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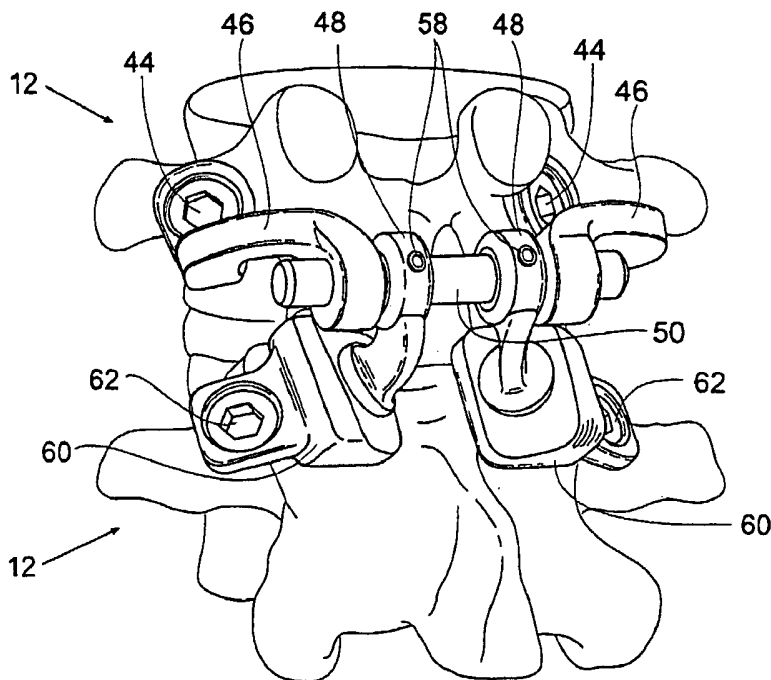
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[Continued on next page]

(54) Title: FACET JOINT PROSTHESES



(57) Abstract: Cephalad and caudal vertebral facet joint prostheses and methods of use are provided. A pair of fixation elements are adapted to be secured within a vertebra in an orientation that best assures a secure and durable attachment to cortical and/or cancellous bone. Artificial facet joint surfaces are mounted on the fixation elements, either directly or with the aid of a support. The artificial facet joint structure may be carried by an arm. The artificial facet joint structure is adapted for articulation with a complementary natural or artificial facet joint structure. Bilateral prostheses may be coupled by a brace to further secure and stabilize the prostheses. Artificial facet joints can be used in combination with artificial intervertebral discs to treat a spinal pathology.

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FACET JOINT PROSTHESES

[0001] This application claims priority to United States Patent Application Serial No. 10/974,009 filed
5 October 25, 2004 entitled "Prostheses, Systems and Method for Replacement of Natural Facet Joints with Artificial
Facet Joint Surfaces."

[0002] This application also claims priority to United States Patent Application 11/122,271, filed
May 3, 2005, and entitled "Crossbar spinal prosthesis having a modular design and related implantation methods,"
which is a continuation-in-part of United States Patent Application Serial No. 11/071,541 filed March 2, 2005,
10 entitled "Crossbar Spinal Prosthesis Having a Modular Design and Related Implantation Methods," which is a
continuation-in-part of U.S. Patent Appl. No. 10/831,657 to Tokish et al., filed April 22, 2004, and entitled "Anti-
Rotation Fixation Element for Spinal Prosthesis," which claims priority under 35 U.S.C. § 119 from the following
patent applications: U.S. Patent Appl. No. 60/602,827 to McLeer, filed August 18, 2004, and entitled "Articulating
Mechanism Locking Device"; U.S. Patent Appl. No. 60/642,321 to Funk et al, filed January 7, 2005, and entitled
15 "Component Selection Instrument"; U.S. Patent Appl. No. 60/642,250 to Charbonneau et al., filed January 7, 2005,
and entitled "Bearing Surface Preloader"; U.S Patent Appl. No. 60/643,556 to McLeer, filed January 13, 2005, and
entitled "Motion Lock Cable Device"; U.S. Patent Appl. No. 60/650,302 to Ralph et al., filed February 4, 2005, and
entitled "Facet Joint Replacement Tools"; this application also claims the benefit under 35 U.S.C. § 119 of U.S.
Patent Appl. No. 60/567,972 to Reiley et al., filed May 3, 2004, and entitled "Spinal Prosthesis for Facet Joint
20 Replacement." The disclosures of these patent applications are all incorporated herein by reference.

FIELD OF THE INVENTION

[0003] This invention relates to prostheses for treating various types of spinal pathologies, as well as to
methods of treating spinal pathologies. This invention also relates to systems and kits for treating spinal pathologies.
The systems and kits include intervertebral discs prosthesis and facet joint prosthesis.

BACKGROUND OF THE INVENTION

I. VERTEBRAL ANATOMY

[0004] As FIG. 1 shows, the human spinal column 10 is comprised of a series of thirty-three stacked
vertebrae 12 divided into five regions. The cervical region includes seven vertebrae 12, known as C1-C7. The
thoracic region includes twelve vertebrae 12, known as T1-T12. The lumbar region contains five vertebrae 12,
30 known as L1-L5. The sacral region is comprised of five vertebrae 12, known as S1-S5. The coccygeal region
contains four vertebrae 12, known as Co1-Co4.

[0005] FIG. 2 shows a normal human lumbar vertebra 12. Although the lumbar vertebrae 12 vary
somewhat according to location, they share many features common to most vertebrae 12. 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
35 form a vertebral arch 18.

[0006] 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 into the
laminae 20 is interrupted by the formation of a series of processes.

[0007] Two transverse processes 24 thrust out laterally on each side from the junction of the pedicle 16
40 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 from the union of the pedicle 16 with the lamina 20. The inferior processes 28 are oval plates of bone that jut downward on each side.

5 [0008] 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 faces downward. As FIG. 3 shows, 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 zygapophysial joint.

[0009] The facet joint 32 is composed of a superior facet and an inferior facet. The superior facet is
10 formed by the vertebral level below the joint 32, and the inferior facet is formed by the vertebral level above the joint 32. For example, in the L4-L5 facet joint, the superior facet of the joint is formed by bony structure on the L-5 vertebra (e.g., a superior articular surface and supporting bone on the L-5 vertebra), and the inferior facet of the joint is formed by bony structure on the L-4 vertebra (e.g., an inferior articular surface and supporting bone on the L-4 vertebra).

15 [0010] As also shown in FIG. 3, an intervertebral disc 34 positioned between each pair of vertebrae 12 permits gliding movement between the vertebrae 12. Thus, the structure and alignment of the vertebrae 12 permit a range of movement of the vertebrae 12 relative to each other.

II. FACET JOINT DYSFUNCTION

[0011] Back pain, particularly in the "small of the back", or lumbosacral (L4-S1) region, is a common
20 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.

[0012] 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.

25 [0013] 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 a "pinched" nerve, 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.

30 [0014] 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.

[0015] 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.

35 [0016] Another type of conventional treatment is decompressive laminectomy. This procedure involves excision of the laminae and/or soft tissues of the spine to relieve compression of nerves.

[0017] These traditional treatments are subject to a variety of limitations and varying success rates. Furthermore, none of the described treatments puts the spine in proper alignment or return the spine to a desired anatomy. In addition, stabilization techniques, by holding the vertebrae in a fixed position, permanently limit a
40 person's mobility.

SUMMARY OF THE INVENTION

[0018] There is a need for prostheses, systems, and methods that overcome the problems and disadvantages associated with current strategies and designs in various treatments for spine pathologies.

[0019] The invention provides prostheses, devices, systems, kits and methods designed to replace natural
5 facet joints and/or 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. The prostheses, systems, and methods can restore a desired anatomy to a spine and give back to an individual a desired range of mobility. The prostheses, systems, and methods also can lessen or alleviate spinal pain by relieving the source nerve compression or impingement.

[0020] For the sake of description, the prostheses that embody features of the invention will be called
10 either "cephalad" or "caudal" with relation to the portion of a given natural facet joint they replace. As previously described, a given natural facet joint has a superior facet and an inferior facet. In anatomical terms, the superior facet of the joint is formed by the vertebral level below the joint (which can thus be called the caudal portion of the facet joint, i.e., because it is near the feet). The inferior facet of the joint is formed by the vertebral level above the joint (which can thus be called the cephalad portion of the facet joint, i.e., because it is near the head). Thus, a prosthesis
15 that, in use, replaces the caudal portion of a facet joint (i.e., the superior facet) will be called a "caudal" prosthesis. Likewise, a prosthesis that, in use, replaces the cephalad portion of a facet joint (i.e., the inferior facet) will be called a "cephalad" prosthesis.

[0021] One aspect of the invention provides a facet joint prosthesis to replace, on a vertebral body, a
20 caudal portion of a natural facet joint (e.g., a superior articular surface and supporting bone structure on the vertebral body). A pair of fixation elements are adapted to be secured within the vertebral body in an orientation that best assures a secure and durable attachment to cortical and/or cancellous bone. Artificial facet joint structures mounted on the fixation elements. In one embodiment, the artificial facet joint structure is mounted on the fixation element by use of a support. The artificial facet joint structures articulate with a complementary natural or artificial facet joint structure. The artificial facet joint structures may be coupled by a brace to further secure and stabilize the
25 prosthesis.

[0022] This aspect of the invention also provides a method of replacing, on a vertebral body, a caudal
30 portion of a natural facet joint. The method removes a caudal portion of the natural facet joint from the vertebral body. Right and left fixation elements are secured within the vertebral body, e.g., to right and left pedicles respectively. An artificial facet joint structure is mounted on each fixation elements. A brace may be coupled to each of the artificial facet joint structures to stabilize the prosthesis.

[0023] Another aspect of the invention provides a facet joint prosthesis to replace, on a vertebral body, a
35 cephalad portion of a natural facet joint (e.g., an inferior articular surface and supporting bone structure on the vertebral body). A pair of fixation elements are adapted to be secured within the vertebral body in an orientation that best assures a secure and durable attachment to cortical and/or cancellous bone. In a preferred embodiment, arms are adapted to be mounted on the fixation elements (e.g., using a brace and/or support). The arms carry an artificial facet joint structure for articulation with a complementary natural or artificial facet joint structure. The arms may be coupled by a brace to further secure and stabilize the prosthesis.

[0024] This aspect of the invention also provides a method of replacing, on a vertebral body, a cephalad
40 portion of a natural facet joint. The method removes a cephalad portion of the natural facet joint from the vertebral body. In one embodiment, right and left fixation elements are secured within the vertebral body, e.g., to the right and left pedicles respectively. A support is mounted on each fixation element. A brace carrying right and left arms (carrying the artificial facet joint structures) is coupled to the supports.

[0025] In an alternative embodiment, right and left fixation elements are secured within the vertebral body, e.g., to the right and left pedicles respectively. A support is mounted on each fixation element. An arm, carrying an artificial facet joint structure, is mounted on each support. A brace may be coupled to each of the arms to stabilize the prosthesis.

5 [0026] Another aspect of the invention provides a facet joint prosthesis to replace, on a vertebral body, a caudal portion of a natural facet joint, including: a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

10 [0027] Yet another aspect of the invention provides a prosthesis for replacing a natural spinal facet joint including: a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

15 [0028] Still another aspect of the invention provides a prosthesis for replacing a natural spinal facet joint comprising: a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

20 [0029] Another aspect of the invention provides a system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

25 [0030] Yet another aspect of the invention provides a system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

30 [0031] Still another aspect of the invention provides a system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

35 [0032] Another aspect of the invention provides a surgical kit for treating spinal pathologies including an intervertebral disc prosthesis and a facet joint prosthesis comprising a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

[0033] Yet another aspect of the invention provides a surgical kit for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

[0034] Still another aspect of the invention provides a surgical kit for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

[0035] Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

INCORPORATION BY REFERENCE

[0036] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] FIG. 1 is a lateral elevation view of a normal human spinal column.

[0038] FIG. 2 is a superior view of a normal human lumbar vertebra.

[0039] FIG. 3 is a lateral elevation view of a vertebral lumbar facet joint.

[0040] FIG. 4 is an exploded perspective view of cephalad and caudal prostheses for replacing, respectively, the inferior and superior halves of a natural facet joint.

[0041] FIG. 5 is an assembled perspective view of the prostheses shown in FIG. 4

[0042] FIG. 6 is a posterior perspective view of the natural left and right facet joints between two lumbar vertebrae.

[0043] FIG. 7 is a posterior perspective view of the lumbar vertebrae shown in FIG. 6, showing one embodiment of a surgical removal of the spinous process and natural inferior processes and related bony structure of the superior vertebra and the surgical removal of the natural superior processes and related bony structure of the inferior vertebra.

[0044] FIG. 8 is a posterior perspective view of the lumbar vertebrae shown in FIGS. 6 and 7, after removal of the inferior and superior halves of the natural facet joints, illustrating the mounting of the left and right support components of the cephalad prosthesis for replacing the inferior halves of the natural facet joints that have been removed onto fixation elements secured within the superior vertebra.

[0045] FIG. 9 is a posterior perspective view of the lumbar vertebrae shown in FIG. 8, illustrating the placement of the transverse rod and left and right cephalad arm components of the cephalad prosthesis onto the superior vertebra for replacing the inferior halves of the natural facet joints that have been removed.

[0046] FIG. 10 is a posterior perspective view of the lumbar vertebrae shown in FIG. 9, illustrating the mounting of caudal prostheses for replacing the superior halves of the natural facet joint that have been removed onto fixation elements secured within the inferior vertebra.

5 [0047] FIG. 11 is a posterior perspective view of the lumbar vertebrae shown in FIG. 10, illustrating the fixation of the cephalad artificial facet joint structures in an articulating configuration with the caudal artificial facet joint structures.

[0048] FIG. 12 is an exploded perspective view of an alternative embodiment of cephalad and caudal prostheses for replacing, respectively, the inferior and superior halves of a natural facet joint.

[0049] FIG. 13 is an assembled perspective view of the prostheses shown in FIG. 12.

10 [0050] FIG. 14 is a posterior perspective view of the lumbar vertebrae shown in FIGS. 6 and 7, after removal of the inferior and superior halves of the natural facet joints, illustrating the placement of fixation elements of the cephalad prosthesis within the superior vertebra.

[0051] FIG. 15 is a posterior perspective view of the lumbar vertebrae shown in FIG. 14, illustrating the mounting of the left and right cephalad support components of the cephalad prosthesis onto the cephalad fixation elements.

15 [0052] FIG. 16 is a posterior perspective view of the lumbar vertebrae shown in FIG. 15, illustrating the mounting of the left and right caudal support components of the caudal prosthesis onto the caudal fixation elements that have been secured with the inferior vertebra.

[0053] FIG. 17 is a posterior perspective view of the lumbar vertebrae shown in FIG. 16, illustrating the mounting of the arm components of the cephalad prosthesis onto the support components of the cephalad prosthesis.

20 [0054] FIG. 18 is a posterior perspective view of the lumbar vertebrae shown in FIG. 14, illustrating the mounting of the left and right cephalad support components of the cephalad prosthesis onto the cephalad fixation elements.

[0055] FIG. 19 is a perspective view of an alternative embodiment of the cephalad prosthesis fixation element shown in FIG. 1, illustrating the body of the fixation element being of a stem configuration.

[0056] FIG. 20 is a perspective view of another alternative embodiment of the caudal prosthesis fixation element shown in FIG. 1, illustrating the body of the fixation element being of a stem configuration.

