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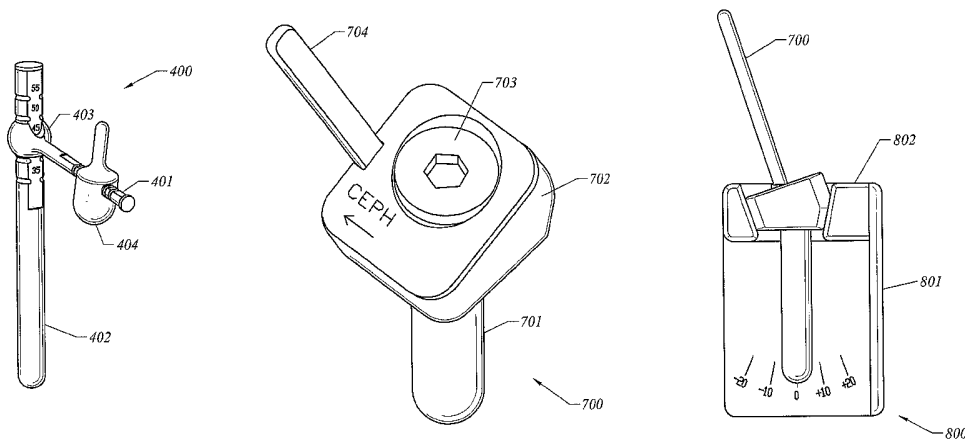
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(54) Title: FACET JOINT PROSTHESIS MEASUREMENT AND IMPLANT TOOLS



(57) Abstract: The present invention provides tools and methods designed to aid in the placement of facet joint prostheses at virtually all-spinal levels. One aspect of the present invention is a measurement tool (400) for installing a cephalad facet joint prosthesis including a fixation measurement element (402) and a support arm element (401). This measurement tool assists in the selection and/or configuration of a cephalad facet joint prosthesis for implantation in a patient. Another aspect is a measurement tool (700) for installing a caudal facet joint prosthesis including a stem element (701) and a trial caudal bearing surface element (702). This measurement tool assists in the selection and/or configuration of a caudal facet joint prosthesis for implantation in a patient. Yet another aspect is a measurement tool holder (800) including a measurement surface (801) connected to a holder element (802). These tool holder assists in determining the measurements obtained with the caudal facet joint prosthesis measurement tool.

WO 2005/107657 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FACET JOINT PROSTHESIS MEASUREMENT AND IMPLANT TOOLS

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

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

The superior and inferior articular processes 26 and 28 each have a natural bony
structure known as a facet. The superior articular facet 30 faces upward, while the inferior
articular facet 31 (see Figure 3) faces downward. When adjacent vertebrae 12 are aligned,

the facets 30 and 31, capped with a smooth articular cartilage, interlock to form a facet joint 32, also known as a zygapophyseal joint.

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

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

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

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

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

One type of conventional treatment of facet joint pathology is spinal stabilization, also known as intervertebral stabilization. Intervertebral stabilization prevents relative motion between the vertebrae. By preventing movement, pain can be reduced. Stabilization can be accomplished by various methods.

One method of stabilization is spinal fusion. Another method of stabilization is fixation of any number of vertebrae to stabilize and prevent movement of the vertebrae. Another type of conventional treatment is decompressive laminectomy. This procedure involves excision of some or all of the laminae to relieve compression of nerves.

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

5 Artificial facet joint prostheses have been proposed as an alternative to spinal fusion. Examples of such prostheses may be found in U.S. Patent No. 6,610,091; U.S. Patent Appl. Publ. No. 2002/0123806 A1; U.S. Patent Appl. Publ. No. 2003/0028250 A1; and U.S. Patent Appl. S.N. 10/737,705, the disclosures of which are incorporated herein by reference. The prostheses and methods described therein help establish a desired anatomy to a spine and
10 return a desired range of mobility to an individual. Such prostheses and methods also help lessen or alleviate spinal pain by relieving the source of nerve compression or impingement.

SUMMARY OF THE INVENTION

What is needed are methods and tools for facilitating the sizing, orientation and
15 implant of spine prostheses such as artificial facet joint prostheses. The present invention provides tools and methods designed to aid in the placement of facet joint prostheses at virtually all spinal levels including, but not limited to, L1-L2, L2-L3, L3-L4, L4-L5, L5-S1, T11-T12, and T12-L1.

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

Because the specific features of a patient's spinal anatomy can vary significantly from patient to patient (and can also vary within the various spinal levels of an individual patient or even vary between the facet joints in a single vertebral level), a prosthesis suitable for implantation into a patient will desirably be configured or tailored to accommodate the

specific features of the patient's spinal anatomy. For example, the size, spacing and orientation of the pedicles, lamina and associated spinal anatomy, as well as the size, spacing and orientation of the individual facet joints to be replaced, can vary widely depending upon the level and/or patient to be treated.

5 In order to accommodate such variations in anatomy, a configurable and/or modular prosthesis system (comprising multiple configurable and/or interchangeable components of varying shapes and/or sizes) may be used to tailor the prosthesis to the varying anatomical demands of a given patient. Once the surgical site has been prepared, the prosthesis can be assembled and/or configured from components chosen by the physician based on anatomical
10 measurements of the treatment site during the surgery. The disclosed invention desirably facilitates such measurements of the treated anatomy.

In one aspect, the present invention provides a measurement tool for configuring and installing a cephalad facet joint prosthesis including a fixation measurement element and a support arm element. This measurement tool assists in the selection of a cephalad facet joint
15 prosthesis for implantation in a patient. The measurement tool can be used in the determination of the dimensions of a cephalad facet joint prosthesis. Particularly, this measurement tool can be used to determine the length of the fixation element and support arm element of the cephalad facet joint prosthesis.

In some embodiments, the connection between the fixation measurement element and
20 support arm element is a polyaxially adjustable connection. In one embodiment, the fixation measurement element has indentations which control the vertical movement of the support arm element. The indentations on the fixation measurement element can also permit the determination of the length of the fixation element of a cephalad facet joint prosthesis.

In one embodiment, the support arm element supports a trial facet joint bearing
25 surface. The bearing surface is intended to predict the location of the facet joint bearing surface of an actual prosthesis intended for implantation in a patient.

The fixation measurement element in one embodiment is adapted and configured to permit measurements for determination of the length of the fixation element of a cephalad
30 facet joint prosthesis for implantation in a patient. In another embodiment, the fixation measurement element includes markings to assist in the determination of the length of the fixation element of a cephalad facet joint prosthesis.

In another aspect, the present invention provides a caudal facet joint prosthesis measurement system including a stem element and a trial caudal bearing surface element connected to each other by a fastener or fastening mechanism. This measurement tool assists

in the selection of a caudal facet joint prosthesis for implantation in a patient. The measurement tool can be used in the determination of the dimensions of a caudal facet joint prosthesis. Particularly, this measurement tool can be used to determine the length of the fixation element of the caudal facet joint prosthesis to be implanted in a patient. Also, this
5 tool can be used to determine the angle between the artificial facet joint element and fixation element of the caudal facet joint prosthesis. If desired, the mechanism can permit motion between the elements for alignment purposes and also allow locking of the chosen configuration/orientation once determined.

In one embodiment, the fastener used in the caudal facet joint prosthesis measurement
10 tool is a screw. Examples of other suitable fasteners could include stems, posts, threads, polyaxial mechanisms, splines, tapers, press fits, bayonet, cap screws, ball detents, friction fits, cams, collets and/or clamps. In certain embodiments, the fastener permits vertical movement of the trial caudal bearing surface element along the stem element. In other
15 embodiments, the fastener permits rotation of the trial caudal bearing surface element in different planes with respect to the stem element. These planes can include movement along the axial and median planes.

