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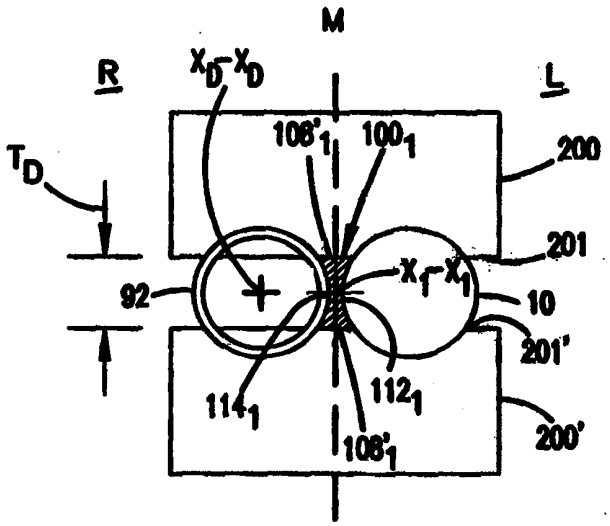
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(54) Title: APPARATUS AND METHOD FOR SPINAL STABILIZATION

(57) Abstract

A surgical method and apparatus for implanting a spinal fusion implant includes a rigid centering guide having a distal end sized to be inserted into the disc space with the guide extending along a longitudinal axis from a distal end to a proximal end. The guide includes a first external guide surface which extends at least partially between the distal end and the proximal end. The external guide surface is shaped complimentary to an external guided surface of a drill guide. The external guide surface and the guided surface are nested such that the guided surface slides against the external guide surface along a path of travel parallel to the longitudinal axis.



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APPARATUS AND METHOD FOR SPINAL STABILIZATION

I. BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to spinal stabilization surgical procedures and apparatus for performing such procedures. More particularly, this invention pertains to an apparatus and method for implanting a fusion spinal implant between two vertebrae.

2. Description of the Prior Art

Chronic back problems cause pain and disability for a large segment of the population. In many cases, chronic back problems are attributed to relative movement between vertebrae in the spine.

Orthopedic surgery includes procedures to stabilize vertebrae. Common stabilization techniques include fusing the vertebrae together.

Recently, spinal implants have been developed to facilitate successful fusion of vertebrae. In such procedures, a bore is formed between opposing vertebrae to be fused. An implant, commonly containing bone growth-inducing material such as harvested bone chips, is placed within the bore.

In order to enhance the successful procedure, a bore should be formed centrally between the vertebrae such that the bore cuts equally into both vertebrae. Also, from time to time, it is desirable to place two implants within the same disc space. In such procedures, it is desirable that the vertebrae be spaced apart by a minimum spacing sufficient to prevent the implants from contacting one another during the implanting procedure. In the prior art, numerous methods have been disclosed for performing spinal stabilization procedures.

A spinal implant and stabilization procedure is taught in U.S. Patent Nos. 5,015,247 and 5,484,437 both to Michaelson, dated May 14, 1991 and January 16, 1996, respectively. That patent teaches a threaded spinal implant as well as a method of implantation including certain tools to form a bore into which the implant is threaded. An implant and surgical method are also shown in U.S.

Patent No. 4,961,740 to Ray, et al., dated October 9, 1990, as well as U.S. Patent No. 5,026,373 to Ray, et al., dated June 25, 1991. The latter patent teaches preparing a bore for the implant by drilling over a pilot rod.

In addition to cylindrical threaded implants such as those shown in U.S. Patent No. 5,015,247, implants may take on different geometries, including non-cylindrical implants such as those shown in U.S. Patent No. 5,609,636 dated March 11, 1997. Also, conical implants have been suggested, where the conical implants have a conical angle approximating a desirable lordosis between the opposing vertebrae.

In surgical procedures involving implants, it is desirable that the surgical procedure be performed accurately to ensure central positioning of the implant within the disc space between the opposing vertebrae. U.S. Patent No. 5,489,307 to Kuslich, et al., dated February 6, 1996, teaches a plurality of instruments and a surgical method for preparing a bore for receiving an implant. That procedure results in accurately positioning an implant centrally between the opposing vertebrae while avoiding certain disadvantages with other prior art techniques as discussed more fully in the '307 patent. Unfortunately, the method and procedure of the '307 patent requires a large number of instruments which must be accurately selected and manipulated throughout the procedure. It is an object of the present invention to provide an apparatus and method for performing spinal stabilization using a reduced number of instruments in order to simplify the procedure without sacrificing the accuracy achieved with the procedure of the '307 patent. Furthermore, it is an object of the present invention to provide a surgical procedure that can be performed posteriorly, anteriorly, laterally, or as a laparoscopic procedure.

II. SUMMARY OF THE INVENTION

According to the preferred embodiment of the present invention, an apparatus and method are disclosed for implanting a spinal fusion implant into a disc space separating a first vertebra and a second vertebra. The method comprises inserting a distal end of a rigid centering guide into the disc space. The guide extends along a longitudinal axis from a distal to a proximal end. The guide has a first external guide surface with a predetermined geometry. A drill guide is placed

against the centering guide. The drill guide is adapted to axially guide a drill. The drill guide has an external guided surface which is shaped complementary to the external guide surface of the centering guide. The external guide surface and the guided surface are mutually nested with the guided surface sliding against the external guide surface along a path of travel parallel to the longitudinal axis of the centering guide. The drill guide is slid toward the vertebrae with the guide surface and the guided surface maintaining movement of the drill guide along the desired path of travel.

III. BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of a prior art implant for use with the method of the present invention;

FIG. 2 is a view of the implant of FIG. 1 with the implant rotated 90° about its axis;

FIG. 3 is a view taken along line 3-3 of FIG. 1;

FIG. 4 is a view taken along line 4-4 of FIG. 3;

FIG. 5 is a view taken along line 5-5 of FIG. 2;

FIG. 6 is a view taken along line 6-6 of FIG. 3;

FIG. 7 is a side elevation of a first embodiment of a centering guide according to the present invention for use in a posterior approach and without a lordotic distal end;

FIG. 8 is a view taken along line 8-8 of FIG. 7;

FIG. 9 is a top plan view of the centering guide of FIG. 7;

FIG. 10 is a side elevation view of a second embodiment of a centering guide according to the present invention for use in an anterior approach and without a lordotic distal end;

FIG. 11 is a view taken along line 11-11 of FIG. 10;

FIG. 12 is a top plan view of the centering guide of FIG. 10;

FIG. 13 is a side elevation view of a third embodiment of a centering guide according to the present invention for use in an anterior approach and with a lordotic distal end;

FIG. 14 is a view taken along line 14-14 of FIG. 13;

FIG. 15 is a top plan view of the centering guide of FIG. 13;

FIG. 16 is a side elevation view of a fourth embodiment of the centering guide according to the present invention for use in a posterior approach and with a lordotic distal end;

FIG. 17 is a view taken along line 17-17 of FIG. 16;

FIG. 18 is a top plan view of the centering guide of FIG. 16;

FIG. 19 is a side elevation tube of a prior art drill tube for use with the present invention;

FIG. 20 is a view taken along line 21-21 of FIG. 19;

FIG. 21 is an enlarged side elevation view of a distal end of the drill tube of FIG. 19;

FIG. 22 is a side elevation view of a prior art boring tool for use with the present invention;

FIG. 23 is an elevation view of a proximal end of the boring tool of FIG. 22;

FIG. 24 is an enlarged view of a boring head of the boring tool of FIG. 22;

FIG. 25 is an end elevation view of a distal end of the boring head of FIG. 24;

FIG. 26 is a side elevation view of a prior art tap for use with the present invention;

FIG. 27 is a view taken along line 27-27 of FIG. 26;

FIG. 28 is an enlarged sectional view of threaded cutting teeth on the tool of FIG. 26;

FIG. 29 is a side elevation view of an implant driver for use with the present invention;

FIG. 30 is an end view of a hub on a distal end of the tool of FIG. 29;

FIG. 31 is a view taken along line 31-31 of FIG. 29;

FIG. 32 is a side elevation view of a shaft of a tool of FIG. 29 showing an attachment collet;

FIG. 33 is a cross sectional view of FIG. 32 taken along line 33-33;

FIG. 34 is a side elevation view of a protective sleeve for use on the drill tube of FIG. 19;

FIG. 35 is an end elevation view of the sleeve of FIG. 34;

FIG. 36 is a schematic posterior to anterior view of two vertebrae separated by a disc space and showing a dura extending centrally along a mid line between the vertebrae;

FIG. 37 is the view of FIG. 30 with a dura retracted to a left side;

FIG. 38 is the view of FIG. 37 with a centering guide of the present invention such as that shown in FIG. 7 inserted into the disc space between the vertebrae prior to the centering guide being rotated to a distraction position;

FIG. 39 is the view of FIG. 38 with the centering guide rotated to a distraction position;

FIG. 40 is a plan view of a disc space showing the elements of FIG. 39;

FIG. 41 is a view taken along line 41-41 of FIG. 40;

FIG. 42 is the view of FIG. 39 with a drill tube of FIG. 19 inserted into position and guided by the centering guide;

FIG. 43 is a plan view of the elements of FIG. 42 with the drill tube shown in section;

FIG. 44 is the view of FIG. 43 following formation of a bore in the disc space and vertebrae and showing retraction of a boring tool through the drill tube;

FIG. 45 is the view of FIG. 44 following formation of a tapped thread in the bore of FIG. 44 and showing removal of the tapping tool through the drill tube;

FIG. 46 is the view of FIG. 45 showing an implant inserted into the threaded bore of FIG. 45 and showing removal of the implant driving tool through the drill tube;

FIG. 47 is a posterior-to-anterior view showing a dura retracted to a right side over an inserted implant and with the centering guide reversed and with a drill tube positioned against the centering guide prior to formation of a bore on the left side of the vertebra;

FIG. 48 is a plan view of the elements of FIG. 47 with the drill tube shown in section;

FIG. 49 is an anterior-to-posterior view of two vertebrae separated by a disc space and showing a non-lordotic, anterior approach centering guide of the present invention (such as that shown in FIG. 10) and shown inserted into the disc space between the vertebrae and with a drill tube being guided by the centering guide;

FIG. 50 is the view of FIG. 49 showing an implant inserted into a formed bore on a left side of the vertebrae and with the drill tube moved to be guided by an opposite side of the centering guide prior to formation of a bore on the right side of the vertebra;

FIG. 51 shows a drill tube of FIG. 19 and a protective sleeve of FIG. 34 guided by a posterior centering guide of FIG. 7;

FIG. 52 shows a still further embodiment of a centering guide;

FIG. 53 is a side elevation view of an alternative embodiment of a drill tube for use with the centering guide of the present invention;

FIG. 54 is a view taken along line 54-54 of FIG. 53;

FIG. 55 is the view of FIG. 53 with drill tube rotated 90° about its longitudinal axis; and

FIG. 56 is a view taken along line 56-56 of FIG. 53.

IV. DESCRIPTION OF THE PREFERRED EMBODIMENT

A. IMPLANT

Referring now to the several drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment of the present invention will now be provided. For purposes of illustrating the preferred embodiment, a description of the surgical procedure will be give with respect to an implant **10** such as that shown and described in commonly assigned U.S. Patent No 5,489,307. It will be appreciated that the present surgical procedures and apparatus can apply to a wide variety of implants including threaded implants such as those shown in U.S. Patent Nos. 5,489,307 and 5,015,247, non-cylindrical implants such as those shown in U.S. Patent No. 5,609,636 as well as conical implants for use in maintaining a desired lordosis. The term "implant" as used herein may also include bone implants as well as metallic implants.

The implant **10** (FIGS. 1-6) is a hollow cylinder **12** having male, square-profile threads **14** exposed on the exterior cylindrical surface of cylinder **12**. The cylinder includes a forward interior chamber **16** and a rear interior chamber **17** separated by a reinforcing rib **19**. A bond slurry or bone chips may be compacted into chambers **16,17**.

A first plurality of holes **18** extend radially through the cylinder wall and communicate with the chambers **16,17**. A second (and enlarged) plurality of holes **21** are disposed on diametrically opposed sides of the implant **10**.

A rear end **22** of the implant has a slot **24** which communicates with the chamber **17**. The slot **24** allows the bone slurry or bone chips to be impacted into the implant **10**. A slot **25** is defined by rib **19**. The slot **25** is sized to receive a distal end of a tool (as will be more fully described) to place the implant within a bore formed between opposing vertebrae. End caps (not shown) may be used with the implant. Such end caps are shown in U.S. Patent No. 5,489,307.

In a preferred embodiment the technique of the present invention will be performed with a prescribed kit of tools. For the purpose of illustrating the preferred embodiment, the tools of the kit will now be described. It will be appreciated that the method of surgery can be practiced using a wide variety of tools of different size and shapes.

Each of the tools of a kit necessary to perform the surgery as described in this application will be separately described. The use of the tools will become apparent with the description of the method of the invention in Section IV.3 of this application. Unless otherwise specified, all tools are formed of stainless steel.

Since vertebrae size and disc space vary from patient-to-patient (and since such sizes vary along the length of the spine of any give patient), several sizes of implants **10** are anticipated. Presently, implants **10** having minor outside diameters (D_m) of 3 mm, 5 mm, 7 mm, 9 mm, 11 mm, 13 mm, 15 mm, 17 mm, 19 mm and 21 mm with lengths (L) of 10 mm, 12 mm, 14, mm 16 mm, 18 mm, 20 mm, 24 mm, 28 mm, 30 mm, 32 mm, 34 mm, 38 mm, 42 mm and 44 mm, respectively, are anticipated to accommodate various spine locations and sizes. The major outside diameters (D_M) of the implants **10** are 2.5 mm larger than the minor outside diameters D_m.

Several of the tools to be described (e.g., a reaming tool **126**) are sized for particular sizes of implants. Namely, the reaming tool **126** must form a bore sized to receive the implant. Since ten sizes of implants are anticipated, ten sizes of boring tools **126** are anticipated as will become apparent to one of ordinary skill in the art.

