(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 September 2011 (29.09.2011)

PCT

(10) International Publication Number
WO 2011/119617 A1

(51) International Patent Classification:
A61B 17/56 (2006.01)

(21) International Application Number:
PCT/US2011/029446

(22) International Filing Date:
22 March 2011 (22.03.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/316,318 22 March 2010 (22.03.2010) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

(54) Title: SPINAL IMPLANT DEVICE, SURGICAL INSTRUMENTATION FOR IMPLANTING AND METHOD

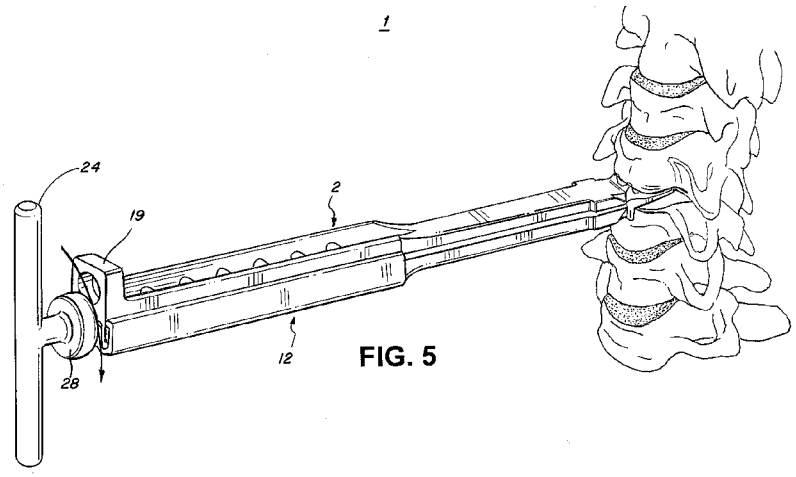

FIG. 5

(57) Abstract: A surgical instrument and method for implanting a two component artificial implant device. A multi component of surgical members can be removably attached to each other to indent cancellous bone for embedding the implant device. The indented holes can be reamed while not compromising the vertebra rim. The implant device can be formed of PEEK with a thin outer layer of osteoblast encouraging material.

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SPINAL IMPLANT DEVICE, SURGICAL INSTRUMENTATION FOR IMPLANTING AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

[0001]

This application claims priority from U.S. Provisional Application Serial No. 61/316,318 filed on March 22, 2010.

BACKGROUND OF THE INVENTION

1. Field of the Invention.

[0002]

The present invention relates to a ball and socket motion preservation artificial spinal implant, procedure, and surgical instrumentation for a spinal implant that can be an artificial two component disc such as used in patients with degenerated discs or otherwise needing disc arthroplasty.

2. Description of Related Art.

[0003]

A normal human spine is segmented with seven cervical, twelve thoracic and five lumbar segments. The lumbar portion of the spine resides on the sacrum, which is attached to the pelvis. The pelvis is supported by the hips and leg bones. The bony vertebral bodies of the spine are separated by intervertebral discs that are fibrocartilaginous cushions which reside sandwiched between the vertebral bodies and operate as shock absorbing joints allowing known degrees of flexion, extension, lateral bending and axial rotation.

[0004]

The intervertebral disc primarily serves as a mechanical cushion between adjacent vertebral bodies, and permits controlled motions within vertebral segments of the axial skeleton. The disc is a multi-element system, having three basic components: the nucleus pulposus ("nucleus"), the annulus fibrosus ("annulus") and two cartilaginous vertebral end plates. The end plates are made of thin cartilage overlying a thin layer of hard, cortical bone that attaches to the spongy, richly vascular, central core cancellous bone of the vertebral body. The plates thereby operate to attach adjacent vertebrae to the disc. In other words, a

transitional zone is created by the end plates between the malleable disc and the bony vertebrae.

[0005]

The annulus of the disc forms the disc perimeter, and is a tough, outer fibrous ring that binds adjacent vertebrae together. The fiber layers of the annulus include fifteen to twenty overlapping plies, which are inserted into the superior and inferior vertebral bodies at roughly a 40 degree angle in both directions. This causes bi-directional torsional resistance, as about half of the angulated fibers will tighten when the vertebrae rotate in either direction.

[0006]

It is surgically known to remove a spinal disc in cases of spinal disc deterioration, disease or spinal injury. The discs sometimes become diseased or damaged such that the intervertebral separation is reduced. Such events cause the height of the disc nucleus to decrease, which in turn causes the annulus to buckle in areas where the laminated plies are loosely bonded. As the overlapping laminated plies of the annulus begin to buckle and separate, either circumferential or radial annular tears may occur. Such disruption to the natural intervertebral separation produces pain, which can be alleviated by removal of the disc and maintenance of the natural separation distance. In cases of chronic back pain resulting from a degenerated or herniated disc, removal of the disc becomes medically necessary.

[0007]

In some cases, the damaged disc may be replaced with a disc prosthesis intended to duplicate the function of the natural spinal disc. In other cases it is desired to fuse the adjacent vertebrae together after removal of the disc, sometimes referred to as "intervertebral fusion" or "interbody fusion."

[0008]

An example of a spinal prosthesis for restoring motion in a spinal joint can be seen in US Patent No. 7,799,083.

[0009]

Method of implanting an invertebrate disc prosthesis by a posterior surgical technique can be found in US Patent No. 7,896,919.

[0010]

There is still a need in the orthopedic field to provide precise and easy to use surgical instruments for preparing vertebrae surfaces for the insertion of an artificial implant device in a spinal cord with precise implant insertion surgical instruments to assist the surgeon in implanting the artificial implant device including, for example, a two part artificial disc in a manner that will not broach the anterior cortical rims of the vertebrae bodies during implant insertion, while potentially could lead to heterotopic ossification, and will permit a desired adjacent vertebrae movement with the respective implants fusing to the cancellous core of the vertebrae.

SUMMARY OF THE INVENTION

[0011]

The present invention is characterized by a spinal implant such as two component implant with a spherical convex surfaces and a concave surface to create a motion preservation disc prosthesis having a variable height caudal and cranial segments that can be implanted into the vertebra disc space along with corresponding surgical instruments required for preparing and providing such installation.

[0012]

The caudal or bottom component of such an implant can utilize a dual convex articulating surface with two separate spherical radii. The generally centralized first convex articulating surface has a radius that is larger than the second convex articulating surface around the implant perimeter. This assists in providing conforming and non-conforming surfaces when mated to an upper component during installation. The bottom component includes an opposite vertebra interface that maintains a spherical radius to account for lordosis and can have a plurality of pillars or posts for insertion into the lower vertebra for stability.

[0013]

The cranial, or upper implant component, can have a concave articulating surface of a configuration to mate with the caudal lower implant dual spherical radii.

[0014]

A plurality of posts, keels, or teeth are provided on the opposite upper vertebra interface surface in addition to a spherical lordotic radius. Again, these stabilizing teeth or keels extend from the top surface for embedding within the cancellous core.

[0015]

The relationship between the caudal and cranial components of the composite disc prosthesis allow for centralized conforming surfaces with non-conforming surfaces around the perimeter of the articulating surfaces. Such a design facilitates excellent wear characteristics at the centralized conforming surfaces and will allow for device translation without excessive rim wear.

[0016]

The articulating surfaces are designed to be relatively broad so that the radii extend close to the edges of the implant to provide stability. Applying a load, especially an eccentric load when the implant device is operable, to a small spherical radius versus a large spherical radius, presents differences with respect to stability. Additionally, the broader radii also allow for more anatomical translation coupled with rotation. The implant components can be made from polyetheretherketone (PEEK) or a similar polymer or other metallic material commonly used within this field.

[0017]

Additionally, the outer interface of the respective components of the implant device provide an interface with an adjacent vertebra end plate and it is desirable that such surfaces be osteoconductive. Accordingly, a coating can be deposited using either chemical or physical deposition procedures such as an atomic fusion deposition process, a thermal spray process such as a titanium plasma spray or hydroxyapatite (HA) plasma spray.

[0018]

The compromised spinal column is appropriately prepared, for example, removing disc material and any protruding osteophytes with pituitaries or similar instruments, such as caspar distracters to assist in accessing the disc space.

[0019]

The disc cartilaginous end plates can be removed and the vertebra bone surface is prepared using curettes or similar instruments. A rasp can be used to grind without altering adjacent tissue. An end plate trialing can be performed to gage the disc height and prepare

the space for a subsequent spinal implant. Stop members in conjunction with caspar pins can also be utilized for spacing purposes.

[0020]

Since the resulting intervertebral space with the compromised disc is small, for example in the cervical region of the spine, traditional preparations have slotted the vertebrae rims and the vertebrae surfaces. Our procedure is intended to preserve the integrity of the rim and vertically indent only the cancellous core for installing the implant device.

[0021]

A surgical instrument for preparing a vertebra surface to secure the implant device can comprise a first impressor member including a handle with a guide unit and a first support member connecting the handle to an impaler member with a design for indenting the vertebra surface of the cancellous core. A second complimentary impressor member of a configuration to engage the first impressor member and move along the guide unit also has a second support member extending along the first impressor member and connected to a force applying member complimentary in a shape to enable an exertion of force on the impaler member. The second impressor member can also have a handle formed by the complimentary surface for engaging and moving along the guide unit of the first impressor member.

[0022]

A force dialator member of a configuration to extend between the respective first and second impressor members when they are joined together can separate the impaler member and the force applying member apart thereby enabling the impaler member indent a vertebra surface when the force applying member and the impaler member are positioned between adjacent vertebrae of a patient. The force applying member is pressed against the opposite vertebra surface for stabilizing and facilitating the application of force to the impaler member. The force dialator member can include a handle member to enable the operator to rotate a camming dialator located at a distal end to apply the force for separating the impaler member and the force applying member.

[0023]

The first impressor member, the second impressor member, and the force dialator member can be separate components that are not permanently fixed to each other. The first impressor member and the second impressor member can be configured to permit limited

pivotal movement to accommodate the application of force by the camming dialator at a distal end. When the first impressor member and the second impressor member are appropriately connected, a bi-convex space is provided with the first impressor member handle having an approximately M shaped configuration with the legs of the M forming a guide for receiving a U shaped cross-sectional configuration of the second impressor member.

[0024]

The exterior lower walls of the U shaped second impressor member sides have a predetermined length of a flange extending outward and of a dimension to be captured within an upper rim that extends inward at the tips of the M cross-sectional shape on the first impressor member. This configuration permits both vertical and limited pivotal movements.

[0025]

The first impressor member, the second impressor member and the force dialator member are separate components that are not permanently fixed to each other and are of an elongated configuration of approximately the same length. The force dialator member can have a rod extending from a bi-convex paddle of a configuration to fit within a bi-convex space formed between the first and second impressor members when connected together.

[0026]

Both the first impressor member and the second impressor member have locational stop members at the distal ends of a smooth configuration for contact with a rim of the vertebra surface without broaching the rim. The location stop member on the first impressor member is of a predetermined dimension from the impaler member to facilitate an accurate placement and alignment with the cancellous core.

[0027]

As can be appreciated, the dimension of the stop member and the relative sizes of both the instruments and the implant device can vary depending upon the respective size of the vertebra, for example, between a cervical vertebra which can be small, through the thoracic to the large lumbar vertebrae of the spinal column.

[0028]

After the appropriate impaler for a first impressor member is mounted on the second impressor member and the vertical indentation in the vertebral surface is accomplished, for example to receive a projecting post on the caudal or bottom component of the implant

device, the first impressor member is replaced with a structurally equivalent first impressor member having an alternative configuration for the impaler member, for example, to provide a keel configuration for the cranial or upper component keels of the other component of the implant device. Again, the force dialator member is inserted between the respective first impressor member and the second impressor member to provide an exertion of force on the appropriate impaler member.

[0029]

An alternative impaler member can have an internal open space and is mounted on a support member for relative movement. The support member is fixed to a sun gear in the internal open space and cylindrical posts can be fixed to planetary gears which are journaled to rotate when the sun gear rotates, wherein relative rotation of the support member and the impaler member can rotate the cylindrical posts after being embedded in the vertebral surface to configure indent holes for receiving corresponding projecting cylindrical posts. Rotating posts and/or keels can extend from the upper and lower surfaces of the impaler member to simultaneously indent the adjacent opposite vertebrae surface at the same time by partly collapsing the vertebrae space.

[0030]

The impaler member could also have the rotating posts and/or keels on only one side. Drive of the sun gear could also be performed by other structure such as a rack moved by the user to engage the sun gear.