In another embodiment, the stem element is adapted and configured to permit
measurement of the length of a fixation element of a caudal facet joint prosthesis to be
implanted in a patient. In yet another embodiment, the stem element of the measurement tool
20 includes markings to permit the measurement of the length of the fixation element.

In one of the embodiments, the measurement tool for the caudal facet joint prosthesis
is adapted and configured to permit measurement of the angle between the artificial facet
joint element and fixation element of a caudal facet joint prosthesis to be implanted in a
patient. The angle measurements can include measurements in the median, horizontal and
25 frontal planes (such measurements could also include measurements relative to the coronal, sagittal and/or axial planes, if desired). In one embodiment, to facilitate the determination of the angle measurement, the trial caudal bearing surface element is adapted and configured to interact with a measurement tool holder.

In one aspect, the invention is a measurement tool holder including a measurement
30 surface connected to a holder element. This tool holder assists in determining the angle measurements obtained with the caudal facet joint prosthesis measurement tool. The caudal facet joint prosthesis measurement tool can be placed in the tool holder and the angle between the artificial facet joint element and fixation element of a caudal facet joint prosthesis can be determined.

In one embodiment, the measurement tool holder is adapted and configured to hold the measurement tool for the caudal facet joint prosthesis. In yet another embodiment, the measurement surface of the tool holder includes two plates at right angles to each other. The plates can include markings to permit determination of the angle measurements, preferably in the horizontal and median planes.

Another aspect of the invention provides a method for determining the dimensions of a cephalad facet joint prosthesis to be implanted in a patient. The method includes the steps of forming a hole at a location in the vertebra and placing a fixation measurement element of a cephalad facet joint prosthesis measurement tool into the hole. Further optional steps include the steps of obtaining a first length measurement to determine length of a fixation element of a cephalad facet joint prosthesis to be implanted in a patient; and obtaining a second length measurement for determining the length of a support arm element of the cephalad facet joint prosthesis. In various embodiment, the measurement tool can be used in conjunction with a caudal prosthesis or other implanted device, or can be used in conjunction with the caudal joint surface or other natural anatomical landmark.

Yet another aspect of the invention provides a method for determining the dimensions of a caudal facet joint prosthesis to be implanted in a patient. The method includes the steps of forming a hole at a location in the vertebra and placing a caudal facet joint prosthesis measurement tool into the hole. Further optional steps include the steps of obtaining a length measurement which indicates the length of a fixation element of a caudal facet joint prosthesis to be implanted in a patient; and obtaining an angle measurement which indicates the angle between a artificial facet joint element and a fixation element of the caudal facet joint prosthesis. In an alternate embodiment, the external surfaces of the measurement tool could incorporate calibrated markings allowing angle measurements to be determined without an associated measurement fixture.

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

FIGS. 5A and 5B are views of one embodiment of a measurement tool for installing a cephalad facet joint prosthesis;

FIGS. 6A, 6B and 6C are views of one embodiment of an installed measurement tool for a cephalad facet joint prosthesis;

5 **FIG. 7** is a perspective view of one embodiment of a caudal prosthesis for replacing the superior half of a natural facet joint on an inferior vertebral body;

FIGS. 8A and 8B are views of one embodiment of a measurement tool for installing a caudal facet joint prosthesis;

10 **FIGS. 9A-D** are views of one embodiment of a measurement tool holder for holding a measurement tool for a caudal facet joint prosthesis; and

FIGS. 10A and 10B are views of one embodiment of an installed measurement tool for a caudal facet joint prosthesis.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

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

FIGS. 5 and 6 depict one embodiment of a measurement tool for installing a cephalad facet joint prosthesis. The measurement tool can be used to assist in the installation of cephalad facet joint prostheses such as those described in U.S. Patent Appl. S.N.
25 10/737,705 or other cephalad facet joint prostheses.

For purposes of illustrating the invention, one example of a cephalad facet joint prosthesis that is suitable for use with the measurement tools and methods described herein is depicted in **FIG. 4**. **FIG. 4** shows an artificial cephalad facet joint prosthesis **40** configured to replace the inferior articulating process of a facet joint, such as after the surgical removal
30 of the articulating process. When the cephalad prosthesis **40** is attached to a vertebra, the artificial facet joint element **44** articulates with the superior half of the facet joint **32**. In this example, prosthesis **40** includes an artificial facet joint element **44** connected to a fixation element **52** via a polyaxial connection **41** that permits facet joint element **44** and fixation element **52** to be rotated with respect to each other around more than one axis. A fixing nut

48 is threadably engaged with the outer periphery of base 42 above the artificial facet joint element 44. Similarly, a set screw 46 is threadably engaged with the inner periphery of base 42 above the artificial facet joint element 44. The artificial facet joint element 44 includes a support arm 72 and a facet joint bearing surface 74.

5 As shown in FIGS. 5A and 5B, a measurement tool 400 suitable for use in installing and configuring the prosthesis of FIG. 4 includes a support arm element 401 and a fixation measurement element 402 via a polyaxial connection element 403. The polyaxial connection element 403 permits movement of the support arm element 401 along the fixation measurement element 402 in multiple axes. The connection 403 permits vertical movement
10 of the support arm element 401 along the fixation measurement element 402 (or fixation element) and also permits horizontal movement of the support arm element 401 relative to the fixation measurement element 402. In this manner, the measurement tool contains aspects of the actual prosthesis. Measurement tools optimized to aid in the implantation of other spine prostheses may have other features containing aspects of those prostheses.

15 The fixation measurement element 402 is adapted and configured to permit measurement of the length of a fixation element of a cephalad facet joint prosthesis to be installed in a patient. Preferably, markings are present on the fixation measurement element 402 which permit the determination of this length measurement. Typically, a hole is formed in the vertebra of the patient at a location wherein the cephalad facet prosthesis is
20 intended to be installed and the measurement tool 400 is placed in this hole. The tool 400 is adjusted to a position similar to that of the cephalad facet joint prosthesis, and then the penetration depth of the fixation measurement element 402 into the hole is determined. This penetration depth assists the user in choosing the length of the fixation element required to attach the cephalad facet joint prosthesis to the vertebra.

25 In one embodiment, the fixation measurement element 402 includes indentations such as those depicted in FIG. 5A. The indentations provide stops for the vertical movement of the support arm 401 along the fixation measurement element 402. The indentations can also permit the determination of the length of the fixation element 52 of a cephalad facet joint prosthesis 40 to be installed in a patient. The indentations may be formed at intervals
30 corresponding to various fixation stems or screw lengths contained in a modular component kit.

Similarly, another length measurement can be obtained using the support arm element 401. Once the measurement tool 400 is placed into the hole drilled in the vertebra, the support arm is positioned into a location wherein the artificial facet joint element 44 of

the cephalad facet joint prosthesis **40** would be located. The distance between the fixation measurement element **402** and the putative location of facet joint bearing surface **74** of the cephalad facet joint prosthesis **40** is measured along the support arm element **401**. This measurement is used to select the length of the support arm **72** of the cephalad facet joint prosthesis **40** to be implanted in a patient. Alternatively, the measurement could correspond to a color coding or number/letter designation that is used to determine the appropriate correspondingly-identified prosthesis.

In one embodiment, a trial facet joint bearing surface **404** can be attached to the support arm element **401**. The trial facet joint bearing surface **404** may be placed in the location that the actual cephalad facet joint prosthesis **40** would be placed and then the length measurement can be obtained which can be used to select the length of the support arm **72** of the cephalad facet joint prosthesis **40**. Once again, the relationship between the measurement tool's fixation measurement element, support arm element and trial facet joint bearing surface corresponds to aspects of the actual facet joint prosthesis whose implant the tool is assisting. Other measurement tools and methods having aspects corresponding to other spine implant features are within the scope of this invention.

