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(54) **METHOD AND APPARATUS FOR ATTACHING CONNECTIVE TISSUES TO BONE USING A KNOTLESS SUTURE ANCHORING DEVICE**

(75) Inventor: **Seth A. Foerster**, San Clemente, CA (US)

Correspondence Address:
Donald E. Stout
Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618 (US)

(73) Assignee: **Opus Medical, Inc.**, San Juan Capistrano, CA

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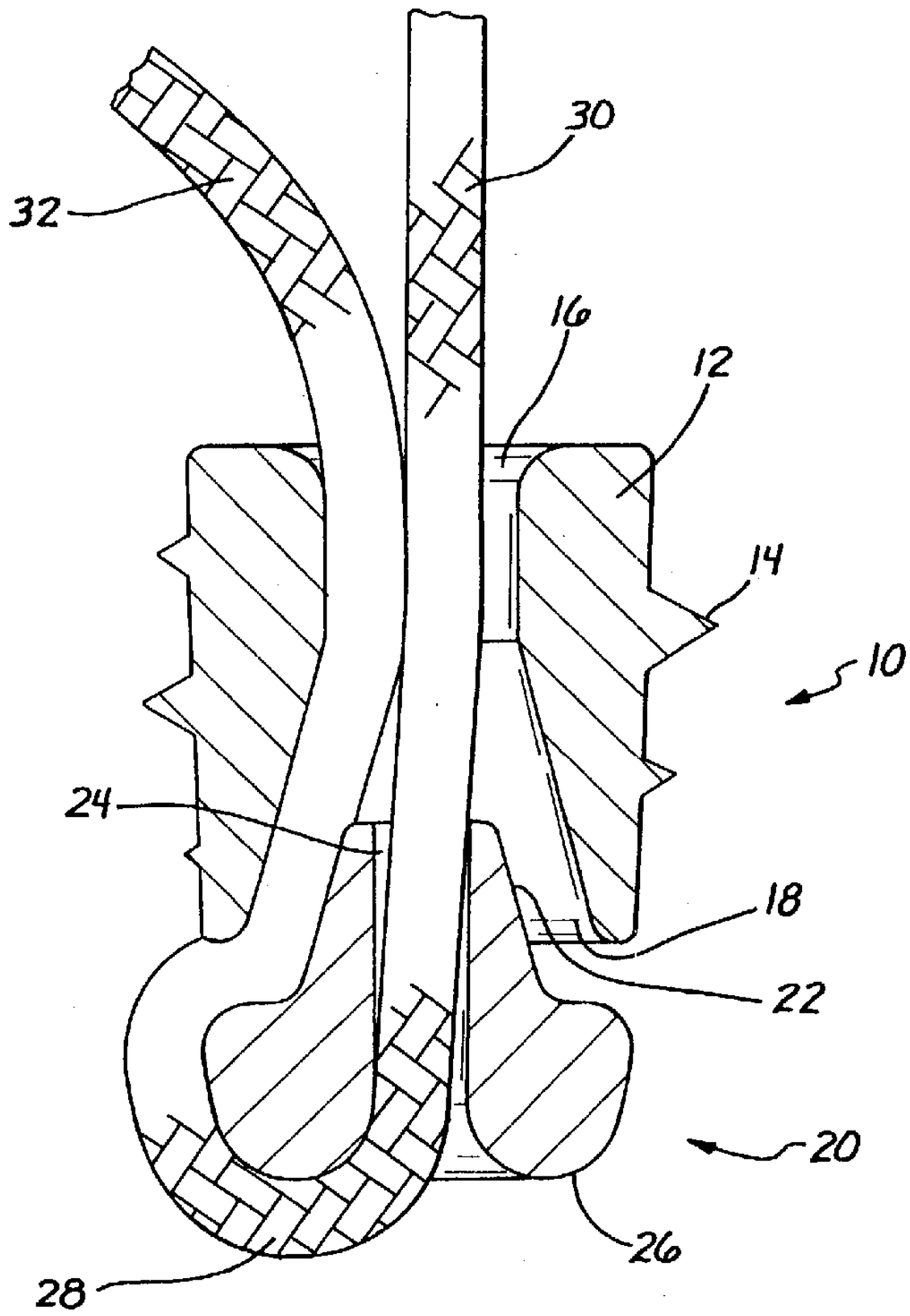
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(57) **ABSTRACT**

An innovative bone anchor and methods for securing connective tissue, such as tendons, to bone, which permit a suture attachment that lies entirely beneath the cortical bone surface. Advantageously, the suturing material between the connective tissue and the bone anchor is secured without the need for tying a knot. The suture attachment to the bone anchor involves the looping of a length of suturing material around a self-locking wedge block in the anchor, thereby avoiding an eyelet connection which requires a kot and which concentrates stress on a very small portion of the suturing material. Thus, failure rates are greatly decreased over conventional techniques, and the innovative procedures are significantly easier to perform than conventional techniques.