[0057] FIG. 21 is an exploded perspective view of an alternative embodiment of cephalad and caudal prostheses for replacing, respectively, the inferior and superior halves of a natural facet joint.

30 [0058] FIG. 22 is an assembled perspective view of the prostheses shown in FIG. 21.

[0059] FIG. 23 is a posterior perspective view of the lumbar vertebrae shown in FIGS. 6 and 7, after removal of the inferior and superior halves of the natural facet joints, illustrating the fixation of the cephalad and caudal prostheses shown in FIG. 21 on the vertebrae.

[0060] FIG. 24 is an exploded perspective view of an alternative embodiment of cephalad and caudal prostheses for replacing, respectively, the inferior and superior halves of a natural facet joint, illustrating the arm of the cephalad prosthesis including a female fitting and the artificial facet joint structure of the cephalad prosthesis including a complementary male fitting.

[0061] FIG. 25 is an alternative embodiment of the cephalad prosthesis shown in FIG. 24, illustrating multiple attachment sites on the arm for attachment of the artificial facet joint structure.

40 [0062] FIG. 26 is an alternative embodiment of the cephalad prosthesis shown in FIG. 24, illustrating the arm including a male fitting and the artificial facet joint structure including a female fitting.

[0063] FIG. 27 is an alternative embodiment of the cephalad prosthesis shown in FIG. 26, and illustrating the artificial facet joint structure having a fitting elongated relative to FIG. 26.

[0064] FIG. 28 is an assembled perspective view of the cephalad and caudal prostheses shown in FIG. 24.

[0065] FIG. 29 is posterior perspective view of the lumbar vertebrae shown in FIG. 8, illustrating a bore reamed in a pedicle of the inferior vertebra.

[0066] FIG. 30 is a posterior perspective view of the lumbar vertebrae shown in FIG. 29, illustrating the placement of a caudal sleeve, with a support mounted on the sleeve, within the bore.

[0067] FIG. 31 is a posterior perspective view of the lumbar vertebrae shown in FIG. 30, illustrating the mounting of a caudal arm, carrying an artificial facet joint structure, on the caudal sleeve.

[0068] FIG. 32 is a posterior perspective view of the lumbar vertebrae shown in FIG. 31, illustrating a bore reamed in the complementary pedicle of the superior vertebra.

[0069] FIG. 33 is a posterior perspective view of the lumbar vertebrae shown in FIG. 32, illustrating the placement of a cephalad sleeve, with a support and arm mounted on the sleeve, within the bore.

[0070] FIG. 34 is a posterior perspective view of the lumbar vertebrae shown in FIG. 33, illustrating the mounting on an artificial facet joint structure on the cephalad arm.

[0071] FIG. 35 is a posterior perspective view of the lumbar vertebrae shown in FIG. 34, illustrating the use of a pedicle screw to secure the mounting of the cephalad support and arm.

[0072] FIG. 36 is an exploded perspective view of a pair of cephalad prostheses joined by a transverse brace.

[0073] FIG. 37 is an exploded perspective view of a pair of caudal prostheses joined by a transverse brace.

[0074] FIG. 38 is a posterior perspective view of the lumbar vertebrae shown in FIG. 35, illustrating bilateral cephalad and caudal prostheses fixed on the vertebrae using a pair of braces.

[0075] FIG. 39 is a sectional view of a bore within bone, and illustrating the placement of mesh material and a sleeve within the bore.

[0076] The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DETAILED DESCRIPTION OF THE INVENTION

[0077] Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention that may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I. VERTEBRAL PROSTHESES

[0078] FIGS. 4 and 5 illustrate prostheses for replacing the superior and inferior portions of natural facet joints 32 (See also FIG. 3). The prostheses are desirably fixed to vertebral bodies 14 following the surgical removal of the respective natural facet joint portions from the vertebral bodies 14.

[0079] The cephalad 36 prosthesis is sized and configured for replacement of the natural inferior facet of a facet joint 32 following removal of the natural inferior facet of the facet joint 32. The caudal prostheses 38 are

sized and configured for replacement of the natural superior facet of a facet joint 32 following removal of the natural superior facet of the facet joint 32.

[0080] As best shown in FIG. 11, the prostheses 36 and 38 are desirably used in articulated association between a given pair of vertebral bodies 14. As FIG. 11 shows, the caudal and cephalad prostheses 36 and 38 form an articulated system that permits total (superior and inferior) facet joint replacement of one or more natural facet joints 32. The system can provide a succession of entirely artificial facet joint structures between two vertebral bodies 14 or along a length of the spinal column 10.

A. The Cephalad Prosthesis

[0081] The cephalad 36 prosthesis shown in FIGS. 4 and 5 is so designated because it provides one or more artificial facet joint structures 40 for repair/replacement of the inferior facet of a natural facet joint 32. The prosthesis 36 allows for the removal of injured, diseased and/or deteriorating natural inferior articular surfaces 28 and supporting bony structure on the vertebra 12 above the facet joint 32. The artificial structures 40 serve to replace the natural inferior processes 28 and supporting bone of the vertebral body 14, which have been desirably removed prior to mounting the prosthesis 36 on the vertebral body 14, as will be described in greater detail later.

[0082] The artificial facet joint structures 40 articulate with the superior facet of the facet joint 32. The superior facet can comprise the natural superior portions of the facet joint 32 (i.e., the natural superior articular surfaces 26 and supporting bony structure on the vertebral body 14 below the facet joint 32). Desirably, however, the superior facet comprises an artificial facet joint structure 42 formed by a caudal joint replacement prosthesis 38.

[0083] The cephalad prosthesis 36 is a modular unit comprising a pair of fixation elements 44 (left and right), a pair of supports 46 (left and right), a pair of arms 48 (left and right), and a brace 50. The modular unit allows assembly of the components in situ on a vertebra. The cephalad prosthesis 36 may be formed of a material commonly used in the prosthetic arts including, but not limited to, polyethylene, rubber, titanium, chrome cobalt, surgical steel, bony in-growth sintering, sintered glass, artificial bone, ceramics, or a combination thereof.

[0084] The left and right fixation elements 44 are fixed to the left and right pedicles 16 respectively, in a position that desirably best assures their fixation to cortical and/or cancellous bone. In the illustrated embodiment, the fixation elements 44 take the form of pedicle screws or nails. The fixation elements 44 are adapted to extend into the right and left pedicles 16 of the vertebral body and serve to anchor the prosthesis 36 in place in an orientation that best assures a secure and durable attachment to bone.

[0085] The supports 46 each carry at least one opening 52 sized and configured to accommodate passage of a fixation element 44 to permit mounting of a support 46 on the fixation element 44. The supports 46 are thereby placed on the vertebra 12 in a position dictated by the placement and orientation of the fixation elements 44.

[0086] The supports 46 also each have an opening 54 to permit passage of the brace 50. In the illustrated embodiment, the brace 50 takes the form of a transverse rod. Similar to the 46 supports, the left and right cephalad arms 48 have openings 56 to permit passage of the brace 50. The brace 50 is sized to extend across the laminae 20 of a vertebral body 14 and passes through the support openings 54 and the arm openings 56 to hold the supports 46 and arms 48 to thereby stabilize the prosthesis 36.

[0087] Each arm 48 carries an artificial facet joint structure 40 for repairing/replacing the inferior facet of a natural facet joint 32. The position of the arms 48 may be adjusted along the brace 50 to bring the artificial facet joint structures 40 of the cephalad prosthesis 36 in articulating configuration with the natural superior facet of the facet joint 32 or an artificial facet joint structure 42 formed by a caudal joint replacement prosthesis 38. The arms 48 can then be secured by locking pins 58 or other suitable mechanism in a desired position.

B. The Caudal Prosthesis

[0088] The caudal prostheses 38 shown in FIGS. 4 and 5 are so designated because they create artificial facet joint structures 42 for the superior facet of a natural facet joint 32. The caudal prostheses 38 allow for the removal of injured, diseased and/or deteriorating natural superior articular surfaces 26 and supporting bony structure on the vertebral body 14 below the facet joint 32. The artificial structures 42 serve to replace the natural superior processes 26 and supporting bone of the vertebral body 14, which have been desirably removed prior to mounting the prosthesis 38 on the vertebral body 14. This aspect will be described in greater detail later.

[0089] In use, the artificial facet joint structure 42 articulates with the inferior facet of the facet joint 32. The inferior facet can comprise the natural inferior portions of the facet joint 32 (i.e., the natural inferior articular surfaces 28 and supporting bony structure on the vertebral body 14 above the facet joint 32). Desirably, however, the inferior facet comprises an artificial facet joint structure 40 formed by a cephalad joint replacement prosthesis 36, as previously described.

[0090] Each prosthesis 38 comprises an artificial facet joint structure 42 and a fixation element 62. Desirably, as FIGS. 4 and 5 illustrate, a pair of fixation elements 62 (right and left) and a pair of artificial facet joint structures 42 (right and left) are provided to permit bilateral facet joint replacement. The left and right fixation elements 62 are fixed to the left and right pedicles 16 respectively, in a position that best assures their fixation to cortical and/or cancellous bone. In the illustrated embodiment, the fixation elements 62 take the form of pedicle screws or nails. The fixation elements 62 are adapted to extend into the right and left pedicles 16 of the vertebral body 14 and serve to anchor the prostheses 38 in place in an orientation that best assures a secure and durable attachment to bone.

[0091] Each artificial facet joint structure 42 has at least one opening 64 sized and configured to accommodate passage of a fixation element 62 to permit mounting of the artificial facet joint structure 42 on a fixation element 62. The artificial facet joint structures 42 are thereby placed on the vertebra 12 in a position dictated by the placement and orientation of the fixation elements 62.

[0092] The artificial facet joint structures 42 articulate with the natural inferior facet portion of the facet joint 32 or an artificial facet joint structure 40 formed by a cephalad joint replacement prosthesis 36, as previously described.

[0093] The caudal prostheses 38 may be formed of a material commonly used in the prosthetic arts including, but not limited to, polyethylene, rubber, titanium, chrome cobalt, surgical steel, bony in-growth sintering, sintered glass, artificial bone, ceramics, or a combination thereof.

C. Artificial Facet Structure Configuration

[0094] In the prostheses 36 and 38, each artificial facet joint structure 40 and 42 creates a bearing surface having a configuration that facilitates articulation with the bearing surface of another artificial facet joint structure 40 or 42. The particular geometry for the bearing surface configuration for a given artificial facet joint structure 40 and 42 can vary. It can, for example, be concave, convex, or flat. It may also include a hybrid of curved and flat bearing surface designs, i.e., Miniscal, hinge, etc.

[0095] The radii of two articulating bearing surface configurations are desirably selected and matched, taking into account the material from which the surfaces are formed, to minimize contact stress during articulation. The features of the two bearing surfaces (as well as the various other features of the facet joint structures) may also be chosen, if desired, to duplicate the natural articulation of the natural facet joint. Alternatively, the features of the two bearing surfaces (as well as the various other features of the facet joint structures) can be chosen to permit the

treated motion segment to experience a lesser or greater degree of articulation than that allowed by the natural motion segment.

[0096] For example, in the embodiment illustrated in FIG. 4, the cephalad prosthesis 36 includes artificial facet structures 40 employing generally convex surfaces 66, forming hemisphere-like artificial facet joint structures.

5 In this arrangement, the caudal prostheses 38 include artificial facet structures 42 employing generally complementary concave surfaces 68, forming socket-like artificial facet joint structures that articulate with the hemisphere-like artificial facet joint structures. It should be appreciated that the articulating surfaces 40 and 42 can be reversed, with the artificial facet structures 40 of the cephalad prosthesis 36 employing generally socket-like surfaces, and the artificial facet structures 42 of the caudal prostheses 38 employing generally hemisphere-like surfaces.

10 [0097] Alternatively, a Miniscal bearing design could be employed, utilizing a conformal curved surface as one artificial facet joint structure 40 or 42, with the bearing side of the opposed artificial facet joint structure 40 or 42 having an essentially flat surface. A hemiarthroplasty design could also alternatively be employed, in which one surface of the opposing surfaces does not incorporate the use of an artificial facet joint structure 40 or 42.

15 [0098] In another arrangement, one surface of an artificial facet joint structure 40 or 42 can have bearing articulation on both sides of the component and have opposing articulation with a receiving artificial facet joint structure 40 or 42 having opposing mating bearing surfaces.

[0099] A variety of materials are suitable for the artificial facet joint structures.40 and 42. Ceramic or ceramic in opposition with a chrome alloy can be used. Suitable stainless steel, including 316L, or titanium alloys, with or without the use of surface hardening and overlay, or hard surface coatings, including zirconia and alumina, can also be employed. The metal surfaces can be made from cast, wrought, hot-forged, or powder-metal consolidated sintered materials. Any of these metals or combination of metals and ceramics can be used in articulation with each other. Biocompatible polymers, e.g., polyethylene, can also be used in articulation with the metals, ceramic, and surface-hardened metals just described. Ultra High Molecular Weight Polyethylene can further be gamma-irradiated, as-molded or as-machined.

20 [0100] The radii of articulating artificial facet joint structures 40 and 42 are desirably closely matched to provide contact stress values less than a given threshold value. The desired contact stress value changes with the material employed.

[0101] For example, the contact stress value for metal-to-metal bearing combinations is desirably less than about 25,000 psi, and preferably less than 12,000 psi. For polymer surfaces bearing against a metal, ceramic, or surface-hardened metal counter bearing surface, the contact stress value is desirably less than 10,000 psi, and preferably less than 5,000 psi.

[0102] For a given material to achieve a desired contact stress value less than the threshold value, the appropriate radii is desirably chosen. Thus, the desired radii may change as material changes.

35 **D. Total Facet Replacement Using the Cephalad and Caudal Prostheses**

[0103] FIG. 6 shows a normal natural human vertebral facet joint 32, e.g., L4-L5. In some cases of disease or trauma, it may be desirable to remove the superior and inferior facets of the natural facet joint 32 and replace them respectively with the caudal prostheses 38 and the cephalad prosthesis 36.

[0104] FIGS. 6 and 7 show the exposed spinous process 22, lamina 20, and facet joint 32 of the L4-L5 joint. In this embodiment, a portion of the inferior lamina 20 and the inferior facet of the natural facet joint 32 (e.g., the articulated inferior processes 28 and its supporting bone of the vertebral body 14 above the facet joint 32) are removed. The lamina 20 is cut for a wide decompressive laminectomy along a decompressive superior-to-inferior

resection line on both sides of the vertebral body 14. The removed natural anatomy is replaced with the cephalad prosthesis 36. The superior facet of the natural facet joint 32 (e.g., the articulated superior process 26 and its supporting bone of the targeted vertebral body 14) is also removed. Desirably, the mamillary process, the accessory process, a portion of the transverse process, and a portion of the pedicle is removed by being rongeured or reamed.

5 The removed natural anatomy is replaced with the caudal prosthesis 38. The cephalad prosthesis 36, as described above, can be installed over the lamina 20, either before or after placement of the caudal prosthesis 38.

[00105] As best shown in reference to FIG. 7, the embodiment of a surgical procedure exposes the spinous process 22, lamina 20, and facet joints 32 at a desired level of the spine 10 using any method common to those of skill in the medical arts.