B. CENTERING GUIDE

1. Non-Lordotic Anterior

The present invention utilizes a novel centering guide to ensure accurate positioning of a drill tube prior to forming a bore and placing an implant. With initial reference to FIGS. 10-12, a centering guide **100** is shown for use in an anterior approach where a surgeon is approaching the disc space from an anterior side of the patient.

The centering guide $\mathbf{100}_1$ is a rigid rod extending from a distal end $\mathbf{102}_1$ to a proximal end $\mathbf{104}_1$ along a longitudinal axis X_1-X_1. The distal end $\mathbf{102}_1$ is rounded to facilitate easy insertion of the distal end $\mathbf{102}_1$ into the disc space.

The anterior guide $\mathbf{100}_1$ has, in cross section, a major transverse axis Y_1-Y_1 with the guide being symmetrical about the axis Y_1-Y_1 and axis X_1-X_1. At the distal end $\mathbf{102}_1$, the guide $\mathbf{100}_1$ has a distraction portion $\mathbf{106}_1$. The distraction portion $\mathbf{106}_1$ is defined by parallel and spaced-apart side edges $\mathbf{108}_1$ which are spaced apart by a distance equal to desired distraction of the vertebrae.

The side edges $\mathbf{108}_1$ act against the end plates of the opposing vertebrae to urge the vertebrae apart. The end plates hold the centering guide $\mathbf{100}_1$ with the axis X_1-X_1 centrally positioned between the end plates. While the tool proximal end $\mathbf{104}_1$ can be moved left or right relative to the vertebrae, the precise central positioning of the proximal end $\mathbf{104}_1$ can be determined through x-ray analysis following placement of the centering guide $\mathbf{100}_1$ such that a surgeon can be assured that the longitudinal axis X_1-X_1 extends perpendicular to a transverse plane of the vertebrae.

The distraction portion $\mathbf{106}_1$ is provided with a plurality of indicia $\mathbf{110}_1$ in the form of grooves positioned at 5 millimeter increments from the distal end $\mathbf{102}_1$. The grooves $\mathbf{110}_1$ are detectable in x-ray films to permit a surgeon to measure the degree of insertion of the distal end $\mathbf{102}_1$ into a disc space. The guide $\mathbf{100}_1$ includes a stop $\mathbf{109}_1$ on edges $\mathbf{108}_1$. The stop $\mathbf{109}_1$ abuts vertebrae to prevent further insertion of guide $\mathbf{100}_1$ beyond full insertion of portion $\mathbf{106}_1$.

Extending between the side edges $\mathbf{108}_1$ and extending the length from end $\mathbf{102}_1$ to end $\mathbf{104}_1$ are left and right (or first and second) guide surfaces $\mathbf{112}_1$,$\mathbf{114}_1$. The guide surfaces $\mathbf{112}_1$,$\mathbf{114}_1$ are concave and have a radius of curvature equal to a radius of curvature of a drill tube as will be described. While the preferred

embodiment of the present invention will be described with reference to using a drill tube having a geometry which is complimentary to the guide surfaces **112$_1$**, **114$_1$**, it will be appreciated that the present invention could be performed without a drill tube and by using a drill, tap or other implement to facilitate insertion of an implant where the implement has a curved geometry to match the radius of curvature of the guide surfaces **112$_1$**, **114$_1$** in which case the implement is directly guided by the guide surface, rather than being guided by an intermediate drill tube.

The proximal end **104$_1$** is provided with a hole **105$_1$** to permit a surgeon to place a tool (not shown) into the hole **105$_1$** to twist the centering guide **100$_1$** to release the centering guide **100$_1$** if necessary. Also, an angled hole **107$_1$** is provided near portion **106$_1$** to permit insertion of a rod (not shown) into hole **107$_1$** to permit a surgeon to force the guide **100$_1$** to the mid-line of vertebrae. With the centering guide **100$_1$** of FIG. 7 the end plates of the vertebrae will be distracted in parallel spaced apart relation since the side walls **108$_1$** are parallel at the distraction portion **106$_1$**.

2. Non-Lordotic Posterior

FIGURES 7-9 show a centering guide **100$_2$** similar to that of FIGS. 10-13 but differing due to the fact that centering guide **100$_1$** of FIGS. 7-9 is intended for use in a posterior approach where a surgeon approaches the vertebrae from the posterior side of the patient. In the embodiments of FIGS. 7-18, simple elements are numbered similarly with the addition of subscripts to distinguish the embodiments.

Like the centering guide **100$_1$** of FIGS. 10-12, the centering guide **100$_2$** of FIGS. 7-9 is for a non-lordotic parallel distraction appliance where the side edges **108$_2$** are spaced apart in parallel alignment at the distraction portion **106$_2$**. Unlike the centering guide **100$_1$** of FIGS. 10-12, the centering guide **100$_2$** of FIGS. 7-9 is not symmetrical about its major transverse axis Y_2-Y_2 (although it is symmetrical about axis X_2-X_2. Instead, the centering guide **100$_2$** of FIGS. 7-9 includes only a first concave guiding surface **112$_2$** extending on one side of the centering guide **100$_2$**. The opposite surface **114$_2$** is a convex surface to present a smooth surface opposing a dura following insertion of the centering guide **100$_2$** as will be described.

3. Lordotic Posterior

The centering guides $\mathbf{100_1}$,$\mathbf{100_2}$ of FIGS. 7-12 both show distraction portions $\mathbf{106_1}$,$\mathbf{106_2}$ having distracting edges $\mathbf{108_1}$,$\mathbf{108_2}$ which are parallel and spaced apart. From time to time, it may be desirable to ensure that end plates of opposing vertebrae are retained at a desired degree of lordosis (i.e., with a non-parallel angle between end plates of the opposing vertebrae).

FIGS. 16-18 show a centering guide $\mathbf{100_3}$ for a posterior approach and having a lordotic distraction portion $\mathbf{106_3}$. The distraction portion $\mathbf{106_3}$ has side edges $\mathbf{108_3}$ placed at an angle, A, equal to the desired degree of lordosis. In all other respects, the centering guide $\mathbf{100_3}$ of FIGS. 16-18 is identical to that of FIGS. 7-9.

4. Lordotic Anterior

FIGS. 13-15 show a lordotic centering guide $\mathbf{100_4}$ for use in an anterior approach. The distractor end $\mathbf{106_4}$ of the tool $\mathbf{100_4}$ has distracting side edges $\mathbf{108_4}$ set at a lordotic angle, A', equal to but reverse that of the embodiment of FIGS. 16-18. In all other respects, the centering guide $\mathbf{100_4}$ of FIGS. 13-15 is identical to that of FIGS. 10-12.

5. Laparoscopic

Laparoscopic versions of both the lordotic and non-lordotic centering guides can also be provided. Although not shown in the drawings, such laparoscopic centering guides would have a shorter length than the non-laparoscopic centering guides shown in the drawings. For example, a non-lordotic, laparoscopic anterior centering guide would be identical to that of guide $\mathbf{100_1}$ (FIG. 10) but have its axial length detachable so that the terminal end $\mathbf{104_1}$ is spaced from the distal tip $\mathbf{102_1}$ by about 3 inches. After insertion of the portion $\mathbf{106_1}$ into the disc space, approximately 1.5 inches of the guide surfaces $\mathbf{112_1}$, $\mathbf{144_1}$ would protrude beyond the vertebrae and provide a guide surface for directing a laparoscopic drill tube. The design would also permit the maintenance of insufflation.

C. DRILL TUBE

A drill tube **92** (FIGS. 20-22) is provided in the form of a hollow cylindrical tube **94**. The distal end **96** of the tube **94** is provided with axially projecting teeth **98**. The proximal end **99** of the tube **94** is flared outwardly. As will be apparent, ten

sizes of tube **92** are required with inside diameters D_{DT} to slip in close tolerance over ten sizes of implants **10** (i.e., D_{DT} is 0.5 mm larger than D_M).

The teeth **98** each have a length, T_L, of preferably 3 mm. The valleys **97** are flat to provide stop surfaces to hit bone as teeth **98** are forced into vertebrae. This helps prevent the drill tube **92** from being forced too far into bone. The drill tube **92** is identical to that shown in U.S. Patent No. 5,489,307.

An alternative embodiment of a drill tube **192** is illustrated in FIGS. 53-56. The drill tube is a hollow cylindrical tube **194** with an outside diameter having a radius of curvature to match the radius of curvature of the guide surfaces $\mathbf{112_1}$, $\mathbf{114_1}$. The distal end **196** of the tube **194** includes diametrically opposed and axially projecting sharpened teeth **198** for penetration into vertebrae. Diametrically opposed and axially extending retraction paddles **199** are provided ninety degrees offset from the teeth **198** (with reference to the longitudinal axis (X'_D-X'_D). The paddles **199** have a width (W in FIG. 54) equal to the desired distraction of the vertebrae. The proximal end **197** of the tube **194** is a handle to be gripped by a surgeon. The tube **194** has a length L_D measured from the base of the teeth **198** and retraction paddles **199** to the base of the handle **197**. The length L_D is equal to the length of a centering guide (such as the length of guide $\mathbf{100_1}$ of FIG. 10) between the proximal end $\mathbf{104_1}$ and the insertion portion $\mathbf{106_1}$. Therefore, when the insertion portion $\mathbf{106_1}$ is fully inserted into the disc space, the end $\mathbf{104_1}$ buts against the handle **197** when the teeth **198** are forced into the vertebrae.

D. VERTEBRAL REAMER

A vertebral reamer **126** (or boring tool) (FIGS. 22 through 25), is provided for forming a bore. The reamer **126** is such as that shown in U.S. Patent No. 5,489,307. The reamer **126** includes a shaft **128**. A distal end of the shaft is provided with a reamer end **130** having side and end cutting blades **131**. A proximal end of the shaft is provided with an outwardly flared hub **132**. Extending from hub **132** is an axial shaft **134**. For ten sizes of implants **10**, ten sizes of reamers **126** are required with the kit. The outside diameter D_R of reamer **126** equals the minor outside diameter D_m of implants **10**. The diameter D_{RG} of the guide hub **133** equals the inner diameter of the drill tube D_{DT}.

E. BONE TAP

In the event a threaded implant is utilized (as is the case in the preferred embodiment of the present invention), the bores for the implants are partially pre-threaded. To pre-thread, a bone tap **142** (FIGS. 26-28) is provided, having a shaft **144**. The top **142** is such as that shown in U.S. Patent No. 5,489,307. At the distal end of the shaft **144** is a tapping head **146** having tapping threads **148**. Near the proximal end of the shaft **144** is an enlarged diameter portion **156** having an outwardly flared flange **158**. A handle **160** is secured to an enlarged portion **156**. The shaft **144** is also enlarged at portion **162** adjacent tapping head **146**. The enlarged portion **156** is sized with diameter D_8 to be received, in close tolerance, within the drill tube **92** such that the tube **92** will guide the tap **142** as will be more fully described.

Since ten sizes of implants **10** are intended to be utilized, ten sizes of bone taps **142** are required. Diameter D_T is equal to the major outside diameter D_M of implant **10**. The head **146** has a minor outside diameter D_t (i.e., the diameter without threads **148**) equal to the minor outside diameter D_m of the implants **10**.

F. IMPLANT DRIVER

To place implant **10**, an implant driver **164** (FIGS. 29 through 33) is provided. The driver **164** is such as that shown in U.S. Patent No. 5,487,307. A driver is also shown in U.S. Patent No. 5,609,636. The driver **164** includes a shaft **166** having a reduced diameter distal portion **166a**. A distal end of the shaft **166** is provided with a hub **168** sized to be received within slot **24** of the implant **10** to urge the implant **10** to rotate as the implant driver **164** is rotated. The implant driver **164** includes a stepped enlarged portion **170** including a first diameter portion **172**, a second diameter portion **174** and a third diameter portion **176** to accommodate the different diameters of drill tubes **92**. A handle **178** is secured to the shaft **164**. Grooves **180,180a** are formed on the shafts **166,166a** and extend along their axial lengths. The grooves **180** provide a means for a surgeon to sight the alignment of the implant.

FIGS. 32-33 show the implant driver **164** with a collet **171**. The collet **171** has a cylindrical, knurled body **173** slidably carried on shaft **166a**. A pin **175**

extending from body **173** into groove **180a** permits collet **171** to slide on shaft **166** but not rotate. Four prongs **177** extend axially from body **173** toward hub **168**.

In use, shaft **166** is passed through end opening **24** of implant **10**. Hub **168** is received within slot **25**. The prongs **177** are forced by a surgeon pushing on body **171** for the prongs **177** to be urged between opposing surfaces of the implant **10** and shaft **166a** to thereby securely capture the implant **10** on driver **164**. As a result, the implant **10** cannot inadvertently fall off. (For ease of illustration, the Figures showing the method of the invention, e.g., FIG. 46, does not show use of collet **171**).

G. DRILL TUBE SHEATH

Drill tube **92** is passed through a patient's body to an implant site. To avoid risk of teeth **98** damaging vessels, nerves or organs, a drill tube sheath **300** is provided (FIGS. 34,35). The sheath **300** is such as that shown in U.S. Patent No. 5,489,307. The sheath **300** is a hollow tube with inside diameter D_S slightly smaller than the outside diameter of drill tube **92** (accordingly, ten sizes of sheath **300** are required). The sheath **300** has an axial slit **301** extending its entire length. The sheath **300** has a blunt distal end **302** and a flared proximal end **304**.

The sheath is slipped onto the drill tube **92** with end **302** extending beyond the teeth **98**. As the drill tube **92** is passed to an implant site the blunt end **302** covers the teeth and prevents the unwanted cutting of vessels, nerves or organs. When pressed against vertebrae, the end **302** abuts the vertebrae. With continued advancement of the tube **92** toward the vertebrae, the sheath **300** slides on the tube **92** until teeth **98** abut the vertebrae.

