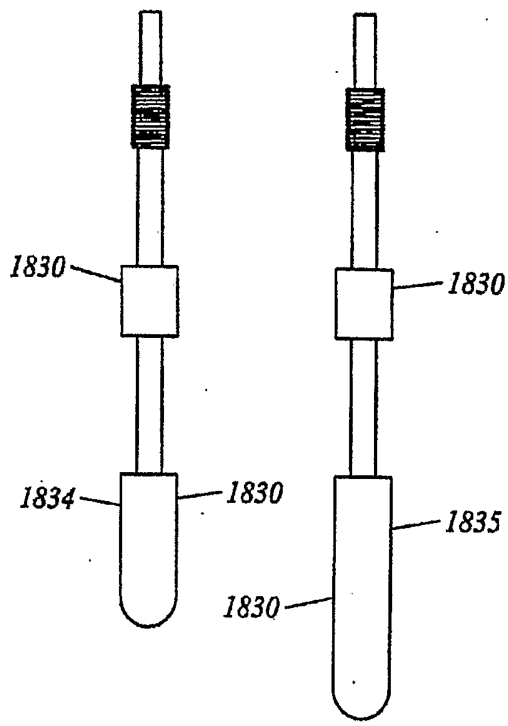

FIG. 18B

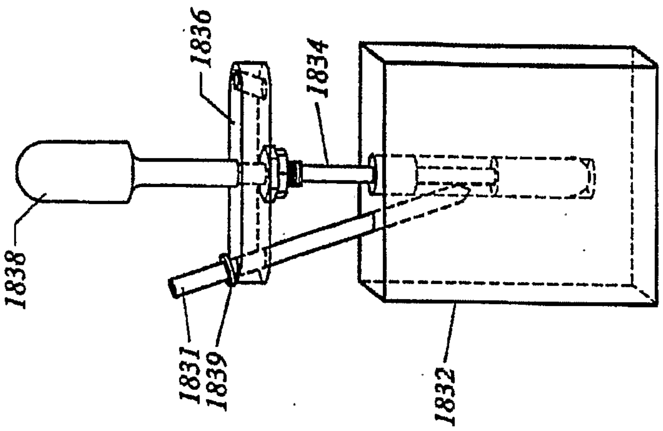

FIG. 18D

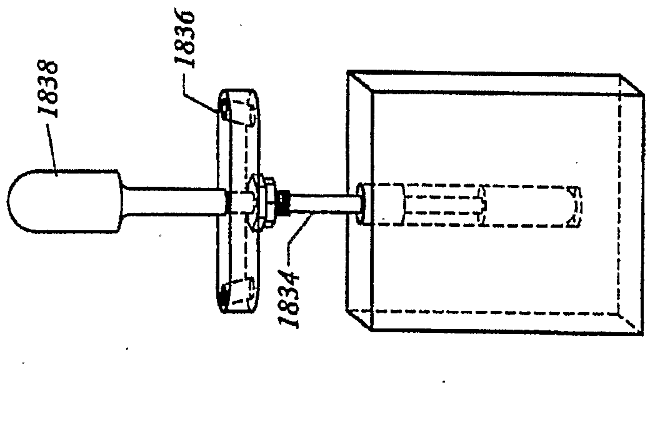

FIG. 18C

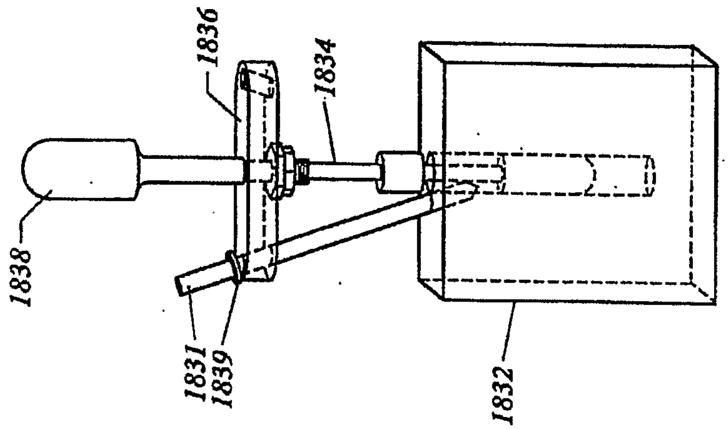

FIG. 18F