10 [00106] A portion of the spinous process 22 of the superior vertebra 12 is desirably removed, as depicted by phantom lines in FIG. 7, using any means common in the field. The inferior facet of the facet joint 32 is cut at or near a selected resection line. Most of the lamina 20 is desirably preserved, as is the facet joint capsule, which may be opened and folded back. The facet joint capsule may be cut perpendicular to its direction. The natural inferior facet of the facet joint 32 may then be retracted from the superior facet. Once the inferior and superior facets of the facet joint are separated, the cut inferior bone, e.g., the inferior articular process 28 and its supporting bone, of the upper half of the joint (e.g., the cut inferior portion of the L4 vertebra in the L4-L5 joint) may be removed, as also depicted by phantom lines in FIG. 7. Alternatively, it may be possible to remove the cut inferior bone while simultaneously separating the facet joint 32.

15 [00107] Prominent bone of the superior facet of the natural facet joint 32, e.g., the superior articular process 26 and its supporting bone, may be also removed, as also depicted by phantom lines in FIG. 7, using any means common in the field. The superior facet of the natural facet joint 32 may also be trimmed to decompress the adjacent nerve root. A reamer or any other instrument that is useful for grinding or scraping bone, may be used to ream the superior facet of the facet joint 32 into the pedicle 16, to reach the geometry shown in FIG. 8, which is desirably suitable for receiving the caudal prosthesis 38.

20 [00108] With reference to FIG. 8, a cephalad support 46 is mounted on each of the cephalad fixation elements 44 and the fixation elements 44 are then placed in a desired position on the pedicles 16 (with one fixation element 44 on each of the right and left pedicles 16) and screwed securely into the superior vertebral body 14.

[00109] As FIG. 9 illustrates, the cephalad arms 48 are then placed medial to the left and right supports 46. The brace 50 is then passed through the openings 54 and 56 of the supports 46 and arms 48.

30 [00110] The caudal artificial facet joint structures 42 are then mounted on the caudal fixation elements 62 and the fixation elements 62 are then placed in a desired position on the pedicles 16 (with one fixation element 62 on each of the right and left pedicles 16) and screwed securely into the inferior vertebral body, as shown in FIG. 10.

[00111] With reference to FIG. 11, the cephalad arms 48 are then positioned to bring the artificial facet joint structures 40 of the cephalad prosthesis 36 in articulating configuration with the artificial facet joint structures 42 of the caudal prosthesis 38. The arms 48 are then secured in the desired position by use of locking screws 58 or other suitable mechanism.

35 [00112] Further details of surgical procedures suitable for installing the prostheses are described in co-pending United States Patent Application Serial No. 09/693,272, filed October 20, 2000, and entitled "Facet Arthroplasty Devices and Methods," which has issued into U.S. Patent 6,610,091, and which is incorporated herein by reference.

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II. FIRST ALTERNATIVE EMBODIMENT**A. Cephalad Prosthesis**

[00113] FIGS. 12 and 13 show alternative embodiments of a cephalad 70 and a caudal 72 vertebral prosthesis. Similar to the previous embodiment, the cephalad prosthesis 70 is a modular unit comprising left and right fixation elements 74, left and right supports 76, left and right arms 78, left and right artificial facet joint structures 79 for the superior facet of a natural facet joint 32, and a transverse brace 80 that allows assembly of the components in situ. Components are mounted in situ on the fixation elements 74 that are secured to the pedicle 16 in an orientation that provides secure fixation to bone.

[00114] The left and right fixation elements 74 are fixed to the left and right pedicles 16 respectively, in a position that best assures their fixation to cortical and/or cancellous bone. In the illustrated embodiment, the fixation elements 74 take the form of pedicle screws or nails. The fixation elements 74 are adapted to extend into the right and left pedicles 16 of the vertebral body 14 and serve to anchor the prosthesis 70 in place in an orientation that best assures a secure and durable attachment to bone.

[00115] The fixation elements 74 have a threaded body 82 configured to screw into the pedicle 16. A spacing collar 84 may be provided to add additional length to the fixation element 74 if necessary to assure its fixation in the vertebra 12. A nut 86 may be provided to couple with a wrench or other tool to facilitate screwing the fixation element 74 into the vertebra 12. An end portion 88 passes through an opening 90 in the support 76 and permits attachment of the support 76 to be secured by nut 92 or other fixation means, e.g., by threaded engagement.

[00116] FIG. 19 shows an alternative embodiment of a fixation element 74 in which the body 82 is a stem configuration. In this arrangement, the fixation element 74 is placed into a hole that has been reamed into the bone and secured by adhesive or boney in-growth material. The stem may include a series of serrated vanes 94 to prevent rotation in bone.

[00117] With reference back to FIG. 12, in the illustrated embodiment, the support 76 takes the form of a right angle connector. The support 76 is sized and configured to couple with the arm 78, e.g., by Morse taper. The arm 78 is a generally cylindrical member having a first bore 96 configured, e.g., tapered, to receive the support 76. A second bore 98 permits the arm 78 to couple with an artificial facet joint structure 78 for repairing/replacing the inferior facet of a natural facet joint 32, e.g., the bore 98 may be tapered to couple with the artificial facet joint structure 78 by Morse taper. A third bore 100 receives a fixation element 102, e.g., screw, to secure the arm 78 to brace 80.

[00118] The transverse brace 80 comprises a right component 104 and a left component 106. An end opening 108 in each of the components 104 and 106 receives a fixation element 102 to fix the right and left components 104 and 106 to the right and left arms 78 respectively, e.g., by threaded engagement. Each component 104 and 106 desirably has a medial opening 110. The medial openings 110 are sized and configured to overlap and permit passage of a fixation element 112, which may be secured by nut 114 or similar mechanism, to thereby couple the components 104 and 106 together to form the transverse brace 80. Similar to brace 50 described in relation to the previous embodiment, the brace 80 extends across the laminae 20 of a vertebral body 14, providing a width-adjustable load-bearing support that further stabilizes the prosthesis 70.

B. Caudal Prosthesis

[00119] With continued reference to FIGS. 12 and 13, the caudal prosthesis 72 is a modular unit comprising left and right fixation elements 118, left and right artificial facet joint structures 120, and a transverse brace 122 that allows assembly of the components in situ. Components are mounted in situ on the fixation elements 118 that are secured to the pedicle 16 in an orientation that provides secure fixation to bone.

[00120] The left and right fixation elements 118 are fixed to the left and right pedicles 16 respectively, in a position that best assures their fixation to cortical and/or cancellous bone. In the illustrated embodiment, the fixation elements 118 take the form of pedicle screws or nails. The fixation elements 118 are adapted to extend into the right and left pedicles 16 of the vertebral body 14 and serve to anchor the prosthesis 72 in place in an orientation that best assures a secure and durable attachment to bone.

[00121] The fixation elements 118 have a threaded body 124 configured to screw into the pedicle 16. A nut 126 may be provided to couple with a wrench or other tool to facilitate screwing the fixation element 118 into the vertebra 12. An end portion 128 is configured to couple with a support 120, e.g., may be tapered to couple with the support 120 by Morse taper.

[00122] FIG. 20 shows an alternative embodiment of a fixation element 118 in which the body 124 is a stem configuration. In this arrangement, the fixation element 118 is placed into a hole that has been reamed into the bone and secured by adhesive or boney in-growth material. The stem may include a series of serrated vanes 94 to prevent rotation in bone.

[00123] Turning back to FIGS. 12 and 13, each artificial facet joint structure 120 is sized and configured to be mounted on a fixation element 118, e.g. has a tapered bore 130 to mate with tapered end portion 128 of the fixation element 118. A second bore 132 receives a fixation element 136 to secure the artificial facet joint structure 120 to the caudal brace 122, e.g., by threaded engagement. The artificial facet joint structures 120 articulate with the natural inferior facet portion of the facet joint 32 or an artificial facet joint structure 79 formed by a cephalad joint replacement prosthesis 70, as previously described.

[00124] In the illustrated embodiment, the brace 122 takes the form of a transverse bar. The brace 122 desirably has right and left end openings 134 that receive fixation elements 136 for attachment to the right and left supports 122 respectively, e.g., by threaded engagement. The brace 122 extends across the laminae 20 of the inferior vertebra 12 to provide a width-adjustable load-bearing support to further stabilize the caudal prosthesis 72.

C. Total Facet Replacement Using the Cephalad and Caudal Prostheses

[00125] In a surgical procedure for total facet replacement using the cephalad and caudal prostheses 70 and 72, the spinous process 22 along with the inferior articular process 28 and its supporting bone, of the upper half of the joint 32 (e.g., the cut inferior facet of the L4 vertebra in the L4-L5 joint) may be removed, as previously described (see FIG. 7). Prominent bone of the superior facet of the natural facet joint 32, e.g., the superior articular process 26 and its supporting bone, may be also removed, as also previously described, using any means common in the field (see FIG. 7).

[00126] As shown in FIG. 14, a cephalad fixation element 74 is placed in a desired position on each of the right and left pedicles 16 of the superior vertebra 12 and secured in the vertebral body 14 by screwing the nut 86.

[00127] A cephalad support 76 is then mounted on each of the fixation elements 74 and secured with a nut 92 or other suitable means, as seen in FIG. 15. With reference to FIG. 16, a caudal fixation element 118 is then placed in a desired position on each of the right and left pedicles 16 of the inferior vertebra 12 and secured in the vertebral body 14 by screwing the nut 126. A caudal support 120 is then mounted on each of the fixation elements 118, as FIG. 16 also shows.

[00128] Referring now to FIG. 17, a cephalad support 76 and a cephalad arm 78 are then mounted on each of the cephalad fixation elements 74. The artificial facet joint structures 79 of cephalad prosthesis 70 are then brought into articulating configuration with artificial facet joint structures 121 of the caudal prosthesis 72 and the arms 78 are secured by nuts 92 or other suitable mechanism.

[00129] As seen in FIG. 18, the right cephalad brace component 104 is then fixed to the to right cephalad arm 78 and the left cephalad brace component 106 is fixed to left cephalad arm 78 with fixation elements 102 or other suitable mechanism. The left and right brace components 104 and 106 are then secured to each other with a fixation element 112 or other suitable means to form a unitary cephalad transverse brace 80. The caudal supports 120 can then be coupled with the caudal brace 122 using fixation elements 136 or other suitable means.

III. SECOND ALTERNATIVE EMBODIMENT

[00130] FIGS. 21-23 illustrate a cephalad prosthesis 138 and a caudal prosthesis 140 similar to the embodiments shown in FIGS. 12 and 13, and like parts will be given like reference numerals.

[00131] Each arm 78 of the cephalad prosthesis 138 includes a slot 142 for receiving a brace 144. In the illustrated embodiment, the brace 144 takes the form of a curvilinear transverse rod. The brace 144 is secured to the arms 78 by fixation elements 146.

[00132] Similar to the cephalad prosthesis 138, each support 120 of the caudal prosthesis 140 has a slot 148 for receiving a brace 150. In the illustrated embodiment, the brace 150 takes the form of a curvilinear transverse rod. The brace 150 is secured to the supports 120 by fixation elements 152.

[00133] The prostheses 138 and 140 are secured in the vertebrae by surgical procedure, as previously described (see also FIGS. 14-18).

IV. THIRD ALTERNATIVE EMBODIMENT

[00134] FIGS. 24-28 illustrate another embodiment of a cephalad prosthesis 154 and a caudal prosthesis 156.

A. Cephalad Prosthesis

[00135] Similar to the previous embodiments, the cephalad prosthesis 154 is a modular unit comprising a fixation element 158, a support 160, and an arm 162 carrying an artificial facet joint structure 176 that allow assembly of the components in situ. A pair of fixation elements 158 (right and left) are desirably provided and sized and configured to be are secured to the right and left pedicles 16 in an orientation that provides secure fixation to bone. Components are mounted in situ on the fixation elements 158 that are secured to the pedicle 16 in an orientation that provides secure fixation to bone.

[00136] In the illustrated embodiment, each fixation element 158 takes the form of a sleeve 164 and a pedicle screw 166. The sleeve 164 is sized and configured for insertion into a bore 168 that has been reamed into the pedicle 16 (see also FIG. 28). The sleeve 164 provides an increased surface area of attachment, further securing the attachment of the prosthesis 154 to bone. Desirably, the sleeve 164 includes a plurality of vanes 170 that resist rotation of the sleeve 164 in bone to further secure the sleeve 164 within the vertebra 12. In one alternative embodiment, the sleeve 164 can comprise an expandable sleeve which expands (in a manner similar to a wall anchor) in diameter (desirably within the bore 168) when the screw 166 is advanced through the sleeve 164.

[00137] The sleeve 164 can be secured for long-term fixation within the bore 168 by adhesive, e.g., bone cement. Alternatively, the sleeve 164 could incorporate a boney in-growth outer surface to which the surrounding bone could grow and adhere. Desirably, the sleeve 164 would fit tightly within the bore 168, with the distal section of the screw 166 anchored within the cancellous bone, thereby securely anchoring the sleeve mechanically while allowing the surrounding bone to biologically adhere to the outer surface of the sleeve. As another alternative (as shown in FIG. 39), the sleeve 164 can be secured by boney in-growth with a mesh material 172 placed within the bore 168. The sleeve 164 is then placed within the bore 168, such that it is surrounded by the mesh material 172.

The mesh material 172 can be made of titanium, chrome, steel, or other suitable metal alloy for boney in-growth to infiltrate. The pedicle screw 166 provides interim mechanical fixation until the sleeve 164 joins the bone.

[00138] A support 160 and arm 162 are integrally formed with the sleeve 164 or otherwise securely mounted on the sleeve 164. An opening 174 in the sleeve 164 extends through the support 160 and serves to receive the pedicle screw 166, e.g., by screwing the pedicle screw 166 into the sleeve 164. The arm 162 is sized and configured to couple with an artificial facet joint structure 176, e.g., by Morse taper or other suitable mechanism that permits rotation (if desired) of the artificial facet joint structure 176 with respect to the support 160 to enable proper orientation of the artificial facet joint structure 176 with the caudal prosthesis 156. In the arrangement illustrated in FIG. 24, the artificial facet joint structure 176 includes a male fitting 178 and the arm 162 includes a complementary female fitting 180. Alternatively, the male fitting 178 and female fitting 180 could comprise a non-circular fitting arrangement (oval, slotted, triangular, polygonal, etc.) that reduces or prevents relative motion between the fittings 178 and 180, but allows the facet joint structure 176 to assume one of two (or more) predetermined positions.

[00139] The arm 162 can be of a fixed length. In a representative embodiment, the arm 162 is approximately 1 cm in length. As FIG. 25 shows, to accommodate individual variations in anatomy and customize the prosthesis 154 to a given individual, the arm 162 may include more than one attachment site 182 for the artificial facet joint structure 176 at different distances along the arm 162. It is contemplated that the number and position of the attachment sites 182 may vary.

[00140] FIG. 26 illustrates an alternative embodiment, in which the arm 162 includes a male fitting 178 and the artificial facet joint structure 176 includes a complementary female fitting 180. FIG. 27 illustrates how the fitting 178 may be extended to accommodate individual variations in anatomy. For example, the fitting 178 may be provided in a series of different lengths, e.g., 5, 6, 7, 8, 9 or 10 mm.

B. Caudal Prosthesis

[00141] Also similar to the previous embodiments, the caudal prosthesis 156 is a modular unit comprising a fixation element 184, a support 186, and an artificial facet joint structure 200 that allow assembly of the components in situ. A pair of fixation elements 184 (right and left) are desirably provided and sized and configured to be secured to the right and left pedicles 16 in an orientation that provides secure fixation to bone. Components are mounted in situ on the fixation elements 184 that are secured to the pedicle 16 in an orientation that provides secure fixation to bone.