Another aspect of the invention is a method of using the measurement tool **400** to measure the dimensions of a cephalad facet joint prosthesis **40** to be used in total facet joint replacement. The cephalad prosthesis **40** is typically attached to a vertebra to replace the articulating function of the cephalad portion of the natural facet joint. Figure **6** shows different views of a measurement tool **400** placed into a vertebra. In one embodiment, for obtaining the measurements, the cephalad measurement tool **400** can be placed in one vertebra and a caudal facet joint prosthesis **600** can be placed in the inferior adjoining vertebra, as depicted in **FIG. 6**. The caudal facet joint prosthesis can be a trial prosthesis or the actual prosthesis. When the measurement tool **400** is used with a caudal facet joint prosthesis, it is preferred that the support arm element **401** bear a trial facet joint bearing surface **404**. To obtain the length measurements, a hole is formed in the location where the actual cephalad prosthesis **40** is to be placed and into this hole the measurement tool **400** is placed. The tool is placed in the hole at a depth that is similar to the depth at which actual cephalad prosthesis **40** is to be placed. The support arm **401** is moved horizontally and/or vertically with respect to the fixation measurement element **402** and placed at about the same location that the artificial facet joint element **44** would be placed. If the measurement tool **400** includes a trial cephalad facet joint bearing surface **404** and is used in combination with a caudal facet joint prosthesis, the trial facet joint bearing surface **404** is placed in the

bearing surface of the caudal prosthesis prior to taking the measurements. In one embodiment, as shown in **FIGS. 5B and 6B**, to determine the length of the support arm **72** of the actual cephalad prosthesis, a window on the trial facet joint bearing surface **404** can be used to read the length from the support arm element **401**. As mentioned above, the length of the fixation element **52** can be determined from the fixation measurement element **402**. Markings and/or indentations on the fixation measurement element **402** can be used to determine the required length of the fixation element **52**.

FIGS. 8-10 depict one embodiment of a measurement tool for installing a caudal facet joint prosthesis. The measurement tool can be used to assist in the installation of caudal joint prostheses such as those described in U.S. Patent Appl. S.N. 10/737,705 or other caudal facet joint prostheses.

One embodiment of a caudal facet joint prosthesis that is suitable for use with the measurement tool described herein is depicted in **FIG. 7**. **FIG. 7** shows an artificial caudal facet joint prosthesis **100** configured to replace the superior portion of a natural facet joint, such as after the surgical removal of the articulating process forming the superior portion of the facet joint. Prosthesis **100** includes an artificial facet joint element **104** connected to a fixation element **116** via a polyaxial connection **115** that permits facet joint element **104** and fixation element **116** to be rotated with respect to each other around more than one axis. The polyaxial connection **115** of caudal prosthesis **100** includes a base **112** connected to a support arm **102** of facet joint element **104**. The artificial facet joint element **104** includes a bearing surface **118**. A fixing nut **108** is threadably engaged with the outer periphery of base **112** above the artificial facet joint element **104**. Similarly, a set screw **106** is threadably engaged with the inner periphery of base **112** above the artificial facet joint element **104**.

A measurement tool **700** suitable for use with the caudal facet joint prosthesis shown in **FIG. 7** is shown in **FIGS. 8A and 8B**. Measurement tool **700** includes a stem element **701** connected to a trial caudal bearing surface **702** via a fastener **703**. Thus, measurement tool **700** contains aspects of the caudal facet joint prosthesis whose implant the tool is assisting. In the embodiment depicted in **FIG. 8A**, the fastener **703** is a set screw. In other embodiments other suitable fasteners can be employed, including, but not limited to, stems, posts, threads, polyaxial mechanisms, splines, cap screws, ball detents, friction fits, tapers, press fits, bayonet, cams, collets and/or clamps.

The stem element **701** is adapted and configured to obtain length measurements which would correspond to the length of the fixation element **116** of the caudal facet joint prosthesis **100**. The stem element can include markings and/or indentations to assist in

obtaining the measurements. If desired, multiples stem elements of varying diameters can be utilized in a similar fashion to size and/or determine the diameter and dimensions of the hole.

The trial caudal bearing surface **702** helps determine the relative positions of, and the angle between, the prosthesis's fixation element and its bearing surface. The trial caudal bearing surface **702** is capable of movement along multiple planes and can rotate relative to the stem element **701** via a lockable ball-joint. If desired, an alternate embodiment of the bearing surface **702** can move vertically (not shown) along the stem element **701**, to permit sizing of the stem element. Other planes of movement can include the median, horizontal and frontal planes. In another embodiment, the caudal bearing surface **702** is connected to a handle **704**. The handle **704** allows the user to move the caudal bearing surface **702** into the desired location and also position it in the right plane. Typically, the handle **704** permits movement of the caudal bearing surface **702** in various planes for alignment. Also, the handle **704** can permit the user to place the stem **701** of the tool into the hole drilled in the vertebra.

In one alternate embodiment, the handle **704** can comprise a radiopaque material with the handle **704** used for fluoroscopic alignment of the caudal bearing surface **702**. In this embodiment, the handle **704** and upper end plate of the caudal vertebral body (not shown) can be examined in a medial-lateral image (using non-invasive and/or fluoroscopic imaging apparatus) of the surgical area. A comparison of the orientation of the handle **704** and the orientation of the upper end plate can be made to determine the desired alignment and positioning of the caudal bearing surface. In one embodiment, the orientation of the handle and the upper end plate can be parallel or nearly parallel.

Another aspect of the invention is a measurement tool holder for use with the caudal measurement tool described above or another measurement tool. One embodiment of the measurement tool holder is depicted in **FIGS. 9A-D**. In this embodiment, the measurement tool holder **800** includes a measurement surface **801** and a holder element **802**. In one embodiment, the measurement surface **801** includes two plates attached to each other at a right angle. The measurement surface **801** is adapted and configured to measure the angle between the caudal bearing surface **702** and stem **701**. This angle measurement is typically used by a user to select, assemble and/or configure a caudal prosthesis for implantation into a patient, such as caudal prosthesis **100** of **FIG. 7**. For example, the selected caudal prosthesis may have an angle measurement between its bearing surface **118** and its fixation element **116** similar to the angle measurement obtained from the caudal measurement

tool **700** and measurement tool holder **800**. Alternatively, the prosthesis may be configurable to orient its fixation element and its bearing surface to match the measured angle.

In one embodiment, the tool holder's measurement surface **801** includes markings to assist in obtaining the desired angle measurements. Also, the top surface of the measurement surface **801** may have a holder element **802** attached thereto. The holder element **802** can be, for example, a square or rectangular block with a portion of the block cut out to fit the caudal bearing surface **702** of the caudal measurement tool **700**. The portion of the holder element **802** that holds the caudal bearing surface **702** is cut out in a shape that is suitable for holding the caudal bearing surface **702**. Thus, the shape of the cut out portion of the holder element **802** will vary depending on the shape of the caudal bearing surface **702** to be used with the measurement holder **800**.

One aspect of the invention is a method for using the caudal measurement tool **700** in combination with, for example, the measurement tool holder **800** described above or with the cephalad measurement tool **400** described above. In one embodiment, a hole is formed at a suitable location in the vertebra (such as by drilling) wherein a caudal prosthesis **100** is intended to be placed. This location typically is the best location for the placement of the caudal prosthesis based on the condition of the bone, easy access to the location, etc. Into this hole the caudal measurement tool **700** is placed in a manner as shown in **FIGS. 10A and 10B**.