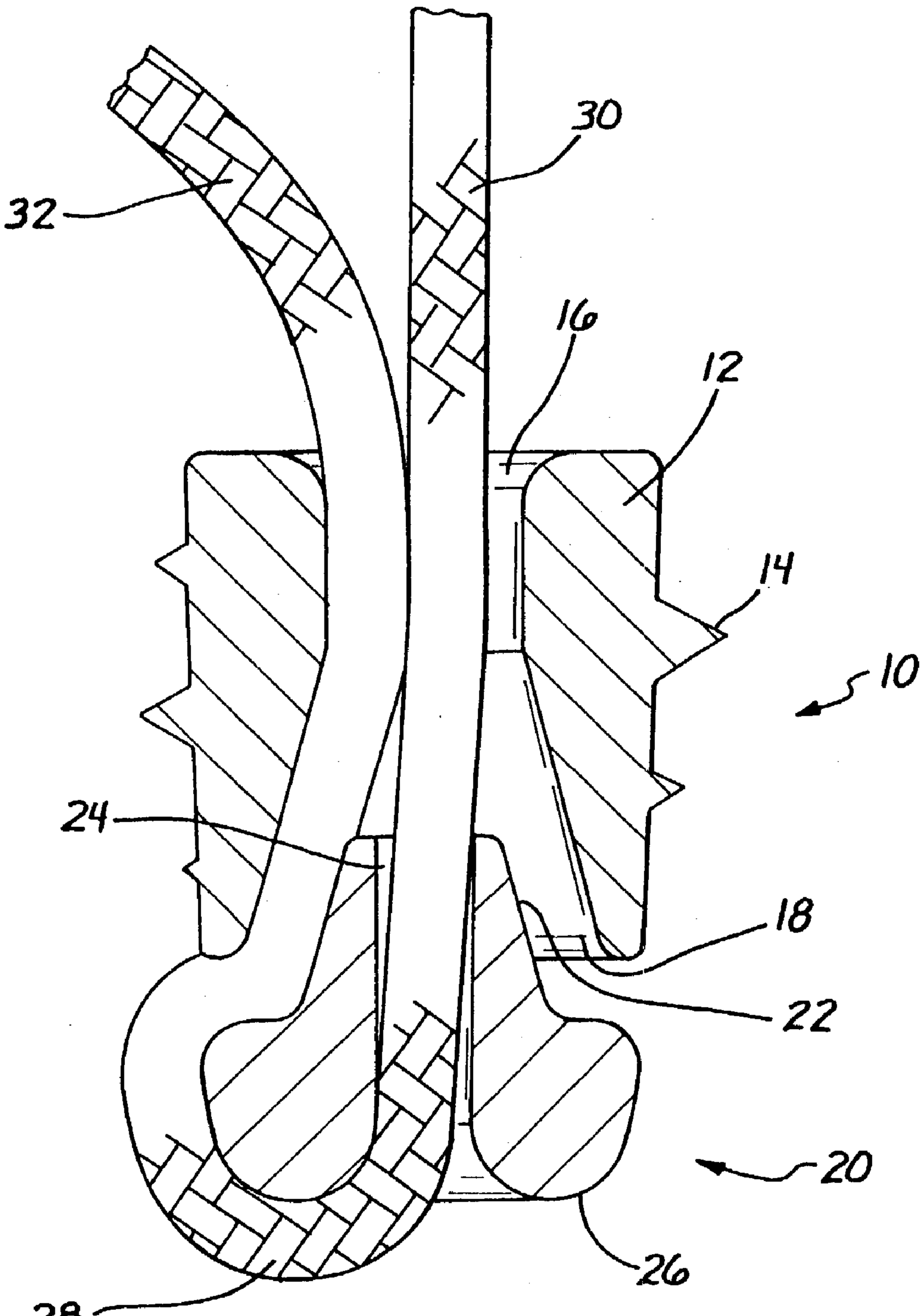


FIG. 1

FIG. 2

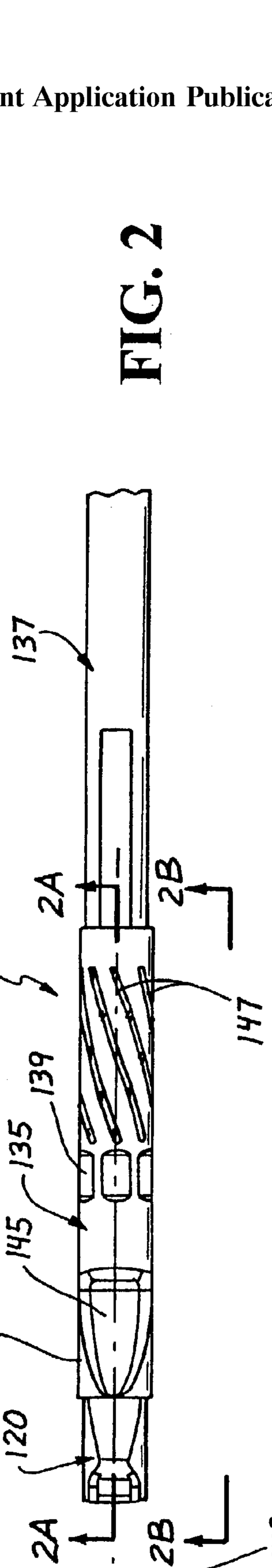


FIG. 2A

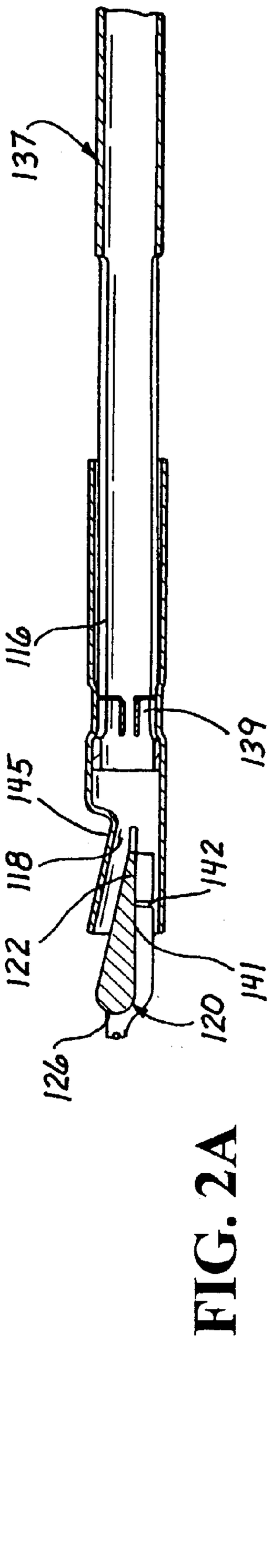
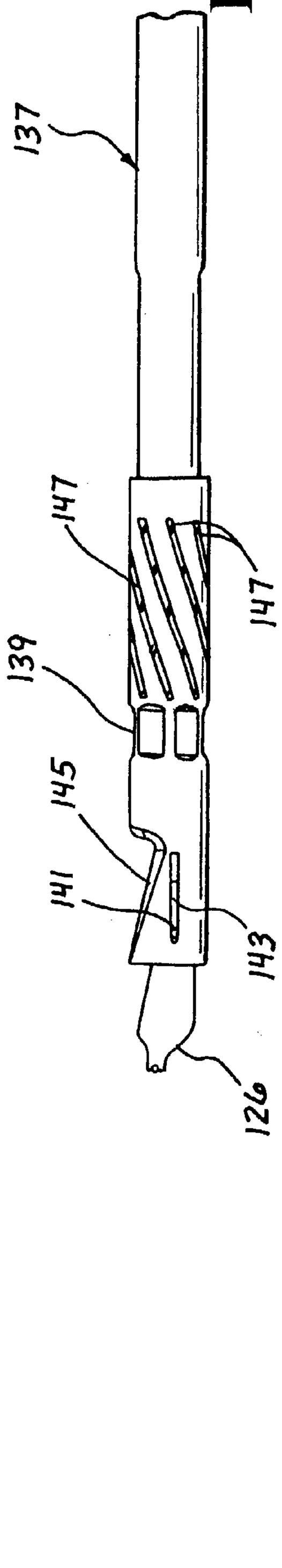