[0031]

An implant inserter surgical instrument for locating the artificial implant device in the spinal column is utilized having a support member with a first end configured to enable a user to grasp the support member and at a distal second end, a configuration to releasably secure the artificial implant device. Also adjacent the second distal second end, a location stop member of a configuration to contact one of an edge of a vertebral surface for aligning the artificial implant device in the spinal column and an edge of an installed component of a two component artificial implant device.

[0032]

The implant inserter surgical instrument includes a sliding holder member with a distal end of a configuration to capture a portion of an implant device with a biasing force to hold the implant device against the support member wherein the user can move the sliding

holder to release the implant device within the vertebrae spacing of the spinal column. The sliding holder member can include an operator member extending upward from the sliding holder member adjacent the first end or handle and configured for activation by the user's thumb while grasping the supporting member or handle.

[0033]

In one form of the implant insertion surgical instrument, a relatively flat support platform can be provided at the distal second end with a lower configuration surface complimentary to a surface of a first installed component and an upper inclined surface to enable the sliding holder member to slide a second component of the artificial implant device onto the first installed component.

[0034]

The implant insertion surgical instrument can have a support member with a support surface at the distal second end with a configuration complimentary to a surface of the artificial implant wherein the sliding holder member can release, for example, the caudal implant device when positioned above the indented vertebrae surface to permit the user to press down the distal second end with a configuration complimentary to the surface of the artificial implant to vertically locate posts within the indentations.

[0035]

Our invention also includes a surgical instrument for preparing a vertebral surface to secure an artificial implant device having a projecting support member that is to be embedded into a vertebral surface. The surgical instrument includes a support member having, at a first end, a configuration to enable a user to grasp the support member, the support member having, adjacent a second end, an impaler configuration for indenting a vertebrae surface with one or more holes configured complimentary to the projecting support member. Additionally, adjacent the second end, a location stop member of a configuration to contact an edge of a vertebral surface for aligning the impaler configuration over the vertebral surface is provided.

[0036]

The impaler configuration can include a plurality of cylindrical posts with conical points for indenting a cancellous core. Alternatively, the impaler configuration can include a plurality of spaced peaked walls to provide keels. The impaler configuration is spaced from the location stop member to only contact the cancellous core of the vertebrae surface while

the contact surface of the stop member is configured to prevent any broaching of the edge or anterior rim of the vertebral surface.

[0037]

A method of preparing and implanting a spinal prosthesis in a space between adjacent vertebrae surfaces that does not compromise the anterior rims includes the steps of:

inserting a first impaler member with projecting members to indent a first vertebrae surface into a space between adjacent vertebrae;

securing the first impaler member by contacting an opposing second vertebrae surface;

applying a force sufficient to vertically embed the projecting members into the first vertebrae surface;

removing the first impaler member;

inserting a second impaler member with projecting members to indent a second vertebrae surface into the space between adjacent vertebrae;

securing the second impaler member by contacting the opposing first vertebrae surface;

applying a force sufficient to vertically embed the projecting member into the second vertebrae surface;

removing the second impaler member;

inserting a first implant component with complementary supporting projecting member into the indented vertebrae surface and a first curved bearing surface positioned facing the opposing second vertebrae surface;

inserting a second implant component with second complementary supporting projecting members with a second complementary curved bearing surface to the first implant component by sliding the second complementary curved bearing surface across the first curved bearing surface until second complementary supporting projecting members are aligned with the indented vertebrae surface of the second vertebrae surface; and

closing the space between the adjacent vertebrae to seat the perspective supporting projecting members and enable relative rotation between the first and second implant components.

[0038]

The surgical instruments can be formed from stainless steel or other material that can be autoclaved for sterilization purposes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039]

The objects and features of the present invention, which are believed to be novel, are set forth with particularity in the appended claims. The present invention, both as to its organization and manner of operation, together with further objects and advantages, may best be understood by reference to the following description, taken in connection with the accompanying drawings.

[0040]

Figure 1 is a perspective view of a first and second impressor member in an exploded configuration relative to a spinal column;

[0041]

Figure 2 is a partial view of the distal end of a second impressor member with a force applying member located within the vertebra space;

[0042]

Figure 3 is a perspective view of the first and second impressor members joined together and receiving a bi-convex paddle of a force dialator member;

[0043]

Figure 4 is a prospective view of the force dialator member;

[0044]

Figure 4a is a cross-section view of a force paddle shown in Figure 4;

[0045]

Figure 5 is a perspective view of the surgical instrument located within the vertebra space before exerting a force on the impaler member;

[0046]

Figure 5a is a partial perspective view of the distal end with a first impressor member and second impressor member with an application of vertical force to indent the lower vertebra surface with post holes;

[0047]

Figure 6 is a perspective view of an alternative first impressor member having an impaler member to indent keel holes in the superior vertebral surface prior to receiving the force dialator member;

[0048]

Figure 7 is a partial perspective view of the application of vertical force for indenting keel holes in the superior vertebral surface;

[0049]

Figure 8 is a perspective bottom view of an implant inserter surgical instrument;

[0050]

Figure 9 is a view of Figure 8 with a sliding holder member advanced to hold one component of an implant device at a distal end;

[0051]

Figure 10 is a perspective view of the implant instrument locating the implant device over post holes in an inferior vertebral surface;

[0052]

Figure 11 is an exploded view of an alternative superior implant inserter surgical instrument;

[0053]

Figure 12 is a cross-sectional view of the superior implant inserter surgical instrument of Figure 11;

[0054]

Figure 13 is a partial perspective view of the alternative implant inserter surgical instrument mounting the superior component implant device for insertion above the implanted inferior implant component;

[0055]

Figure 14 is a perspective view of the implant inserter surgical instrument for installing the superior implant component;

[0056]

Figure 15 is a view of the implant device installed in the space between two vertebrae;

[0057]

Figure 16 is an exploded view of an inferior component and a superior component of a cervical implant device;

[0058]

Figure 17 is a partial cross-sectional side view of the superior component and a side perspective view of the inferior component of the implant device;

[0059]

Figure 18 is a schematic disclosing the relative range of motion of the superior implant component relative to the inferior implant component, for example, when a person has bent his head back and the implant is in the cervical region of the neck;

[0060]

Figure 19 is a schematic side view of an alternative impaler instrument with rotating keels and posts;

[0061]

Figure 20 is a schematic plan view disclosing the gear arrangement for rotating posts and keels by relative handle movement; and

[0062]

Figure 21 is a modified impaler instrument with only posts driven on one side for confined spaces.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0063]

Reference will now be made in detail to the preferred embodiments of the invention which set forth the best modes contemplated to carry out the invention, examples of which are illustrated in the accompanying drawings. While the invention will be described in conjunction with the preferred embodiments, it will be understood that they are not intended to limit the invention to these embodiments. On the contrary, the invention is intended to cover alternatives, modifications and equivalents, which may be included within the spirit and scope of the invention as defined by the appended claims. Furthermore, in the following detailed description of the present invention, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be obvious to one of ordinary skill in the art that the present invention may be practiced without these

specific details. In other instances, well known methods, procedures, components, and circuits have not been described in detail as not to unnecessarily obscure aspects of the present invention.

[0064]

Referring to Figure 1, an exploded view of a first impressor member 2 and a second impressor member 12 is disclosed relative to a spinal column 3, for example in the cervical region of a patient with disc material removed to leave a gap or a space 5 between two adjacent vertebrae surfaces.

[0065]

The surgeon can remove the disc material and any protruding osteophytes from an anterior side of the spinal column 3 using pituitaries or similar instruments and while not shown, caspar distracters may aid in accessing the disc space 5, as known in the surgical field. Pins or screws can also be utilized to assist in expanding and contracting the space between the respective vertebrae to provide operational space for the surgeon.

[0066]

The cartilaginous end plates of the disc would usually be removed and a vertebra bone surface is prepared using curettes or similar instruments prior to a rasp preparation of the disc space as needed, for example a sharp diamond cut face without altering adjacent tissues.

[0067]

Subsequently, trials can be introduced to gauge the specific desired disc height and prepare the space for an appropriately sized implant.

[0068]

The first impressor member 2 has a first support member 6 that can be configured to form a handle 4 having a cross-sectional M shape. The end of the handle 4 has a guide unit 8 comprising inwardly directed flanges on either upper side with a recessed sidewall 9. Channels or grooves 11 extend parallel along the entire length of the handle 4.

[0069]

The first support member 6 further has an impaler member 10 at the distal end of the first support member 6 for indenting a vertebra surface. The impaler member 10 can have one or a plurality of narrow configuration posts, keels or other projecting members suitable for indenting a vertebral surface. A location stop 7 prevents any broaching of the anterior rim

of the vertebra segment and can position the impaler member 10 at a location above a cancellous core of the vertebra and interior of its cortical wall.

[0070]

Side rails or walls 13 are positioned on a shallow curved recess on the surface of the support member 6 adjust the impaler member 10.

[0071]

The second impressor member 12 also has a handle 16 of a cross-sectional U shape with a pair of outwardly extending flanges 17 of a complementary configuration to the guide unit 8, the recess sidewalls 9, and the parallel channels or grooves 11. Above the flanges 17 is an abutment 19 with a bore hole to assist in removing or pulling back the second impressor member 12 from the vertebrae. The first impressor member 10 can be initially inserted within the vertebrae space 5 and subsequently the second impressor member 12 can be slid across and into the vertebrae space 5.

[0072]

As seen in the handle 16, holes can be provided in the second impressor member 12 and also in the first impressor member 2 to lighten the weight of the instrument. The instrument can be prepared, preferably from an autoclavable material such as stainless steel. It should be appreciated that these instruments are designed for a particular size of vertebra and that the vertebra will vary in size from, respectively, the cervical through the thoracic to the lumbar areas of the spine. Thus, different sized instruments, at least with regards to the distal ends, are contemplated to be selected by the surgeon, for the particular patient.

[0073]

The distal end of the second support member 14 has a force applying member 20, for example, of a paddle configuration with a smooth surface for contacting, anchoring and providing an application of vertical force to a core surface of a vertebra within the gap space 5 opposite an impaler member 10. The underside of the second support member 14, as shown in Figure 1, also has a shallow camming curve surface with similar rails 18 to that of the rails 13 for abutting and positioning the distal location. The force applying member 20 with the paddle configuration, is substantially wider than its thickness.

[0074]

Figure 2 is a perspective view of a distal end of the first impressor member 2 inserted within the vertebra gap of the spinal column. As can be determined, the location stop 7 has a

curved smooth surface complementary to the general configuration of the anterior edge or rim of the cortical wall to avoid any broaching of the wall that would encourage bone growth.

[0075]

Figure 3 discloses the first impressor member 2 and the second impressor member 12 operatively mounted together with the guide flanges 17 mounted within the parallel channels or groves 11 and operatively positioned within the recess sidewalls 9. This arrangement permits a relative pivotal and vertical movement about the flanges 17 within the confines of the recess sidewalls 9. At the distal end, the side rails 18 of the second impressor member 12 are positioned above and aligned with the side rails 13 of the first impressor member 2. Likewise, the location stop 7 for the first impressor member 2 and the location stop 15 for the second impressor member 12 limit the movement into the vertebra gap space 5.

[0076]

The force dialator member 22 has a traverse operator handle member 24 at one end, a third support member 26 in the form of a rod, a position disc 28, a first camming flange 30 adjacent the position disc 28 and at the distal end, a second camming paddle 32 with a greater width than the first camming flange 30 as shown in Figure 4. This permits the relative movement of the handle portions 4 and 16 to separate a fixed vertical distance while applying a positive vertical force at the impaler member 10 with the second camming flange 32 providing a degree of pivoting between the first impressor member 2 and the second impressor member 12 at the respective distal ends, thereby providing a controlled vertical force to the impaler member 10 to only indent the cancellous core of the vertebral surface with the appropriate holes. The second camming flange 32 has a bi-convex configuration with a greater width than the rounder bi-convex configuration of the first camming flange 30, see Figure 4a. The central space between the respective handle members 4 and 16 is also bi-convex to align and accept the force dialator member 22.

[0077]

Referring to Figure 5, a surgical instrument 1 for preparing a vertebral surface to secure an artificial implant device 72 is disclosed with the configuration of the first impressor member 2 mounted on the second impressor member 12 and the force dialator member 22 secured in the central bi-convex space. Rotation by the arrow shown in Figure 5 will actuate and apply the controlled force to the distal ends.