The caudal measurement tool **700** may be placed into the hole using the handle **704**. The handle **704** and the set screw **703** are used to place the measurement tool at the required depth and also to place the caudal bearing surface **702** at the required angle. To obtain the appropriate angle of the caudal bearing surface **702** with respect to the stem **701**, the fastener **703** is loosened and the caudal bearing surface **702** is positioned at the appropriate angle. Once the appropriate angle is obtained (typically based on orientation relationships with anatomical landmarks, which can include the orientation of the cephalad bearing surface as well as anatomical positioning and/or intervening anatomical features), the fastener **703** is tightened to maintain the angle for measurement purposes. In one embodiment, the caudal measurement tool **700** is used in combination with a cephalad prosthesis (such as cephalad prosthesis **40** described above) or a cephalad measurement tool (such as tool **400** described above). When used in combination with a cephalad prosthesis or a cephalad measurement tool, the caudal bearing surface **702** is placed in contact with the facet joint bearing surface of the cephalad prosthesis or the trial facet joint bearing surface. Then, the position of the caudal bearing surface **702** is adjusted by manipulating the fastener **703** (as described above)

to get good articulation with the facet joint bearing surface or the trial facet joint bearing surface.

After the caudal measurement tool **700** is appropriately placed, the length and angle measurements are obtained. Preferably, the caudal measurement tool **700** is removed from the hole to take the measurements. One of the measurements that can be obtained with the caudal measurement tool **700** is the fixation length measurement. This measurement is obtained from the stem element **701** and indicates the length of the fixation element **116** of the caudal prosthesis to be implanted in a patient. Also, the caudal measurement tool **700** can be used to obtain an angle measurement between the caudal bearing surface **702** (or alignment fixation measurement) and stem element **701**. This measurement may be obtained by placing the caudal measurement tool **700** into a measurement tool holder (such as holder **800** described above) and reading the angle, such as from a measuring surface **801**. When used with the caudal prosthesis **100** of **FIG. 7**, this angle measurement is used to determine the angle between the artificial facet joint element **104** and fixation element **116** of the caudal prosthesis **100**. In one alternate embodiment, the caudal bearing surface is positioned and secured to the vertebral body first, and then the cephalad bearing surface is positioned and secured relative to the caudal bearing surface.

One aspect of the invention is a method for selecting suitable caudal and/or cephalad prostheses from a set of prostheses for implantation into a patient. In one embodiment, the cephalad measurement tool **400** is used to obtain the two length measurements from the fixation measurement **402** and support arm **401**. A user uses these measurements to select a suitable cephalad prosthesis **40** for implantation in a patient. The selected prosthesis preferably has a fixation element **52** length and support arm **72** length that are similar to the support arm **401** and fixation measurement **402** length measurements, respectively, obtained from the cephalad measurement tool **400**. The term "similar" is used to herein to mean values that correspond to each other but are not necessarily identical. In another embodiment, the caudal measurement tool **700** is used to obtain length and angle measurements and a user uses these measurements to select a suitable cephalad prosthesis for implantation in a patient. The selected prosthesis preferably has a stem **701** length similar to the length measurement from the caudal tool **700** and has an angle between the artificial facet joint element and fixation element similar to the angle measurement obtained from the tool.

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

use with a modular prosthesis system, it should be understood that the present inventions have utility in conjunction with the measurement and placement of other prosthesis systems, including single component, multi-component and custom-made prosthesis, with varying results. Further, the trialing system described herein can comprise single or multi-component
5 tools and devices.

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.

What is claimed is:

1. A measurement tool adapted and configured to determine a characteristic of a cephalad facet joint prosthesis, the tool comprising a fixation measurement element and a support arm element.
5
2. The measurement tool of claim 1 wherein the fixation measurement element is connected to the support arm element through a polyaxially adjustable connection.
3. The measurement tool of claim 1 wherein the fixation measurement element is adapted and configured to provide at least one measurement for determination of a length of a fixation element for the cephalad facet joint prosthesis.
10
4. The measurement tool of claim 1 wherein the fixation measurement element comprises markings to permit measurements for determination of required length of a fixation element for a cephalad facet joint prosthesis.
5. The measurement tool of claim 1 further comprising a trial facet joint bearing surface supported by the support arm.
15
6. The measurement tool of claim 1 wherein the support arm element is adapted and configured to permit measurements for determination of required support arm length of a cephalad facet joint prosthesis.
7. The measurement tool of claim 1 wherein the support arm element comprises markings to permit measurements for determination of required support arm length of a cephalad facet joint prosthesis.
20
8. The measurement tool of claim 1 wherein the support arm element is adapted and configured to permit horizontal movement around the fixation measurement element.
9. The measurement tool of claim 1 wherein the support arm element is adapted and configured to permit vertical movement along the fixation measurement element.
25
10. The measurement tool of claim 1 wherein the vertical movement of the support arm element is controlled by indentations on the fixation measurement element and at least one ridge on the support arm element, the ridge on the support arm element being capable of moving in and out of the indentations on the fixation measurement element.
- 30 11. A caudal facet joint prosthesis measurement system comprising a measurement tool adapted and configured to determine a characteristic of a caudal facet joint prosthesis, the tool comprising a stem element and a trial caudal bearing surface element.
12. The system of claim 11 further comprising a measurement tool holder adapted and configured to interact with the trial caudal bearing surface element.

13. The system of claim 11 further comprising a connection between the stem element and the trial caudal bearing surface element adapted and configured to permit measurement for determination of angle between artificial facet joint element and fixation element of a caudal facet joint prosthesis.

5 14. The system of claim 13 wherein the connection between the stem element and the trial caudal bearing surface element is adapted and configured to permit measurement for determination of angle in median plane between artificial facet joint element and fixation element of the caudal facet joint prosthesis.

10 15. The system of claim 13 wherein the connection between the stem element and the trial caudal bearing surface element is adapted and configured to permit measurement for determination of angle in horizontal plane between artificial facet joint element and fixation element of the caudal facet joint prosthesis.

15 16. The system of claim 11 wherein the fastener is selected from the group consisting of a screw, stem, post, thread, polyaxial mechanism, spline, cap screw, ball detent, friction fit, taper, press fit, bayonet, cam, collet and clamp.

17. The system of claim 11 wherein the stem element is adapted and configured to permit measurements for determination of required length of fixation element of a caudal facet joint prosthesis.

20 18. The system of claim 11 wherein the stem element has markings to permit measurements for determination of required length of fixation element of a caudal facet joint prosthesis.

19. The system of claim 11 further comprising a handle element adapted and configured to facilitate placement and movement of the measurement tool on a patient's vertebra.

25 20. The system of claim 11 further comprising a measurement tool holder adapted and configured to hold the measurement tool and to provide measurement of an angle between the stem element and the trial caudal bearing surface element.

21. A facet joint prosthesis measurement tool holder comprising a measurement surface connected to a holder element adapted and configured to hold a facet joint prosthesis measurement tool.

30 22. The measurement tool holder of claim 21 wherein the measurement surface comprises two plates, the plates being at right angles to each other.

23. The measurement tool holder of claim 21 wherein the holder element is adapted and configured to permit measurement of an angle between a stem element and a caudal bearing surface element of the facet joint prosthesis measurement tool.

24. The measurement tool holder of claim 21 wherein the measurement surface is adapted and configured to permit measurement of an angle between a stem element and a caudal bearing surface element of the facet joint prosthesis measurement tool.

5 25. The measurement tool holder of claim 24 wherein the measurement surface is adapted and configured to permit measurement of an angle in a horizontal plane between the stem element and the caudal bearing surface element of the caudal facet joint prosthesis measurement tool.

10 26. The measurement tool holder of claim 24 wherein the measurement surface is adapted and configured to permit measurement of an angle in a median plane between the stem element and the caudal bearing surface element of the caudal facet joint prosthesis measurement tool.