In the method of the invention, sheath **300** remains in place whenever drill tube **92** are used. However, for ease of illustration, sheath 300 is not shown in FIGS. 42-50.

H. POSTERIOR TECHNIQUE

The present invention will first be described with reference to use in a posterior approach. In a posterior approach, a surgeon seeks access to the spine through the back of the patient. Another alternative approach is the lateral approach, where the patient is on his side and a single cage is inserted across the disk space. An alternative approach is an anterior approach where the surgeon seeks access to

the spine through the abdomen of a patient. The approaches can be done through open surgery or through laparoscopic surgery.

While a posterior approach will be described in detail, it will be appreciated that the present invention can be used in an anterior or lateral approach for both laparoscopic or non-laparoscopic procedures.

With initial reference to FIG. 36, once a surgeon has identified two vertebrae **200,200'** which are to be fused together, the surgeon identifies an implant **10** of desired size and the surgeon determines the desired amount of distraction of the disc space **202** to be required before placement of the implant **10**. In selecting the implant size, the surgeon should ensure that the device will remain within the lateral borders of the intervertebral disc space **202** while also penetrating at least 3 mm into the vertebral bodies **200,200'** cephalad and caudal to the disc.

In the posterior technique, a patient is placed on the operating table in either a prone or kneeling-sitting position. At the discretion of the surgeon, the spine is flexed slightly. Anesthesia is administered.

Exposure of the intervertebral disc is obtained through any suitable technique well-known in the art. The facet of the vertebrae is removed in as limited amount as possible to permit insertion of the instruments and the implants. Preferably, bone dissected from the lamina, facets and spinous process are preserved for later use as bone graft.

FIG. 36 shows two vertebrae **200,200'** separated by a disc space **202**. For ease of illustration, disc material is not shown in space **202** having an undistracted thickness T_R. In the posterior P to anterior A view, a dura **204** extends between the vertebrae **200,200'** and is centrally positioned along a medial line, M, between the vertebrae **200,200'**. The line M separates the disc space **202** and vertebrae **200,200'** into a left side L and right side R corresponding to the patient's left and right sides.

As shown in FIG. 37, the dura **204** is first retracted to the left through any suitable means to expose the disc space **202** and vertebrae **200,200'** at the medial line, M. A distal end $\mathbf{102_2}$ of the centering guide $\mathbf{100_2}$ of FIGS. 7-9 is inserted into the disc space **202** in the manner illustrated in FIG. 38 with the distracting side edges $\mathbf{108_2}$ opposing and in line with the disc space **202**.

After initial insertion of the distal end **102_2** into the disc space, the centering tool **100_2** is rotated 90° to the position shown in FIG. 39 such that the side edges **108_2** of the distraction portion **106_2** oppose and distract the vertebrae and the convex surface **114_2** is opposing the dura **204** to prevent damage to the dura **204**. The vertebrae **200,200'** are now distracted to a spacing of T_D equal to the distance between side edges **108_2**.

The distraction portion **106_2** of the guide **100_2** is forced into the disc space **202** at the mid line M of the disc space **202**. The size (i.e., the spacing between the side edges **108_2**) of the centering guide **100_2** is selected to distract the annulus fibrosus without causing damage to the surrounding vertebral bone, annular fibers or spinal nerves. Accordingly, it is recommended that a surgeon initially insert a relatively narrow distal end centering guide (e.g., 6 millimeters) followed by successively larger guides until the annulus is distracted to the surgeon's satisfaction.

Once the correct maximum size distraction portion **106_2** has been chosen, it is left in place. The disc space **202** has now been stretched so that a parallel distraction of the end plates **201,201'** of the vertebrae **200,200'** has occurred on both the left and right sides of the vertebrae. The distraction portion **106_2** is fully inserted such that the indicia **110_2** are flush or slightly recessed within the disc space.

Following placement of the distracting centering guide **100_2**, the drill tube **92** is placed against the centering guide **100_2**. Since the guiding surface **112_2** of the centering guide **100_2** is concave with a radius of curvature matching the outer radius of curvature of the drill tube **92**, the drill tube **92** can be slid along the length of the guide **100_2** into precise position with the axis X_D-X_D of the drill tube **92** centrally positioned between the end plates **201,201'** of the vertebrae **200,200'**.

In a preferred embodiment, the drill tube **92** will be surrounded by a sliding protective sleeve **300** such as that shown in FIGS. 34-35 and described fully in U.S. Patent No. 5,489,307. The thin wall of the drill sleeve **300** has substantially the same radius of curvature as the drill tube **92** and does not materially affect the positioning. At most, the addition of the protective sleeve **300** increases the spacing of the axis X_D-X_D of the drill tube **92** from the axis X_2-X_2 of the guide **100_2** (FIG. 51) but does not alter the central positioning of the axis X_D-X_D of the drill tube **92**

between the end plates **201,201'**. For ease of illustration, the drill sleeve protective sleeve is not shown in FIGS. 42-50.

With the drill tube **92** in place, the preparation of the implant bore **206** is completed by inserting the reamer **126** into the drill tube **92** (FIG. 44). The reamer **126** is rotated with any suitable driver (such as driver 136 shown in U.S. Patent No. 5,489,307).

Since the drill tube **92** is centrally placed with the axis X_D-X_D of the drill tube **92** centrally positioned between the end plates **201,201'**, the reamer **126** will bore into the disc space **202** and bore equally into and through the end plates **201,201'** of the opposing vertebrae. The reamer **126** is selected to form a bore **206** having a diameter D_m equal to the minor outside diameter of the implant **10** (in the case of a cylindrical implant such as that shown in FIGS. 1-6).

For use with a threaded implant **10** such as that shown in FIGS. 1-6, a bone tap **142** is passed through the drill tube **92** and rotated to at least partially pretap the bore (FIG. 45). The tap is then removed to expose a tapped bore **207** with the drill tube **92** remaining in place. The implant **10** may then be packed with a bone graft material. The graft may be autograft obtained previously from the iliac crest or some other graft material (e.g., allograft or artificial bone). The implant **10** is attached to the implant driver **164** by placing the hub **168** within the slot **25** and securing the implant **10** with the collet **171**. The implant **10** is then passed through the drill tube **92**. The implant **10** is threaded into the bore **207** with the implant driver **164** by the surgeon rotating the driver **164** and advancing it into the drill tube **92**. As disclosed in U.S. Patent No. 5,489,307, it is desirable that the larger holes of the implant are oriented in a superior-inferior direction (i.e., the larger holes are facing the vertebrae **200,200'**).

After the implant **10** is fully in place, the implant driver **164** is removed through the drill tube **92** (FIG. 47). The drill tube **92** is then removed. The dura **204** is retracted slightly and the centering guide **100** is then removed. The dura **204** is then retracted to the opposite side and the centering guide $\mathbf{100_2}$ is repositioned with the disc space **204** but rotated 180° relative to FIG. 39 so that the rounded side $\mathbf{114_2}$ is facing both the dura **204** and the previously placed implant **10** and the guide surface $\mathbf{112_2}$ is facing the opposite side of the disc space **202**. The procedure can

then be repeated by placing the drill tube **92** against the vertebrae with the drill tube **92** aligned by the guide $\mathbf{100}_2$ as previously described (FIG. 47).

I. Anterior Approach

The foregoing discussion illustrates the use and method of an apparatus of the invention in a posterior approach. It will be noted that for placing two implants **10**, the centering guide $\mathbf{100}_2$ is removed and reinserted into the disc space **202** to reorient the guiding surface $\mathbf{112}_2$.

When performing an anterior approach, the surgeon uses the anterior guide $\mathbf{100,100}_4$ which has concave guiding surfaces **112,114** on opposite sides of the centering guide **100**. With such structure, the anterior centering guide **100** is placed at the mid line M and a drill tube **92** is guided by a first **112** of the guiding surfaces **112,114** so that a first bore can be formed, tapped and an implant **10** inserted through the drill tube (FIG. 50). After the implant **10** is inserted, the centering guide **100** remains in place but the drill tube **92** is moved to the opposite side and guided into position by the second guiding surface **114** (FIG. 51). With the drill tube **92** in position on the second side, a bore **206** is then formed by passing the reamer and tap through the drill tube and a second implant is inserted through the drill tube.

J. Lateral Approach

The present invention is particularly suited for a lateral approach where an elongated single implant is to be placed in the inner vertebral space. The present invention requires smaller access space to the disc space which is of particular advantage in a lateral approach where there is substantial anatomic structure limiting access to the disc space in a lateral approach at certain vertebrae locations.

K. Additional Embodiments

In the foregoing description, the guide surface has been shown as a concave surface **112** having the same radius of curvature of the guided surface of the cylindrical drill tube. It will be appreciated that while a circular arc of a guide surface corresponding to a radius of curvature of a cylindrical drill tube is preferred, a plurality of complementary geometries could be used for the guide surface and the guiding surface.

In the present invention, if the surgeon were to place the drill tube **92** such that the axis X_D-X_D of the drill tube **92** is not parallel to the longitudinal axis X_2-X_2

of the centering guide **100_2**, such misalignment could be detected at the proximal end **104_2** of the guide **100_2** and be indicated by a spacing between the centering guide **100_2** and the drill tube **92**. An alternative embodiment would be to provide a guiding surface on the centering guide which locks with a guided surface on the drill tube such that non-parallel alignment of the axis of the drill tube and the centering guide is not possible. For example, the guide surface **112'** on the centering guide **100'** could be dovetail grooved and the guided surface on the drill tube **92'** could be a complementary shaped dovetail rail **93'** which slides within the dovetail groove **112'**. Such a modification would preclude non-parallel alignment of the axis X_D'-X_D' of the drill tube **92'** and the longitudinal axis X'-X' of the centering guide **100'**. However, such a modification would require accurate alignment of the drill tube **92'**, whereas in the preferred embodiment previously disclosed, the drill tube **92** may be rotated about its axis X_D-X_D.

From the foregoing detailed description of the present invention it has been shown how the objects of the invention have been obtained in a preferred manner. However, modifications and equivalence of the disclosed concepts such as those which would occur to one of ordinary skill in the art are intended to be included within the scope of the present invention.

WHAT IS CLAIMED IS:

1. A surgical method for implanting a spinal fusion implant into a disc space separating a first vertebra and a second vertebra, said method comprising:

inserting a distal end of a rigid centering guide into said disc space with said guide extending along a longitudinal axis from said distal end to a proximal end exterior of said disc space and with said guide having a first external guide surface of predetermined geometry;

placing an implement against said centering guide with said implement having an external guided surface shaped complementary to said first external guide surface for said first external guide surface and said guided surface to be nested with said guided surface sliding against said first guide surface along a path of travel parallel to said longitudinal axis;

sliding said implement toward said vertebrae with said first guide surface and said guided surface maintaining movement of said implement along said path of travel.

2. A method according to claim 1 comprising selecting said distal end to be sized to distract said disc space upon insertion of said distal end into said disc space and distracting said disc space by insertion of said distal end into said disc space.

3. A method according to claim 2 comprising inserting said distal end from an anterior approach and selecting said distal end to have opposite side edges defining an angle approximate to a desired angle of lordosis between said disc space.

4. A method according to claim 2 comprising inserting said distal end from a posterior approach and selecting said distal end to have opposite side edges defining an angle approximate to a desired angle of lordosis between said disc space, said distal end inserted by first inserting said distal end into said disc space with said side edges rotated to oppose said disc space and subsequently rotating said distal end within said disc space for said side edges to oppose and distract said vertebra.

5. A method according to claim 1 wherein said guide includes said first external guide surface and a second external guide surface, said first and second external guide surfaces positioned on opposite sides of said longitudinal axis with each of said first and second external guide surfaces shaped complementary to said external guided surface of said implement for a selected one of said first and second external guide surfaces to nest with said guided surface for said guided surface to slide against said selected one along said path of travel, and wherein said implement is a drill guide adapted to axially guide a drill, said method further comprising:

sliding said drill guide toward said vertebrae against said first guide surface;

inserting a drill through said drill guide and boring a first bore;

inserting an implant into said first bore;

sliding a drill guide toward said vertebrae against said second guide surface;

inserting a drill through said drill guide and boring a second bore; and

inserting an implant into said second bore.

6. A method according to claim 1 wherein said guide includes an external second surface on a side of said longitudinal axis opposite said first guide surface, said second surface being convex to present a smooth surface opposing a dura, said method including:

retracting a dura before inserting said distal end into said disc space; and

placing said distal end into said disc space with said second surface opposing said dura.

7. An apparatus for use in implanting a spinal fusion implant into a disc space separating a first vertebra and a second vertebra, said apparatus comprising:

a rigid centering guide having a distal end sized to be inserted into said disc space with said guide extending along a longitudinal axis from said distal end to a proximal end exterior of said disc space;

a first external guide surface extending at least partially between said distal end and said proximal end; and

said external guide surface shaped complementary to an external guided surface of an implement for said first external guide surface and said guided surface to be nested with said guided surface sliding against said first guide surface along a path of travel parallel to said longitudinal axis.

8. An apparatus according to claim 7 wherein said distal end is sized to distract said disc space upon insertion of said distal end into said disc space.

9. An apparatus according to claim 8 wherein said distal end includes side edges spaced apart by a desired distraction and with said side edges defining an angle approximate to a desired lordosis angle between said first and second vertebrae.

10. An apparatus according to claim 9 wherein said angle is selected for an anterior approach with said distal end having a narrowest spacing between said side edges at said distal end.

11. An apparatus according to claim 9 wherein said angle is selected for a posterior approach with said distal end having a narrowest spacing between said side edges at a location spaced rearwardly from said distal end.