[0078]

As can be seen in Figure 5a, the impaler member 10 has solid posts with conical tips 60 and side indentations 61 that can be forced into the cancellous core with appropriate positioning by the location stop 7 and a corresponding positioning of the force applying member 20 with a smooth curved surface on the superior or upper vertebra surface. The paddle 32 when rotated, spreads the respective first impressor member 2 and the second impressor member 12 to create the vertical impaler force.

[0079]

Figure 6 disclosed an alternative surgical instrument for preparing a vertebra surface to secure an artificial implant device where a different second impressor member 58 with impaler member 62 having a different configuration of spaced peaked walls of a keel configuration 64, which is utilized to provide appropriate vertical aligned indentations in the upper or superior vertebra surface. The only difference in the second impressor member 58 from the previously described first impressor member 2 is the addition of a different impaler member 62. The remaining structure and operation remains the same as previously described with the first impressor member 2.

[0080]

As can be seen, the second impressor member 12 is simply inverted and again performs the same function of providing a counter vertical force on the lower inferior surface of the vertebra.

[0081]

As shown in Figure 7, the same operation of the force dialator member 32 can force the spaced peaked walls of the keel configuration 64 to indent into the superior surface of the upper vertebra. The provision of spaced peaked walls is to capture segments of the cancellous core and physically remove them from the indented keel holes. A similar approach was provided by the indentations 61 in the cylindrical posts 60 with conical points for removing material from the indented holes.

[0082]

Referring to Figure 8, an implant inserter surgical instrument 36 is shown, having a support member 38 and a hollow handle 40 to permit the user to grasp and manipulate the instrument. A sliding holder member 42 is configured to releasably secure the caudal or inferior component of the implant device. A support surface at the distal end of the support

member 38 is configured to receive the convex surface of the lower implant component with a complementary surface platform 43 and an operating member 44 is configured for operation by the thumb of the user when he/she is holding the handle 40. The operating member 44 is connected to the sliding holder member 42 and retracting the member 42 can release the bottom surface of the inferior implant component, as shown in Figure 9.

[0083]

In operation, the implanter inserter surgical tool 36 is rotated to locate a predetermined pattern of a plurality of posts 60 so that they can be vertically mounted on the inferior vertebra surface that has been appropriately indented with complementary holes. The control member 44, when the posts 60 are secured, is retracted as shown in Figure 10 and the sliding holder member 42 is pulled back while a downward vertical force is applied by the user through the support platform 43 to push the inferior implant component into place.

[0084]

A superior implant inserter surgical instrument 46 is shown in Figure 11 in an exploded view. A support member 48 and a handle 50 are slotted and connected to a superior sliding holder member 52. Again, an operator member 54 having a configuration that is operable by a thumb is disclosed. The superior sliding holder member is connected within the slot by a screw and spring arrangement 54 to provide a biasing gentle force.

[0085]

Referring respectively to Figures 12, 13 and 14, the operation of the superior insertion surgical instrument 46 can be understood by a person of ordinary skill in this field.

[0086]

Referring to the cross-sectional view of Figure 12, the superior implant component with keels 66 is mounted on a support surface 56 adjacent an upwardly inclining sloping platform 58. The under surface and forward edge of the platform 58 is configured to match the concave surface of the already implanted inferior implant component. A lower locator step 70 can be used to contact a rim of the lower vertebra while the concaved conforming lower platform 68 can rest upon a perimeter of the inferior implant.

[0087]

A perspective view is shown in Figure 13 with the side of the notches at the distal end of the superior sliding holder member 52 not only capturing but extending between the respective keels in a three keel pattern. As shown in Figure 13, the convex surface of the

inferior implant member is shown as Element 72. It should be appreciated that the underside of the superior implant component 74 has a matching concave surface whose perimeter can slide across the platform 58.

[0088]

The user can activate the control surface 51 with his/her thumb and the superior implant component 74 can be slid across the platform 58 so that the underside surface of the superior implant member 74 of a concave configuration will center itself on the upper convex configuration of the inferior implant component 72. Figure 14 discloses the final insertion of the superior implant component 74 into the vertebrae space 5.

[0089]

Referring to Figure 15, an exaggerated perspective view of the spinal implant device is disclosed with the superior component 74 having keels 66 located within the cancellous core 76 and the inferior component 72 having posts 60 likewise located within the cancellous core 76 of the lower vertebra inward from the cortical rim 78.

[0090]

A cervical two component implant device 80 is shown in Figure 16 in an exploded view with the inferior implant component 72 having a central spherical convex surface of a diameter "a" as shown in Figure 17. Figure 17 also shows the respective inferior and superior implant components 72 and 74 in a cross-sectional view and schematically shows the relationship of the spherical radius R and the outer perimeter radius Ro. The width of the implant is shown as "b."

[0091]

The respective implant devices will vary depending on the size of the particular vertebrae dimensions of the patient, and the location of the vertebrae along the spinal column. For purposes of illustration and without limitations, Figures 16-18 are representative of a cervical implant device 80 with the dimension "a" being .243 inches and the width "b" being .543 inches, while a transverse width would be .512 inches. Generally the two spherical radii that form the dual convex articulating surface R and Ro can be between .7 and .3 inches with the radius R having a larger dimension than a second convex articulating surface around the perimeter, Ro, which is also further offset along an axis from R.

[0092]

The number of posts 60 or keels 66 are generally from 1 to 5 members for stability. The vertical length of the post or keels can generally be in a range of 0.05 to 0.1 inches in length and diameter. The keels can protrude at a 45 ± 25° angle and generally can raise .03 to .08 inches off of the top surface of the superior component 74. As can be appreciated, the drawings are for illustration purposes and not necessarily drawn to scale. Additionally, the dimensions will vary from a cervical implant device 80 to an implant device which is utilized for a thoracic or lumbar implantation.

[0093]

By have confirming radii R on the center convex and concave surfaces and using, for example, a PEEK, polyetheretherketone biocompatible polymer having a hardness stiffness characteristic similar to that of the vertebrae, extended wear characteristics can be achieved. Alternatively, a carbon fiber reinforced PEEK (CFR PEEK) could be utilized. These polymers can reduce stress shielding by evenly distributing the forces or load from the articulating surfaces to enhance the lifetime use of the prosthesis implant device. The implant devices can have a flexural modulus on the GPA scale within a range of about 4 to 25 and can be molded.

[0094]

As shown in Figure 16, the outer surfaces of the superior implant component 74 and inferior implant component 72 can be appropriately roughened or configured to assist in anchoring a thin coating 82 or layer of a bone on growth friendly material such as titanium, calcium phosphate or hydroxyapatit. The roughening can be accomplished by an appropriate abrasive resorbable media such as kieserite. The purpose of such a coating 82 is not to materially increase the stiffness of the implant device but to encourage a bone growth infusion while still permitting a shock absorbing feature of the PEEK material for translating force loads along the spinal column. PEEK material can be injection molded and the PEEK or CRF PEEK (carbon film) can provide a flexural modulus comparable to that of the cortical bone.

[0095]

A coating of titanium within an approximate range of 0.5 to 15 microns in thickness can be utilized to enable a bone on growth while maintaining an appropriate distribution of forces to permit the stress shielding characteristics of the PEEK to be fully utilized. It should

be noted that the PEEK material is a relatively inert material with excellent wear characteristics and will not distort medical image techniques. The thin coating can be applied using a thermal spray such as a titanium plasma spray or hydroxyapatit plasma spray.

[0096]

By simulating the chemical composition of natural bone, such as by use of a hydroxyapatite type of coating an enhanced osseointegration between the implant device and the juxtapositioned bone surface can be realized. Additionally, by providing a roughened surface on the underlining PEEK material, a thin coating of titanium can replicate the roughened configuration. For example, a relatively low temperature ionic plasma deposition of titanium can be applied to the PEEK material to improve osteoblast functions with the utilization of a thin coating of titanium decreasing any fibroblast functions that would contribute to fibrous tissue growth for the orthopedic implant surface.

[0097]

Figure 18 discloses a potential displacement or relative motion between the superior implant component 74 and the inferior implant component 72 to accommodate a patient's head movement, such as extending the head to stare at the sky.

[0098]

Referring to Figure 19, an alternative impaler device 84 is shown in a schematic format. A user handle 86 is connected to an elongated support member 88 to provide an impaler assembly 94 at the distal end from the handle 86. In this embodiment, respective indented posts 90 are arranged in a prearranged fixed pattern and can rotate by radial movement of the handle 86 by the user. A rotation of keels 92 can also be journaled to extend from the opposite side of the impaler assembly 94 by the same gear drive arrangement.

[0099]

In operation, this impaler assembly 94 can be inserted within a vertebrae space or gap 5 with or without arbitrarily locator stops, not shown, for accurately positioning the impaler assembly relative to a cancellous core of the adjacent vertebrae. The location stops can, like the earlier embodiments of the present invention, provide a desired location from the cortical rim without compromising the rim. The conventional instrumentation holding the adjacent vertebrae apart to provide the spacer gap 5 can be adjusted to permit the impaler assembly 94 to embed the respective posts 90 and keels 92 in a vertical manner that can be aligned with

the subsequent implanted implant device. The user can then radially rotate the handle 86 through a limited range of approximately 40° thereby causing, as shown in Figure 20, a rotation of a sun gear 96 that is journaled and fixed relative to the support member 88 and handle 86. The respective posts 90 and keels 92 are embedded within the cancellous core and mounted on planetary gears 98, thereby causing the posts 90 and keels 92 to rotate in place to ream the cancellous core material by activation of the gear unit for driving the embedded post 90 and keels 92 as a drive unit.

[0100]

A cover plate 108 with a fixing/tab 109 includes curved oblong guide openings 100 on a surface to facilitate a relative rotation of the impaler assembly 94 without disturbing the static location of the posts 90 and keels 92. Arc shape locators 102 can be journaled in the interior space 104 within the housing perimeter 106 to stabilize the respective posts and keels that are mounted and driven by the same type of planetary gears 98. The internal open space 104 provides sufficient space to facilitate this rotation while the housing perimeter can be designed to accommodate and mount the arc shape locators 102 in a fixed position relative to the support member 88.

[0101]

The impaler assembly 94 can be formed with an open C configuration extending from the support member 88 and appropriate indents or tabs, such as tab 109, can secure an upper cover 108 and a similar lower cover (not shown) with equivalent openings to provide structure to support the arc shape locators 102 and to fasten the sun gear 96 so that it is journaled in alignment with the axis of the handle 86.

[0102]

Figure 21 represents a variation of the impaler device embodiment of Figure 19, wherein only one side of the impaler assembly 114 would have a structure to indent and ream holes in the cancellous core. As shown posts 90 are disclosed but other configurations such as keels could be utilized. This impaler assembly 110 has a handle 112 and adjacent the handle 112 is a journaled control member 116 to be activated with limited motion by the user thumb control structure 116 to manual power a drive unit for the posts 90. The support member 118 is hollow and accommodates a relatively slidable rod 120 connected to the thumb control member 116 and having at the distal end, a rack 122 which can be journaled within the impaler assembly 114 to operate a sun gear, not shown, in a similar manner as that

in the embodiment of Figures 19 and 20 but with a rack and sun gear drive unit instead of a gear drive unit with rotation of the handle.

[0103]

Thus, an operator dealing with a restricted vertebrae space, can insert the impaler assembly 110 and manually ream the embedded post 90 to provide holes clear of debris with a subsequent implantation of an implant device component.

[0104]

Those skilled in the art will appreciate that various adaptations and modifications of the just-described preferred embodiment can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the amended claims, the invention may be practiced other than as specifically described herein.

CLAIMS

What Is Claimed Is:

1. A surgical instrument for preparing a vertebrae surface to secure an artificial implant device, comprising;

a first impressor member including a handle with a guide unit, and a first support member connecting the handle to an impaler member for indenting a vertebral surface;

a second impressor member of a complimenting configuration to engage the first impressor member and move along the guide unit and having a second support member extending along the first impressor member and connected to a force applying member complimentary in shape to enable an exertion of force on the impaler member; and

a force dialator member of a configuration to extend between the first and second impressor members and separate the impaler member and the force applying member apart thereby enabling the impaler member to indent a vertebrae surface when the force applying member and the impaler member are positioned between adjacent vertebrae of a patient.

2. The surgical instrument of Claim 1 wherein the force dialator member includes a handle member to enable an operator to rotate a camming dialator to separate the impaler member and the force applying member.

3. The surgical instrument of Claim 1 wherein the first impressor member, second impressor member and force dialator member are separate components that are not fixed to each other.

4. The surgical instrument of Claim 1 wherein the first impressor member, second impressor member and force dialator member are each singular elongated members of approximately the same length.