FIG. 2B



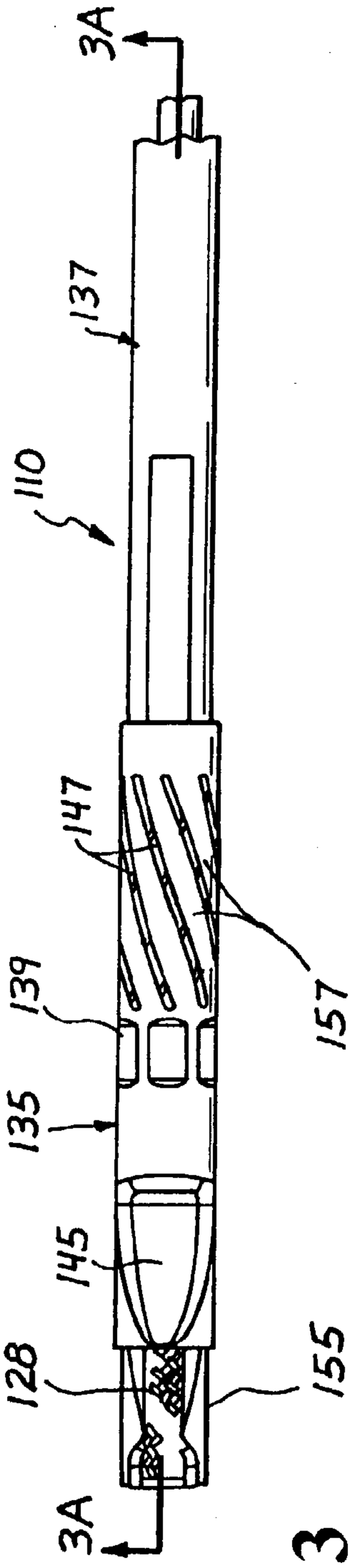


FIG. 3

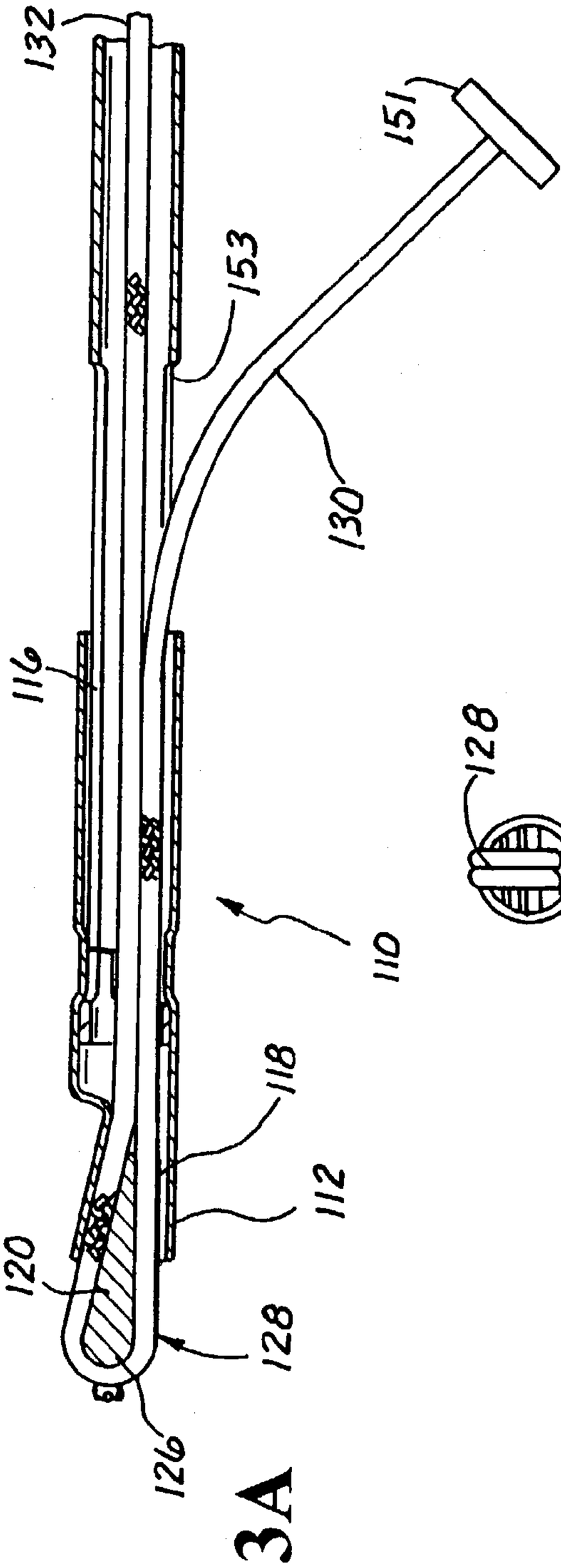


FIG. 3A

FIG. 3B

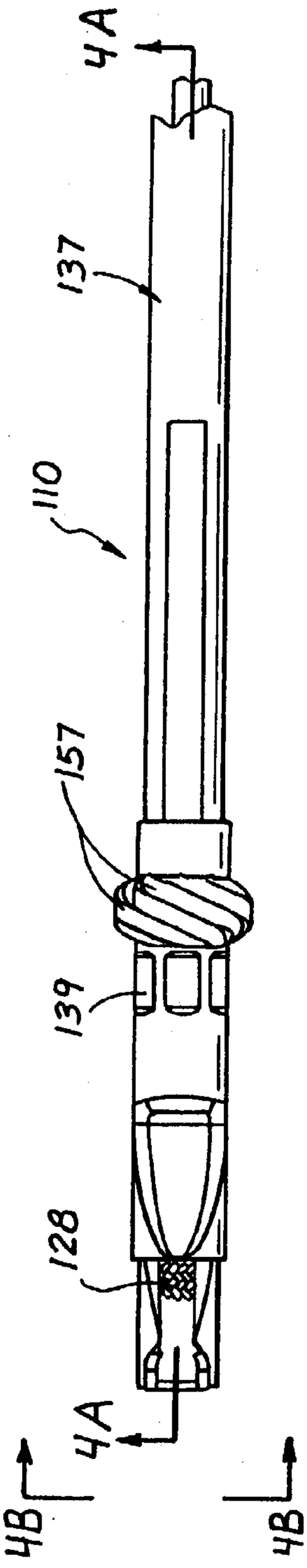