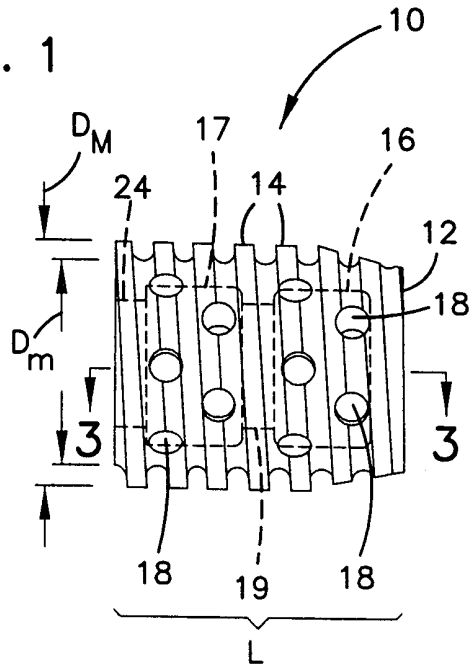
12. An apparatus according to claim 7 wherein said guide includes said first external guide surface and a second external guide surface, said first and second external guide surfaces positioned on opposite sides of said longitudinal axis with each of said first and second external guide surfaces shaped complementary to said external guided surface of said implement for a selected one of said first and second external guide surfaces to nest with said guided surface for said guided surface to slide against said selected one along said path of travel.

13. An apparatus according to claim 7 wherein said guide includes an external second surface on a side of said longitudinal axis opposite said first guide surface, said second surface being convex to present a smooth surface opposing a dura.

14. An apparatus according to claim 7 wherein said guide includes a plurality of x-ray detectable indicia at a plurality of positions at said distal end.

15. An apparatus according to claim 7 wherein said drill guide is cylindrical and said first external guide surface is a convex arc taken in cross-section orthogonal to said longitudinal axis and having a radius of curvature approximate to an external radius of said implement.

FIG. 1



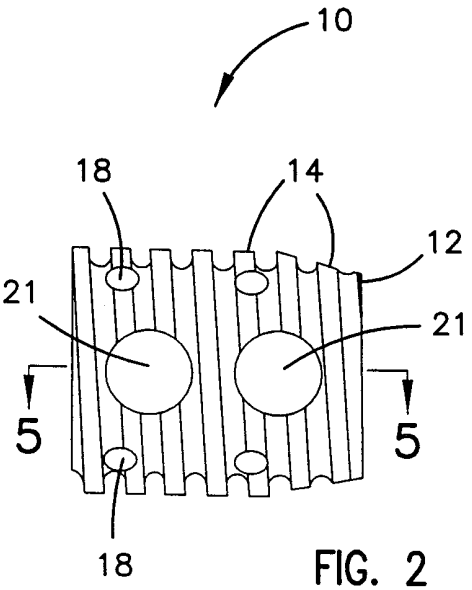


FIG. 2

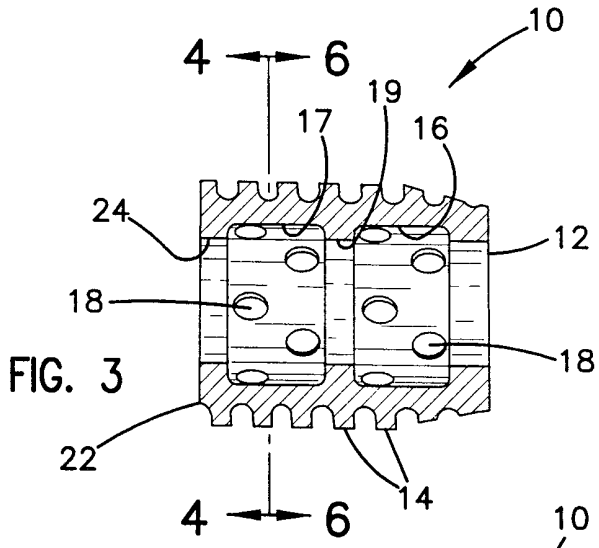
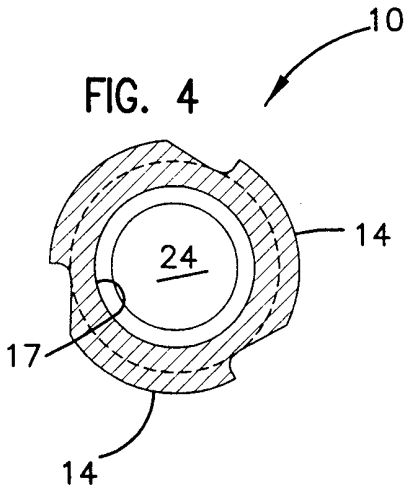


FIG. 3

FIG. 4



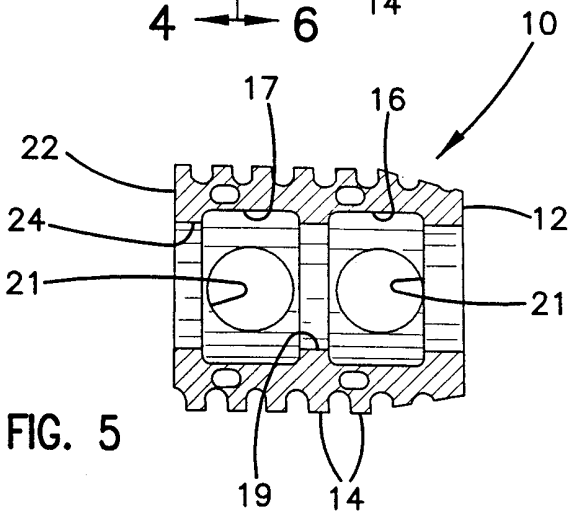


FIG. 5

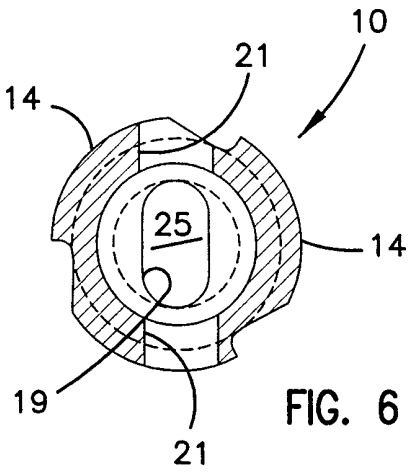


FIG. 6

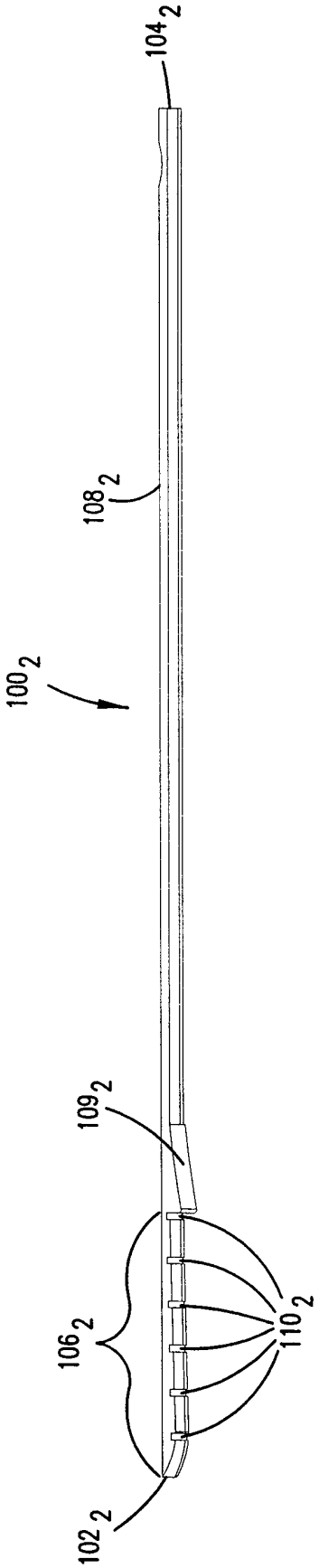

104_2
108_2
100_2
109_2
106_2
110_2
102_2

FIG. 9

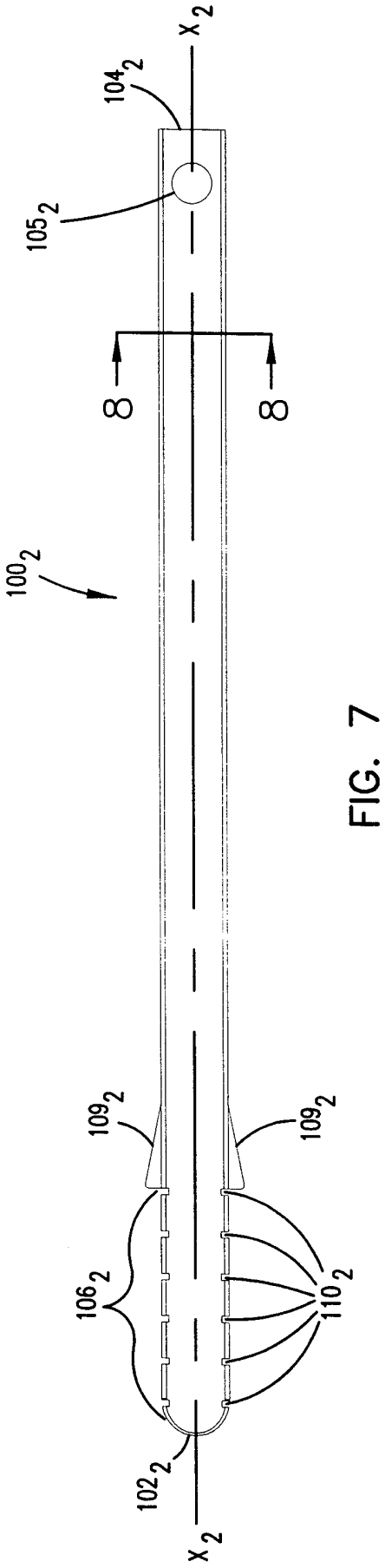

X_2
104_2
105_2
8
8
100_2
109_2
109_2
106_2
110_2
102_2
X_2

FIG. 7

FIG. 8

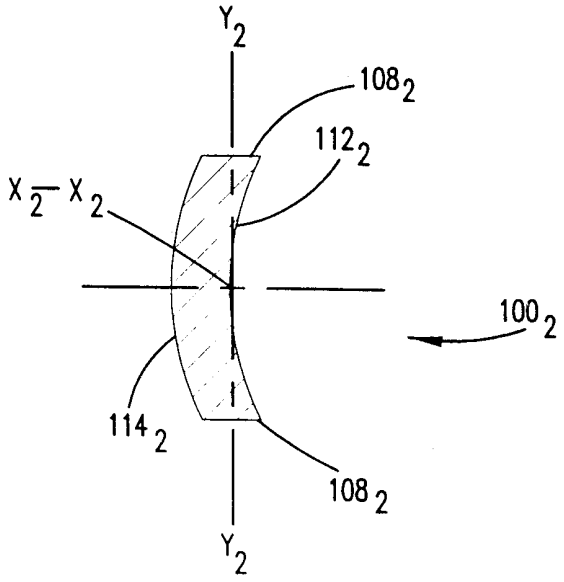
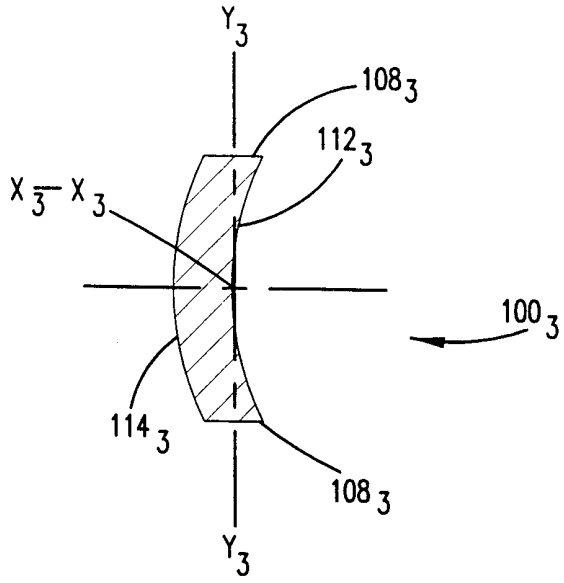