5. The surgical instrument of Claim 1 wherein the force applying member of the second impressor member has a paddle configuration with at least one surface of a smooth configuration for contacting a vertebrae surface.

6. The surgical instrument of Claim 1 wherein the force dialator member includes a handle member at one end and an expander member sufficiently wider than a thickness traverse to the width, to enable a camming movement to separate the impaler member and force applying member.

7. The surgical instrument of Claim 1 wherein the expander member has a paddle configuration.

8. The surgical instrument of Claim 1 wherein the first impressor member has a location stop member at a distal end from the handle of a configuration to contact an edge of the vertebral surfaces for aligning the position of the impaler member.

9. The surgical instrument of Claim 1 wherein the handle has an approximately M cross shape with a parallel pair of grooves of configuration to receive the second impressor member that has an approximately U cross-sectional shape to extend into the grooves.

10. The surgical instrument of Claim 9 wherein complimentary securement structures are provided on the respective first impressor member and second impressor

member to enable a relative pivoting movement about an end distal from the impaler member.

11. The surgical instrument of Claim 10 wherein the securement structure is one of an undercut recessed side wall and a flange captured by the recessed side wall, the flange having a length to enable relative pivotal movement within the grooves of the first and second impressor members.

12. The surgical instrument of Claim 9 wherein a central open space between engaged first impressor member and the second impressor member is bi-convex and the force dialator member includes a bi-convex camming paddle member of a size to slide into the central space at one end and a handle at the other end for rotating the force dialator member to enable a camming movement to separate the impaler member and the force applying member.

13. An implant inserter surgical instrument for locating an artificial implant device in a spinal column, comprising:

a support member having, at a first end, a configuration to enable a user to grasp the support member and at a distal second end a configuration to releaseably secure the artificial implant device; and

adjacent the distal second end, a location stop member of a configuration to contact one of an edge of a vertebral surface for aligning the artificial implant device in the spinal column and an edge of an installed component of a two component artificial implant device.

14. The implant inserter surgical instrument of Claim 9 further including a sliding holder member with a distal end of a configuration to capture a portion of the implant device with a biasing force to hold the implant device against the support member, wherein the user can move the sliding holder to release the implant device within the spinal column.

15. The implant insertion surgical instrument of Claim 14 wherein the sliding holder member includes an operator member extending upward from the sliding holder member adjacent the first end and configured for activation by a user's thumb while grasping the support member.

16. The implant insertion surgical instrument of Claim 14 wherein the support member has a support platform at the distal second end with a lower configuration surface and platform edge complimentary to a surface of a first installed component and an upper surface to enable the sliding holder member to slide a second component of the artificial implant onto the first installed component.

17. The implant insertion surgical instrument of Claim 14 wherein the support member has a support surface at the distal second end with a configuration complimentary to a surface of the artificial implant for holding a component of the artificial implant.

18. A surgical instrument for preparing a vertebrae surface to secure an artificial implant device having a projecting support member that is to be embedded in a vertebrae surface, comprising;

a support member bearing, at a first end, a configuration to enable a user to grasp the support member; the support member having, adjacent a second end, an impaler

configured for indenting a vertebral surface with a hole configured complimentary to the projecting support member; and

adjacent the second end, a location stop member of a configuration to contact an edge of a vertebral surface for aligning the impaler configuration over the vertebrae surface.

19. The surgical instrument of Claim 18 wherein the impaler configuration is spaced from the location stop member to only contact the cancellous core of the vertebrae surface for indentation.

20. The surgical instrument of Claim 19 wherein the contact surface of the stop member is configured to prevent any broaching of an edge of the vertebrae surface.

21. The surgical instrument of Claim 19 wherein the impaler configuration includes a plurality of cylindrical posts with conical points for indenting a cancellous core.

22. The surgical instrument of Claim 21 wherein the cylindrical posts are rotable when embedded within the vertebrae surface to extract vertebrae material and indent holes in the vertebrae surface.

23. The surgical instrument of Claim 22 wherein the cylindrical posts have side indentations configured to remove vertebrae material when rotated.

24. The surgical instrument of Claim 21 wherein the impaler has an internal open space and is mounted on the support member for relative movement, the support member is fixed to a sun gear in the internal open space and the cylindrical posts are fixed to planetary gears which are journalled to rotate when the sun gear rotates, wherein relative rotation of the

support member and the impaler can rotate the cylindrical posts after being embedded in the vertebral surface to configured indent holes for receiving corresponding projecting support members.

25. The surgical instrument of Claim 18 wherein the impaler configuration includes a plurality of paired spaced peaked walls for securing cancellous material between the paired spaced peaked walls.

26. The surgical instrument of Claim 18 wherein, to enable a user to grasp, the support member has an approximately M cross-sectional shape with a parallel pair of grooves to facilitate alignment of a complimentary auxiliary component.

27. A motion restoring prosthesis, to be interposed between adjacent vertebrae surfaces, comprising

two components, each component defining an outer surface for attachment to a vertebrae surface and an interior articulating surface of the other component,

a central portion of each component having conforming radii to provide a self centering articulating and anatomical translation to enable relative rotation and alignment of the two components between adjacent vertebrae surfaces, the conforming radii are offset from a perimeter of each component and having the offset portion to the perimeter of each component provided with non-conforming radii to enable translation without excessive rim wear,

the outer surface of each component having one or more protrusions to enable embedding the protrusions into an abutting adjacent vertebrae surface.

28. The motion restoring prosthesis of Claim 27 wherein the components are formed of polyetheretherketone (PEEK) with an outer surface having a roughened texture and coated with a layer of titanium of sufficient thickness to replicate the roughened texture while facilitating osteoblast adhesion when implanted and transferring loads to the PEEK material through the titanium layer.

29. The motion restoring prosthesis of Claim 28 wherein a flexible modulus on the GPA scale of the components are within a range of about 4 to 25.

30. An impaler instrument for reaming holes in a vertebra surface to anchor an implant device comprising;

a support member configured to be grasped by a user;

an impaler unit mounted on the support member with one or more embedding members extending outward; and

a drive unit for rotating the embedding member to remove material from the vertebra.

31. The impaler instrument of Claim 30 wherein the drive unit includes a sun gear unit for driving the embedding member in a rotational manner by relative movement of the support member.

32. The impaler instrument of Claim 30 wherein the drive unit includes a rack for driving a sun gear and a planetary gear connected to the embedding member in the form of one of a post and keel.

33. A method of preparing and implanting a spinal prosthesis in a space between adjacent vertebrae surfaces that does not compromise the anterior rims, comprising the steps of;

inserting a first impaler member with projecting members to indent a first vertebrae surface into a space between adjacent vertebrae;

securing the first impaler member by contacting an opposing second vertebrae surface;

applying a force sufficient to vertically embed the projecting members into the first vertebrae surface;

removing the first impaler member;

inserting a second impaler member with projecting members to indent a second vertebrae surface into the space between adjacent vertebrae;

securing the second impaler member by contacting the opposing first vertebrae surface;

applying a force sufficient to vertically embed the projecting member into the second vertebrae surface;

removing the second impaler member;

inserting a first implant component with complementary supporting projecting member into the indented vertebrae surface and a first curved bearing surface positioned facing the opposing second vertebrae surface;

inserting a second implant component with second complementary supporting projecting members with a second complementary curved bearing surface to the first implant component by sliding the second complementary curved bearing surface across the first

curved bearing surface until second complementary supporting projecting members are aligned with the indented vertebrae surface of the second vertebrae surface; and

closing the space between the adjacent vertebrae to seat the perspective supporting projecting members and enable relative rotation between the first and second implant components.