27. The measurement tool holder of claim 21 wherein the measurement surface has markings to permit measurement of an angle between a stem element and a caudal bearing surface element of the facet joint prosthesis measurement tool.

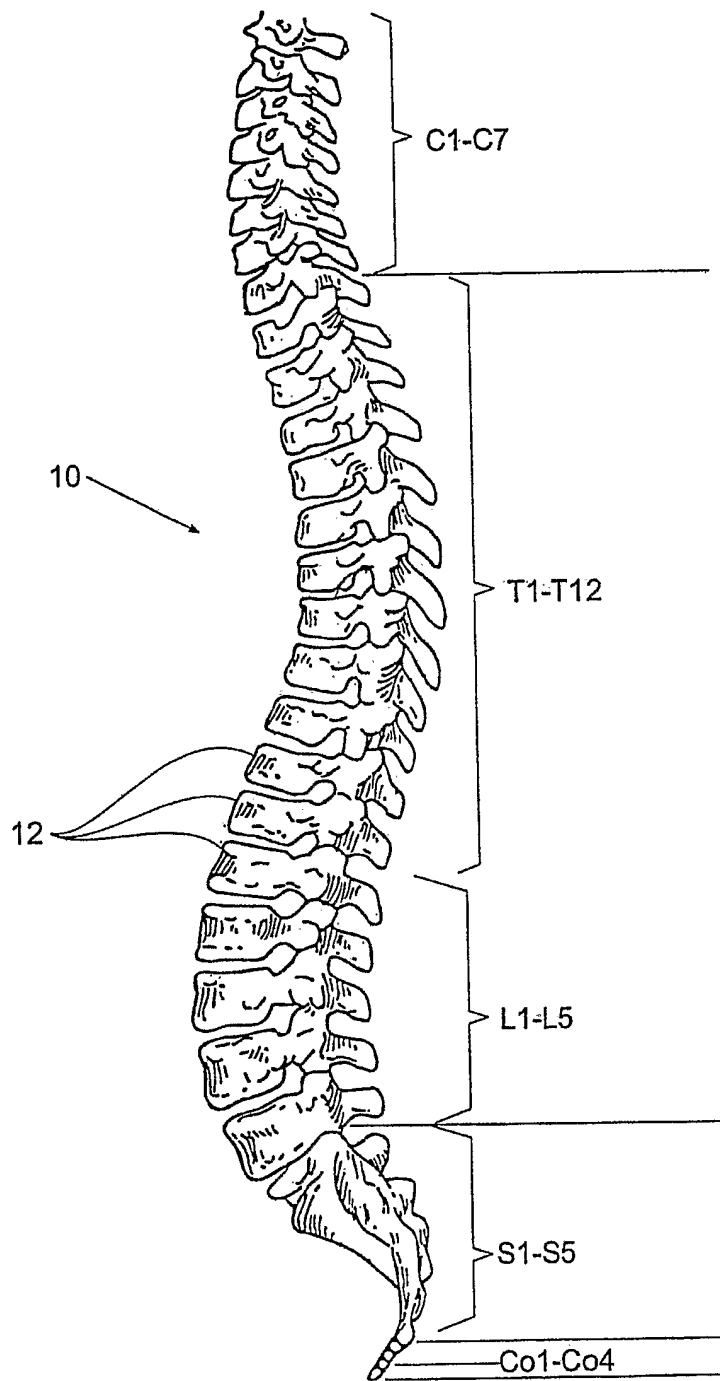


Fig. 1

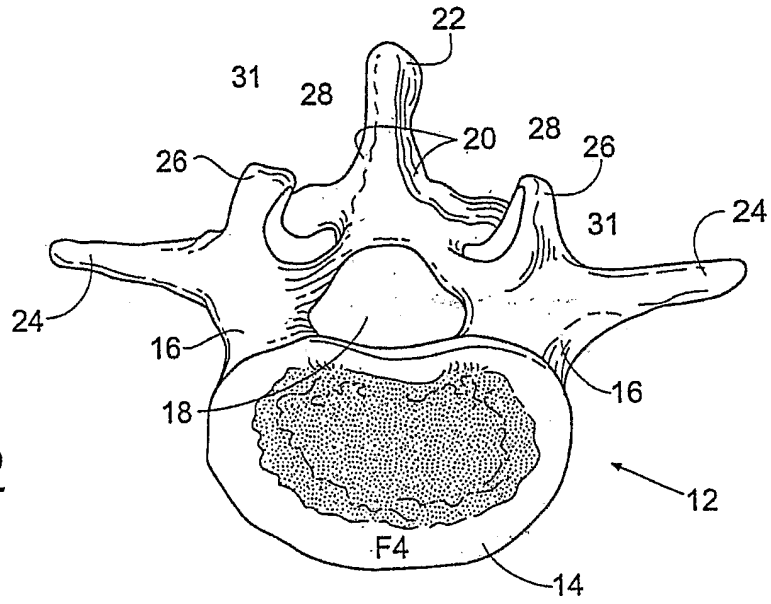


Fig. 2

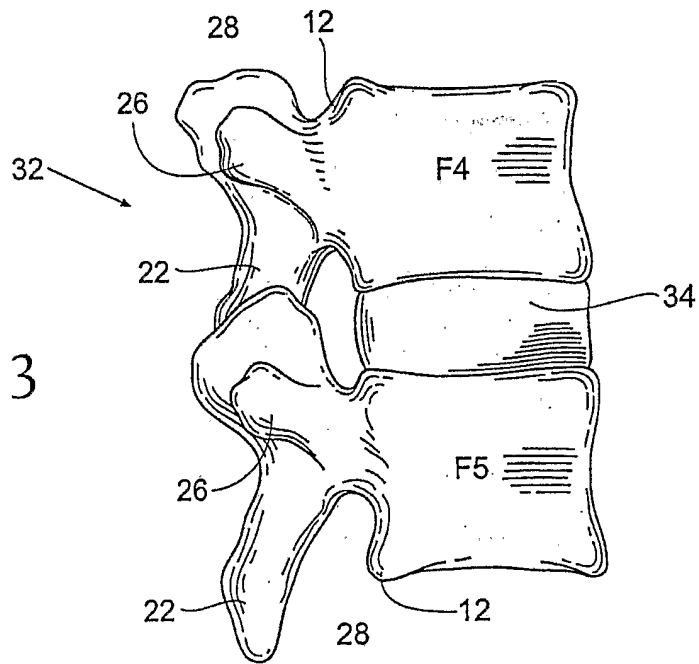


Fig. 3

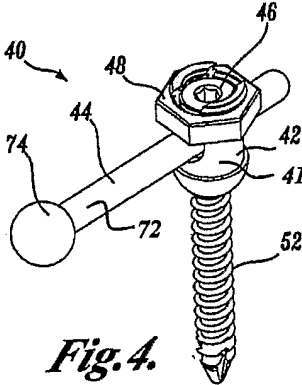


Fig. 4.