FIG. 4

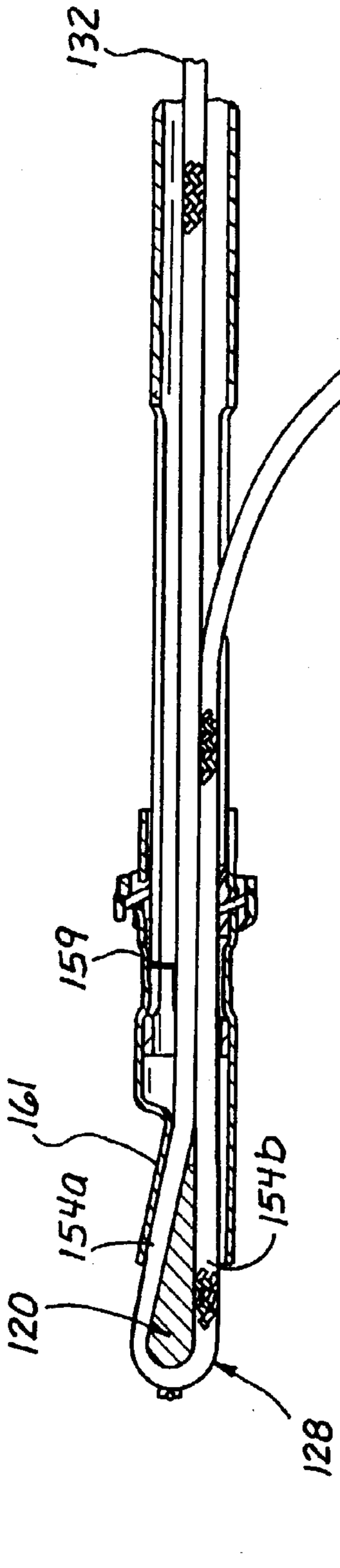


FIG. 4A

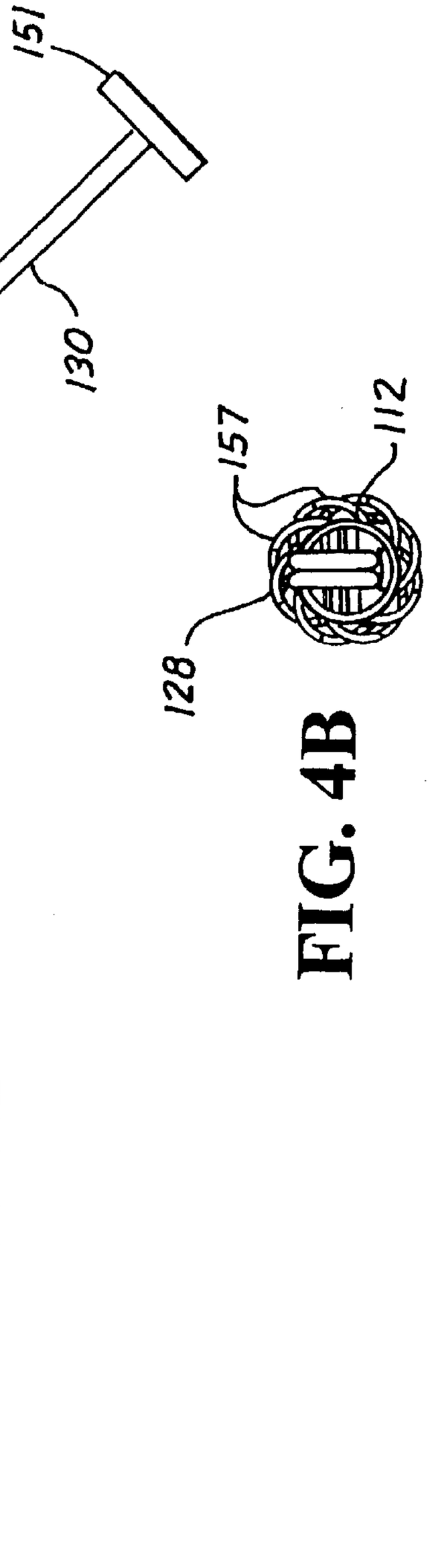


FIG. 4B

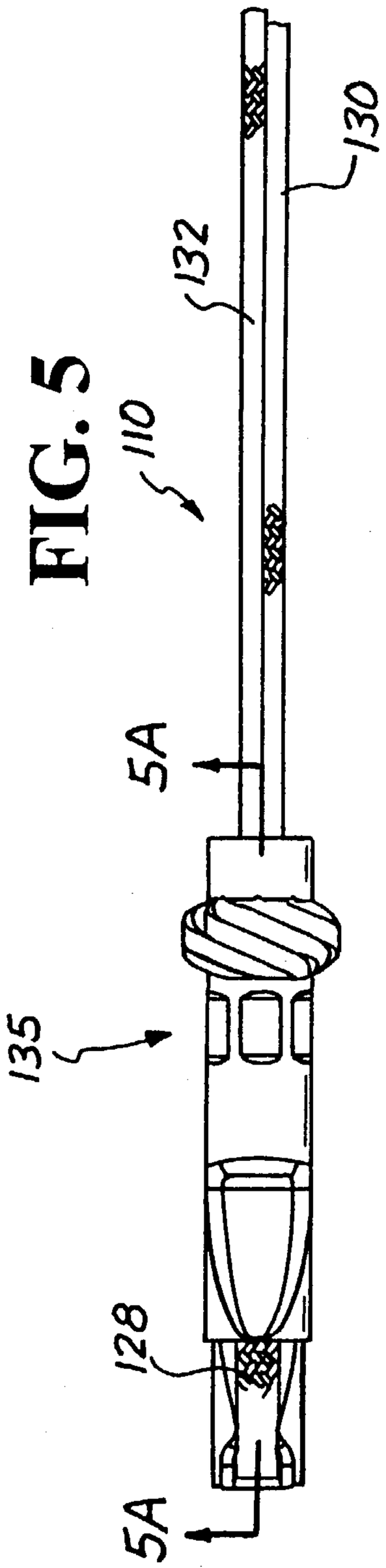