Y2
108 2
112 2
X 2 — X 2
100 2
114 2
108 2
Y2

FIG. 17


Y3
108 3
112 3
X 3 — X 3
100 3
114 3
108 3
Y3

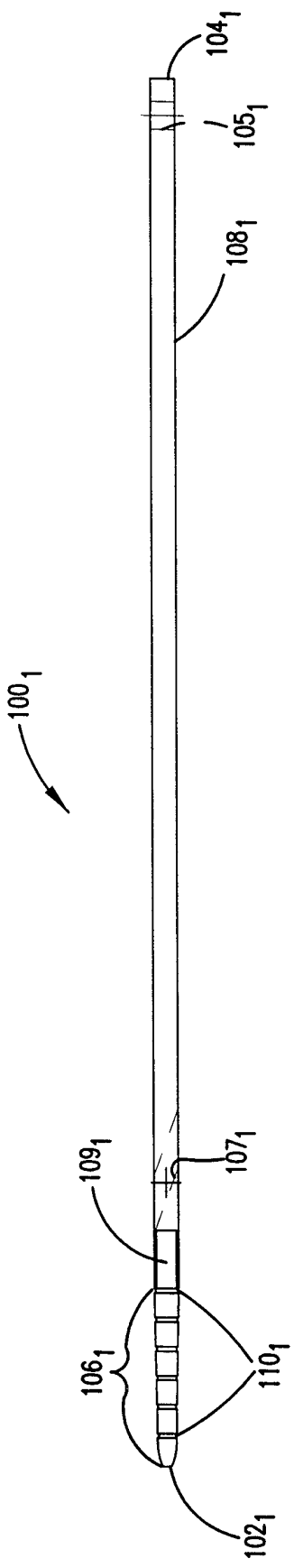

100_1
104_1
105_1
108_1
109_1
107_1
106_1
110_1
102_1

FIG. 12

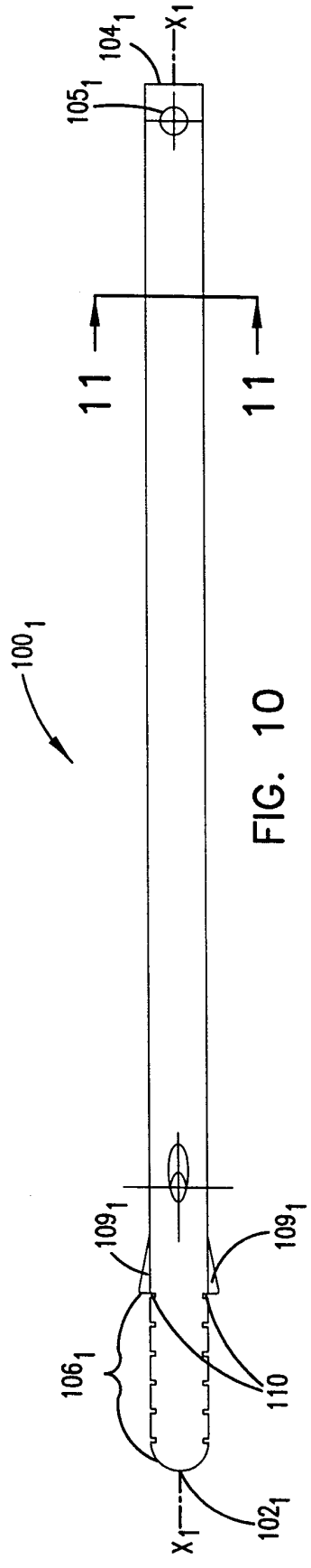

100_1
104_1
X_1
105_1
11
11
109_1
109_1
106_1
110
X_1
102_1

FIG. 10

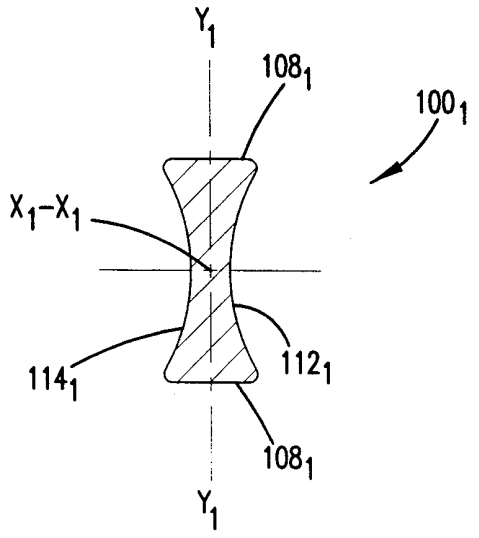

Y_1
108_1
100_1
X_1–X_1
114_1
112_1
108_1
Y_1

FIG. 11

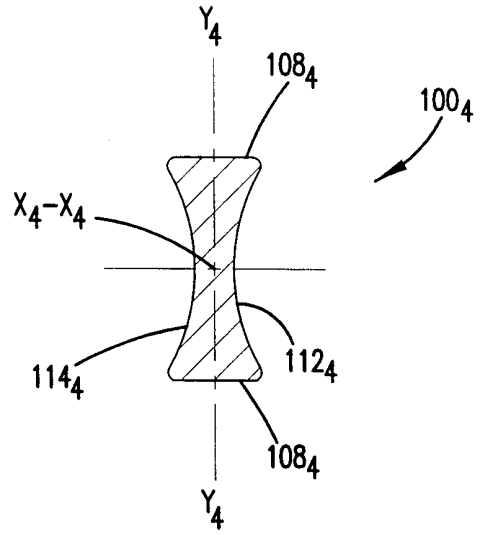

Y_4
108_4
100_4
X_4–X_4
114_4
112_4
108_4
Y_4

FIG. 14

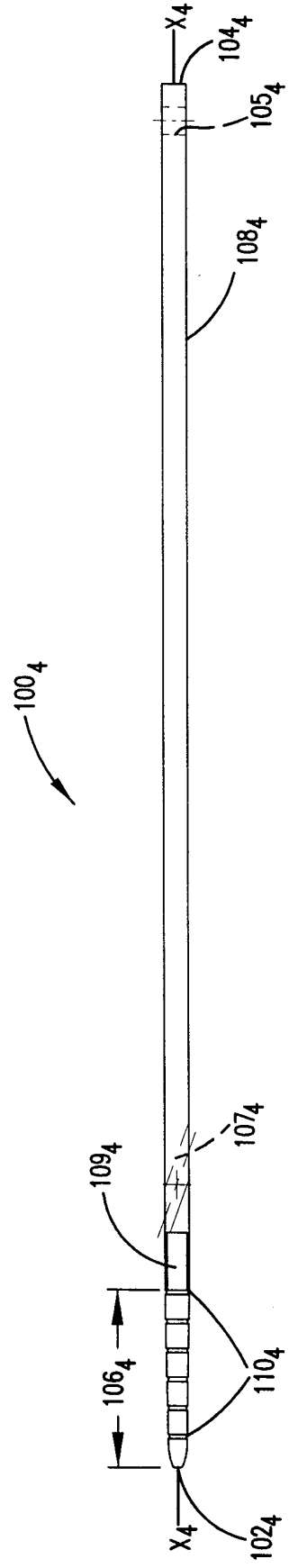

100_4
X_4
104_4
105_4
108_4
107_4
109_4
106_4
110_4
X_4
102_4

FIG. 15

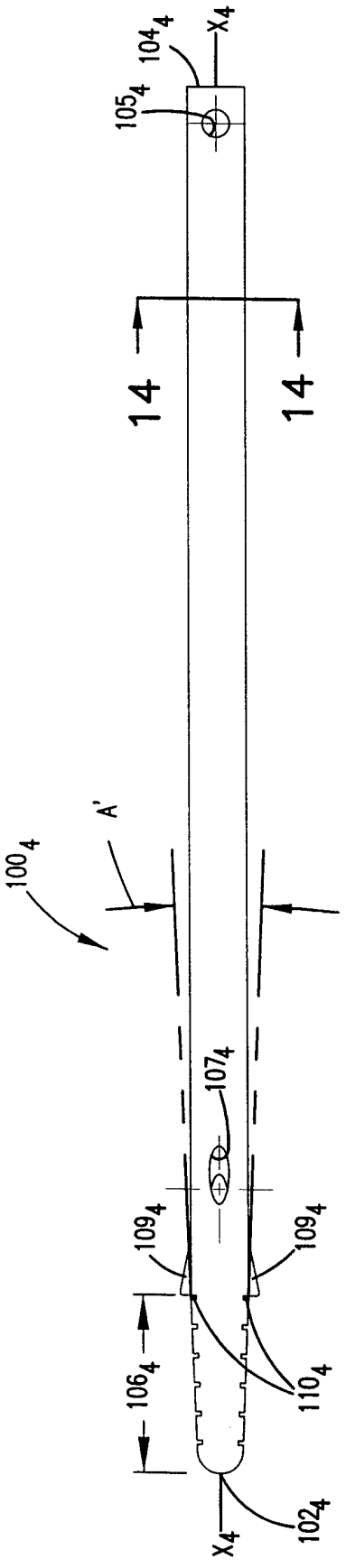

105_4
104_4
X_4
14
14
A'
100_4
107_4
109_4
109_4
106_4
110_4
X_4
102_4

FIG. 13

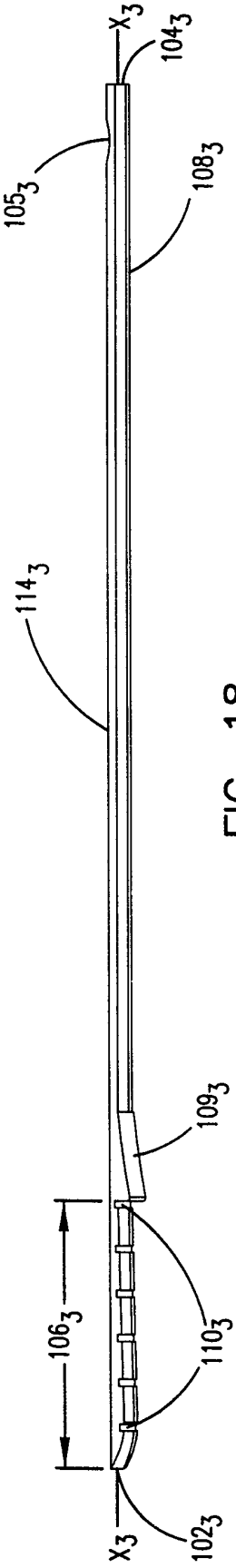

X_3
104_3
105_3
108_3
114_3
109_3
106_3
110_3
X_3
102_3

FIG. 18

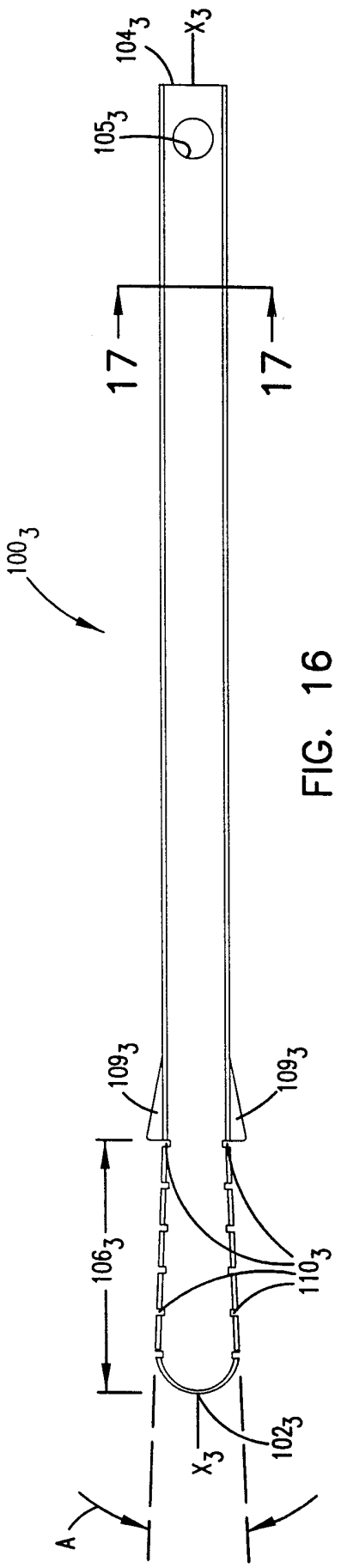