[00142] In the illustrated embodiment, each fixation element 184 takes the form of a sleeve 190 and a pedicle screw 192, similar to the cephalad prosthesis 154. The sleeve 190 is sized and configured for placement within a bore 168 reamed in bone and can be secured by adhesive or by boney in-growth, as previously described. The sleeve 190 provides an increased surface area of attachment, further securing the attachment of the prosthesis 156 to bone. Desirably, the sleeve 190 includes a plurality of vanes 170 that resist rotation of the sleeve 190 in bone to further secure the sleeve 190 within the vertebra 12, as also previously described.

[00143] A support 186 is integrally formed with the sleeve 190 or otherwise securely mounted on the sleeve 190. An opening 194 in the sleeve 190 extends through the support 186 and serves to receive the pedicle screw 192, e.g., by screwing the pedicle screw 192 into the sleeve 190. The support 186 is adapted to couple with the artificial facet joint structure 200. For example, in the illustrated embodiment, the support 186 carries a lip 196 which mates with a complementary lip 198 on the structure 200 to couple the structure with the support 186. The artificial facet joint structure 200 is sized and configured to articulate with the natural inferior facet portion of the facet joint 32 or an artificial facet joint structure 176 carried by the cephalad prosthesis 154 (FIG. 28).

C. Total Facet Replacement Using the Cephalad and Caudal Prostheses

[00144] In a surgical procedure for total facet replacement using the cephalad and caudal prostheses 154 and 156, some or all of the spinous process 22, along with the inferior articular process 28 and its supporting bone, of the upper half of the joint 32 (e.g., the cut inferior facet of the L4 vertebra in the L4-L5 joint) may be removed, as previously described (see FIG. 7). Prominent bone of the superior facet of the natural facet joint 32 (e.g., the superior articular process 26 and its supporting bone), may be also removed, as also previously described, using any means common in the field (see FIG. 7).

[00145] As shown in FIG. 29, a bore 168 is reamed in a desired position in the pedicle 16 of the inferior vertebra 12 by conventional methods. If desired, mesh material 172 promoting boney in-growth is placed within the bore 168, as previously described (see FIG. 39). Alternatively, an adhesive material is placed within the bore 168 or along the outside of the caudal sleeve 190, as also previously described. The sleeve 190, with attached support 186, is then placed within the bore 168 and secured with a pedicle screw 192, as seen in FIG. 30.

[00146] The caudal artificial facet joint structure 200, is then mounted on the caudal support 186, as shown in FIG. 31.

[00147] As FIG. 32 illustrates, a bore 168 is reamed in a desired position in the corresponding pedicle 16 of the superior vertebra 12. The cephalad sleeve 164, with attached support 160 and arm 162 components, is placed within the bore 168 and secured by adhesive and/or boney in-growth mesh material 172, as shown in FIG. 39.

[00148] Next, with reference to FIG. 34, the cephalad artificial facet joint structure 176 is mounted on the cephalad arm 162. The position of the artificial facet structure 176 is then adjusted to assure articulation between artificial facet joint structures 200 and 176. The arm 162 is then secured in the desired position with a pedicle screw 166, as shown in FIG. 35.

[00149] While FIGS. 29-35 illustrate unilateral facet joint replacement, it is often desirable to perform a bilateral facet joint replacement. In such an arrangement, as shown in FIG. 36, the left and right cephalad prostheses 154 may be coupled with a transverse brace 202. It is apparent that the brace 202 can be variously constructed. In the illustrated embodiment, brace 202 includes a right component 204 and a left component 206. An end opening 208 in each of the components 204 and 206 receives a fixation element 210 to fix the right and left components 204 and 206 to the right and left arms 162 respectively, e.g., by threaded engagement. Each component 204 and 206 desirably also has a medial opening 212. The medial openings 212 are sized and configured to overlap and permit passage of a fixation element 214, which may be secured by a nut 216 and bolt 214 or similar mechanism, to thereby couple the components 204 and 206 together to form the transverse brace 202. The brace 202 extends across the laminae 20 of a vertebral body 14, providing load-bearing support that further stabilizes the prostheses 154.

[00150] Similarly, as seen in FIG. 37, the left and right caudal prostheses 156 may be coupled with a transverse brace 218. In the illustrated embodiment, the brace 218 takes the form of a transverse bar. The brace 218 includes a pair of end openings 220 (left and right) that permit passage of fixation elements 222 to secure the brace 218 to the left and right artificial facet joint structures 200, e.g., by threaded engagement. The braces 202 and 218 provide increased stability to the prostheses 154 and 156, as previously described.

[00151] In this arrangement, as shown in FIG. 38, left and right cephalad prostheses 154 are secured within the left and right pedicles 16, respectively, of the superior vertebra 12, as previously described. Left and right caudal prostheses 156 are secured within the left and right pedicles 16, respectively, of the inferior vertebra 12, as also previously described. The cephalad prosthesis 154 are then coupled with brace 202, and the caudal prostheses 156 are coupled with brace 218.

[00152] It should be understood that, while the embodiments disclosed herein generally describe the complete repair/replacement of a pair of natural facet joints, the teachings of the present invention could be equally applicable to the repair/replacement of a single facet joint, or even the repair/replacement of a single cephalad or caudal portion of a single facet joint, or any combination thereof.

5 V. SPINAL UNIT REPLACEMENT

[00153] The various embodiments disclosed herein are well suited for implantation in conjunction with various spinal surgical procedures and spinal implants, including artificial disc replacement, nucleus replacement, annular repair and/or stenosis treatment (including decompressive laminectomy). If desired, the facet replacement prosthesis can be specifically designed to accommodate a specific treatment regimen, or a single type or design of spinal implant, or a facet replacement prosthesis could be suitable for use with more than one treatment regimen and/or spinal type or design of spinal implant.

10 [00154] In the case of the combination of a facet replacement prosthesis with an artificial disc (desirably creating a total joint replacement in one or more functional spinal units), one or more components of the facet replacement prosthesis can be implanted into the vertebral body, into the artificial disc, or into a combination of both. One concern currently existing with artificial disc replacement devices is the potential or tendency for the disk replacement components to "slip" or migrate within (or partially or totally out of) the inter-disc space post-surgery, especially where these components migrate towards the spinal cord, exiting nerve roots, or major spinal vasculature. Where the facet replacement prosthesis attaches to, connects to, or contacts (in some manner) one or more portions of the artificial disc prosthesis, however, the facet replacement prosthesis may advantageously reduce or eliminate the opportunity for the artificial disc prosthesis to migrate from a desired position within the disk space. Desirably, the facet replacement prosthesis is well secured into one or both of the vertebral bodies of the functional spinal unit, thereby well anchoring the artificial disc prosthesis as well. In fact, where the artificial disc prosthesis and the facet joint replacement prosthesis are each secured to each of the vertebral bodies (i.e., the facet joint replacement prosthesis secured into the pedicles and/or lamina of the vertebral bodies, and the artificial disc replacement prosthesis secured into the upper and lower endplates of the vertebral bodies), the resulting spine joint replacement construct would be extremely well anchored and unlikely to migrate or loosen. However, even where a portion of the facet replacement prosthesis is simply in contact with an artificial disc replacement device (or possibly positioned between the artificial disc replacement and the spinal cord, and not actually connected to or in immediate contact with the disc replacement), the presence of the facet replacement components could be a barrier to artificial disc components migrating towards the spinal cord.

20 [00155] The facet joint replacement components could connect or attach to an artificial disc replacement prosthesis in various manners, including through the interior of one or more vertebral bodies, or around the anterior, lateral or posterior walls of the vertebral body (and into the inter-disc space), or some combination of both.

25 [00156] In the case of annular repair and/or implantation of an artificial disc nucleus, it may be desirable that the facet replacement prosthesis bear a disproportionately higher share of the spinal load, thereby shielding the repaired and/or damaged tissue during natural healing or to prevent further degeneration or unacceptable loading on the other portions of the spine.

30 [00157] The above described embodiments of this invention are merely descriptive of its principles and are not to be limited. The scope of this invention instead shall be determined from the scope of the following claims, including their equivalents.

40

WHAT IS CLAIMED IS:

1. A facet joint prosthesis to replace, on a vertebral body, a caudal portion of a natural facet joint, comprising:

5 a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and

a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

2. The facet joint prosthesis of claim 1 wherein the support component is sized to span a portion of the vertebral body between a left lamina and a right lamina.

10 3. The facet joint prosthesis of claim 1 wherein the support component is sized to span a portion of the vertebral body between a left pedicle and a right pedicle.

4. The facet joint prosthesis of claim 1 further comprising a kit comprising a plurality of support components having different lengths.

15 5. The facet joint prosthesis of claim 1 wherein the support component is further adapted to have an adjustable width.

6. The facet joint prosthesis of claim 1 further comprising one fixation element adapted to secure both prosthetic caudal facet elements to the vertebral body.

20 7. The facet joint prosthesis of claim 1 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the prosthetic caudal facet elements being further adapted to be movable with respect to the fixation element and the support component.

8. The facet joint prosthesis of claim 1 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the support component being further adapted to be movable with respect to the fixation element and the prosthetic caudal facet elements.

25 9. The facet joint prosthesis of claim 1 wherein the support component is a curvilinear transverse rod.

10. The facet joint prosthesis of claim 1 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide a symmetric anatomical solution.

11. The facet joint prosthesis of claim 1 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide an asymmetric anatomical solution.

30 12. The facet joint prosthesis of claim 1 wherein the support component has an opening to receive the caudal prosthesis elements.

13. The facet joint prosthesis of claim 12 wherein the prosthetic caudal facet elements are placed in the opening.

35 14. The facet joint prosthesis of claim 12 wherein the prosthetic caudal facet elements are adapted to be connected to the support component with a fixation element placed through the opening.

15. The facet joint prosthesis of claim 14 wherein the prosthetic caudal facet elements are adapted to be connected to the support component after the pair of caudal elements are secured to the vertebral body.

16. A prosthesis for replacing a natural spinal facet joint comprising:

40 a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and

a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms

and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

17. The prosthesis of claim 16 wherein each of the arms is configured to receive a fixation element.

5 18. The prosthesis of claim 16 wherein the arms are adapted to be positionable with respect to the brace.

19. A prosthesis for replacing a natural spinal facet joint comprising:

a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and

10 a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

15 20. The prosthesis of claim 19 wherein at least one of the caudal facet elements is positionable with respect to the caudal brace.

21. The prosthesis of claim 19 wherein the cephalad brace further comprising a cephalad facet element spacing adjustment mechanism.

20 22. A system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

23. The system of claim 22 wherein the support component is sized to span a portion of the vertebral body between a left lamina and a right lamina.

25 24. The system of claim 22 wherein the support component is sized to span a portion of the vertebral body between a left pedicle and a right pedicle.

25. The system of claim 22 further wherein the support component is selected from a plurality of support components having different lengths.

26. The system of claim 22 wherein the support component is further adapted to have an adjustable width.

30 27. The system of claim 22 further comprising one fixation element adapted to secure both prosthetic caudal facet elements to the vertebral body.

28. The system of claim 22 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the prosthetic caudal facet elements being further adapted to be movable with respect to the fixation element and the support component.

35 29. The system of claim 22 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the support component being further adapted to be movable with respect to the fixation element and the prosthetic caudal facet elements.

30. The system of claim 22 wherein the support component is a curvilinear transverse rod.

40 31. The system of claim 22 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide a symmetric anatomical solution.

32. The system of claim 22 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide an asymmetric anatomical solution.

33. The system of claim 22 wherein the support component has an opening to receive the caudal prosthesis elements.

34. The system of claim 33 wherein the prosthetic caudal facet elements are placed in the opening.

5 35. The system of claim 33 wherein the prosthetic caudal facet elements are adapted to be connected to the support component with a fixation element placed through the opening.

36. The system of claim 35 wherein the prosthetic caudal facet elements are adapted to be connected to the support component after the pair of caudal elements are secured to the vertebral body.

10 37. A system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements

38. The system of claim 37 wherein each of the arms is configured to receive a fixation element.

15 39. The system of claim 37 wherein the arms are adapted to be positionable with respect to the brace.

20 40. A system for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

41. The system of claim 40 wherein at least one of the caudal facet elements is positionable with respect to the caudal brace.

25 42. The system of claim 40 wherein the cephalad brace further comprising a cephalad facet element spacing adjustment mechanism.

30 43. A surgical kit for treating spinal pathologies including an intervertebral disc prosthesis and a facet joint prosthesis comprising a support component adapted to span a portion of the vertebral body and to support prosthetic caudal facet elements; and a pair of prosthetic caudal facet elements adjustable relative to the support component and adapted to replace the caudal portion of the natural facet joint.

44. The surgical kit of claim 43 wherein the support component is sized to span a portion of the vertebral body between a left lamina and a right lamina.

45. The surgical kit of claim 43 wherein the support component is sized to span a portion of the vertebral body between a left pedicle and a right pedicle.

35 46. The surgical kit of claim 43 further wherein a plurality of support components having different lengths are provided.

47. The surgical kit of claim 43 wherein the support component is further adapted to have an adjustable width.

40 48. The surgical kit of claim 43 further comprising one fixation element adapted to secure both prosthetic caudal facet elements to the vertebral body.

49. The surgical kit of claim 43 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the prosthetic caudal facet elements being further adapted to be movable with respect to the fixation element and the support component.

50. The surgical kit of claim 43 further comprising a fixation element adapted to attach the prosthesis to the vertebral body, the support component being further adapted to be movable with respect to the fixation element and the prosthetic caudal facet elements.

51. The surgical kit of claim 43 wherein the support component is a curvilinear transverse rod.

52. The surgical kit of claim 43 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide a symmetric anatomical solution.

53. The surgical kit of claim 43 wherein the prosthetic caudal facet elements are positioned relative to the support component to provide an asymmetric anatomical solution.

54. The surgical kit of claim 43 wherein the support component has an opening to receive the caudal prosthesis elements.

55. The surgical kit of claim 54 wherein the prosthetic caudal facet elements are placed in the opening.

56. The surgical kit of claim 54 wherein the prosthetic caudal facet elements are adapted to be connected to the support component with a fixation element placed through the opening.

57. The surgical kit of claim 56 wherein the prosthetic caudal facet elements are adapted to be connected to the support component after the pair of caudal elements are secured to the vertebral body.

58. A surgical kit for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements

59. The surgical kit of claim 58 wherein each of the arms is configured to receive a fixation element.

60. The surgical kit of claim 58 wherein the arms are adapted to be positionable with respect to the brace.

61. A surgical kit for treating spinal pathologies including an intervertebral disc prosthesis in combination with a facet joint prosthesis comprising a modular caudal prosthesis comprising a pair of prosthetic caudal facet elements configured to replace the caudal portion of the natural facet joint and a caudal brace extending between the caudal facet elements; and a modular cephalad prosthesis configured to articulate with the caudal facet elements, the modular cephalad prosthesis comprising a pair of arms, a pair of supports, and a cephalad brace extending between the arms and the supports, each of the supports having an articulating portion adapted to articulate with the caudal facet elements.

62. The system of claim 61 wherein at least one of the caudal facet elements is positionable with respect to the caudal brace.