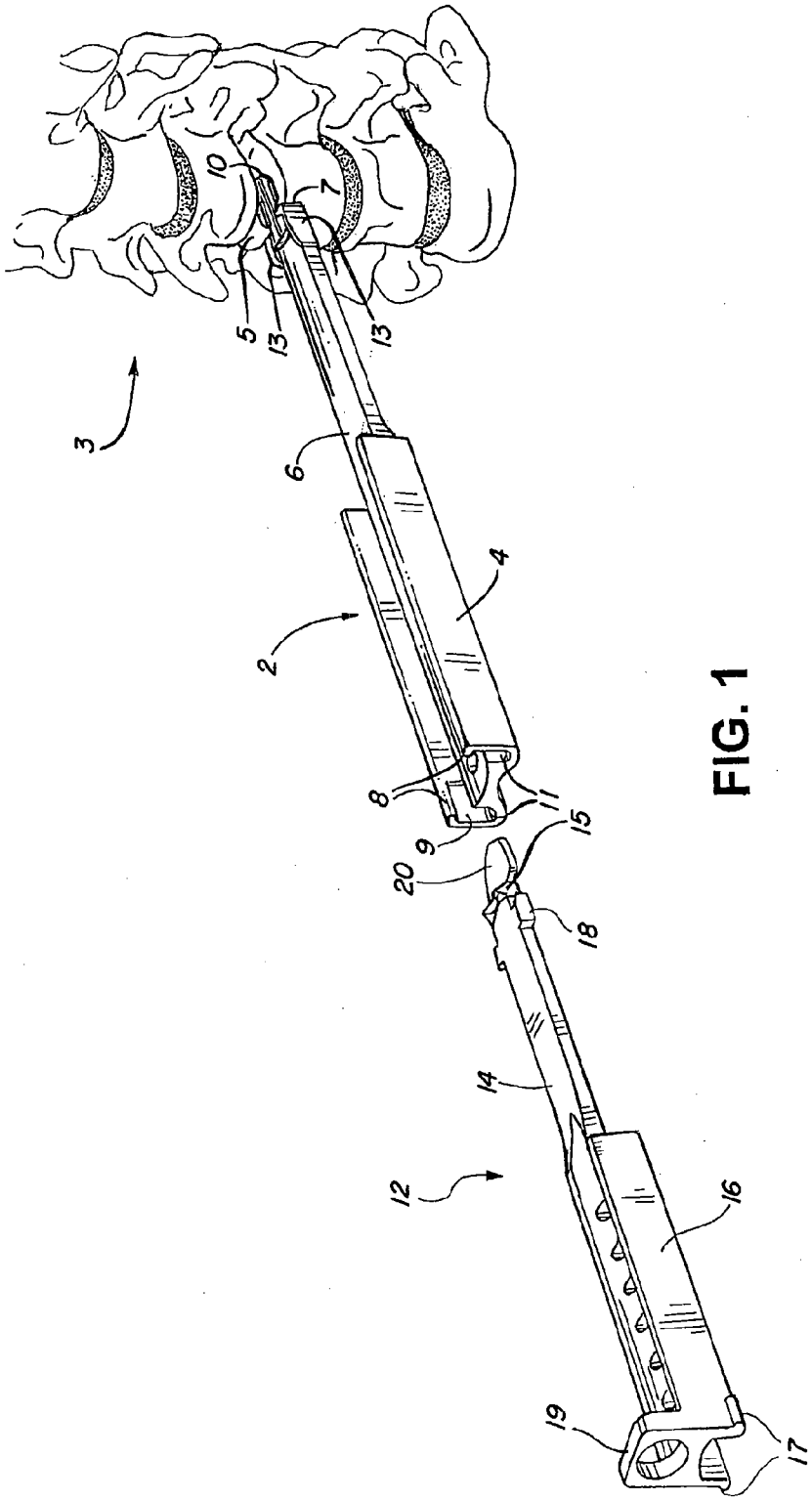

FIG. 1

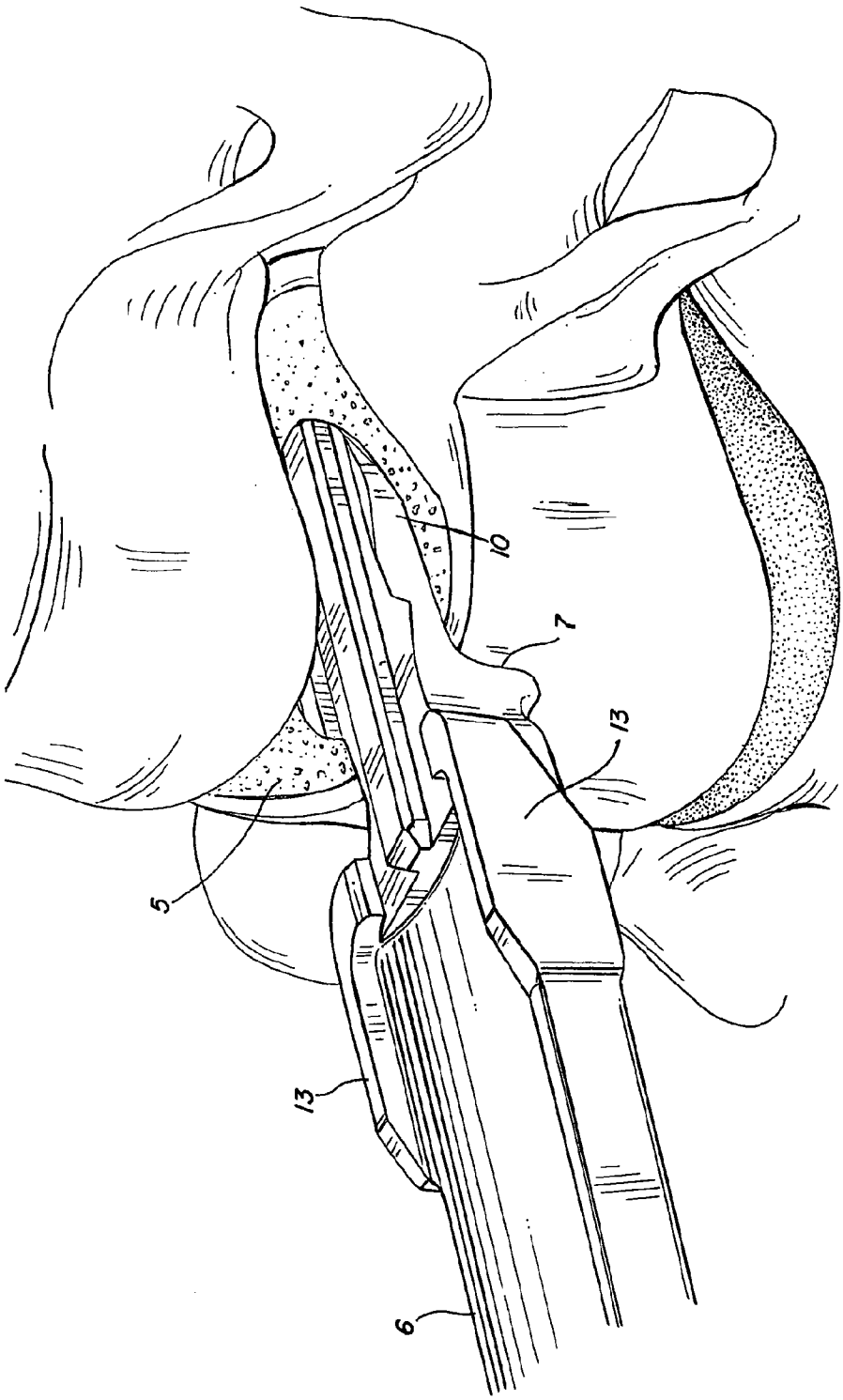

FIG. 2

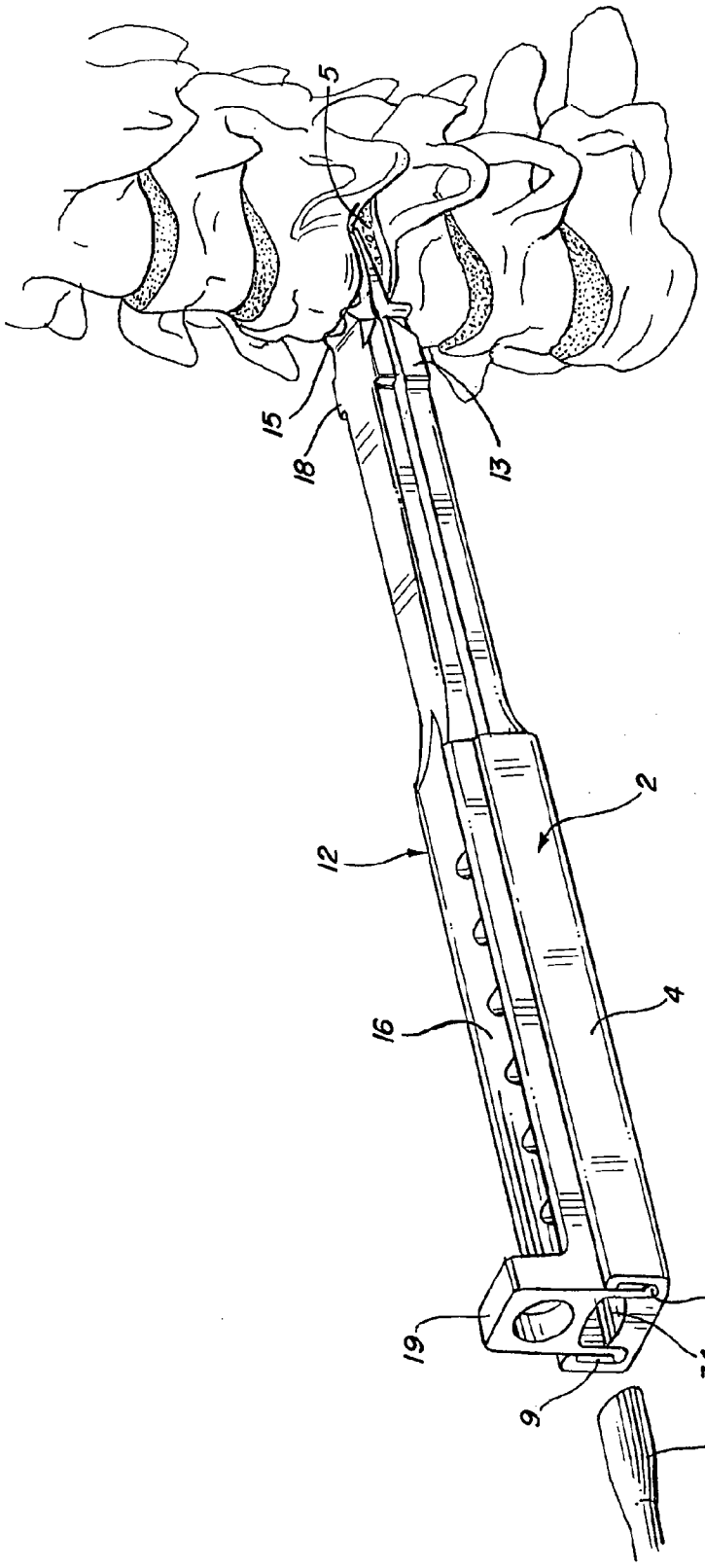

FIG. 3

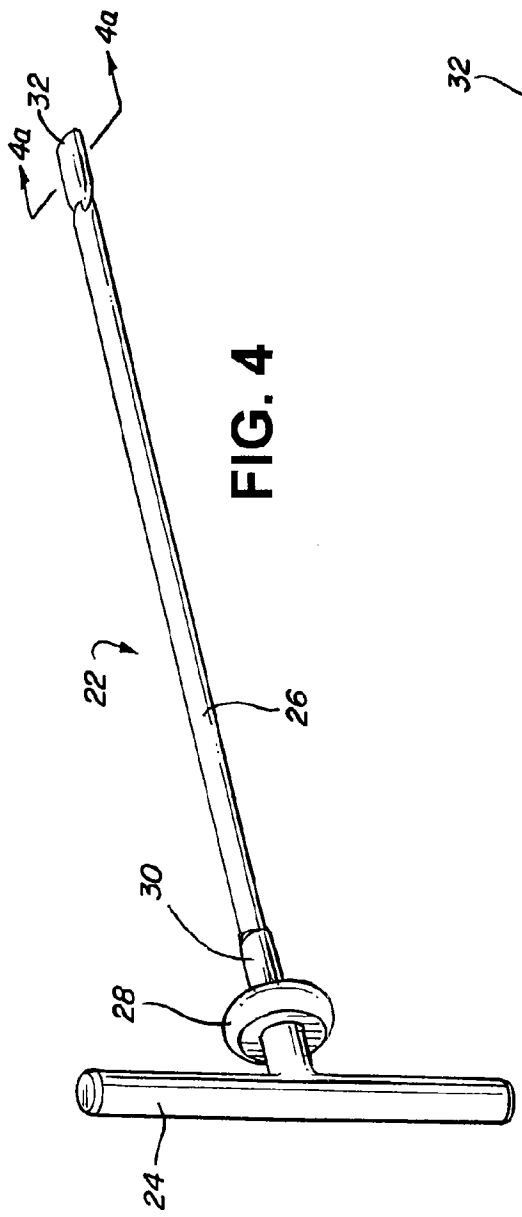

FIG. 4

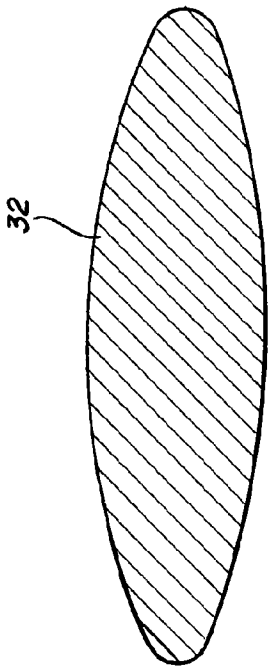

FIG. 4a

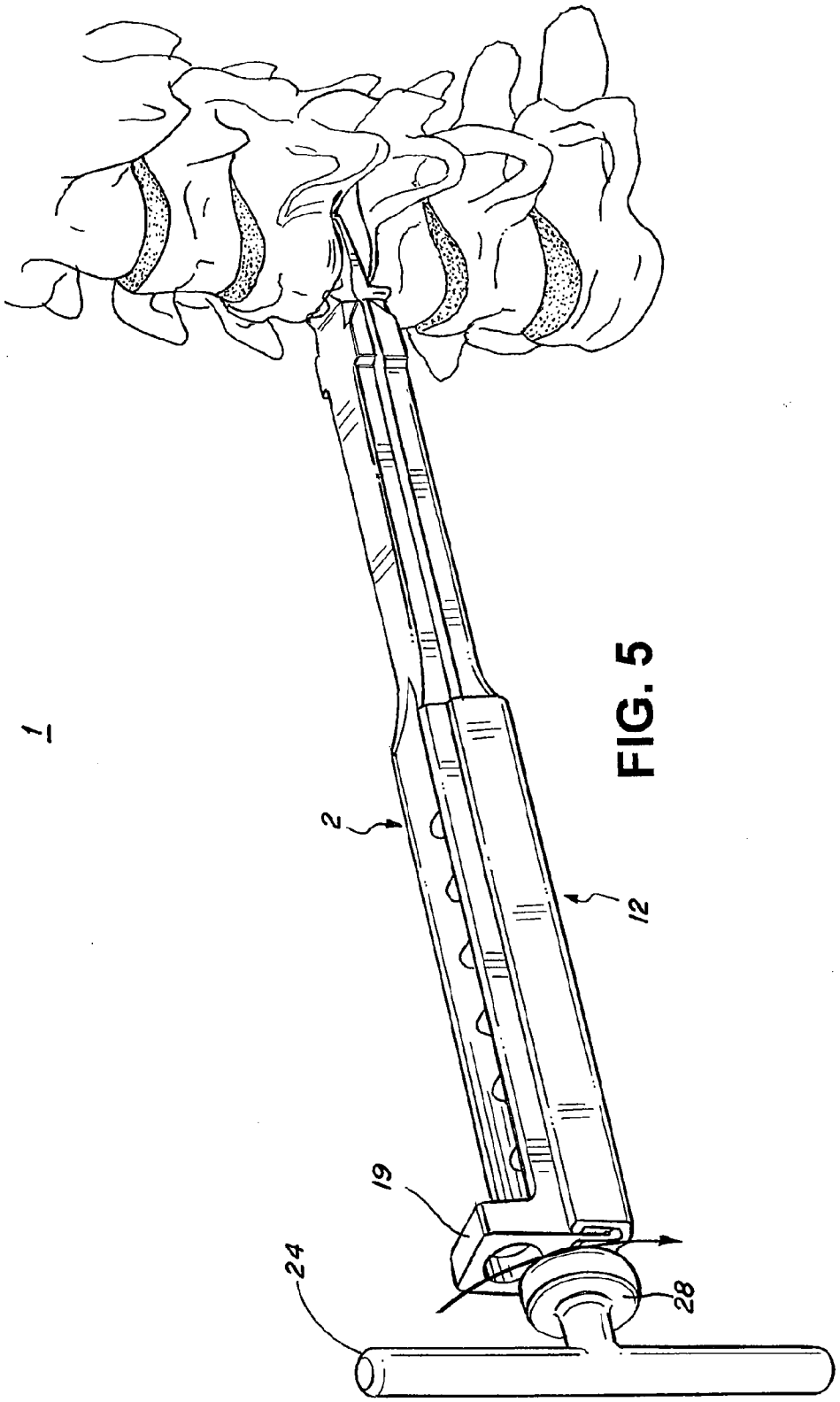

FIG. 5

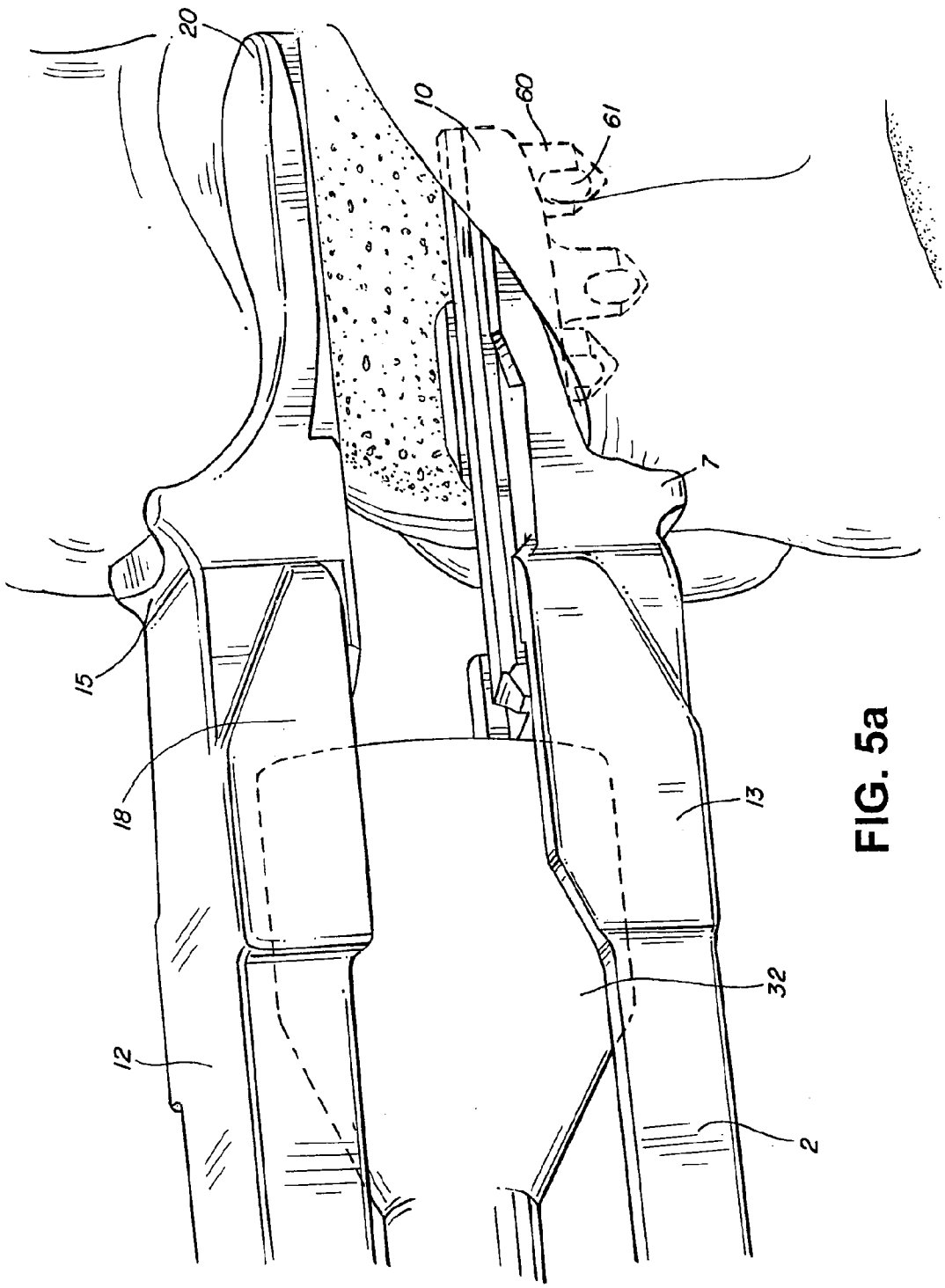

FIG. 5a

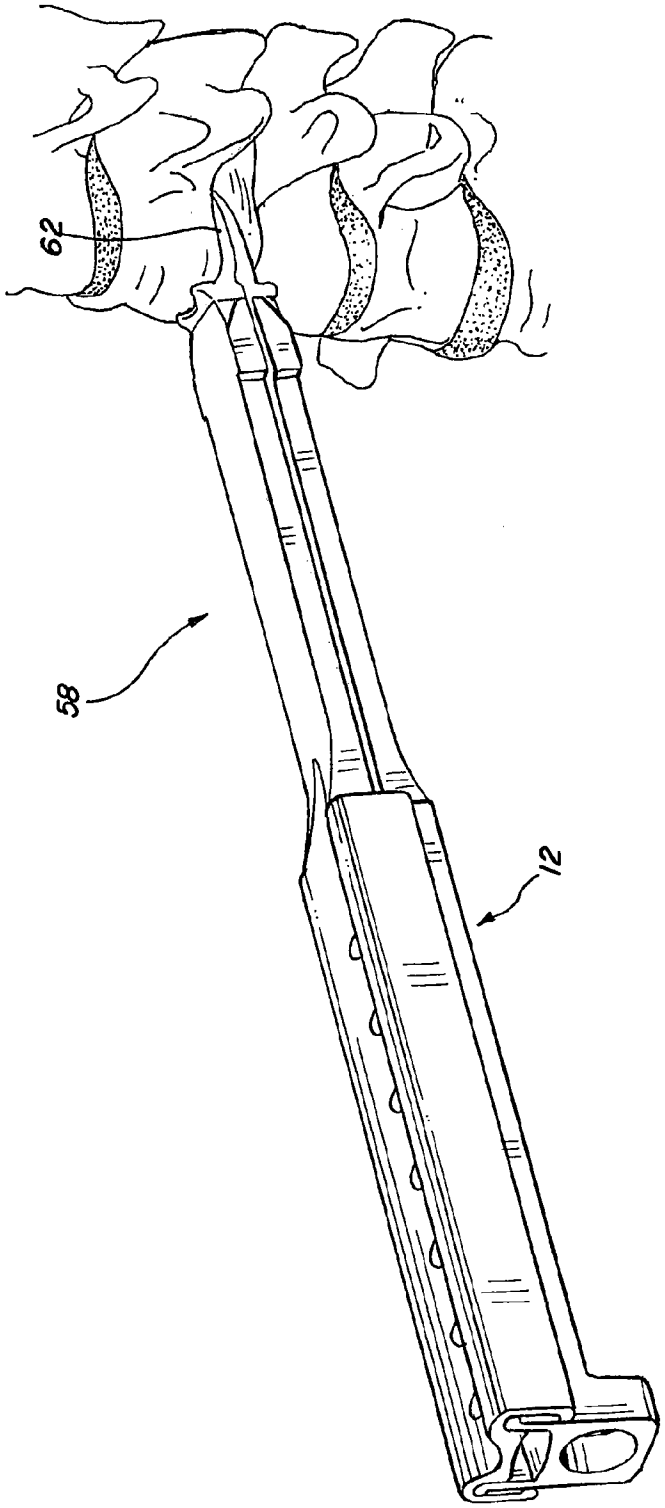

FIG. 6

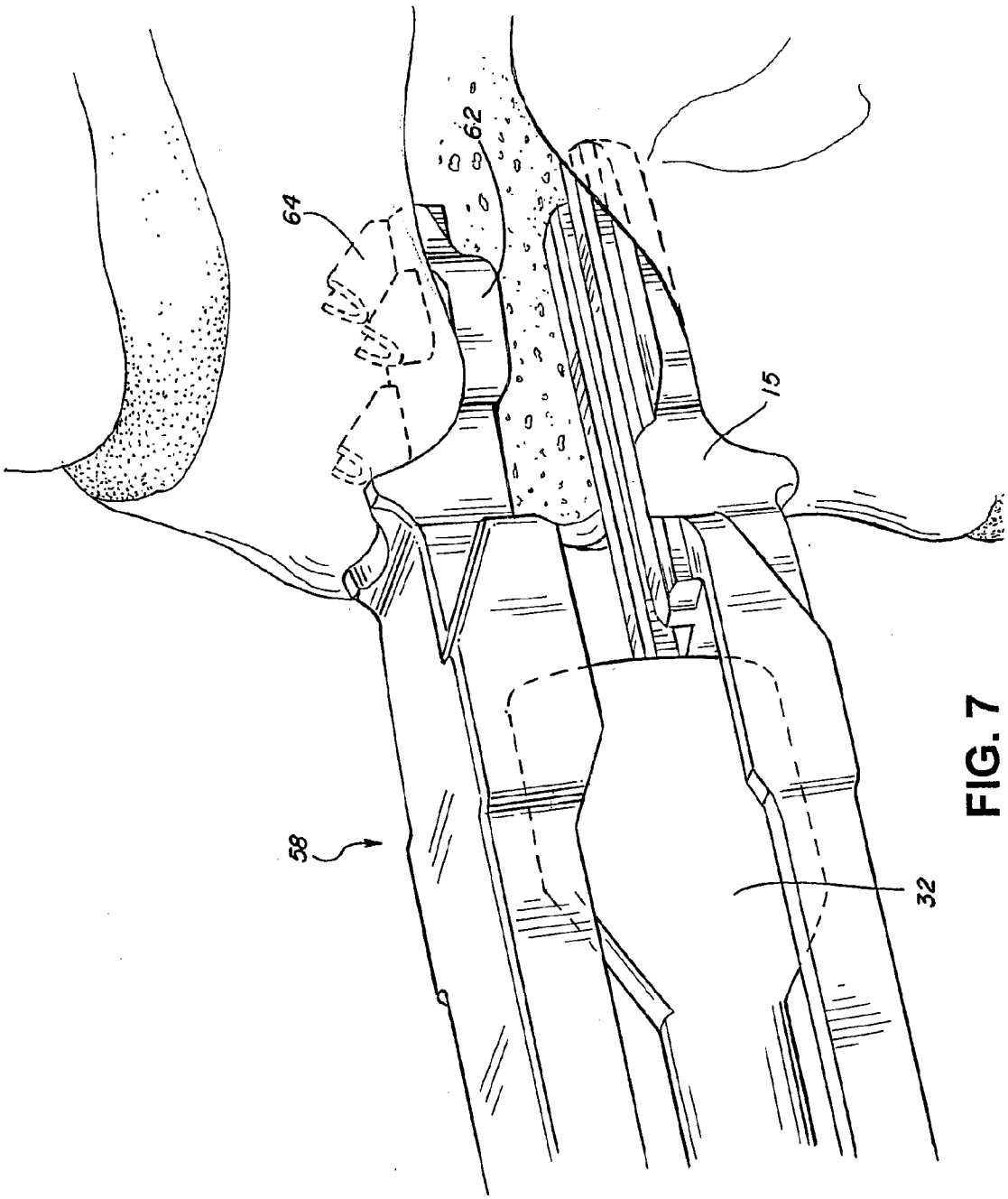

FIG. 7

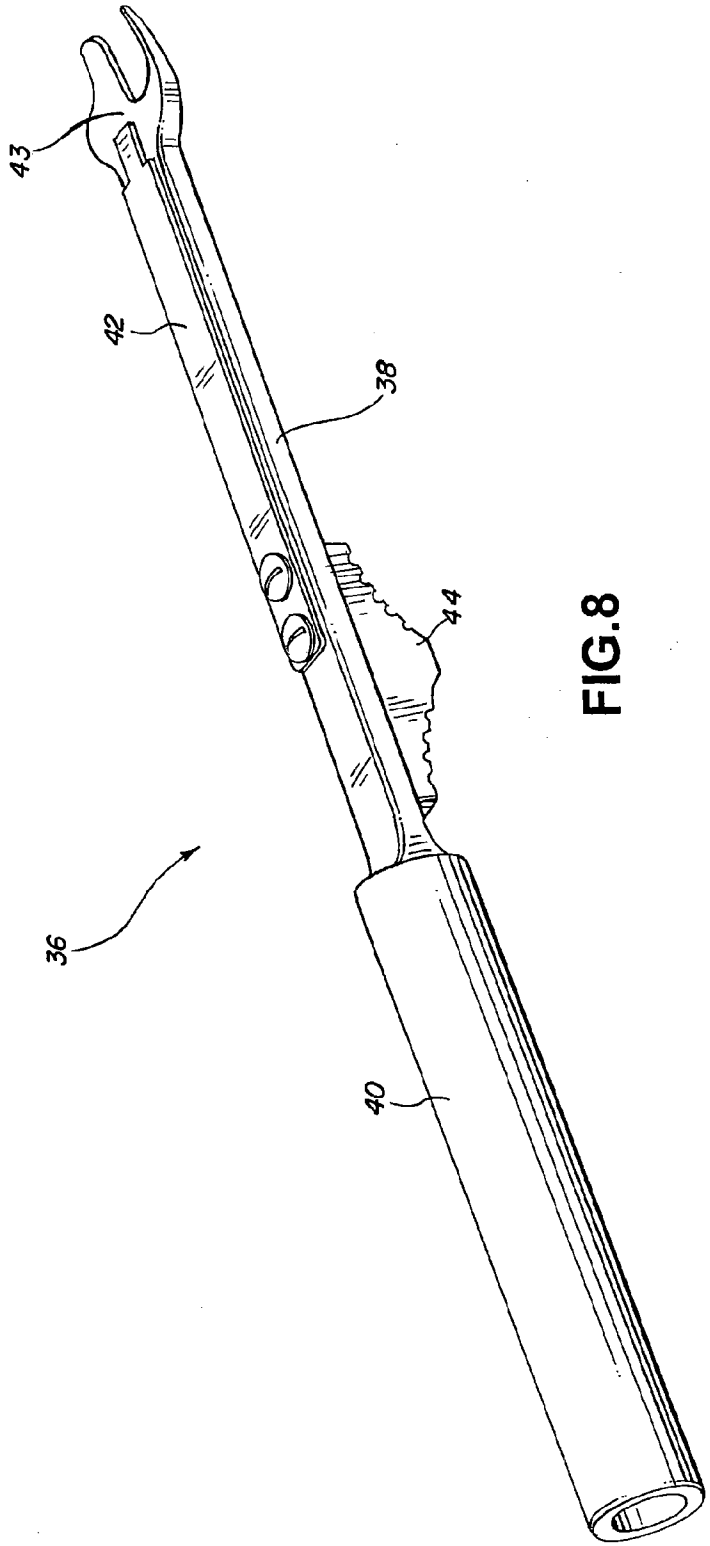

FIG.8

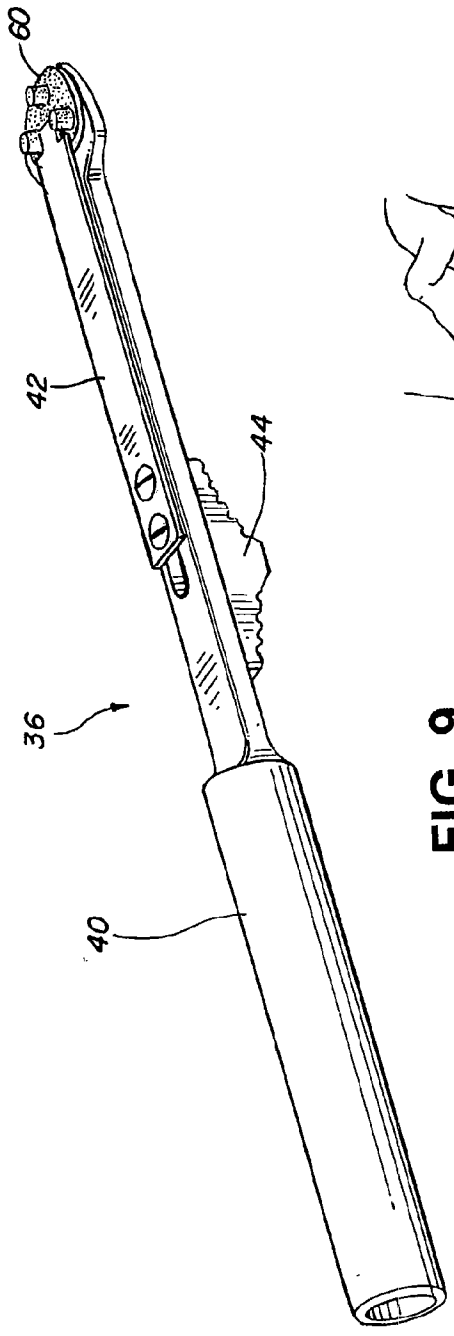

FIG. 9

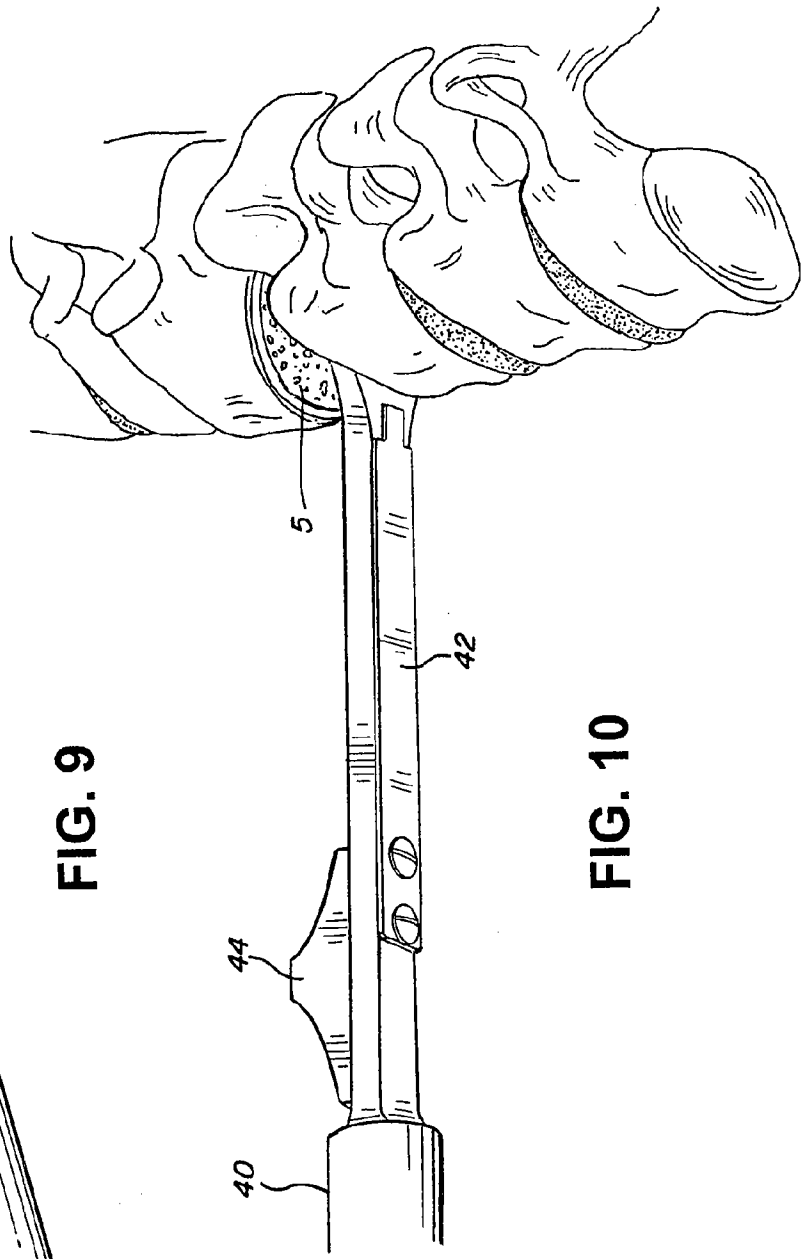

FIG. 10