FIG. 5

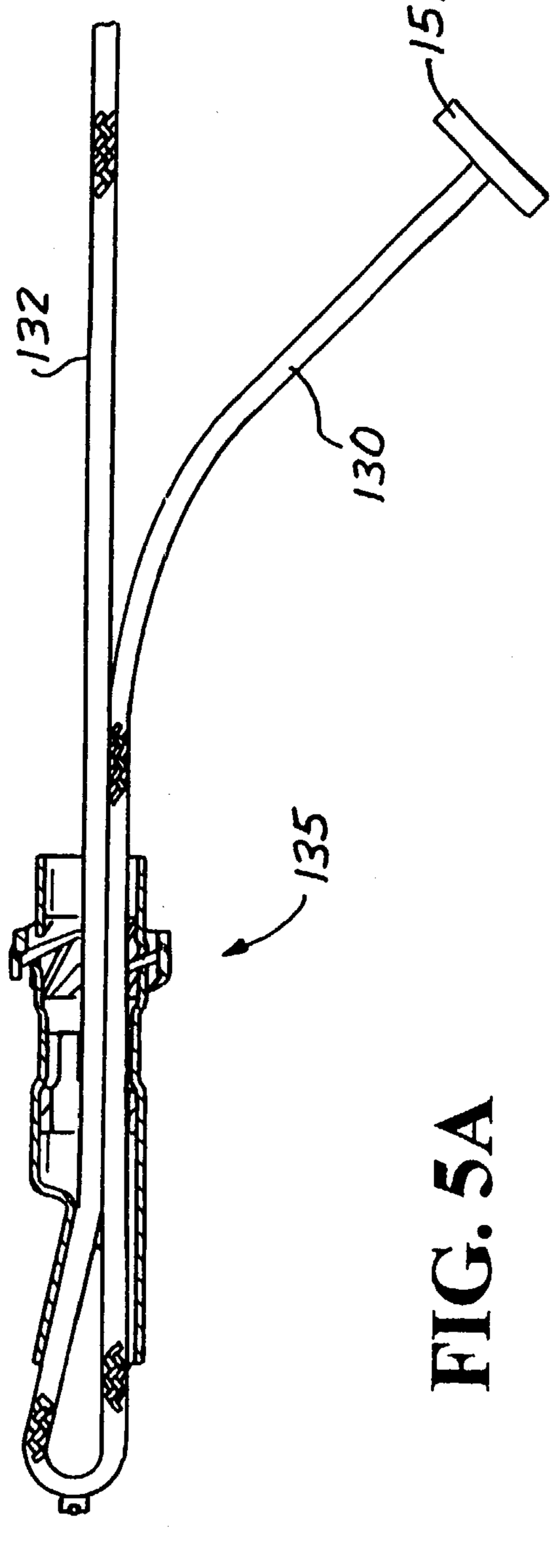


FIG. 5A

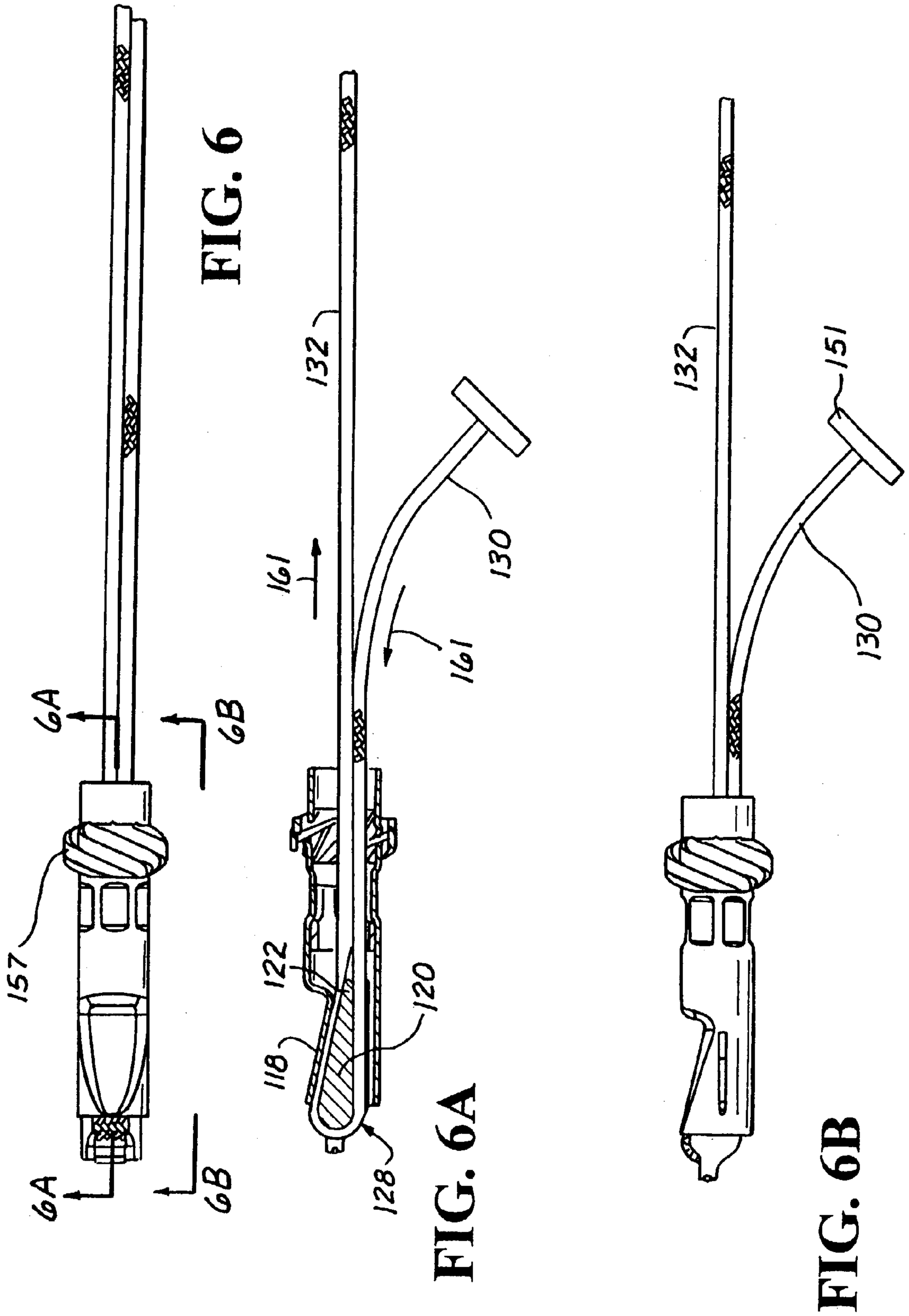


FIG. 6

FIG. 6A

FIG. 6B

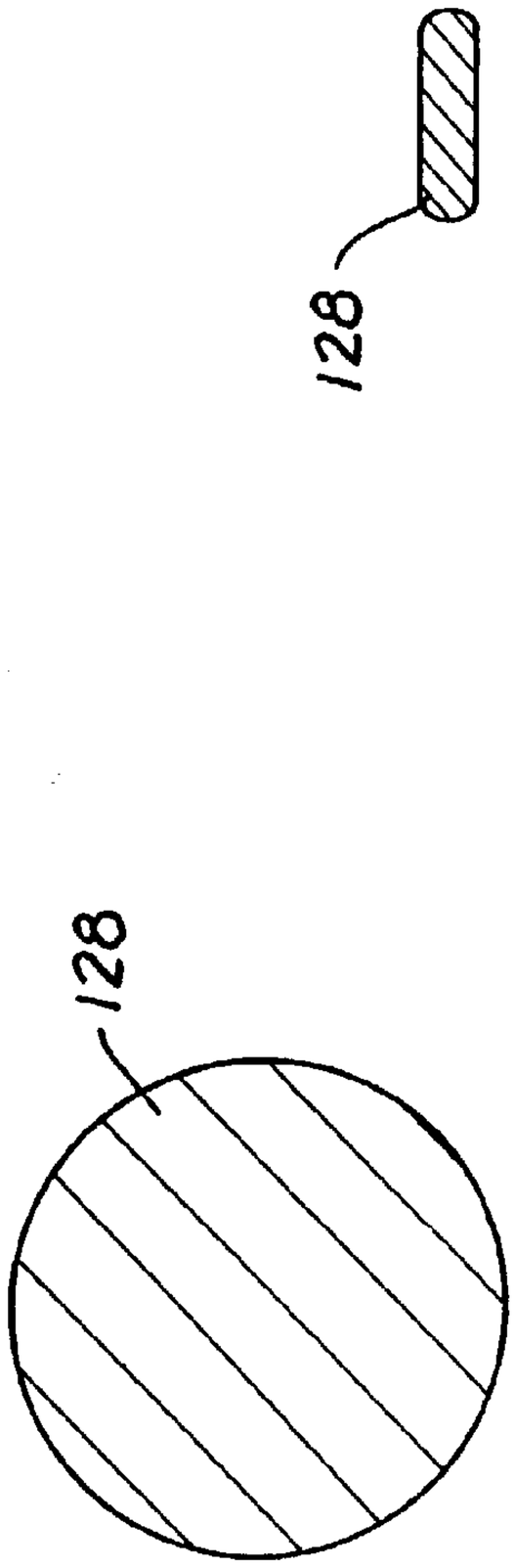