63. The system of claim 61 wherein the cephalad brace further comprising a cephalad facet element spacing adjustment mechanism.

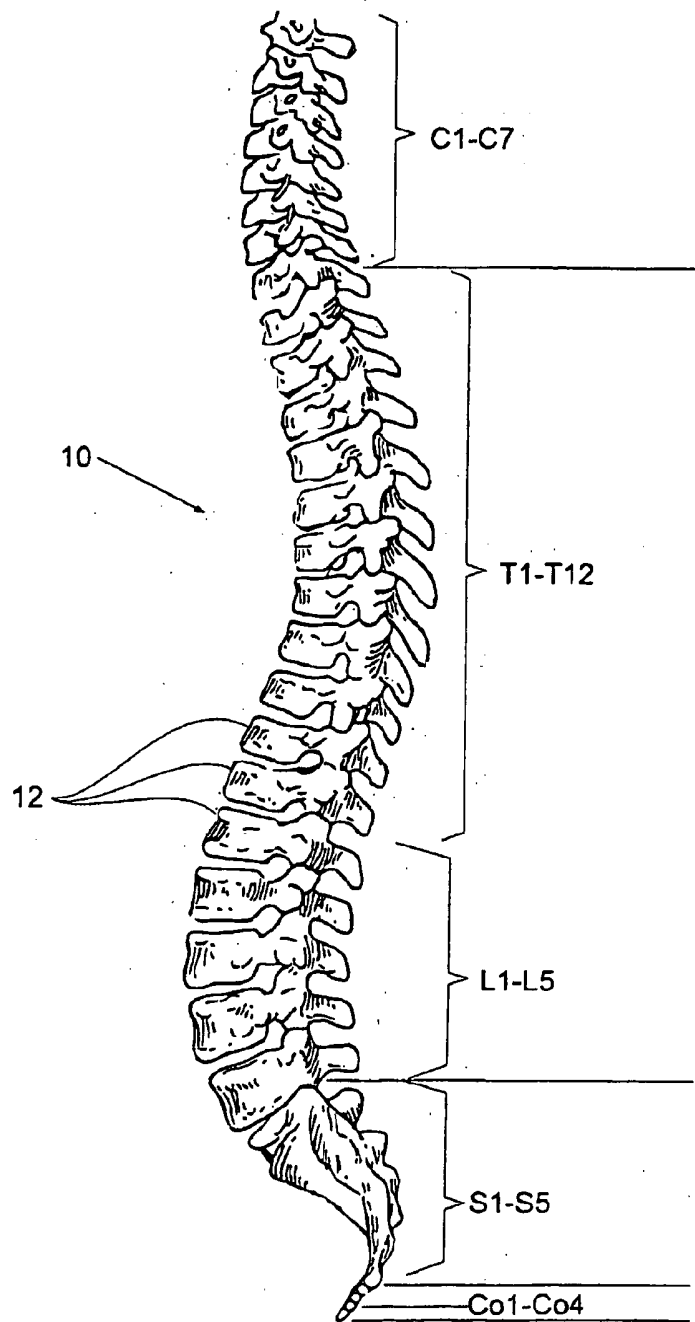
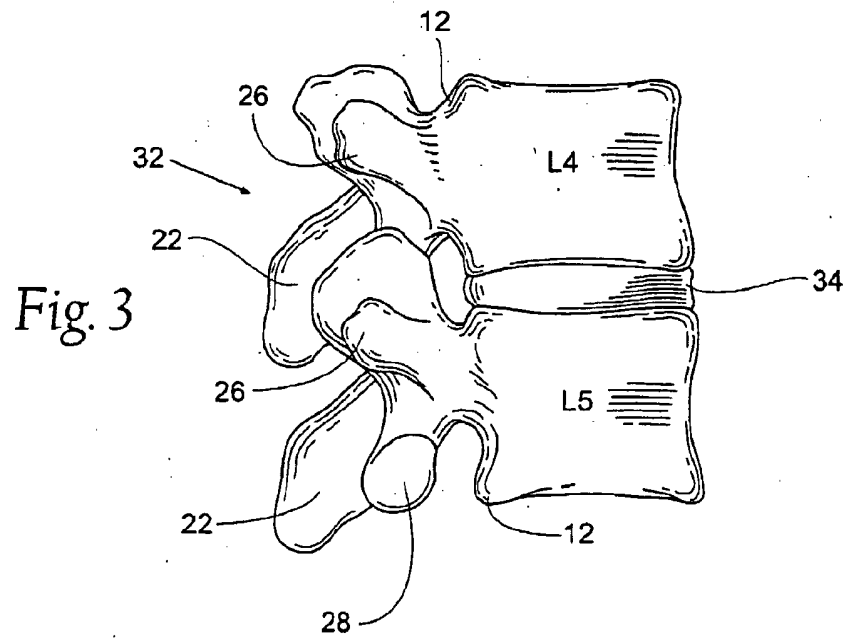
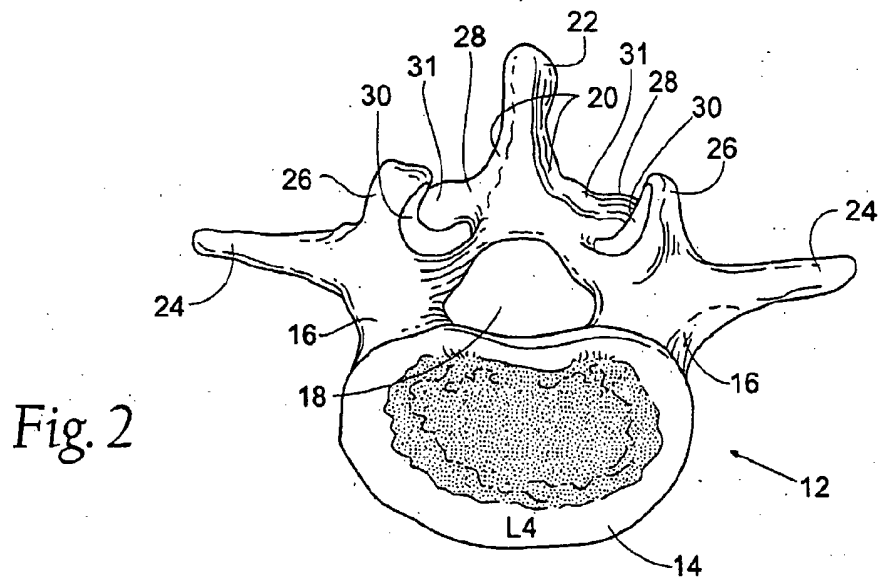
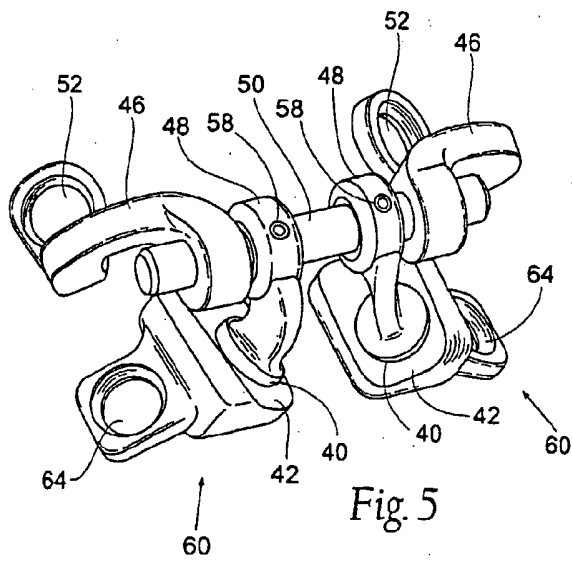
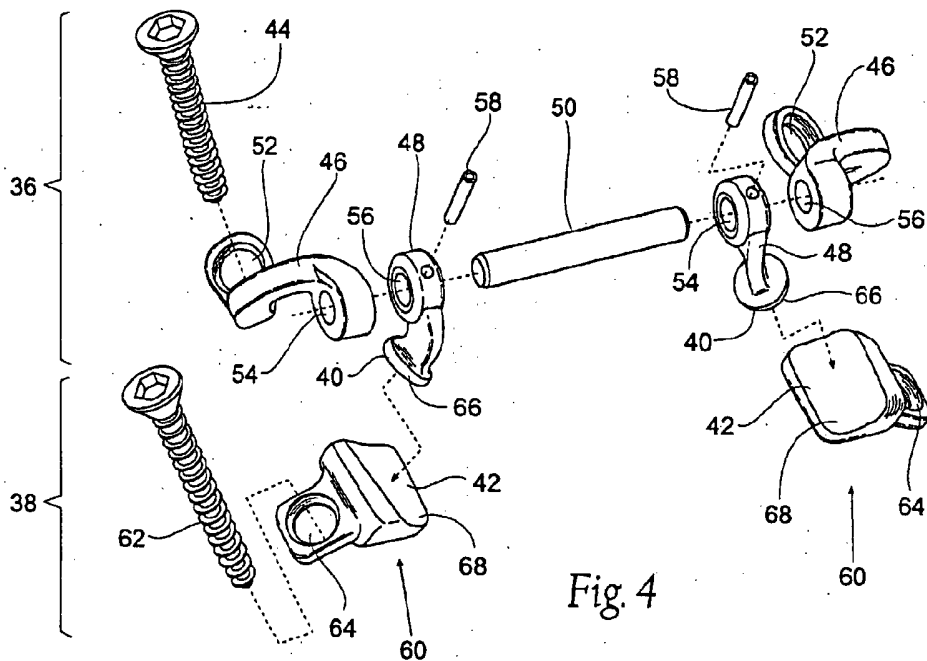