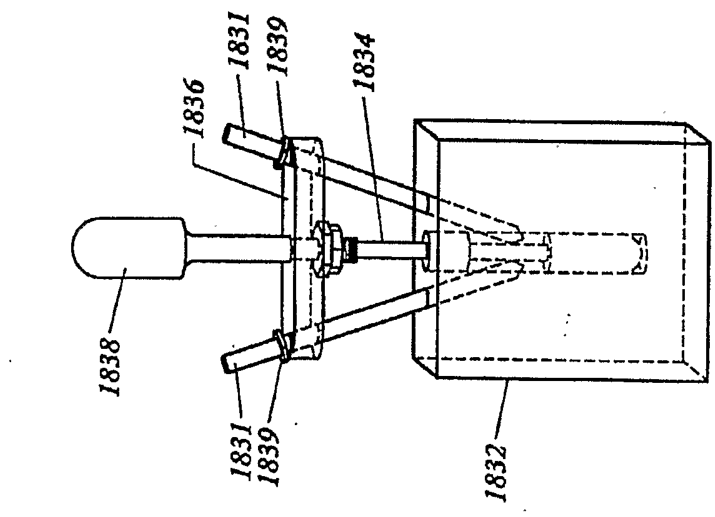

FIG. 18E

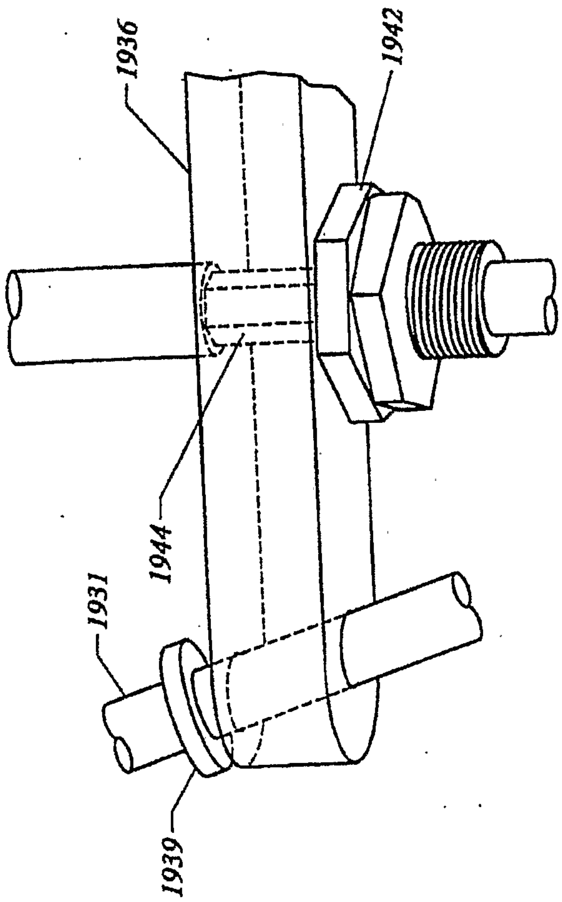

FIG. 19

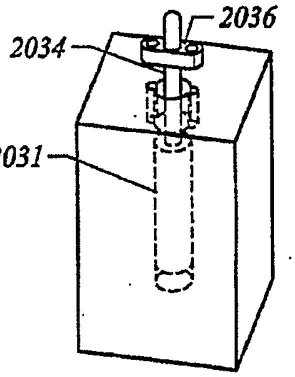

FIG. 20A

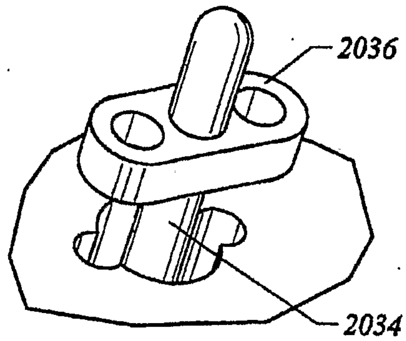

FIG. 20B

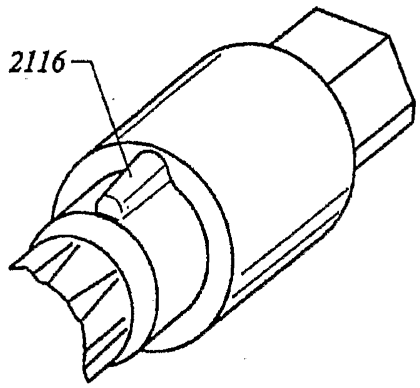