FIG. 6C

FIG. 6D

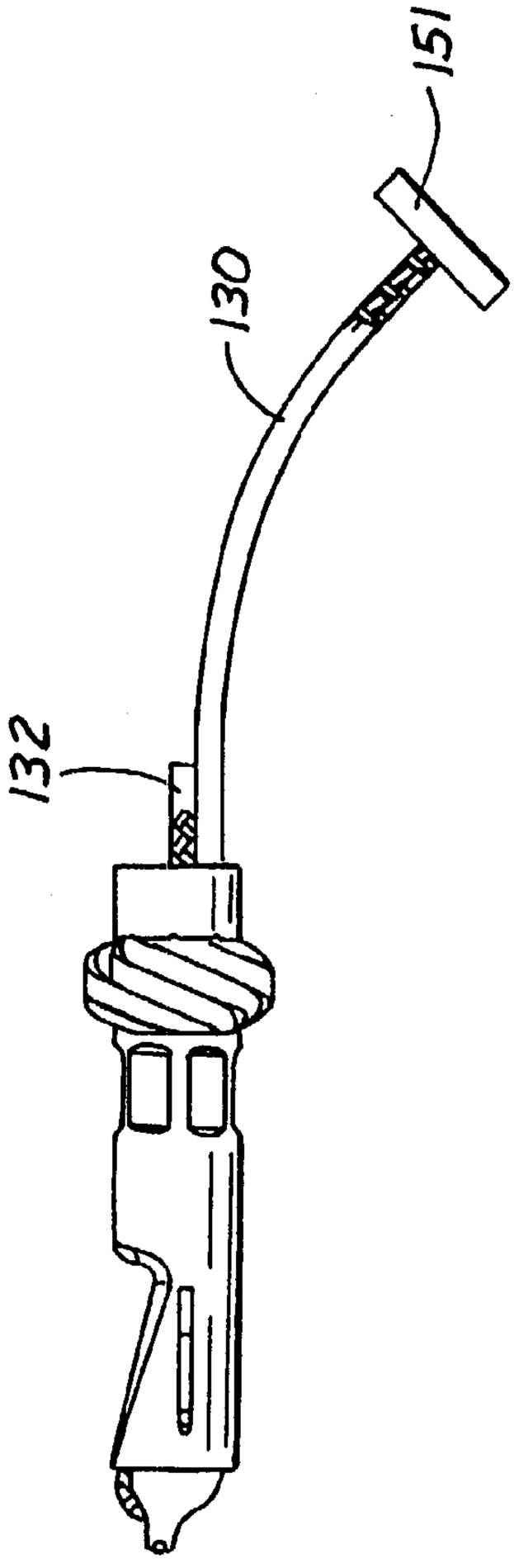


FIG. 7

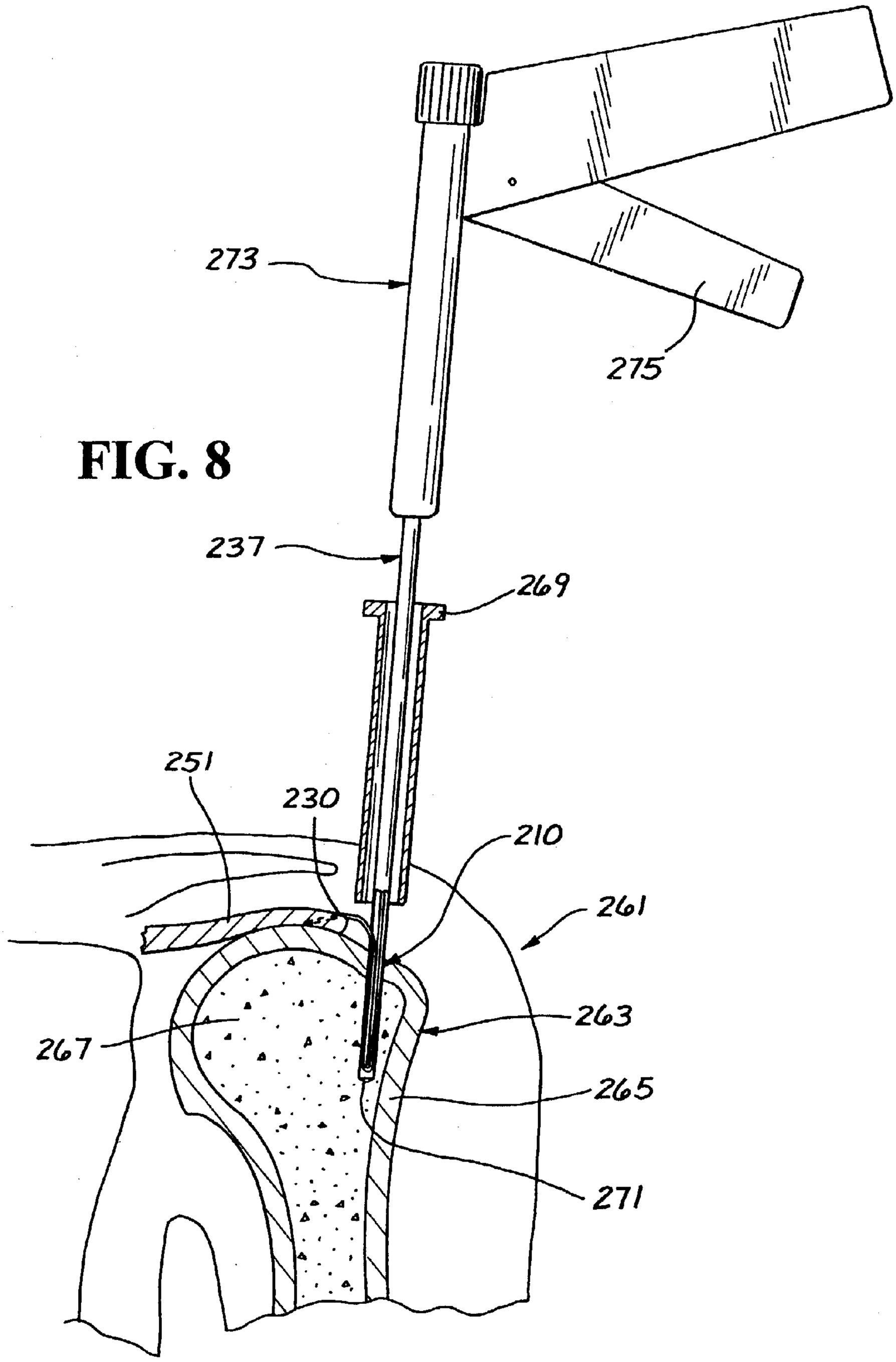


FIG. 8

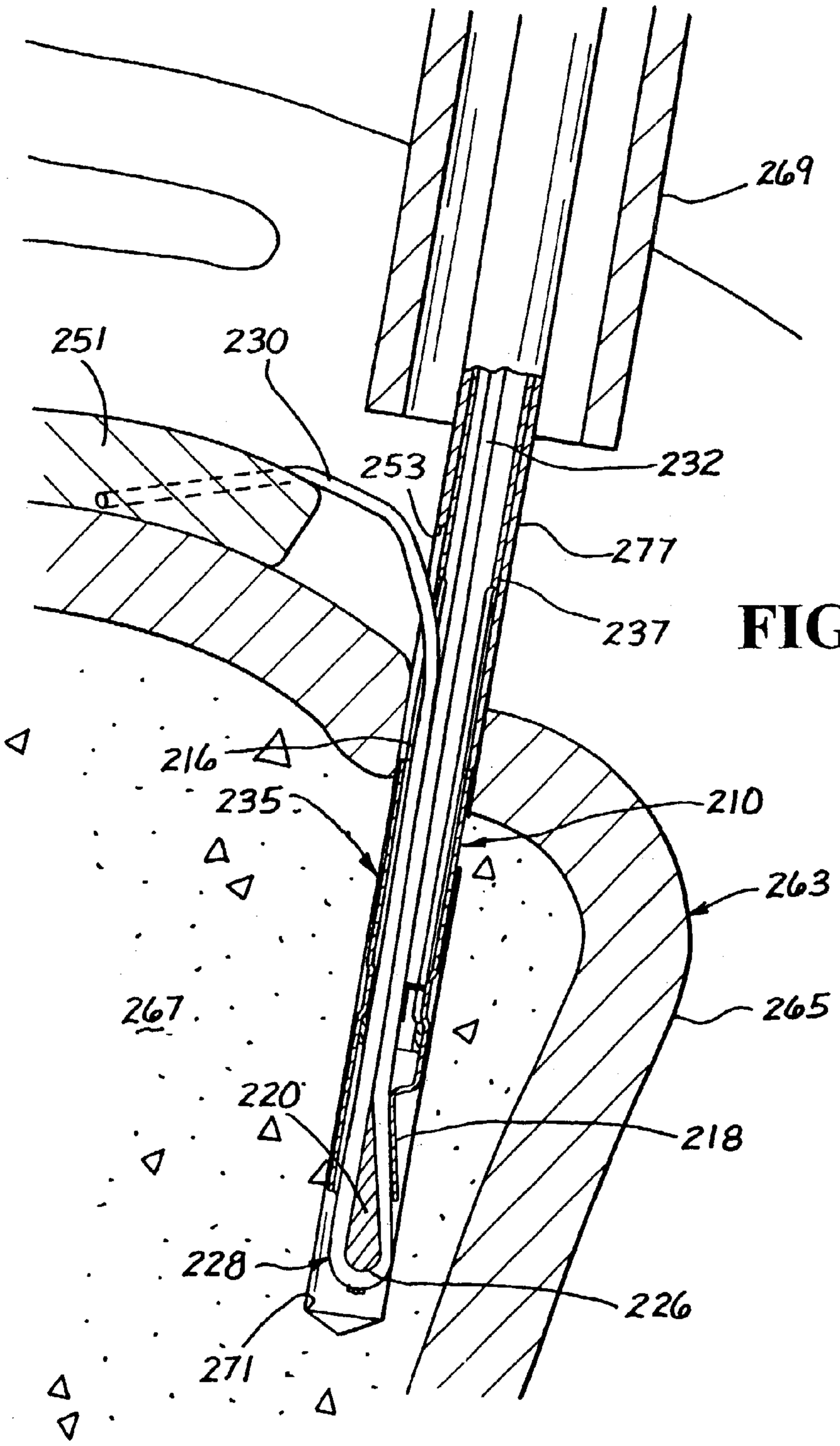