100_3
104_3
X_3
105_3
17
17
109_3
109_3
106_3
110_3
X_3
102_3
A

FIG. 16

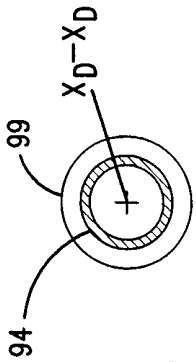


FIG. 20

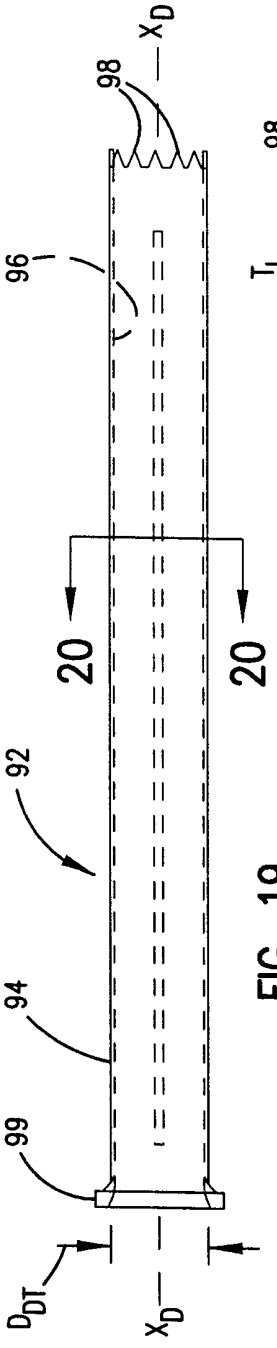


FIG. 19

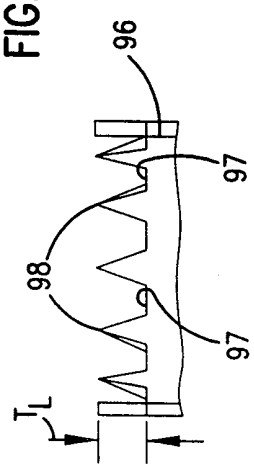


FIG. 21

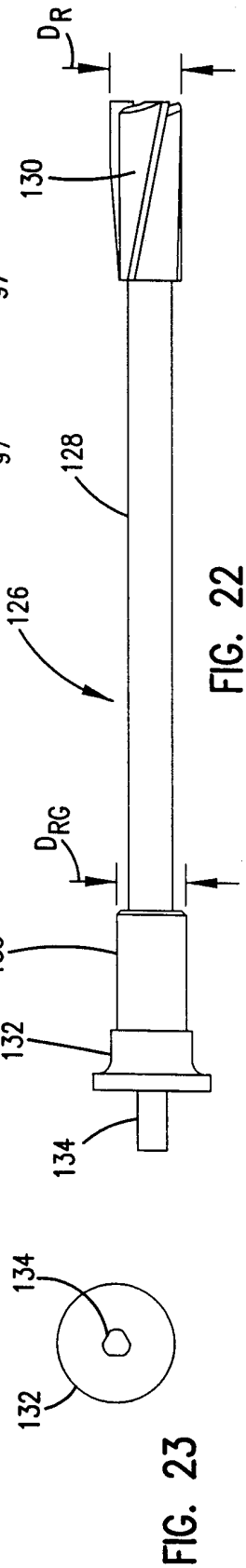


FIG. 22

FIG. 23

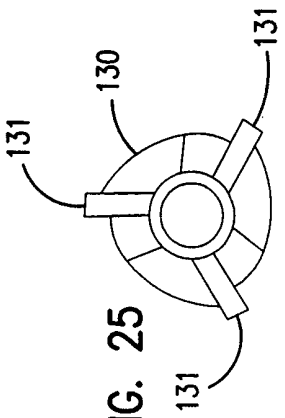


FIG. 25

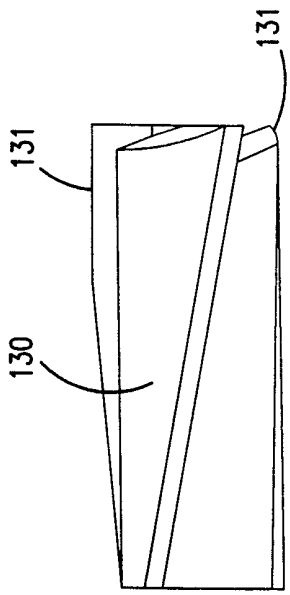


FIG. 24

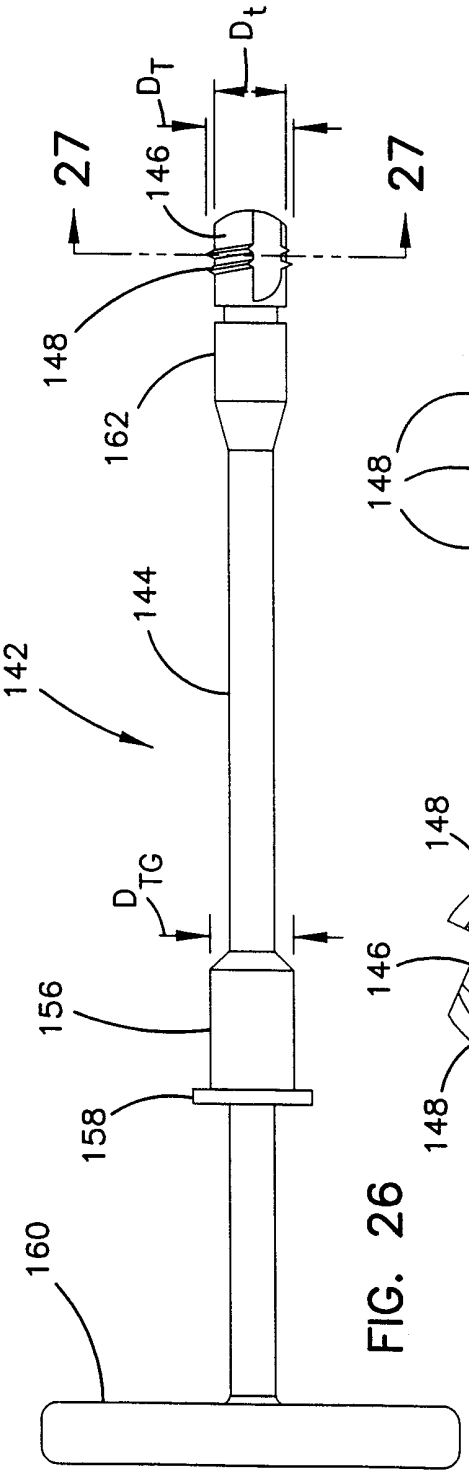


FIG. 26

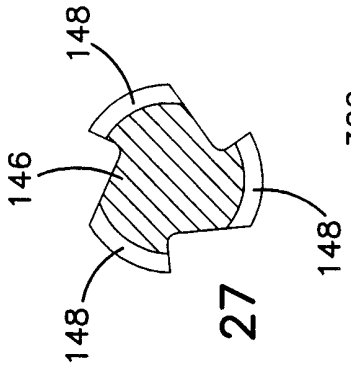


FIG. 27

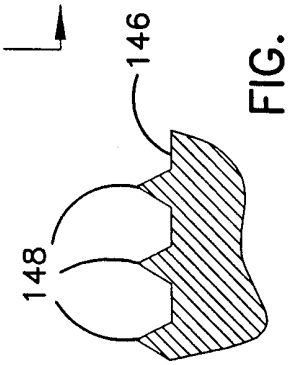


FIG. 28

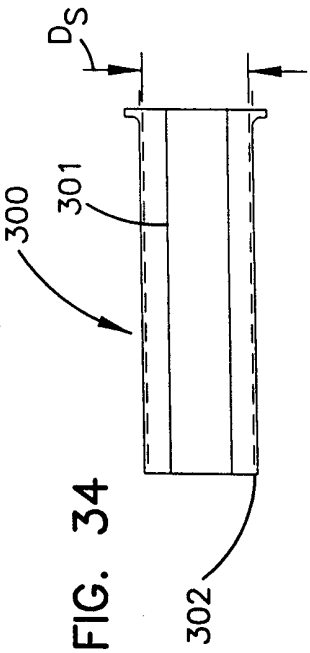


FIG. 34

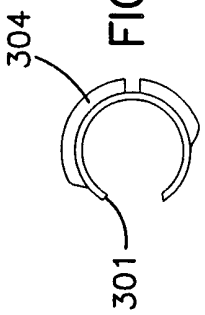


FIG. 35

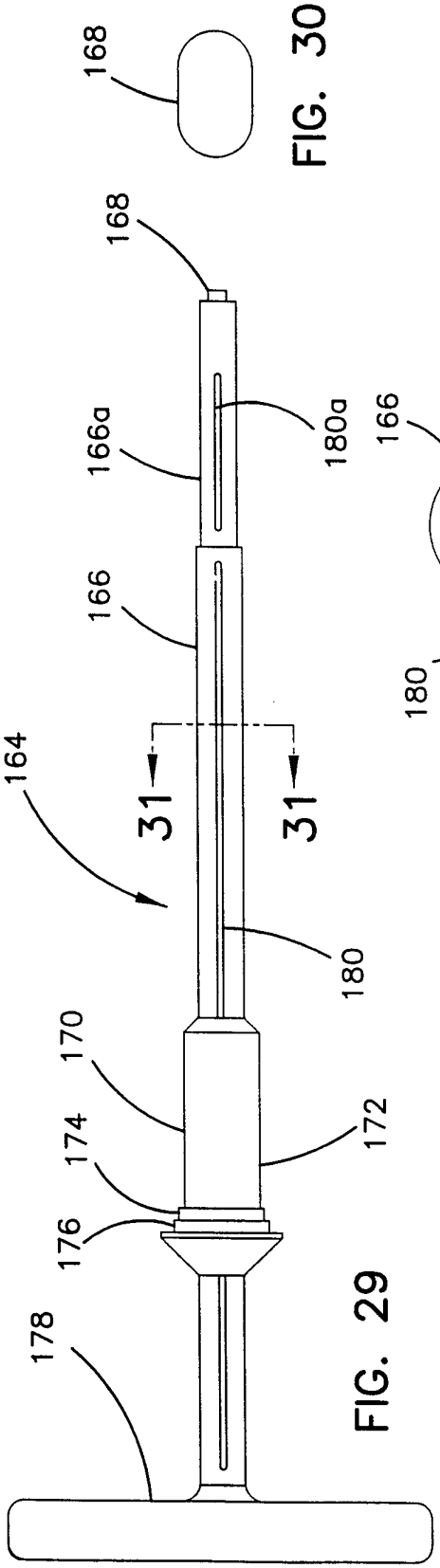


FIG. 29

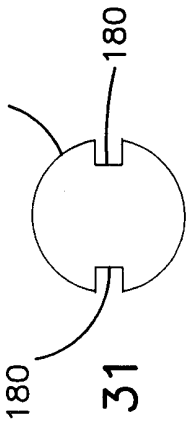


FIG. 30

FIG. 31

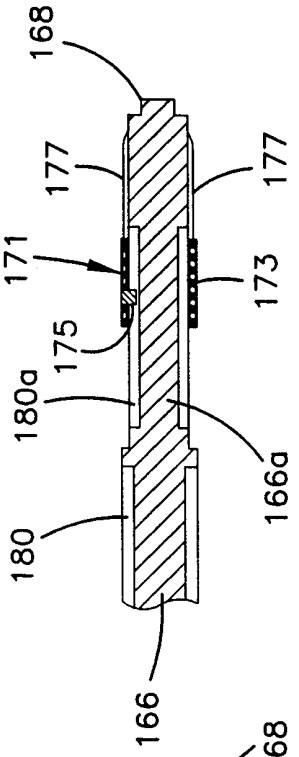


FIG. 33

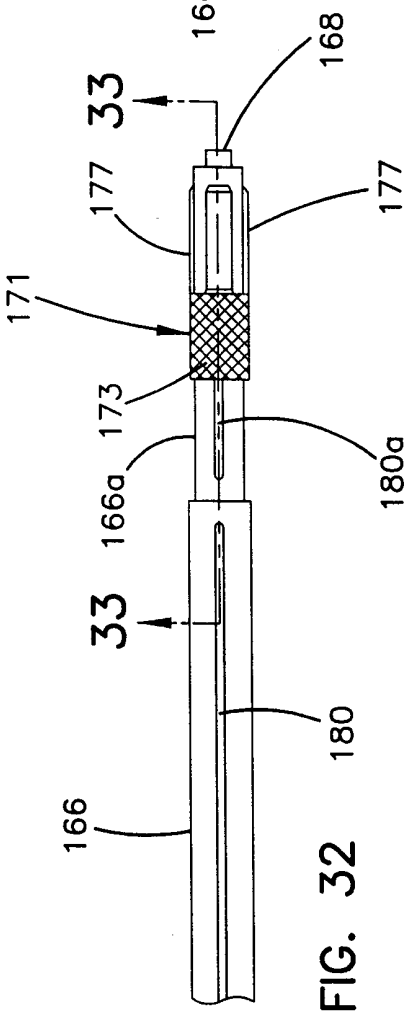


FIG. 32

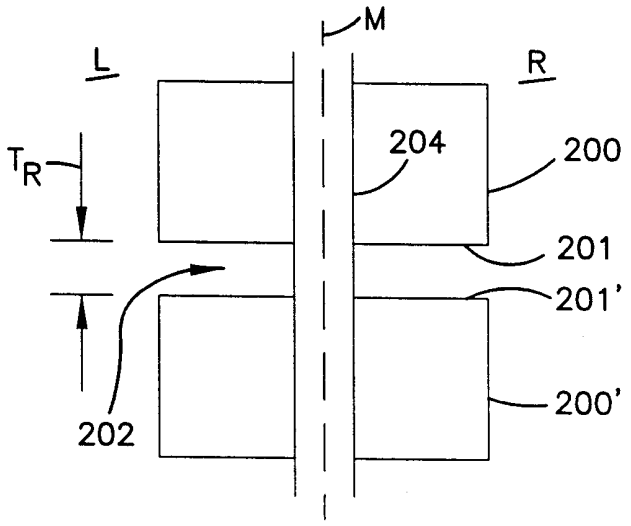