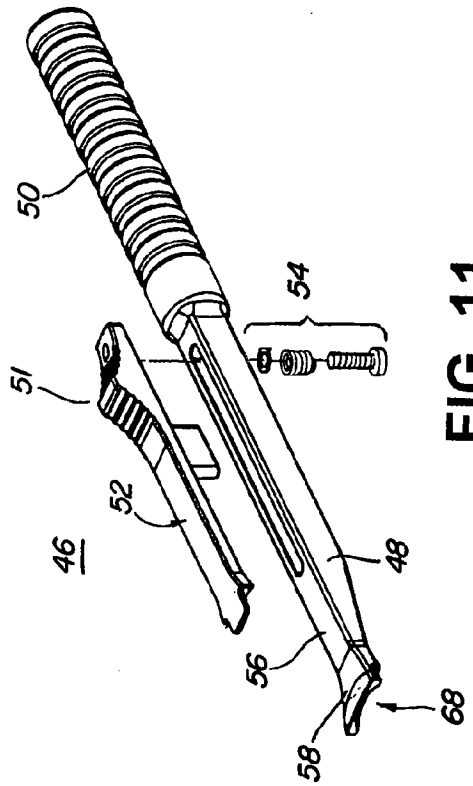

FIG. 11

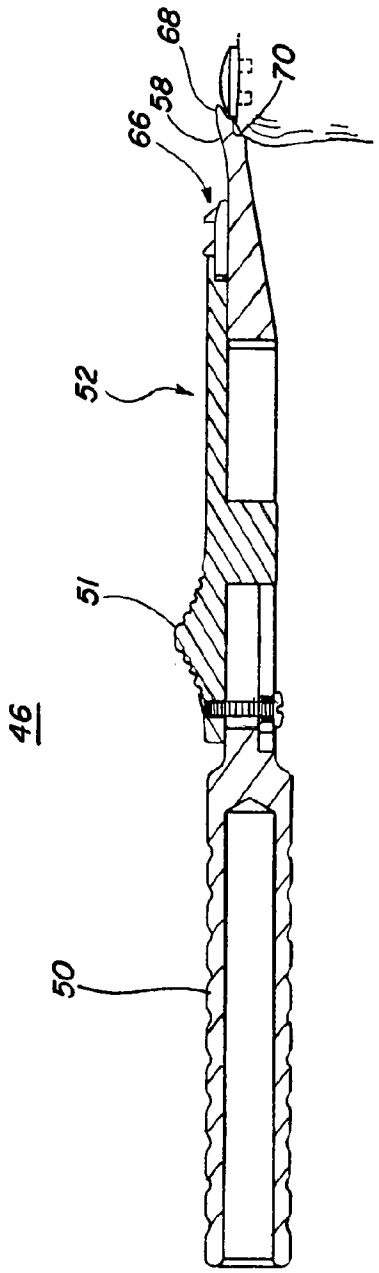

FIG. 12

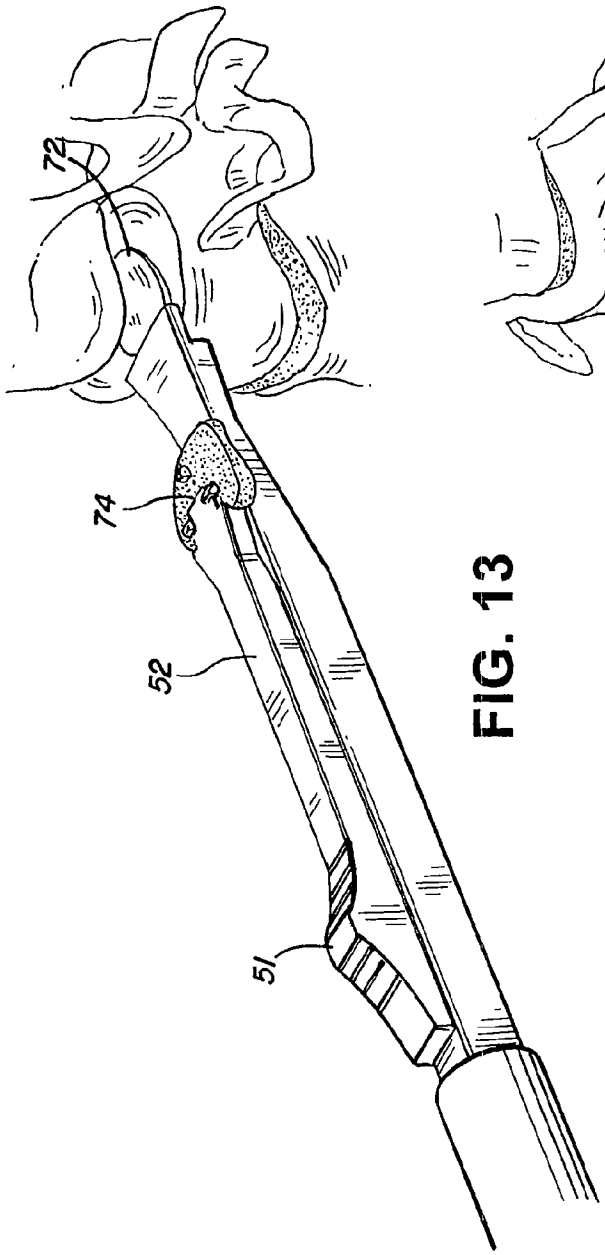

FIG. 13

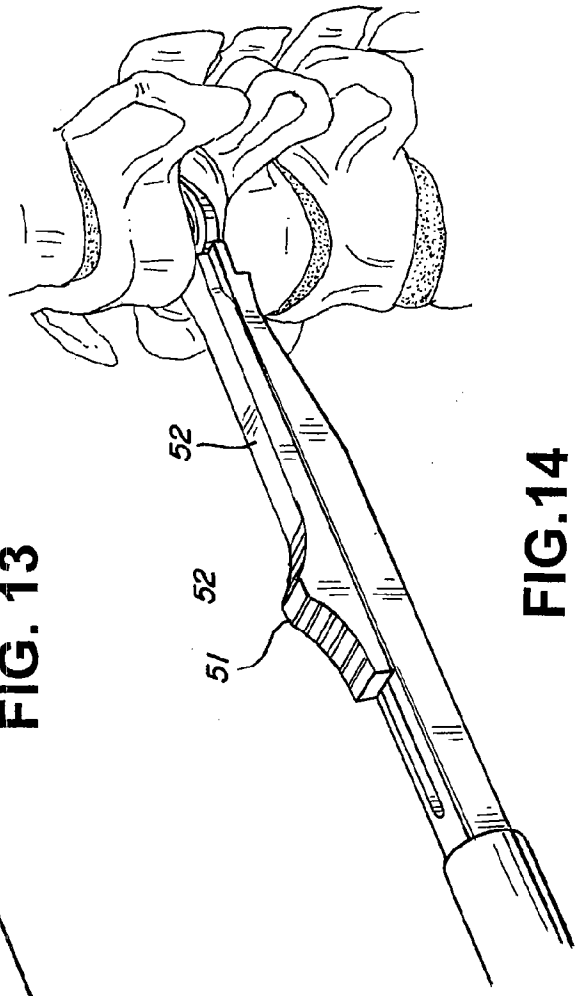

FIG.14

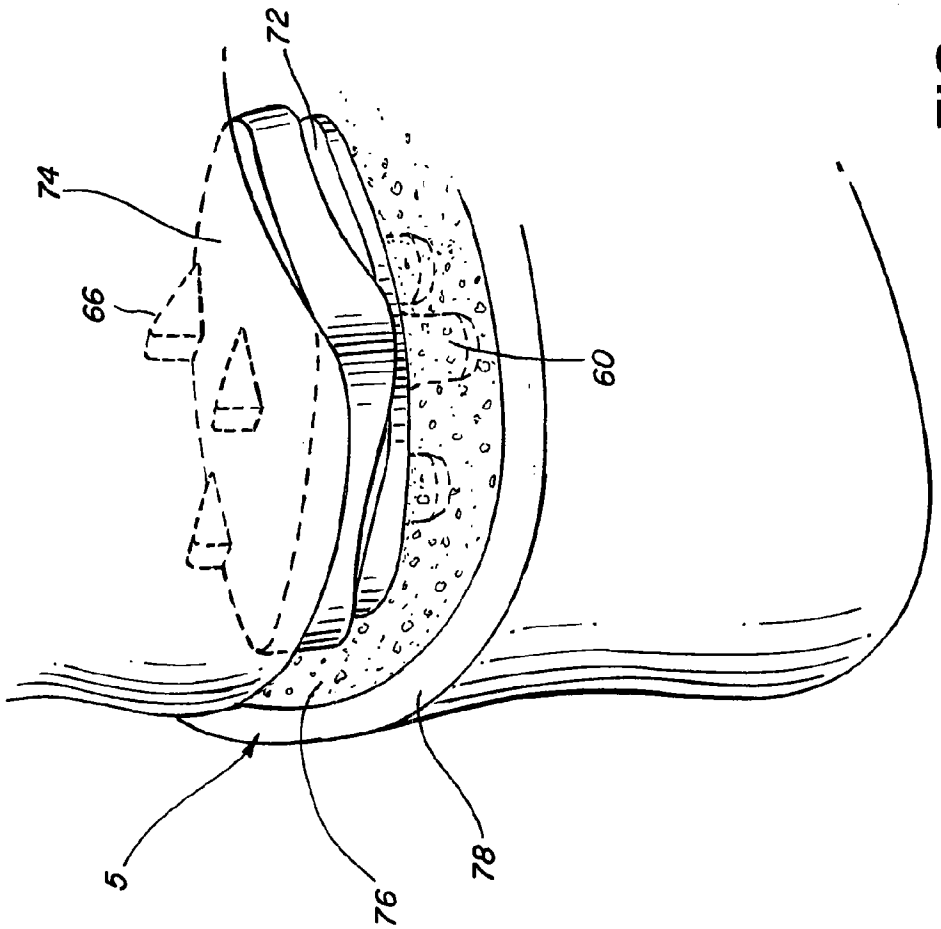

FIG. 15

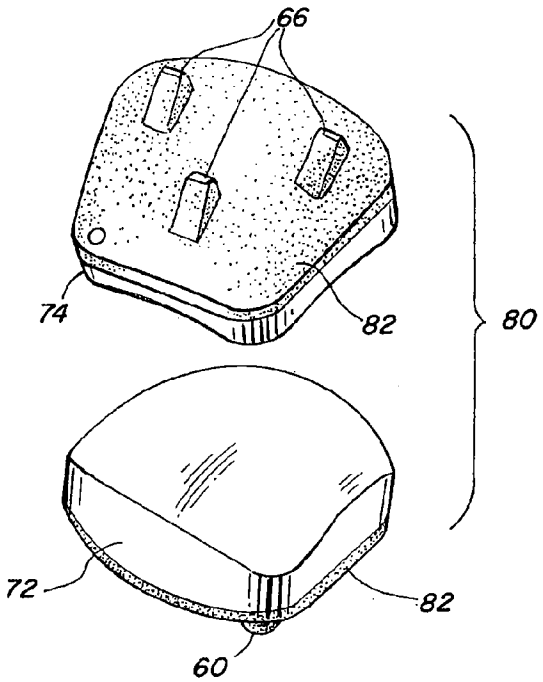

FIG. 16

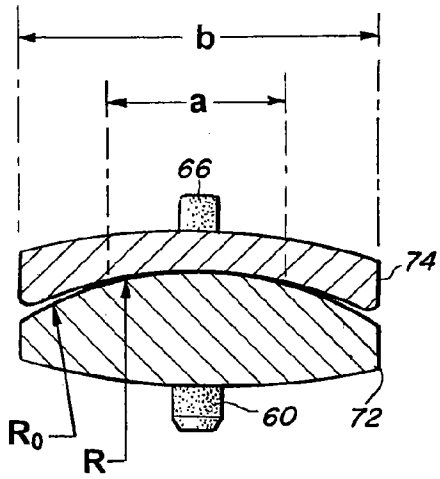

FIG. 17

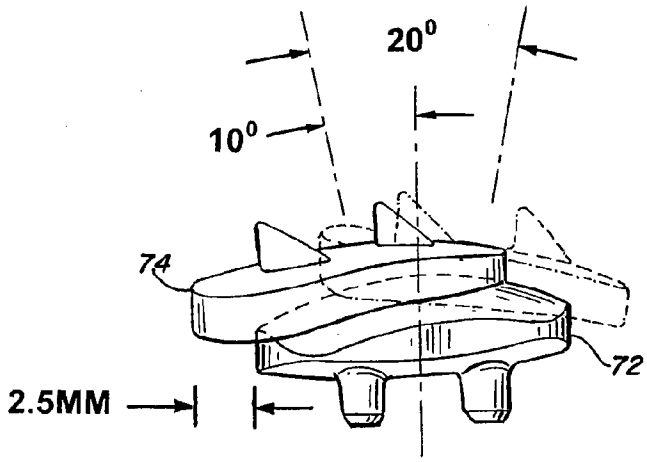

FIG. 18

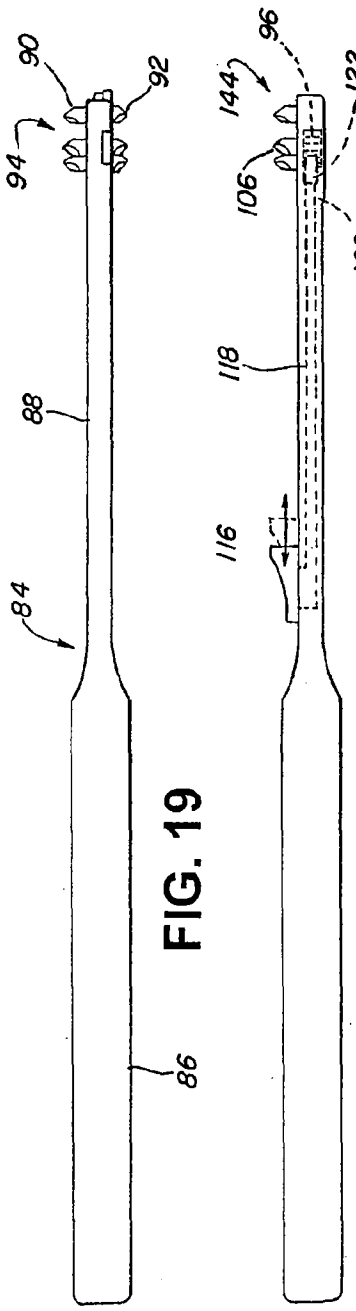

FIG. 19

FIG. 21

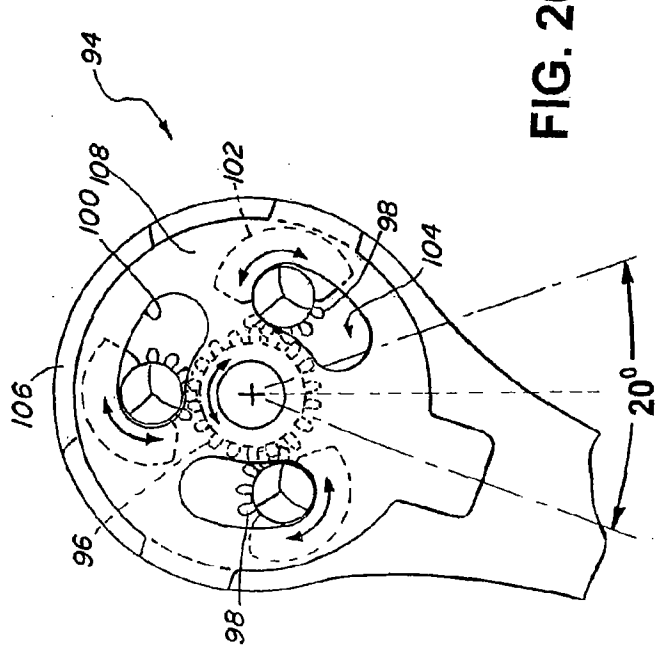

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/029446

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/56 (2011.01)