Fig. 1





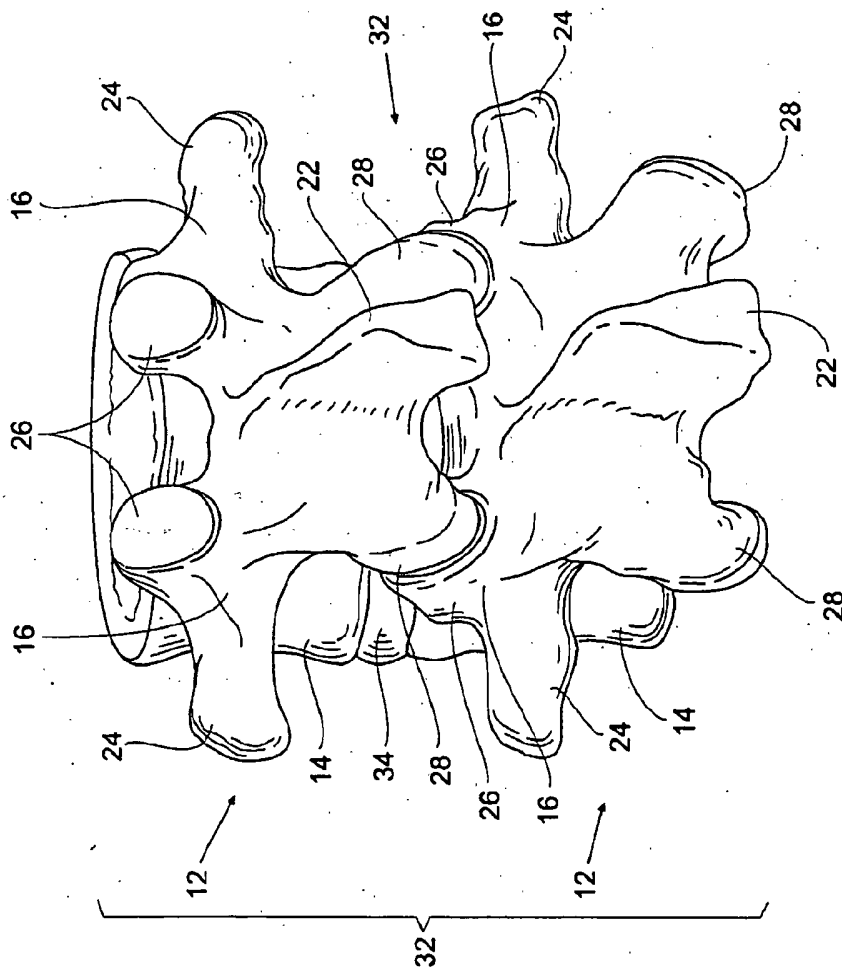


Fig. 6

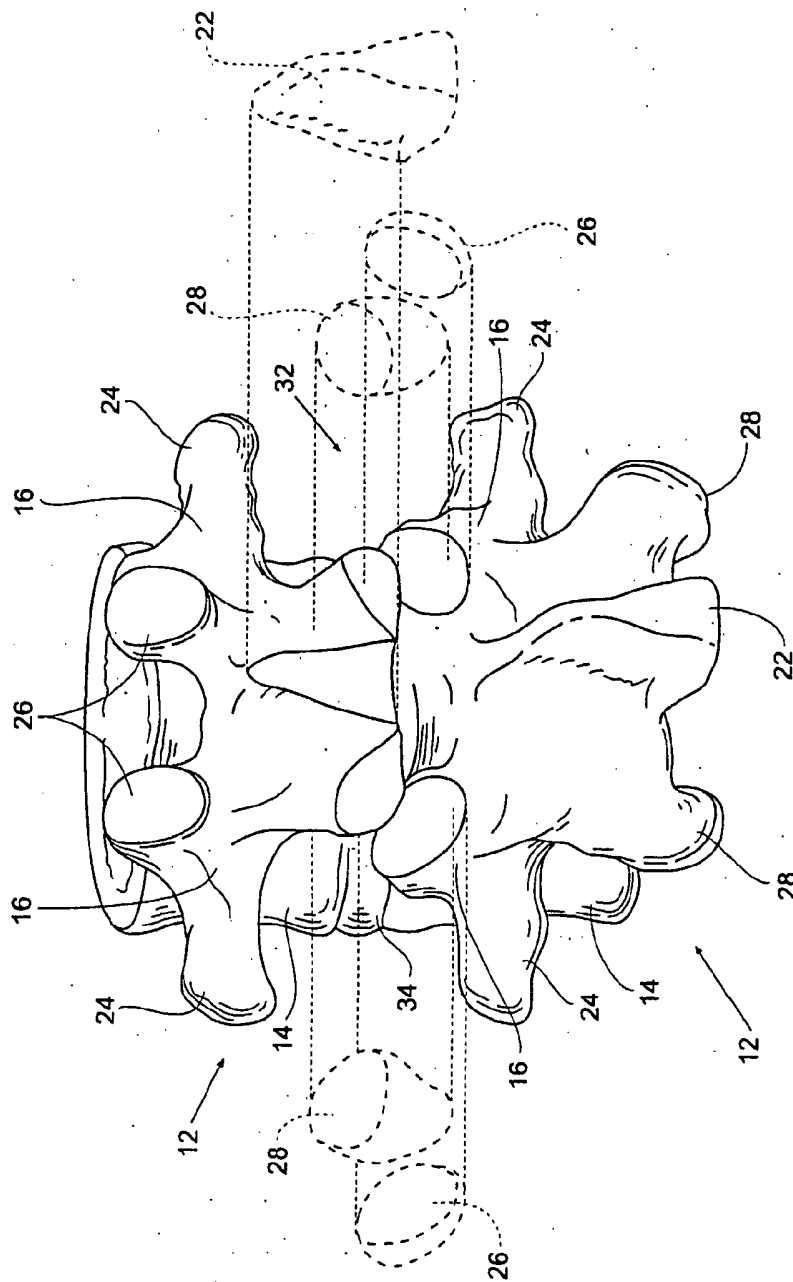


Fig. 7

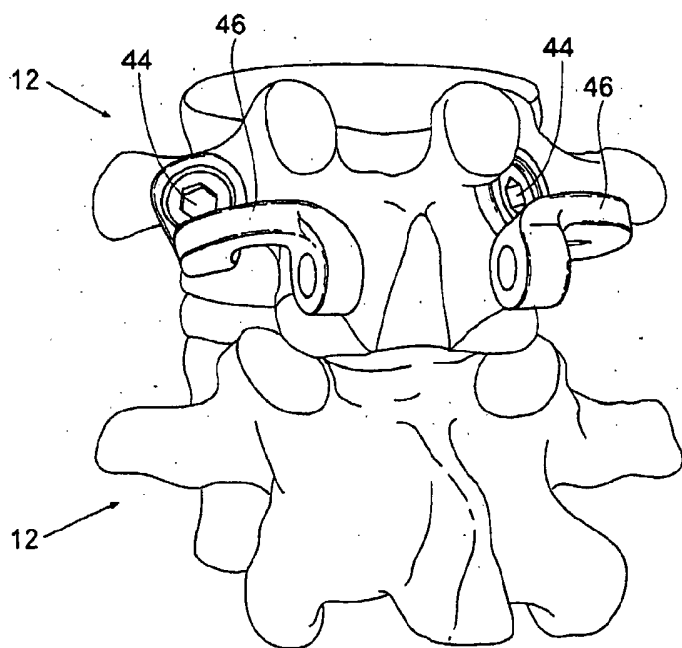


Fig. 8

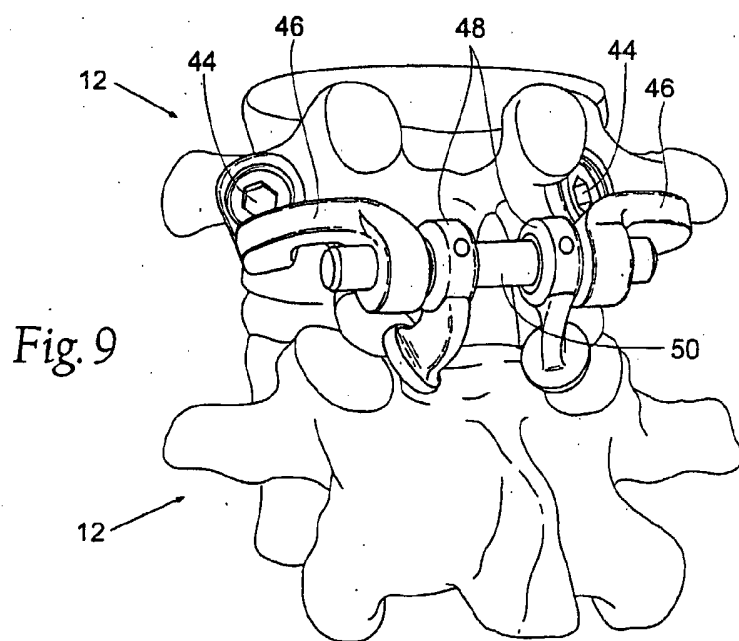
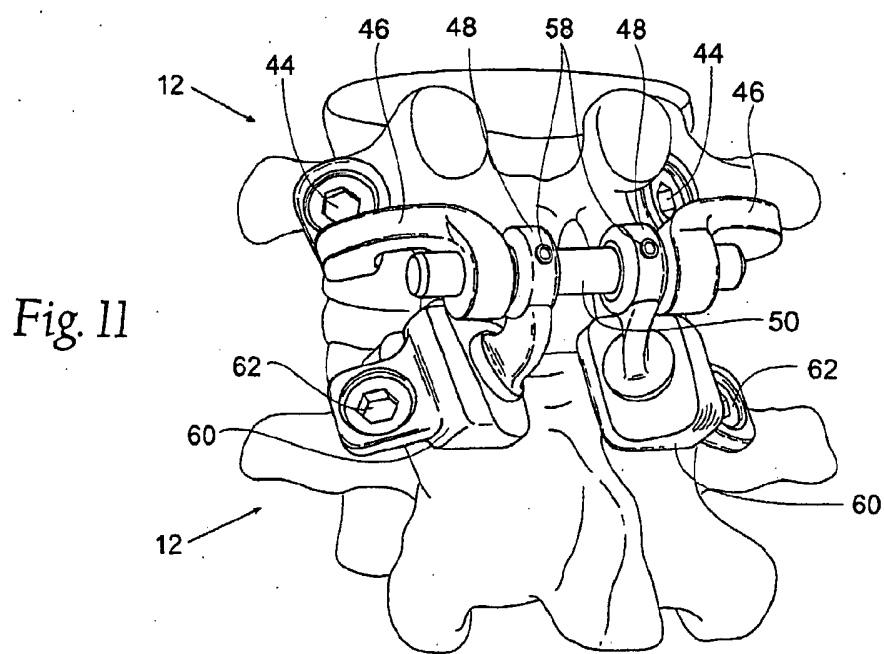
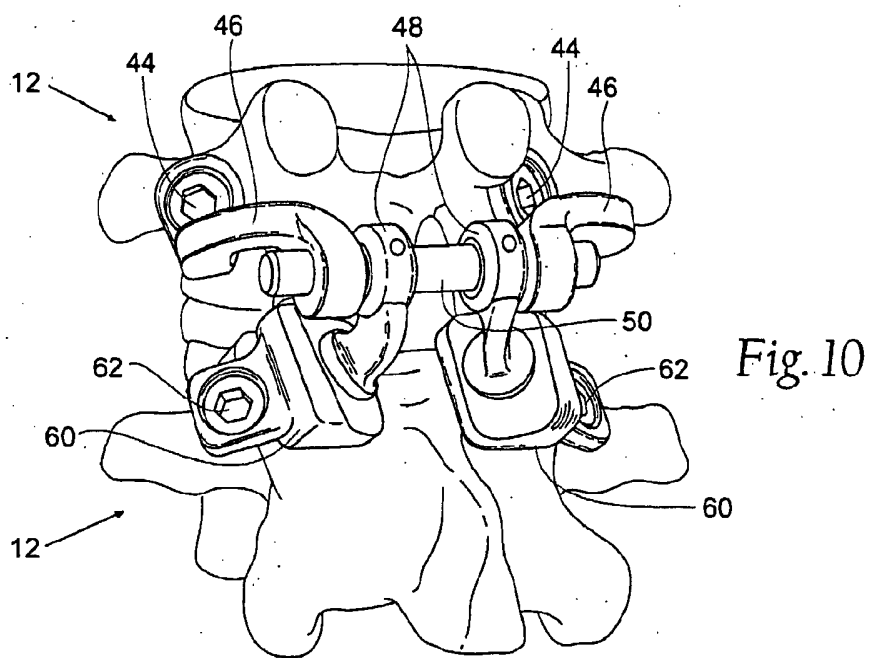