FIG. 36

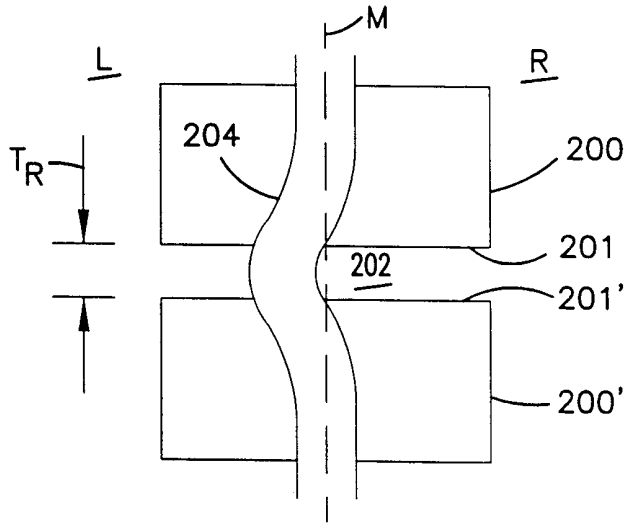


FIG. 37

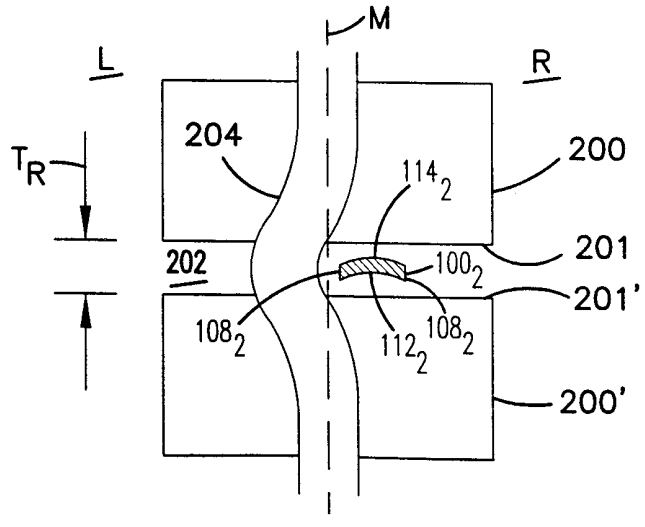


FIG. 38

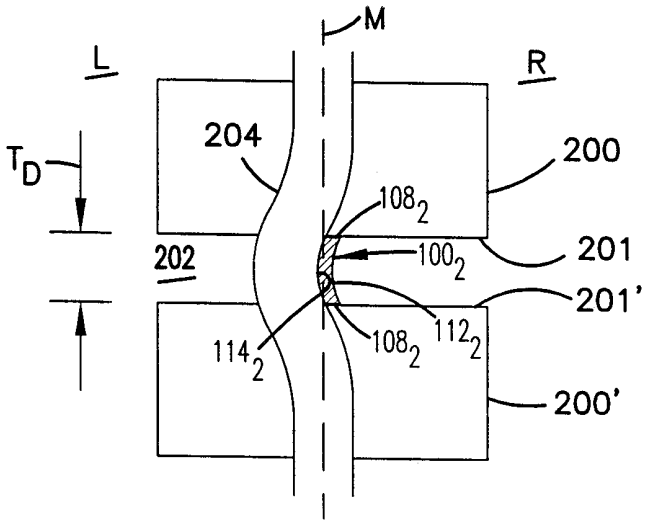


FIG. 39

FIG. 40

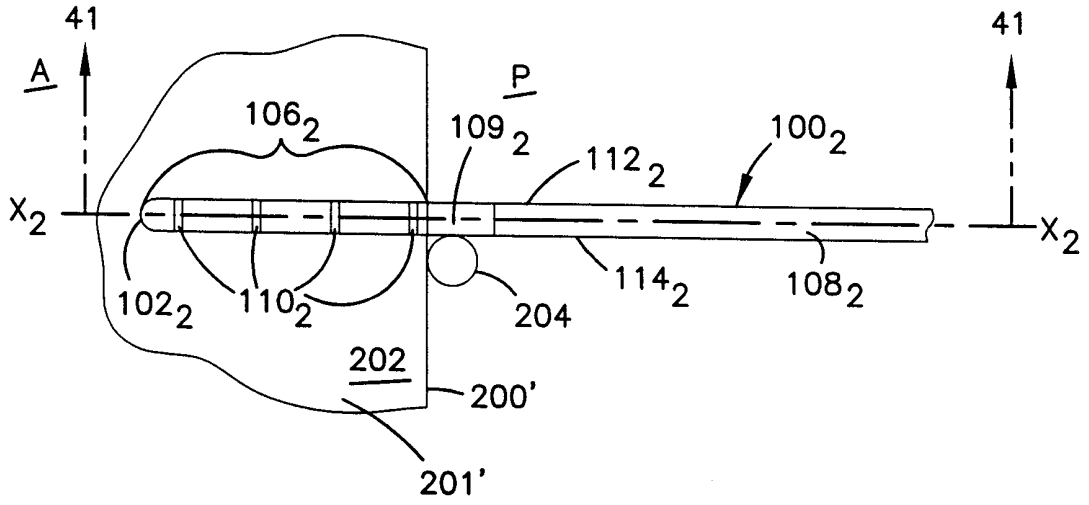
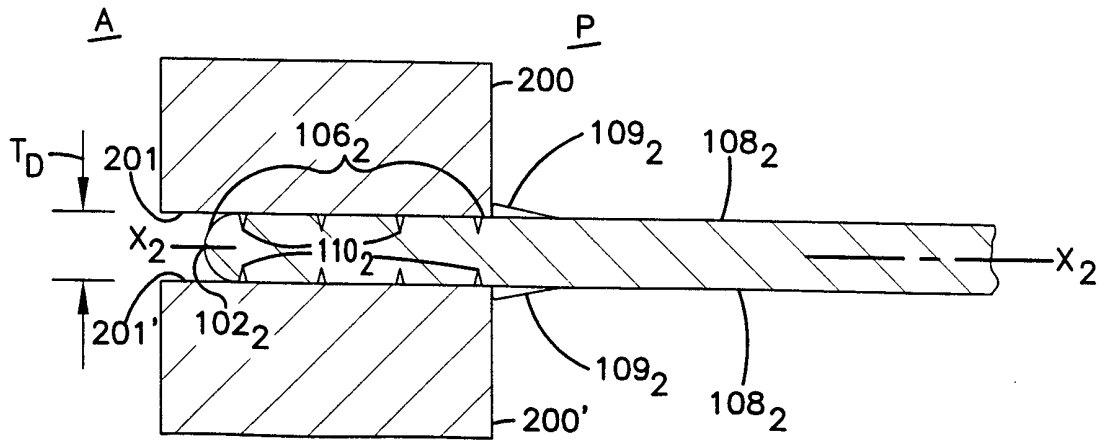


FIG. 41



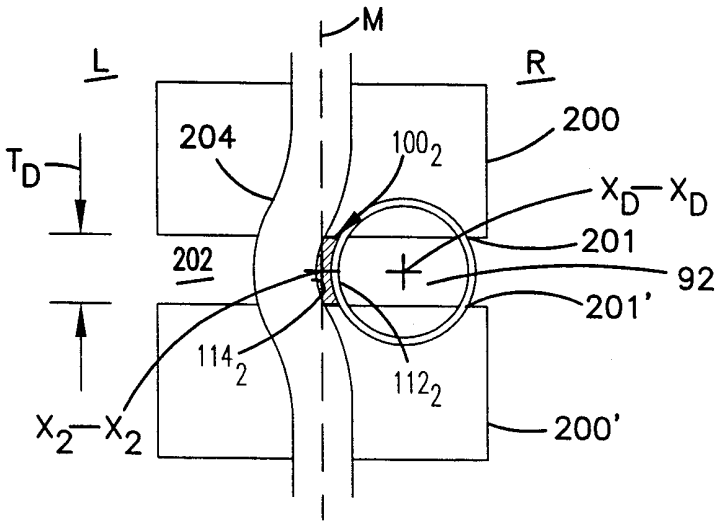

M
L
R
204
100_2
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X_D—X_D
201
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92
201'
114_2
112_2
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200'

FIG. 42

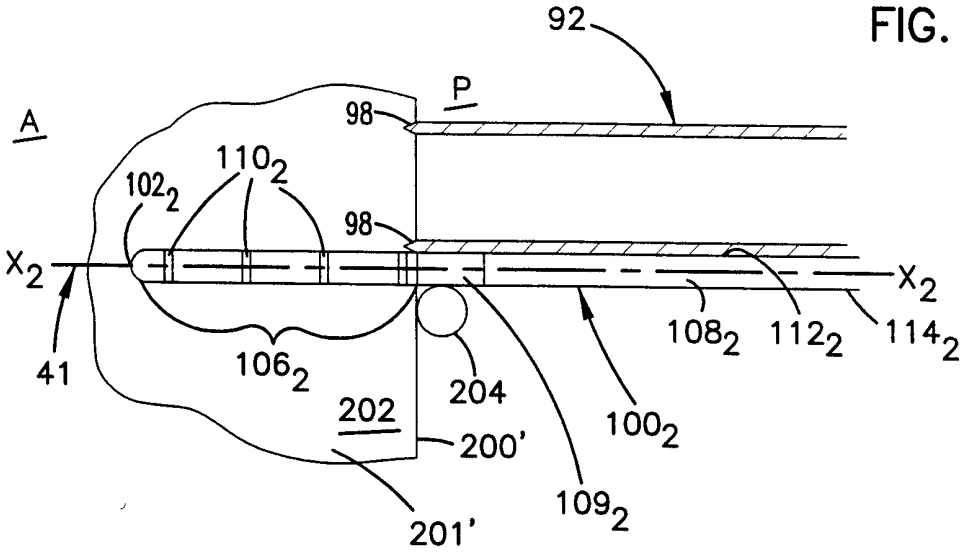

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100_2
109_2
201'

FIG. 43

FIG. 44

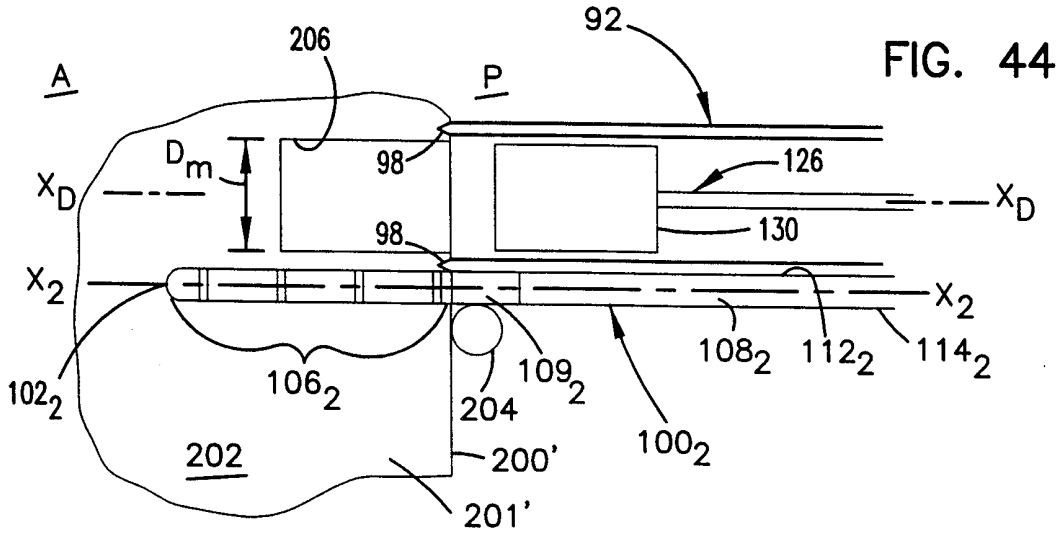


FIG. 45

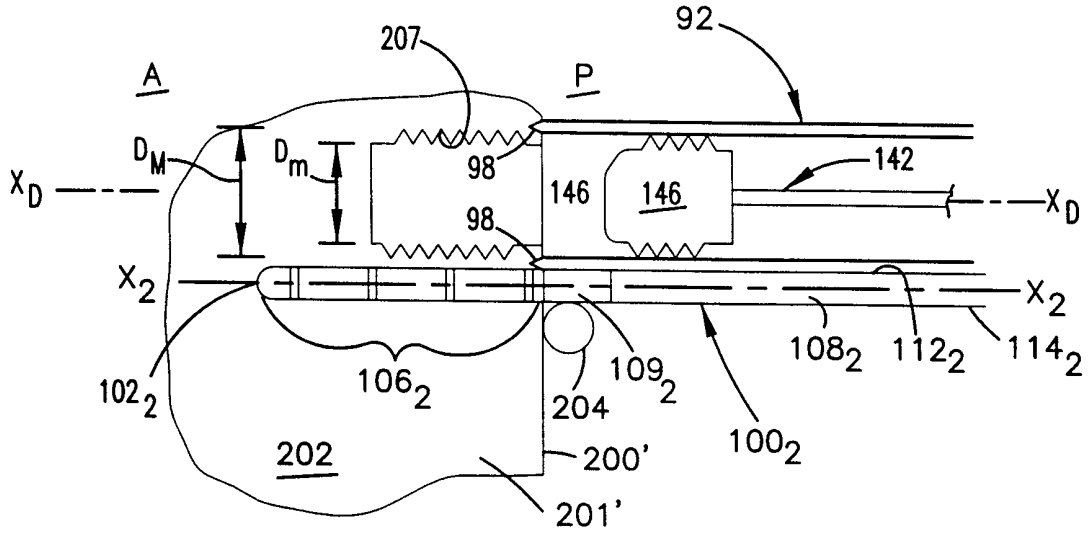
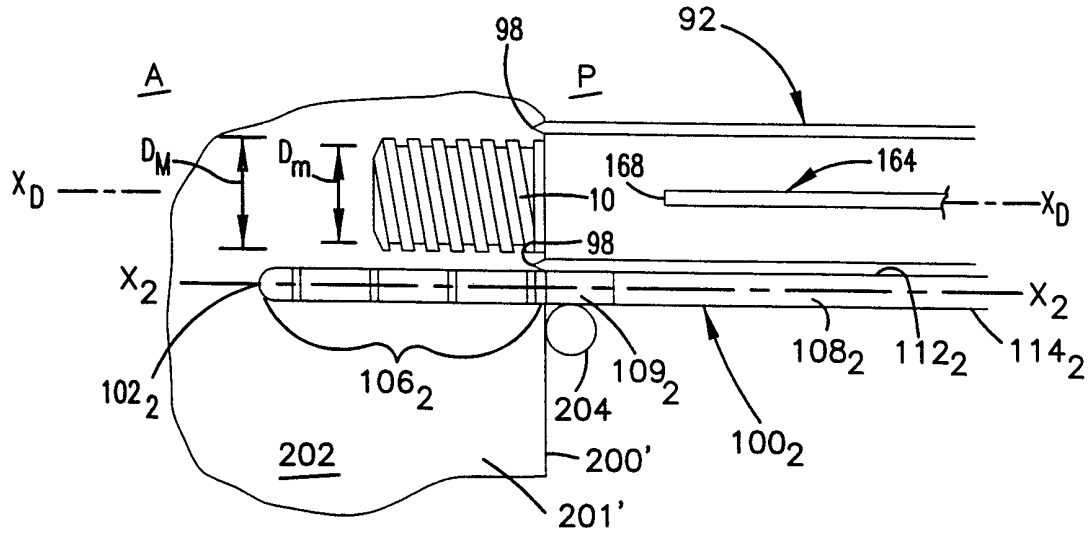


FIG. 46



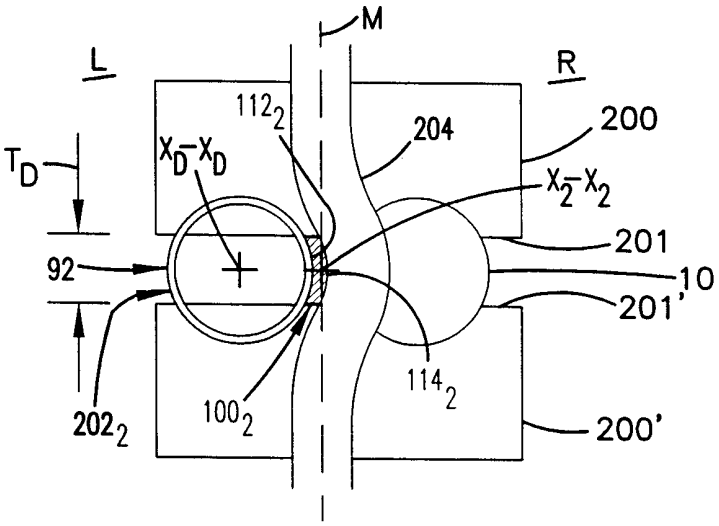
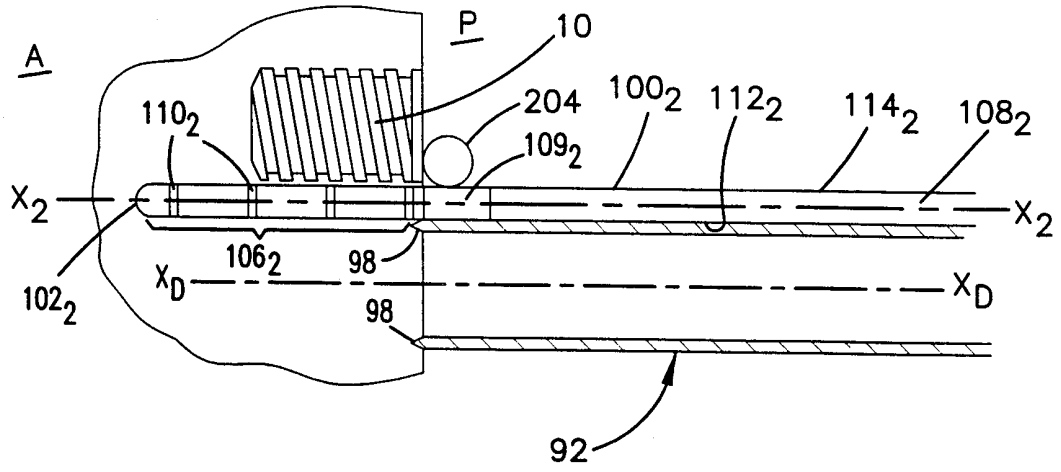