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FIG. 9

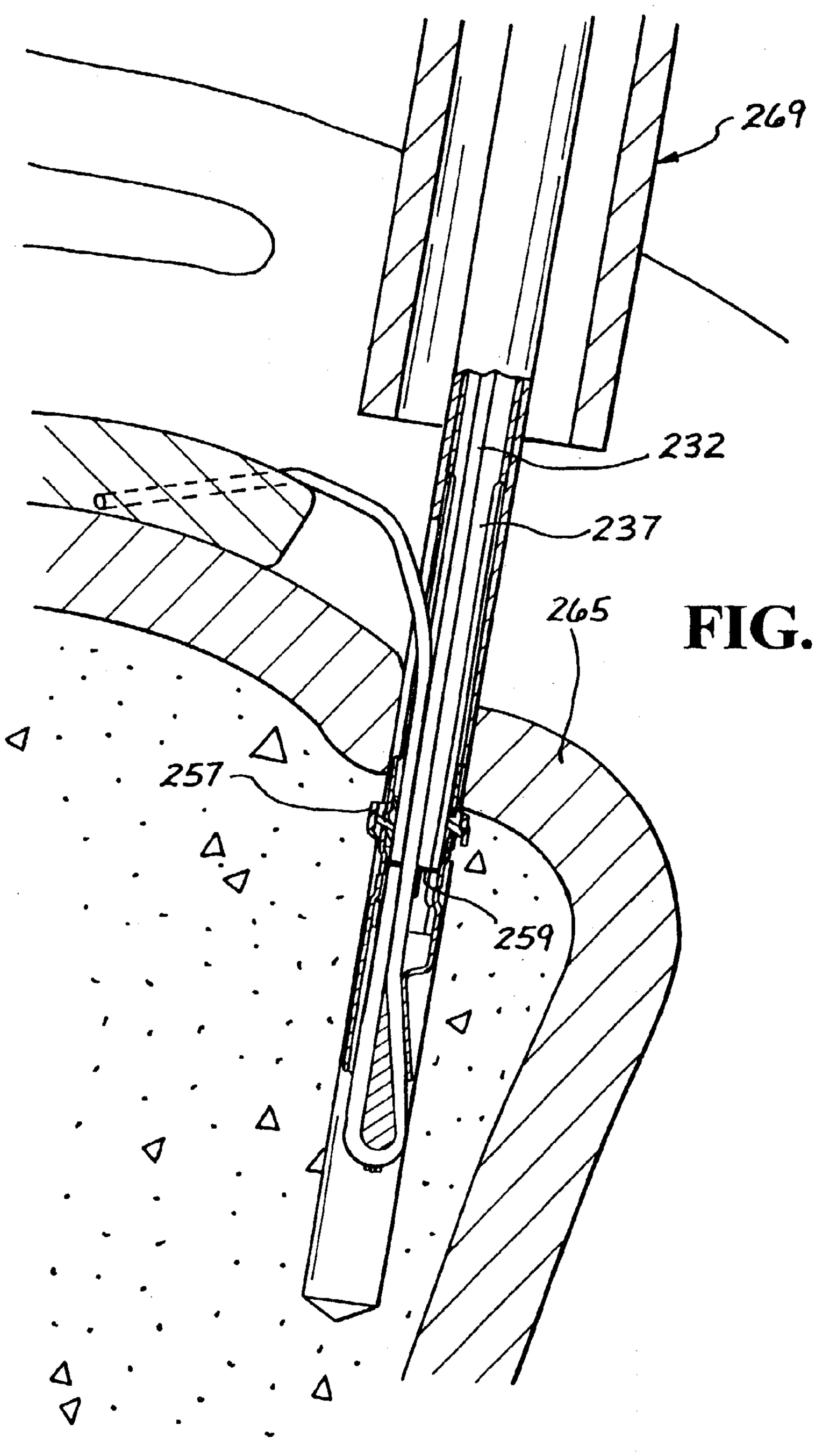


FIG. 10

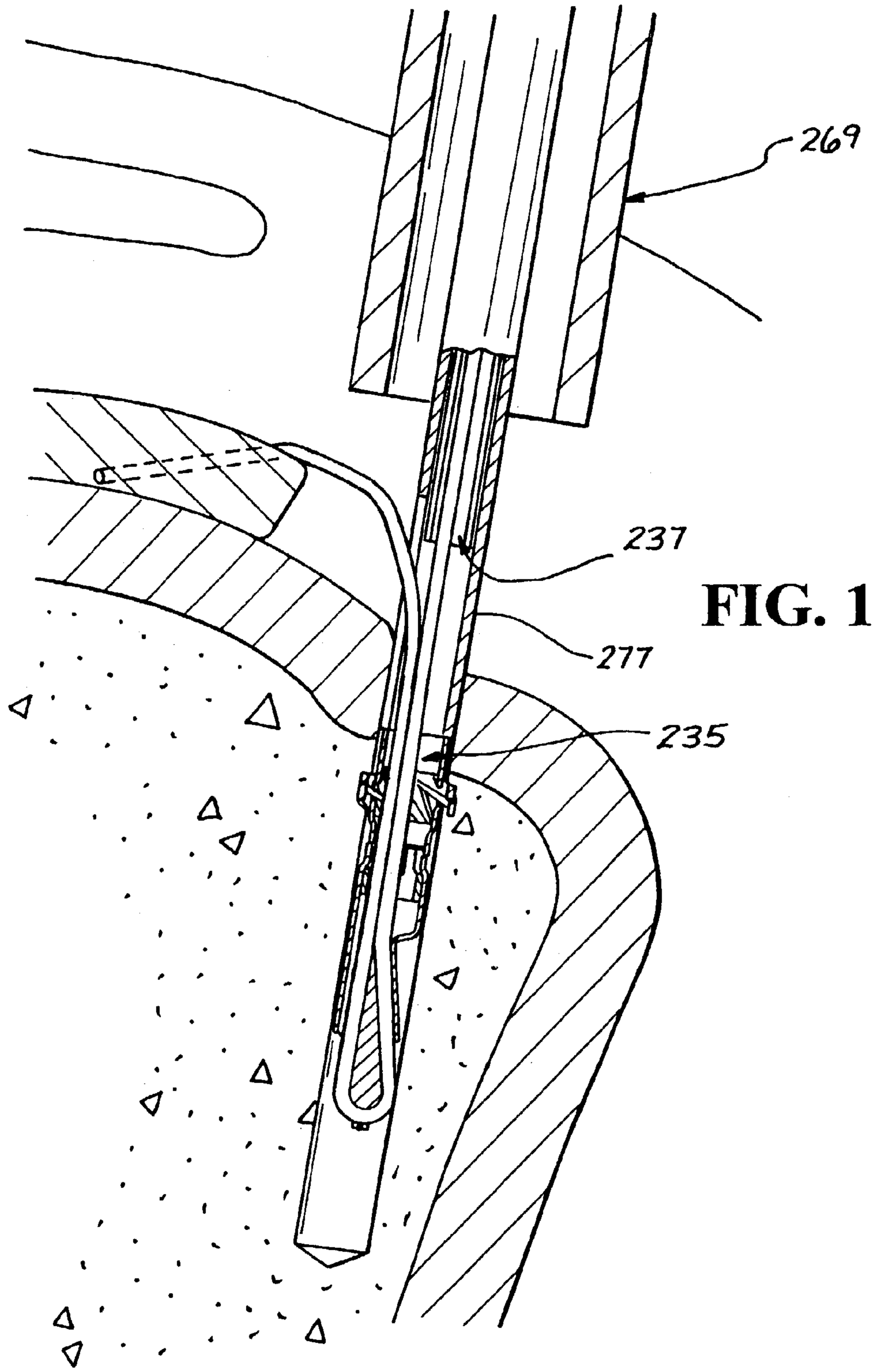