Fig. 9



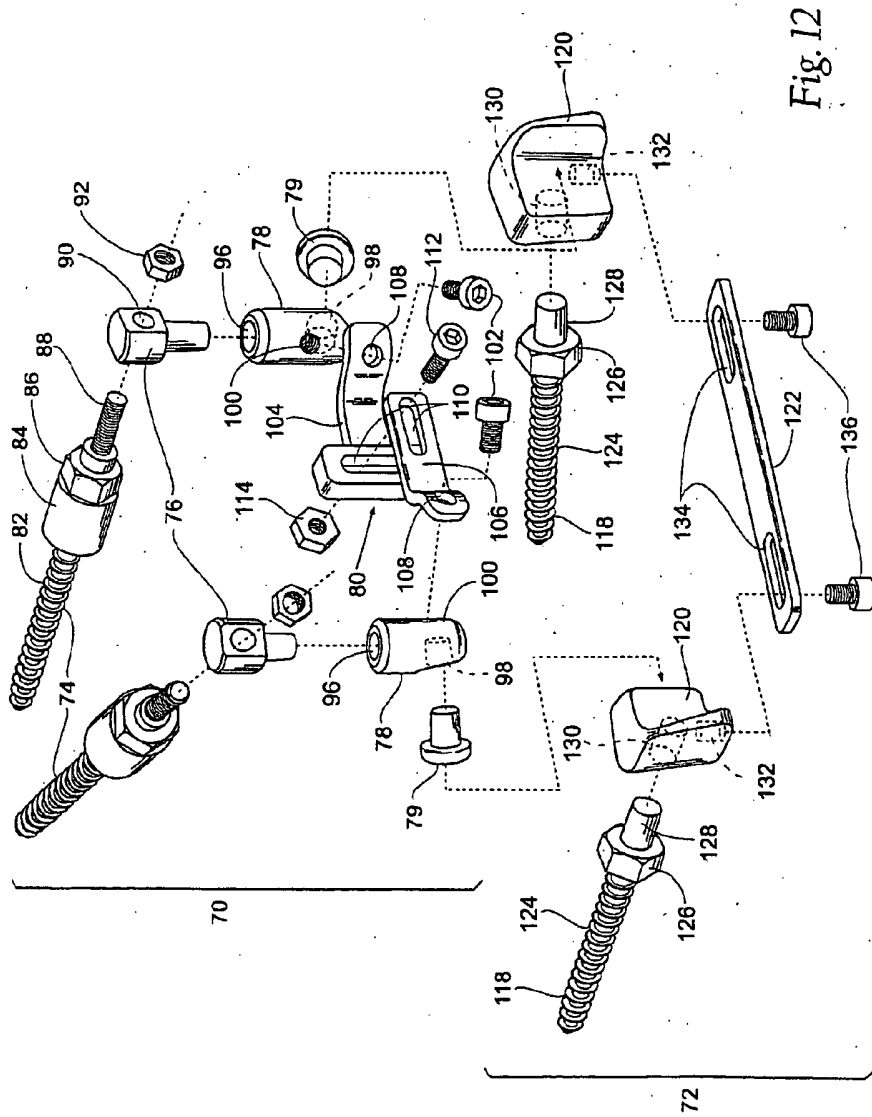


Fig. 12

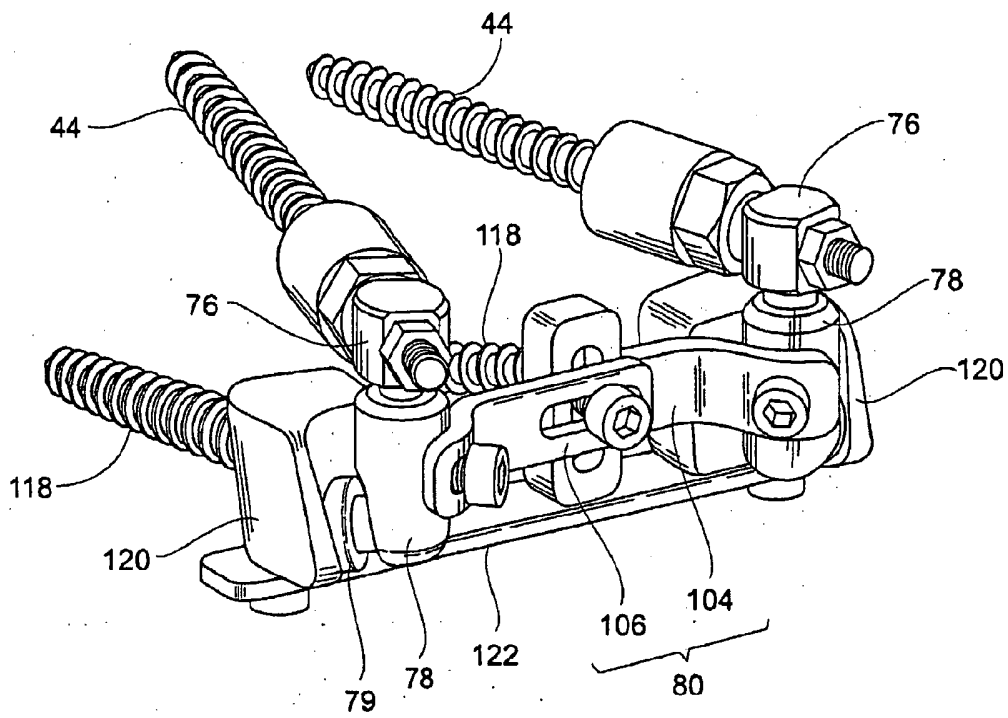


Fig. 13

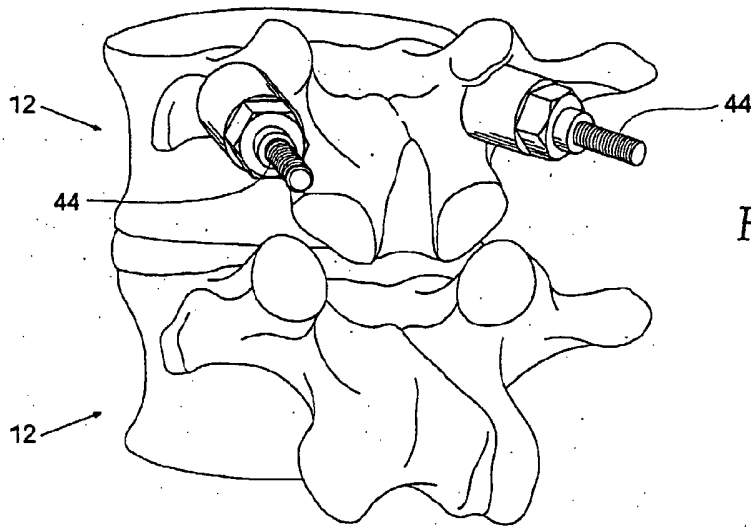


Fig. 14

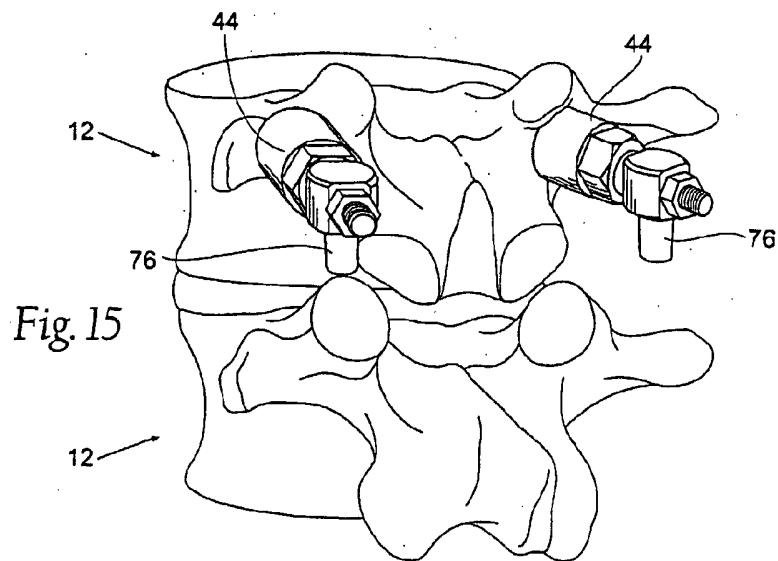
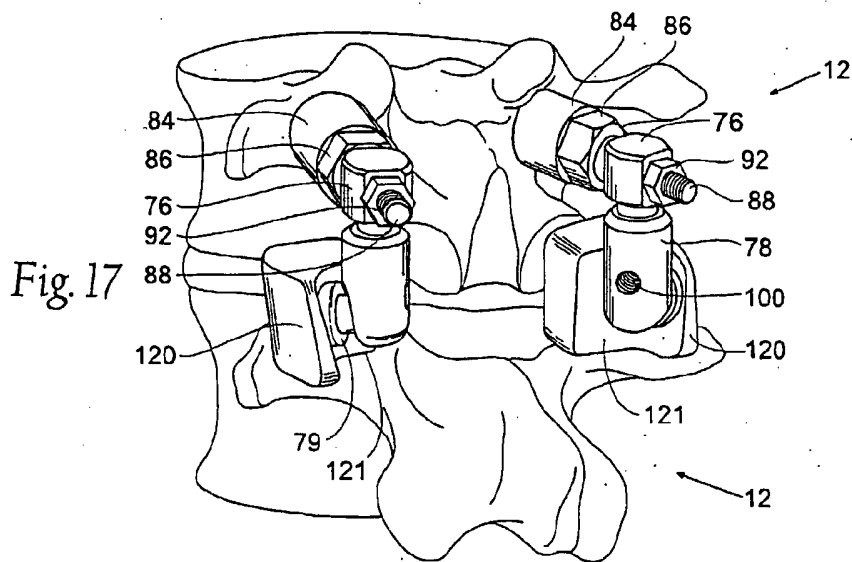
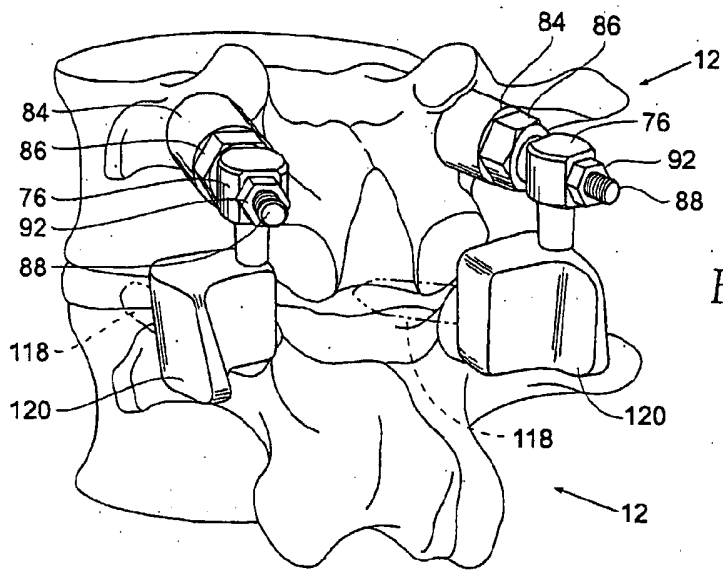


Fig. 15



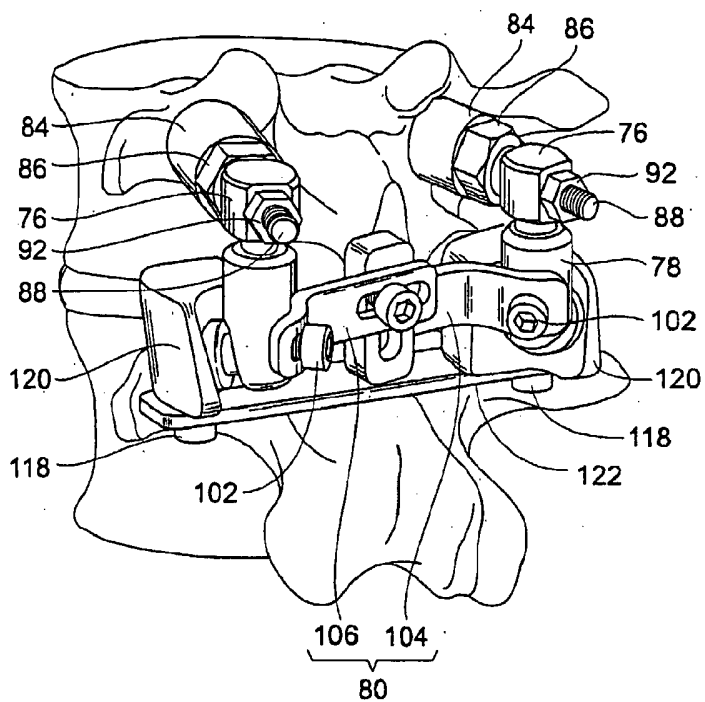


Fig. 18

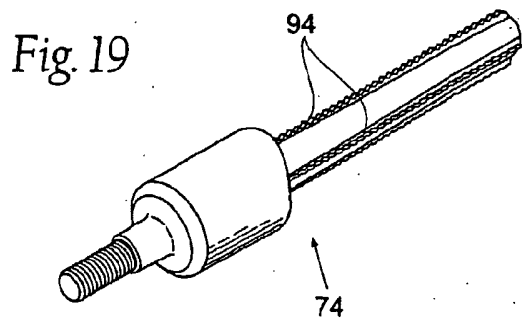


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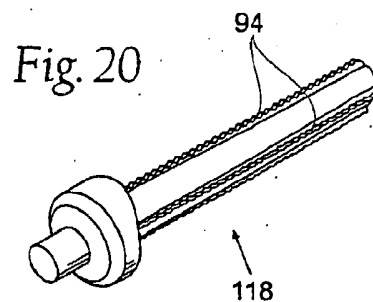


Fig. 20

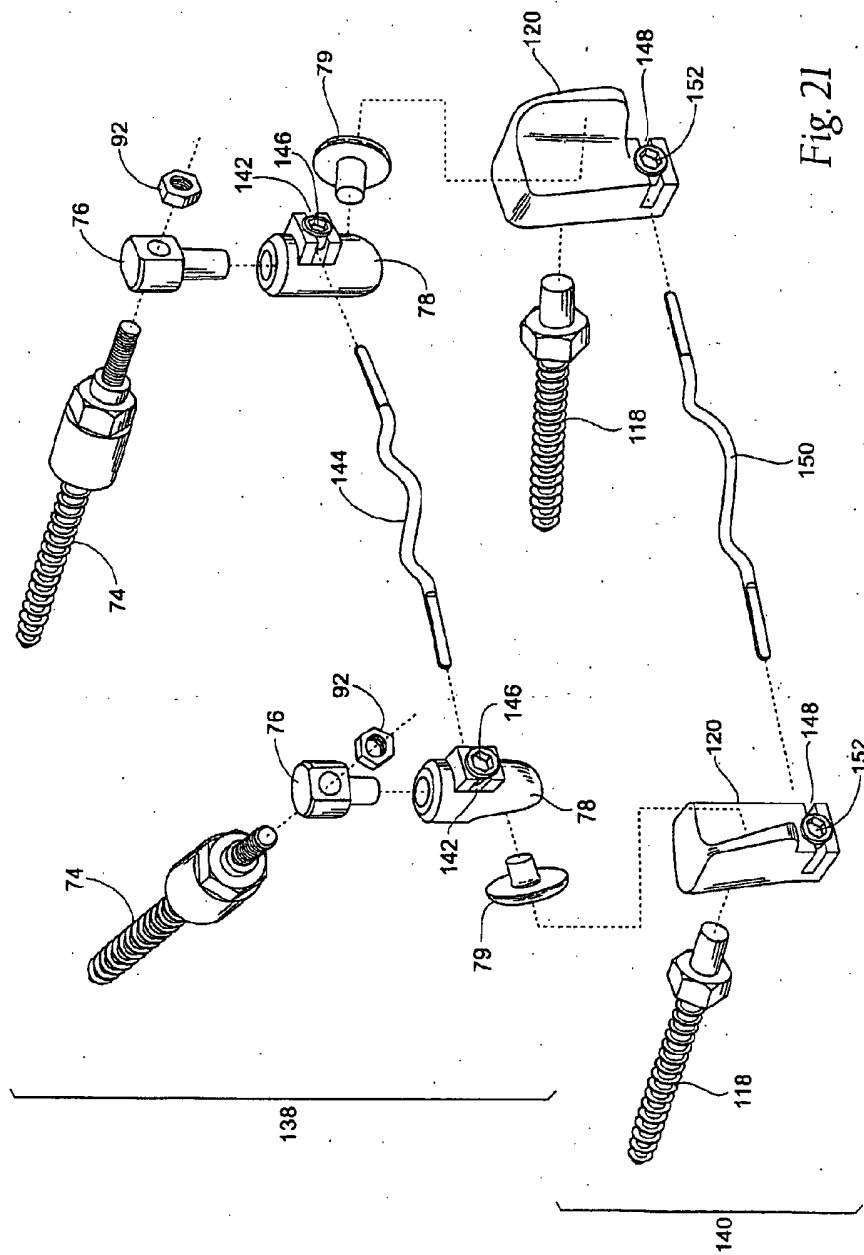
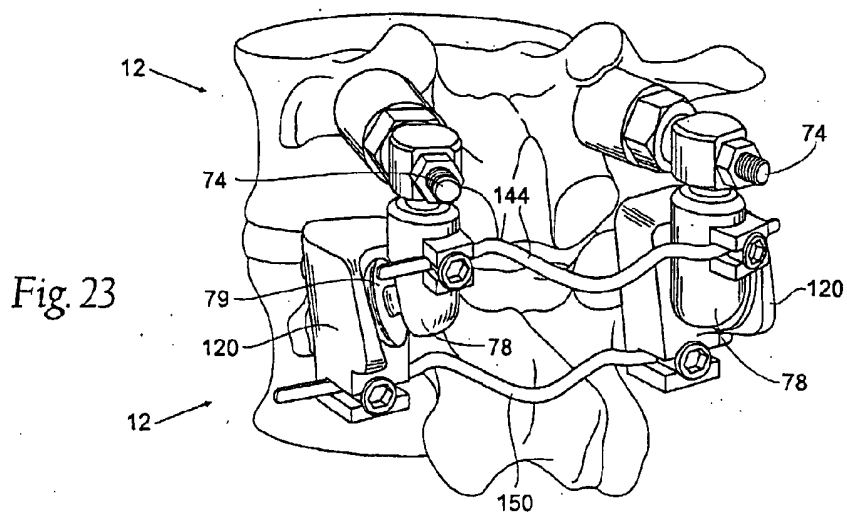
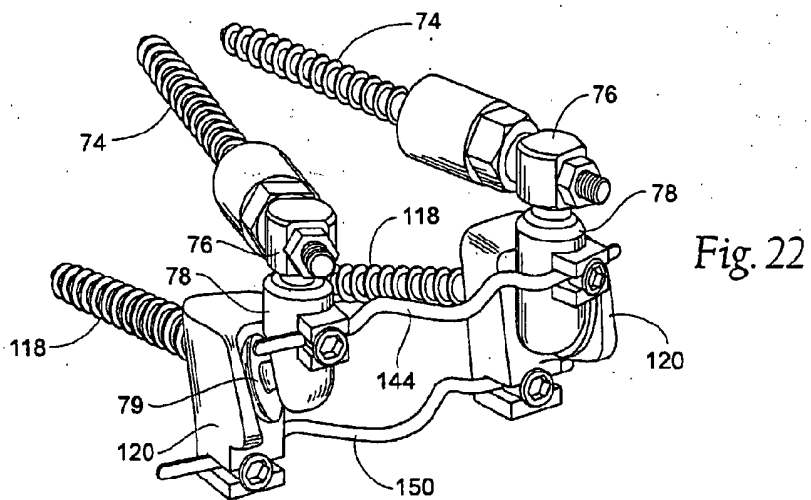


Fig. 21



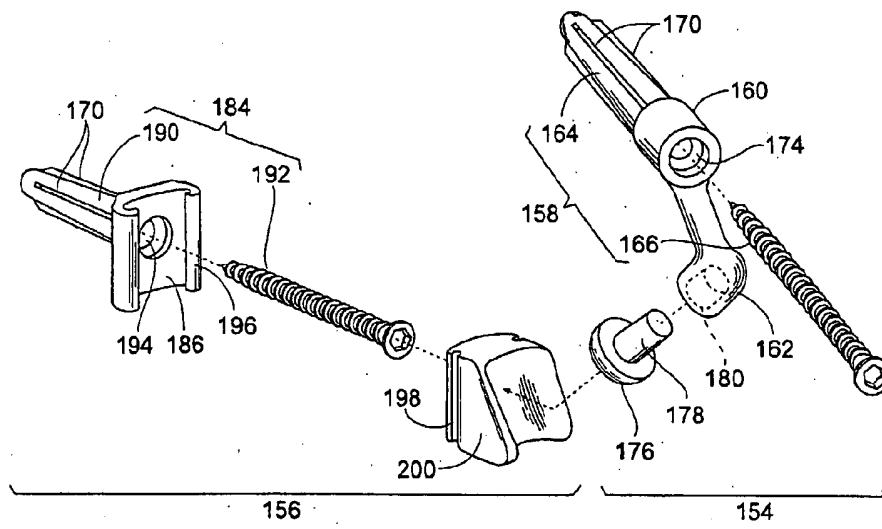


Fig. 24

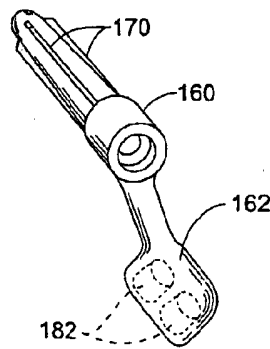


Fig. 25

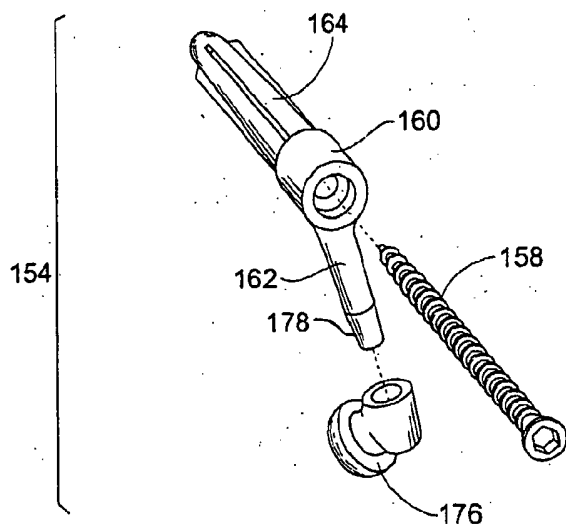


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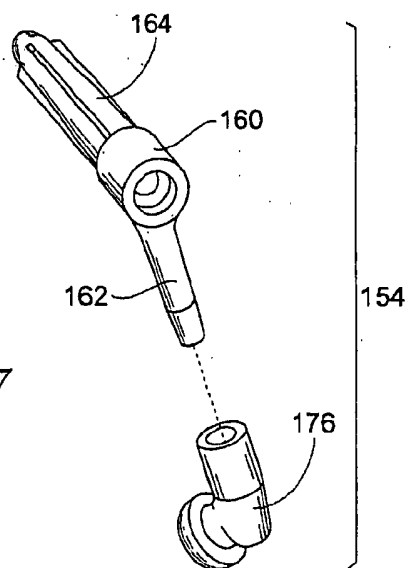