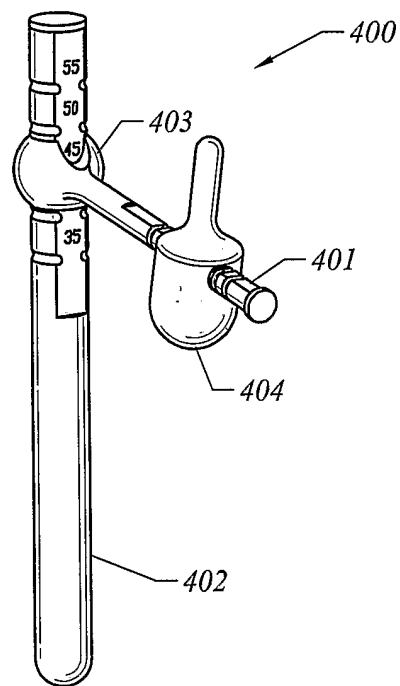


FIG. 5A

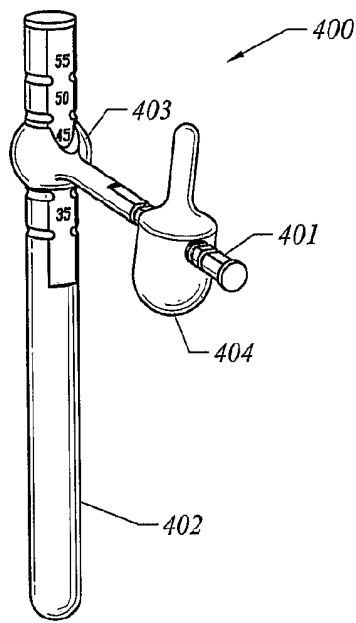


FIG. 5A

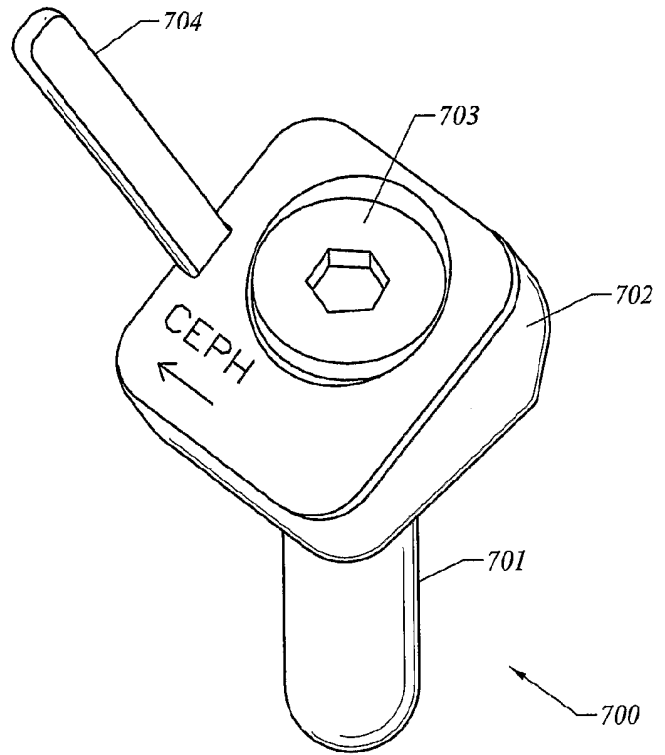


FIG. 8A

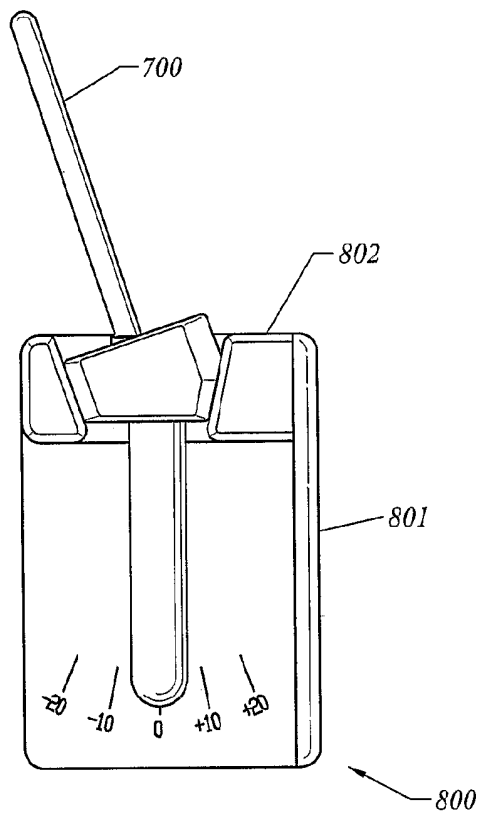


FIG. 9A

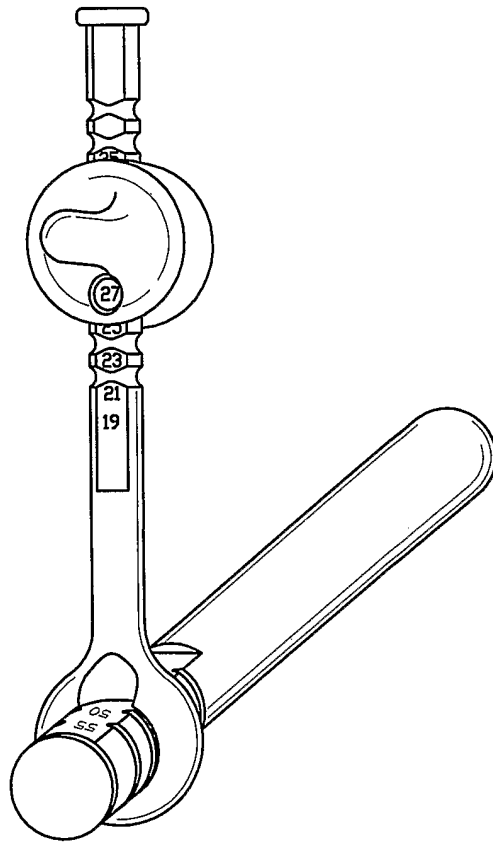