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201
92
10
201'
114_2
202_2
100_2
200'

FIG. 47

FIG. 48


A
P
10
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100_2
112_2
114_2
108_2
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X_2
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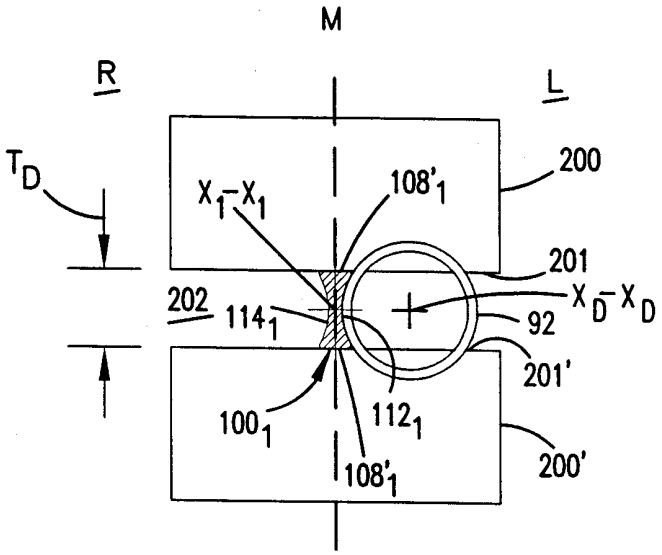

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100_1
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$108'_1$
200'

FIG. 49

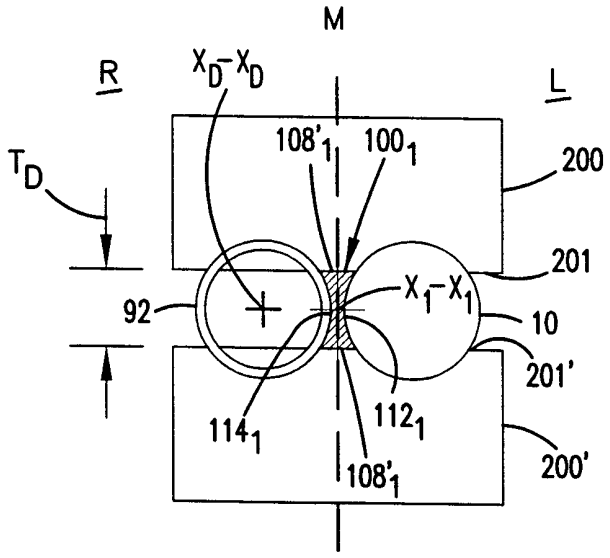

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L
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10
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114_1
112_1
$108'_1$
200'

FIG. 50

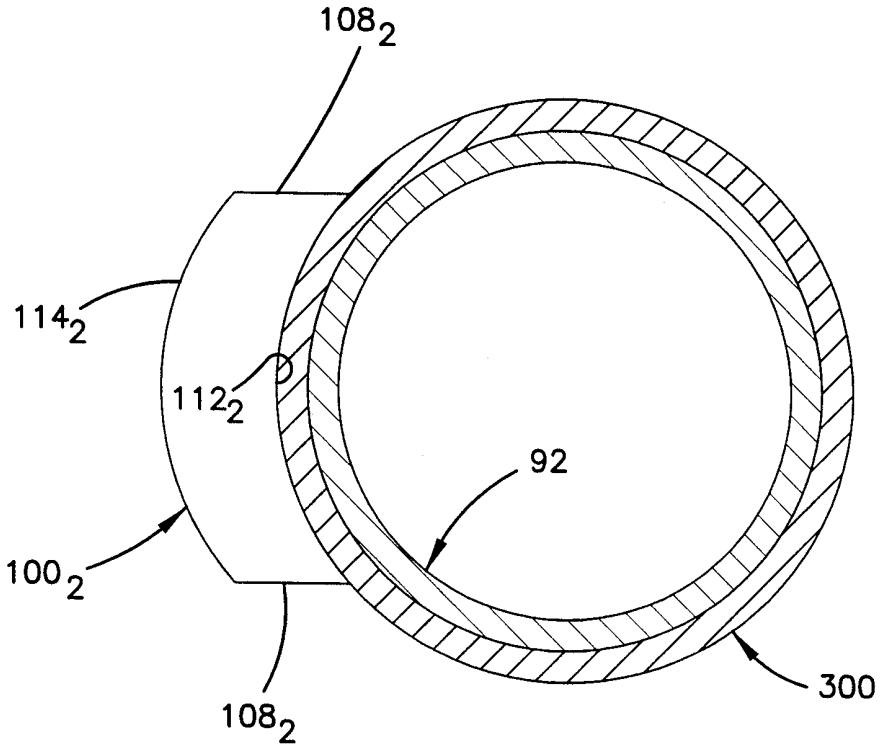


FIG. 51

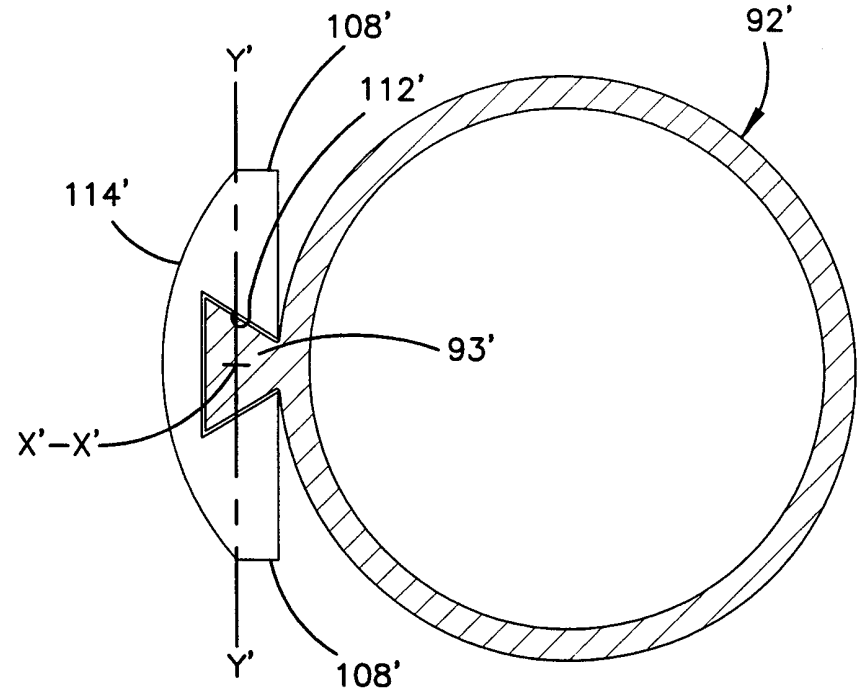


FIG. 52

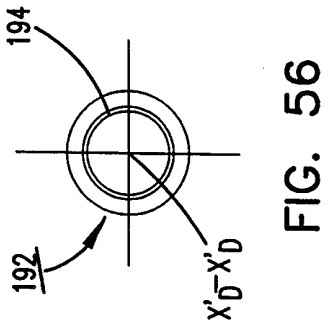


FIG. 56

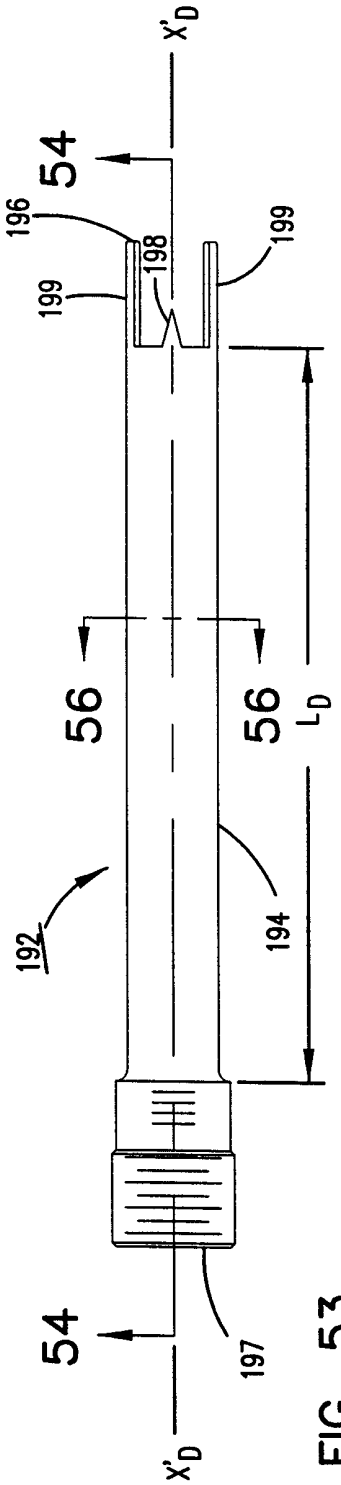


FIG. 53

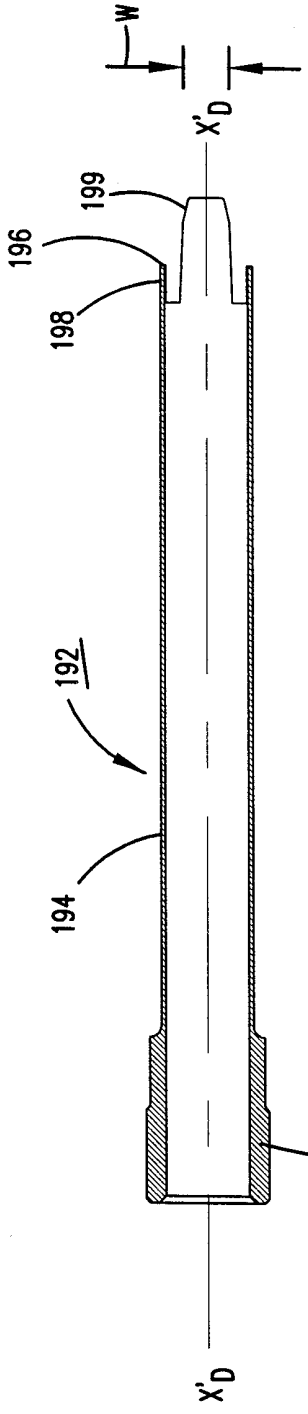


FIG. 54

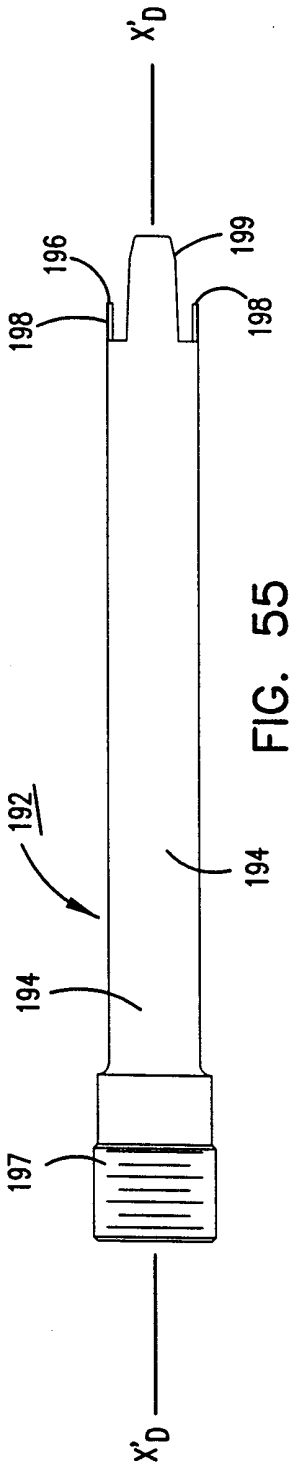


FIG. 55

INTERNATIONAL SEARCH REPORT

In ıtional Application No
PCT/US 98/17646

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/17

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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 571 109 A (R.BERTAGNOLI) 5 November 1996	7-9,11
A	see column 7, line 55 - line 65 see column 8, line 12 - line 19 see column 9, line 5 - line 26 see column 12, line 63 - column 13, line 2 see column 13, line 8 - line 23 see figures 1A-1B,4-5,11	14
A	WO 96 27345 A (G.K.MICHELSON) 12 September 1996 see figures 19,20,25 see figures 30,32	9-11

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 1998	09/12/1998

Name and mailing address of the ISA	Authorized officer
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	Nice, P

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

In. ıtional Application No
PCT/US 98/17646

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 27321 A (G.K.MICHELSON) 12 September 1996 see page 62, line 22 - page 64, line 1 see page 64, line 12 - line 17 see figures 25,26	7-11,15
A	US 5 489 307 A (S.D.KUSLICH) 6 February 1996 cited in the application	

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/ 17646

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ational Application No
PCT/US 98/17646

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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