Fig. 27

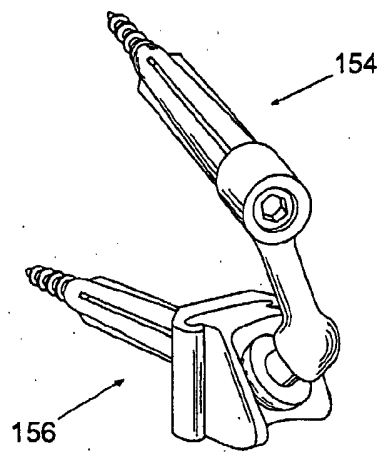


Fig. 28

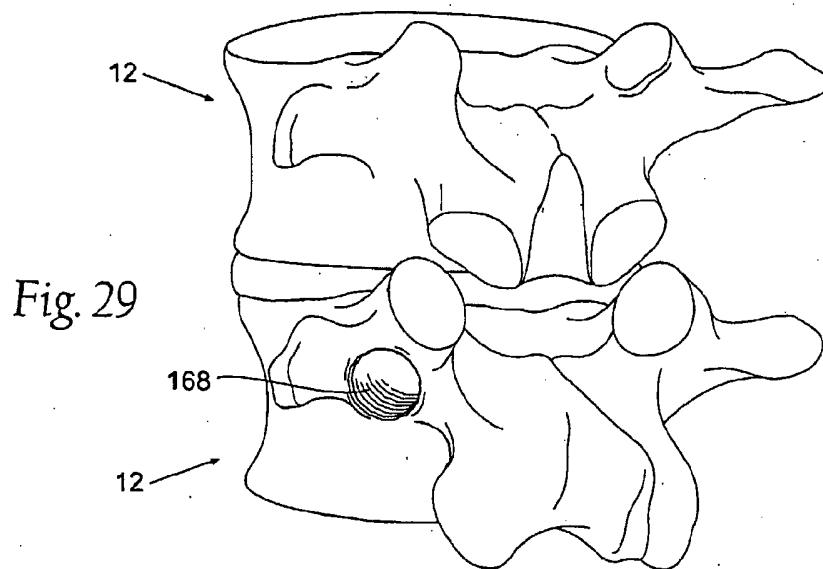


Fig. 29

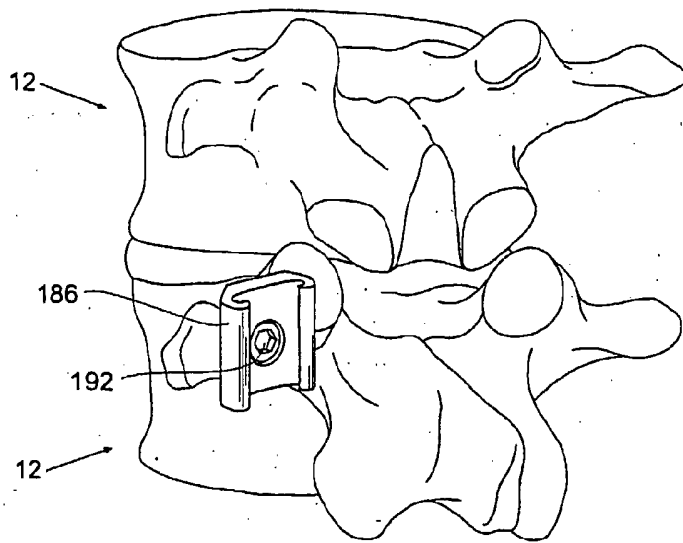


Fig. 30

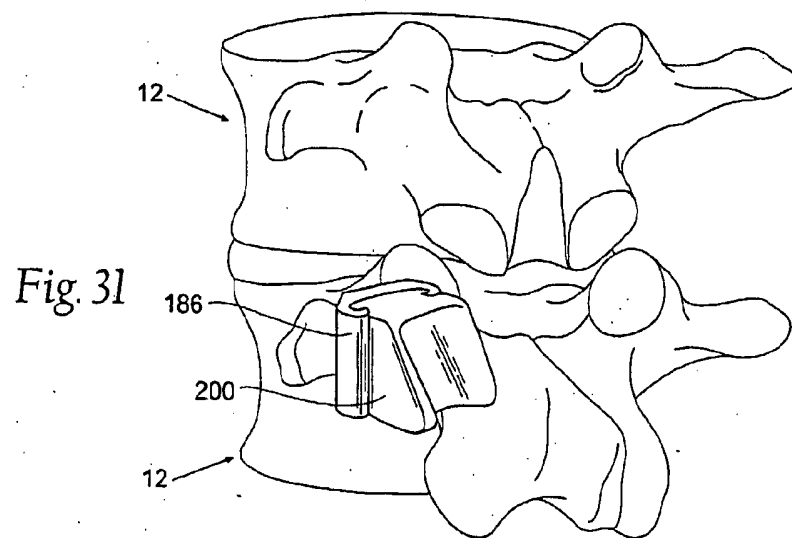


Fig. 31

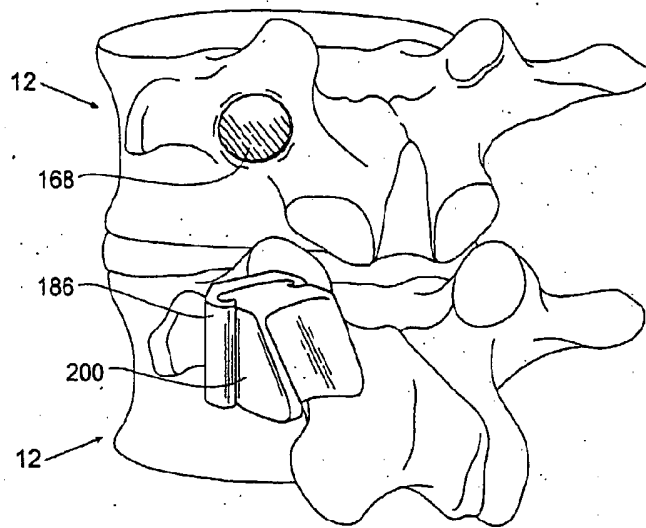


Fig. 32

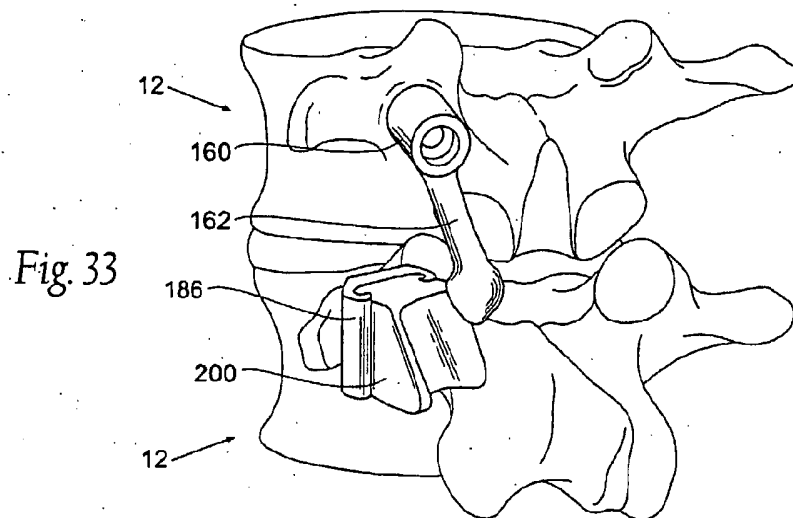


Fig. 33

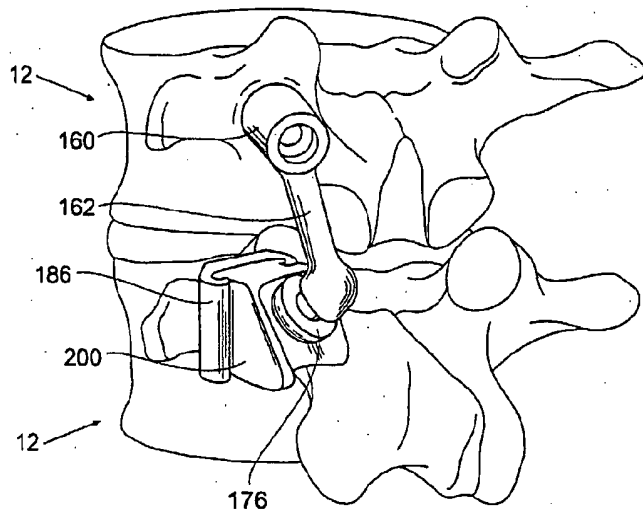


Fig. 34

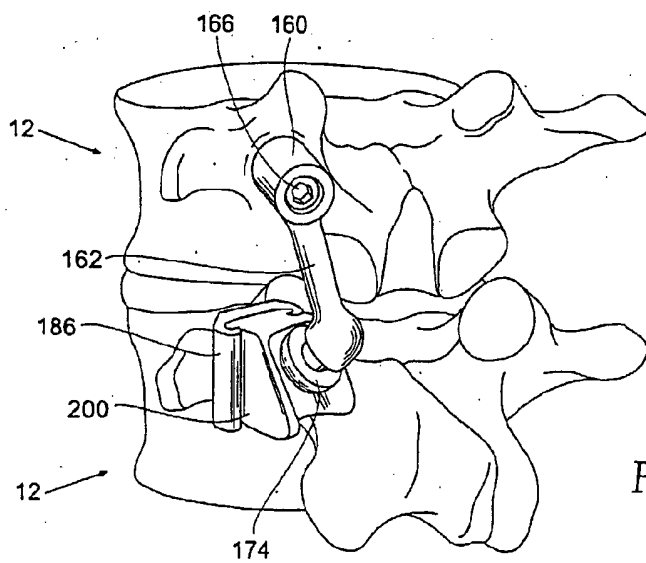


Fig. 35

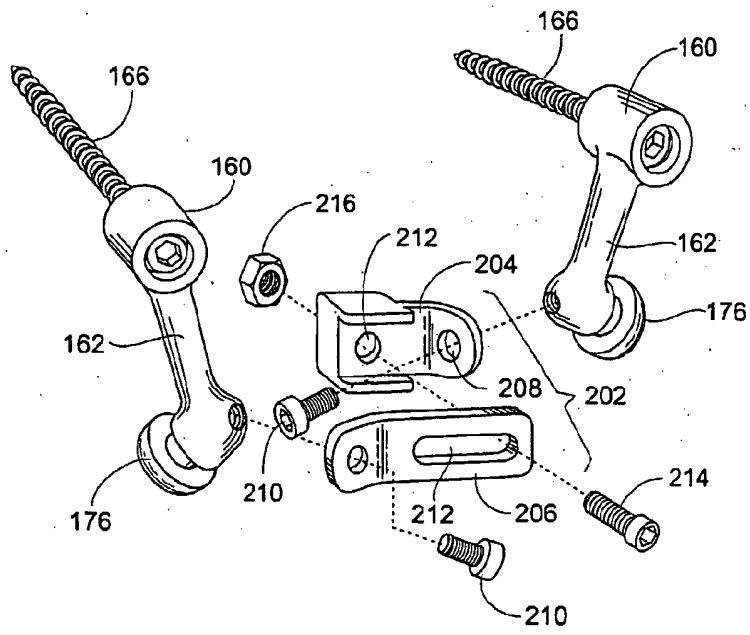


Fig. 36

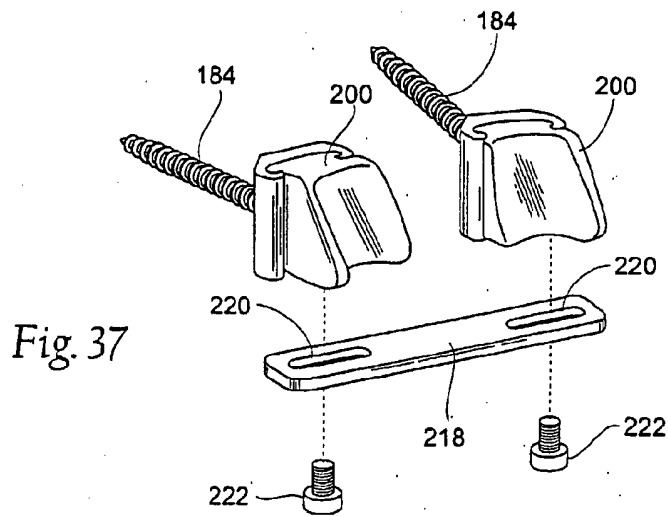


Fig. 37

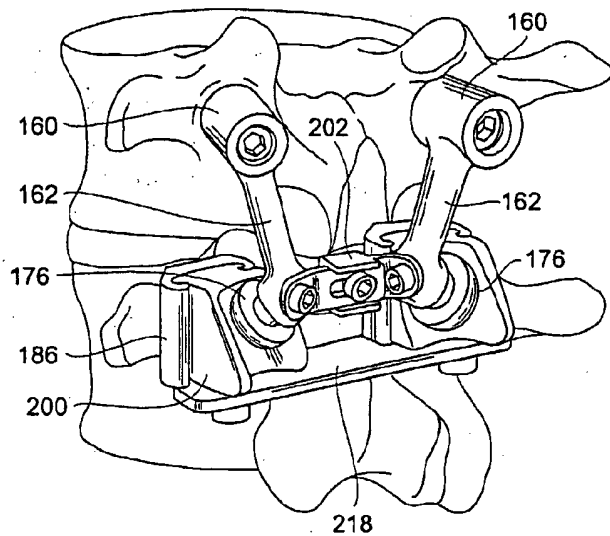


Fig. 38

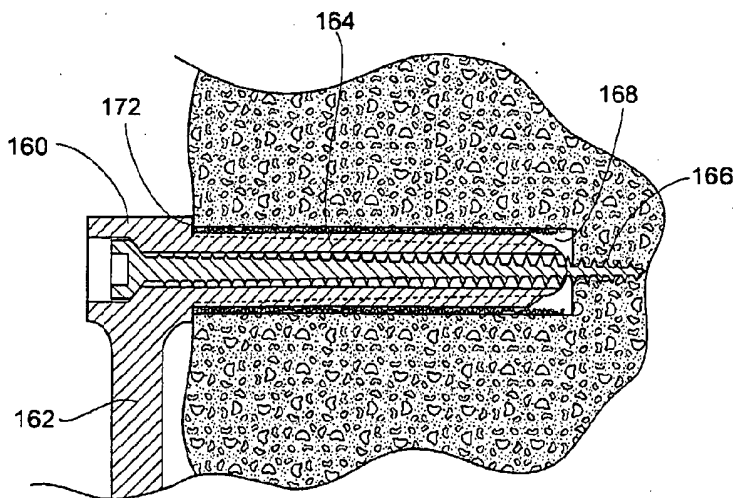


Fig. 39

INTERNATIONAL SEARCH REPORT

national application No
PCT/US2005/038087

A. CLASSIFICATION OF SUBJECT MATTER A61F2/44		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/071358 A (ARCHUS ORTHOPEDICS) 26 August 2004 (2004-08-26)	1-7, 9-14, 16-20
Y	page 15, line 20 - line 29 page 23, line 19 - line 29 page 24, line 20 - line 21 figures 6,9 ----- -/--	8,28-30, 33-36, 39,41, 49-51, 54-56, 60,62
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *G* document member of the same patent family		
Date of the actual completion of the international search 27 February 2006		Date of mailing of the international search report 06/03/2006
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Nice, P

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	page 3, line 4 - line 29; claim 8; figure 2	8, 28-30, 33-36, 39, 41, 49-51, 54-56, 60, 62
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A	figures 4-8	1
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