FIG. 5B

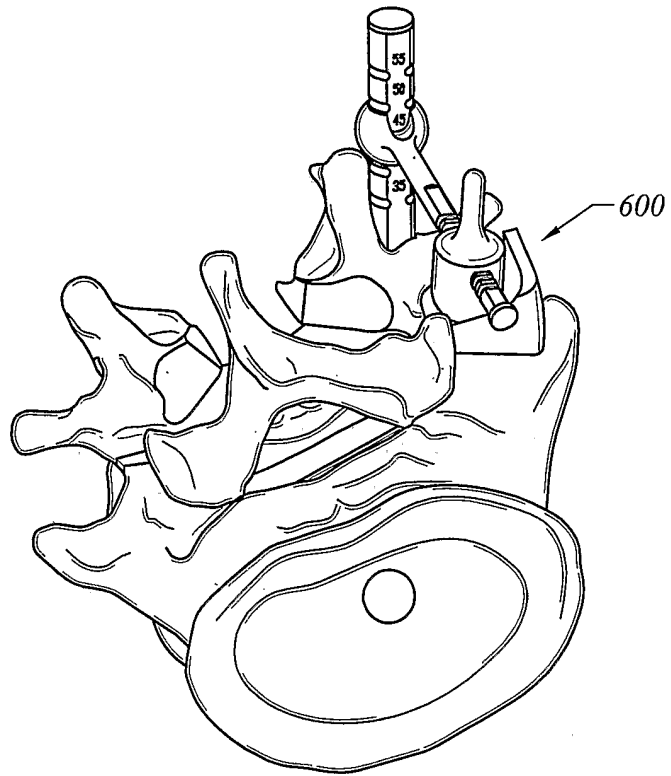


FIG. 6A

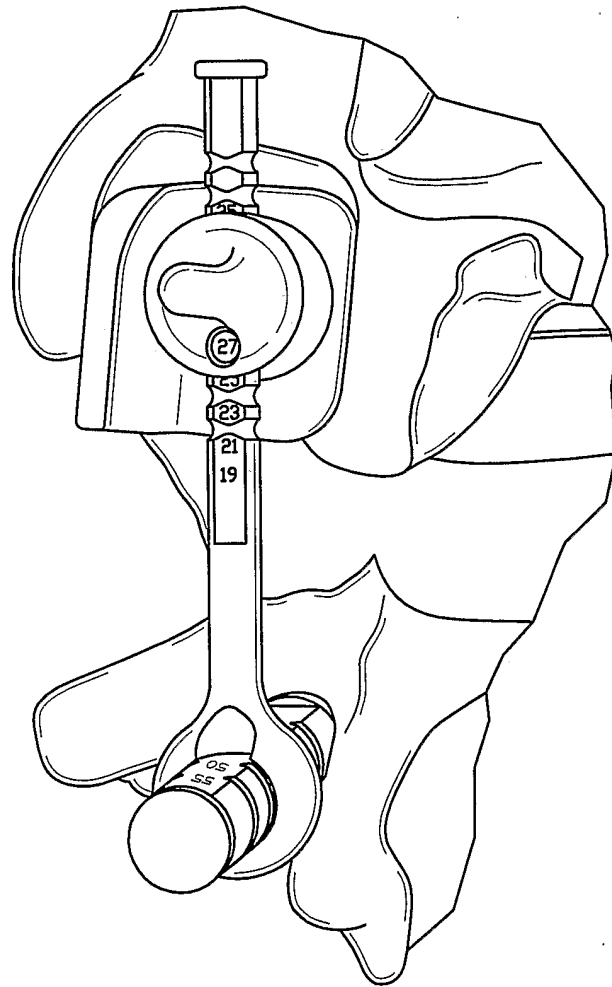


FIG. 6B

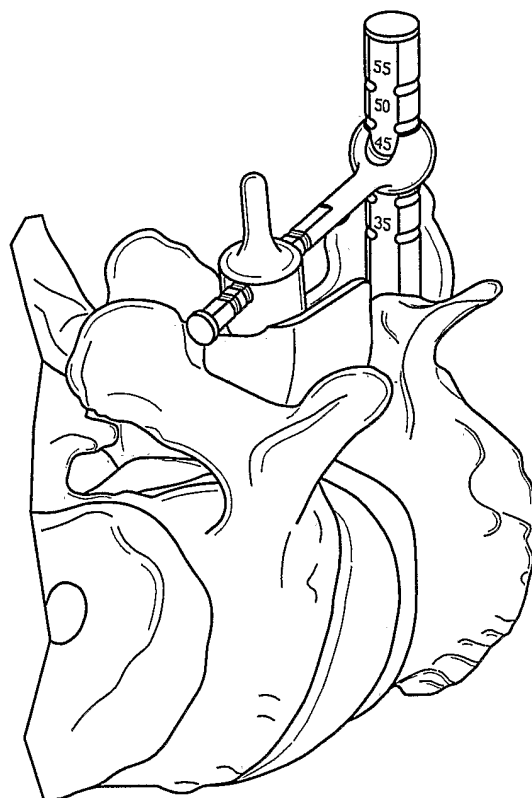
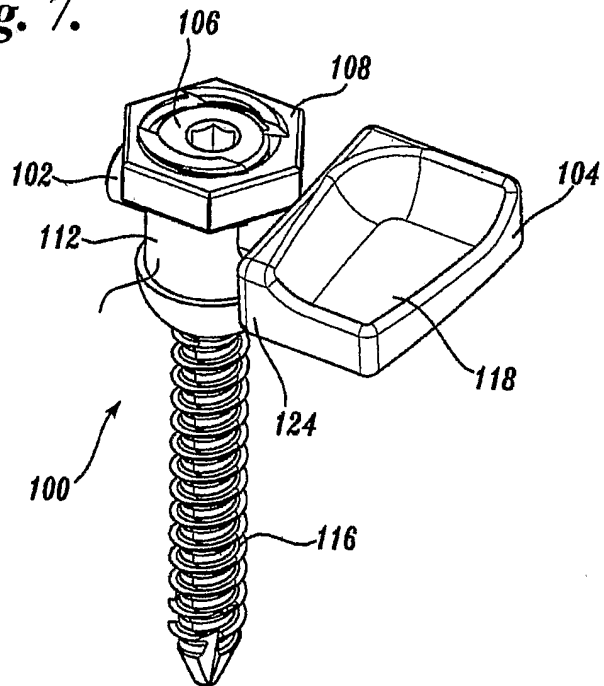


FIG. 6C

Fig. 7.