USPC - 606/99
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(8) - A61B 17/00, 17/02, 17/56, 17/58 (2011.01)
USPC - 81/485; 606/99, 108

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 practicable, search terms used)
Patbase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0149438 A1 (NICHOLS et al) 07 August 2003 (07.08.2003) entire document	13-17
X	US 2009/0082868 A1 (CORDARO et al) 26 March 2009 (26.03.2009) entire document	27-29
X --- Y	US 6,966,912 B2 (MICHELSON) 22 November 2005 (22.11.2005) entire document	30 -------- 31-32
X --- Y	US 2008/0172129 A1 (KIM et al) 17 July 2008 (17.07.2008) entire document	33 ---------- 1-12, 18-26
Y	US 2005/0080422 A1 (OTTE et al) 14 April 2005 (14.04.2005) entire document	1-12, 26
Y	US 6,755,841 B2 (FRASER et al) 29 June 2004 (29.06.2004) entire document	8, 18-26
Y	US 6,553,668 B1 (STEINBERG) 29 April 2003 (29.04.2003) entire document	24, 31-32
Y	US 2009/0177195 A1 (RAWLES et al) 09 July 2009 (09.07.2009) entire document	2, 6-7, 12
Y	US 2007/0233130 A1 (SUDDABY) 04 October 2007 (04.10.2007) entire document	21-24

☐ Further documents are listed in the continuation of Box C. ☐

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