FIG. 21A

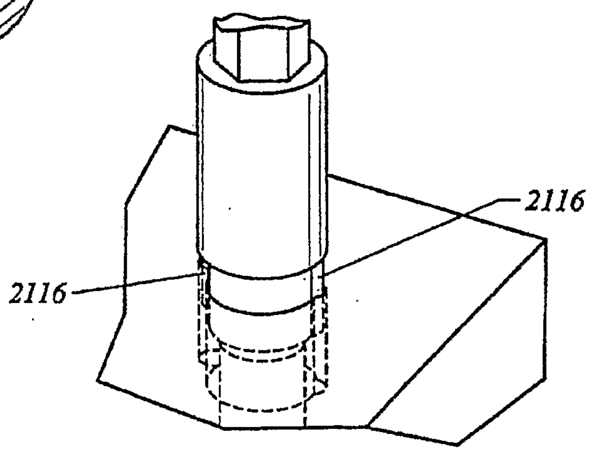

FIG. 21B

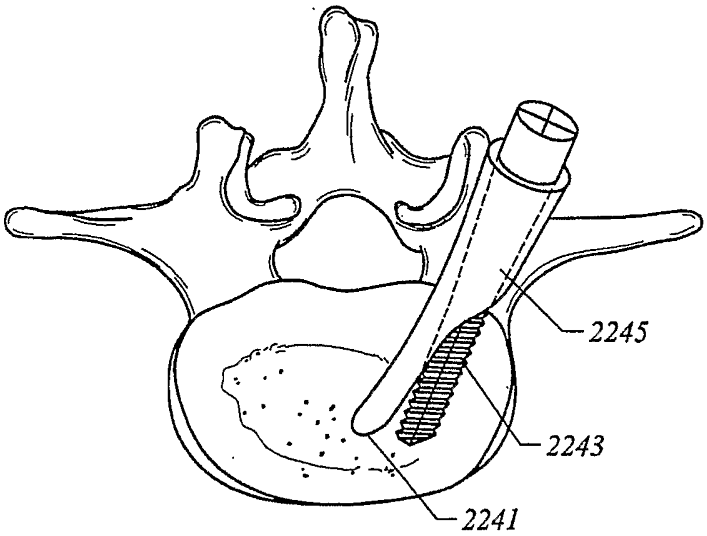

FIG. 22

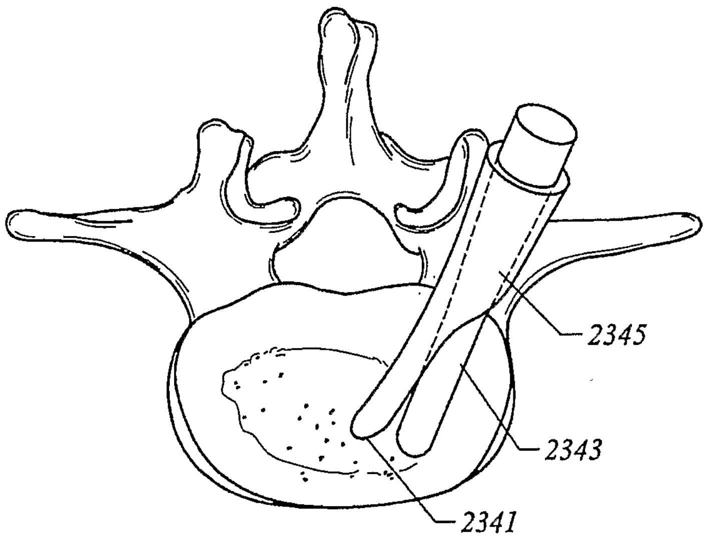

FIG. 23

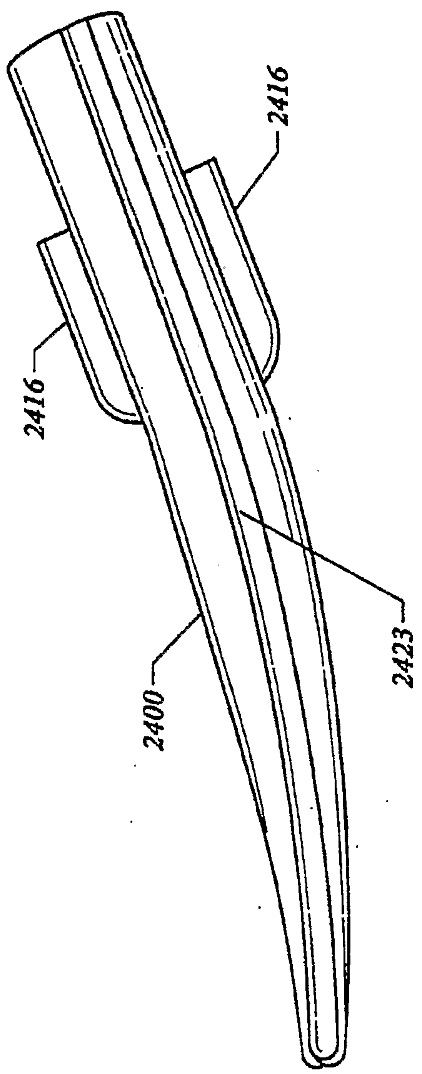

FIG. 24