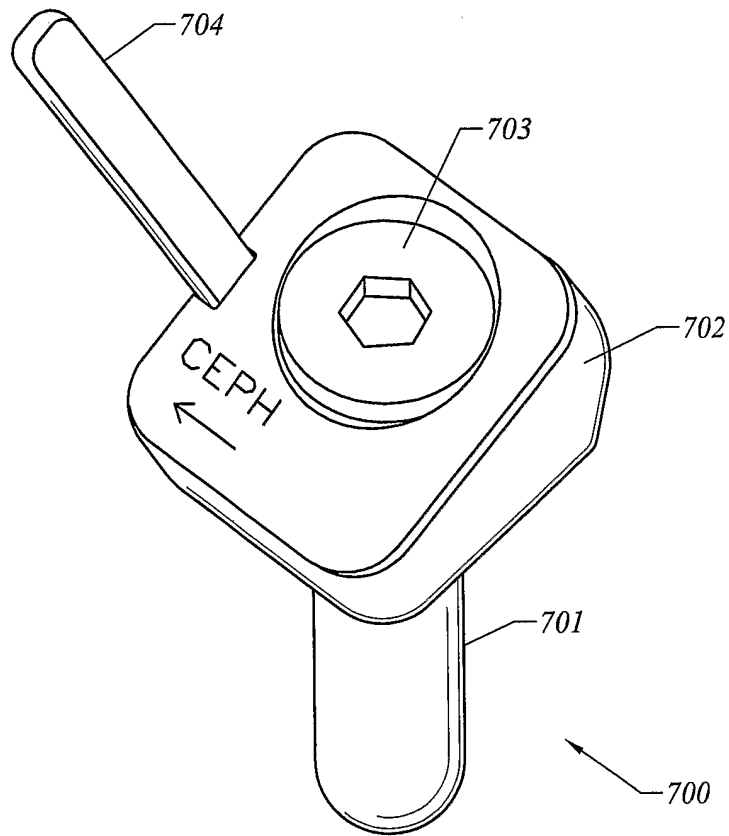


FIG. 8A

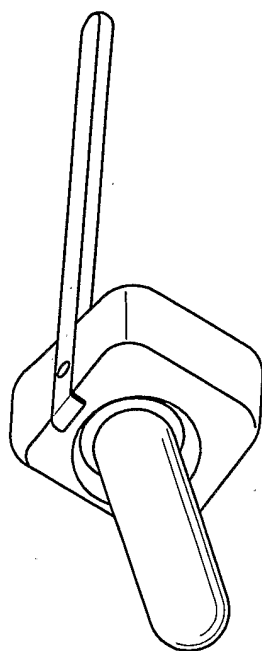


FIG. 8B

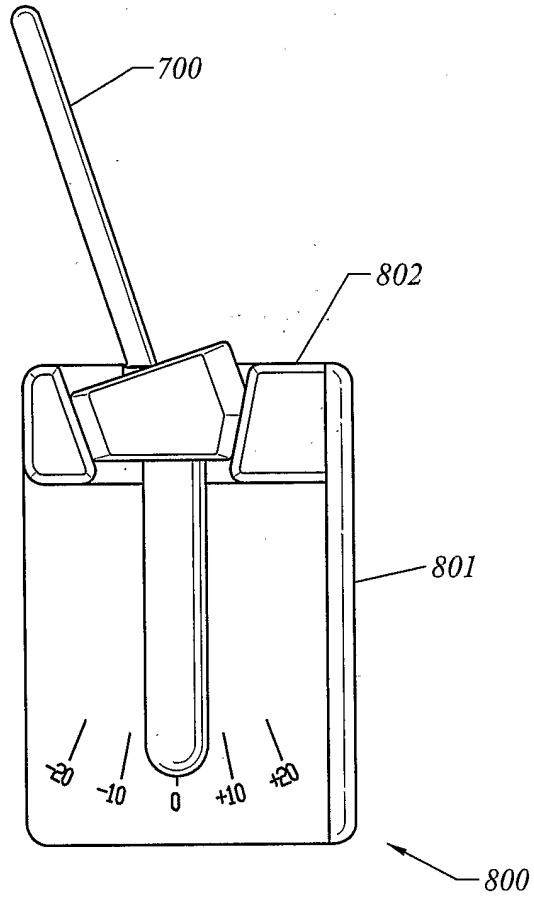


FIG. 9A

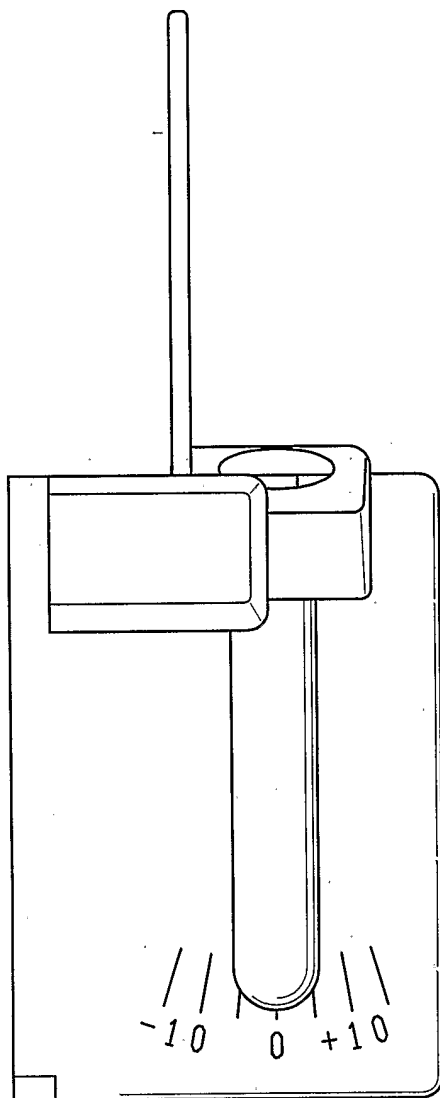


FIG. 9B

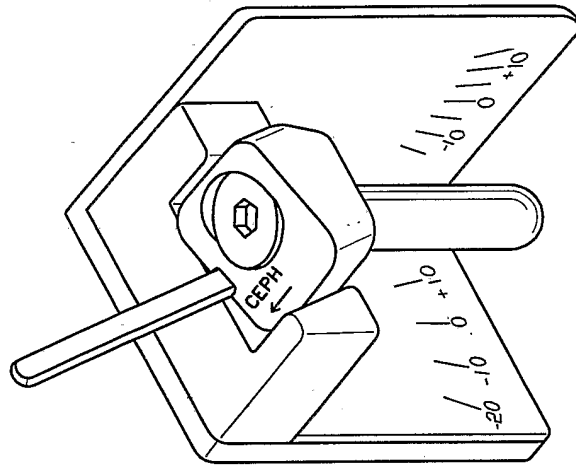


FIG. 9D

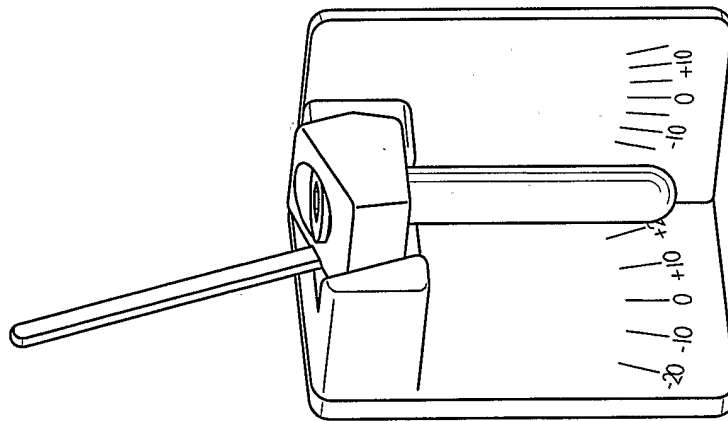


FIG. 9C

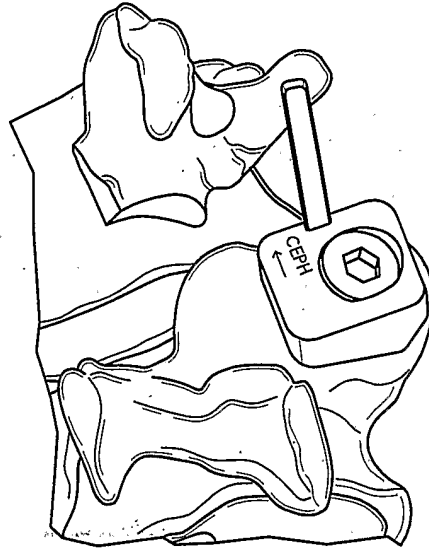


FIG. 10A

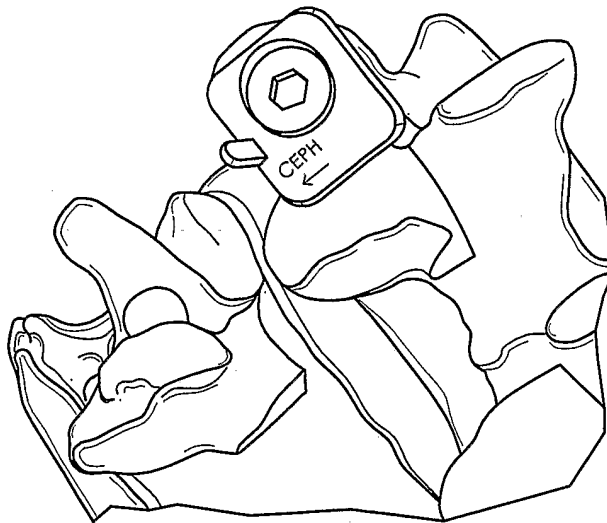


FIG. 10B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/012080

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/46				
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) IPC 7 A61F A61B				
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.		
A	US 6 610 091 B1 (REILEY MARK A) 26 August 2003 (2003-08-26) column 5, line 65 - column 11, line 30 -----	1-27		
A	US 2003/028250 A1 (REILEY MARK A ET AL) 6 February 2003 (2003-02-06) paragraph '0096! - paragraph '0119! -----	1-27		
P,A	WO 2004/103227 A (ARCHUS ORTHOPEDICS, INC; REILEY, MARK; YUAN, HANSEN; STINSON, DAVID; J) 2 December 2004 (2004-12-02) the whole document -----	1-27		
<input type="checkbox"/> Further documents are listed in the continuation of box C.				
<input checked="" type="checkbox"/> Patent family members are listed in annex.				
° Special categories of cited documents :				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top; padding: 5px;"> *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 </td> <td style="width: 50%; vertical-align: top; padding: 5px;"> *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. *&* document member of the same patent family </td> </tr> </table>			*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. *&* document member of the same patent family
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. *&* document member of the same patent family			
Date of the actual completion of the international search <p style="text-align: center;">21 July 2005</p>	Date of mailing of the international search report <p style="text-align: center;">01/08/2005</p>			
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 <p style="text-align: center;">Buchmann, G</p>			

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