FIG. 11

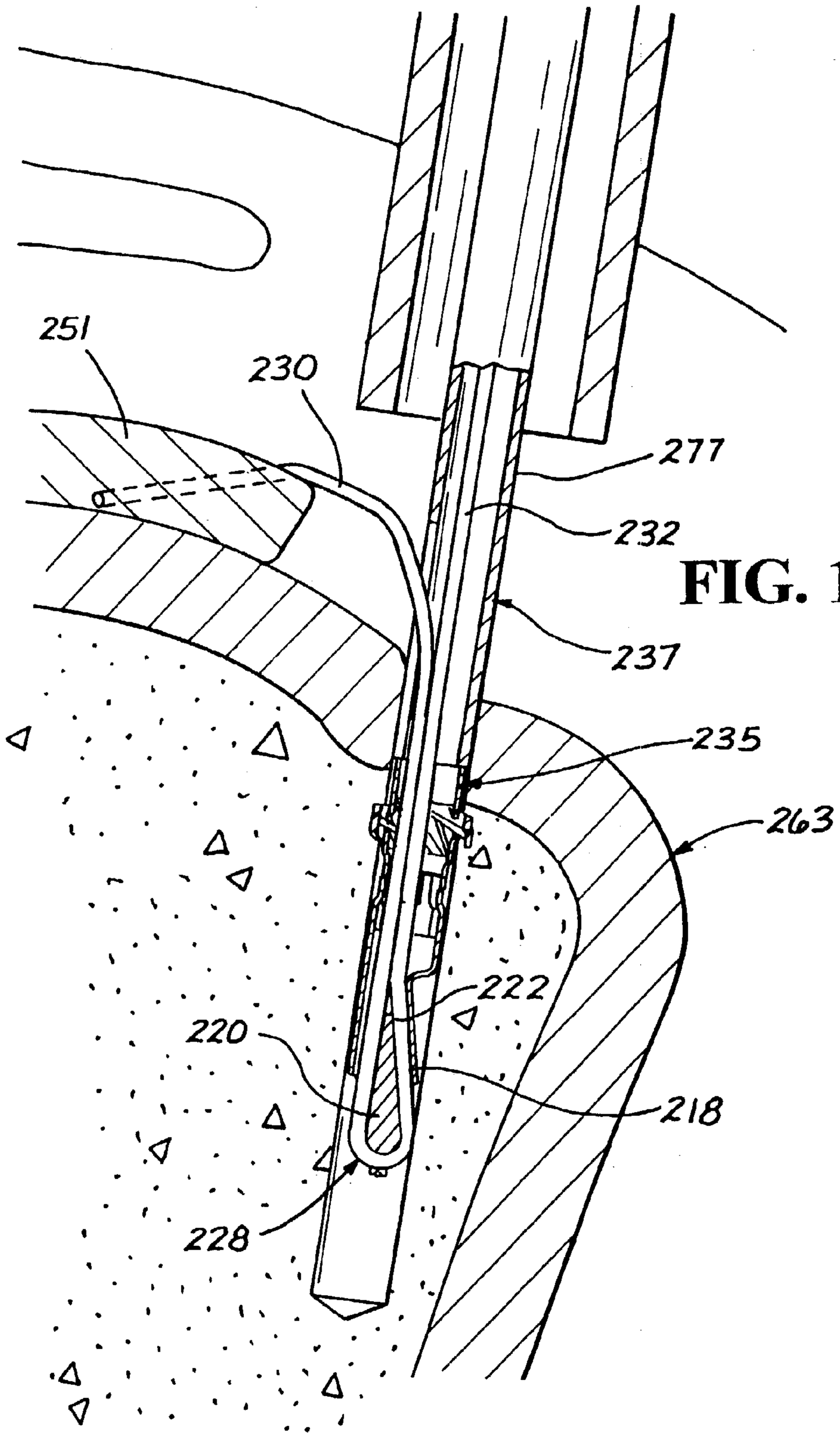


FIG. 12

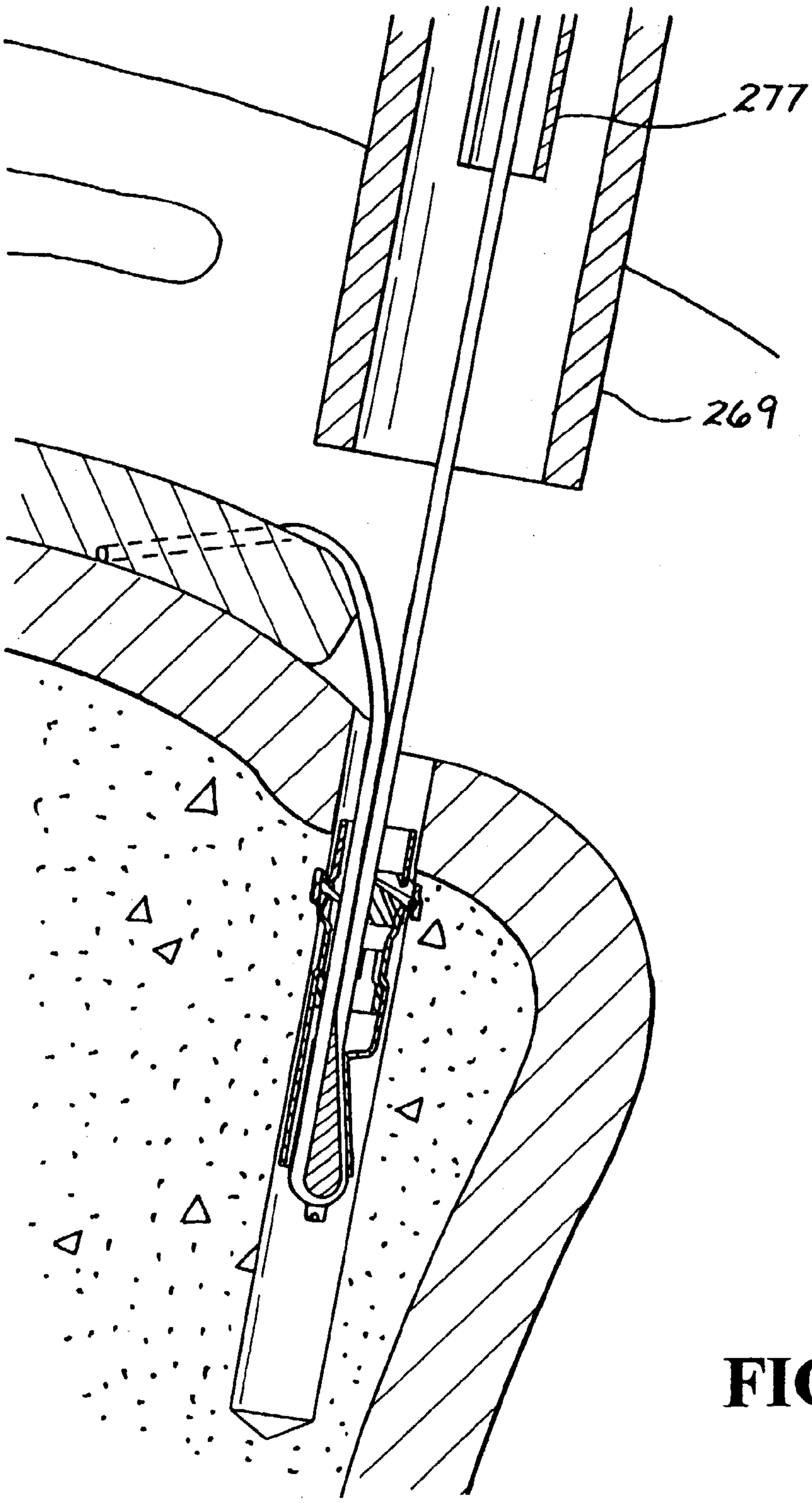


FIG. 13

FIG. 14

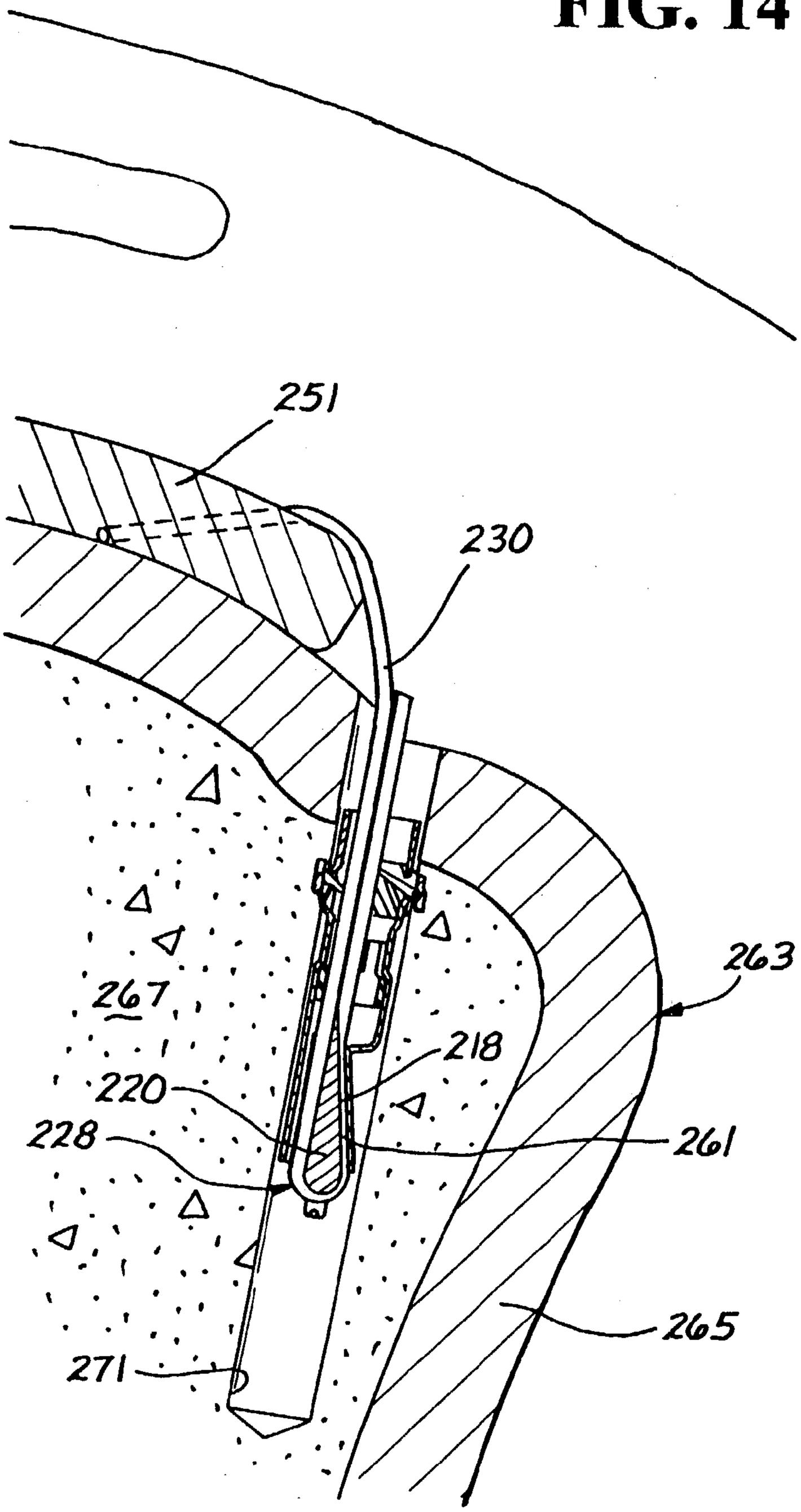
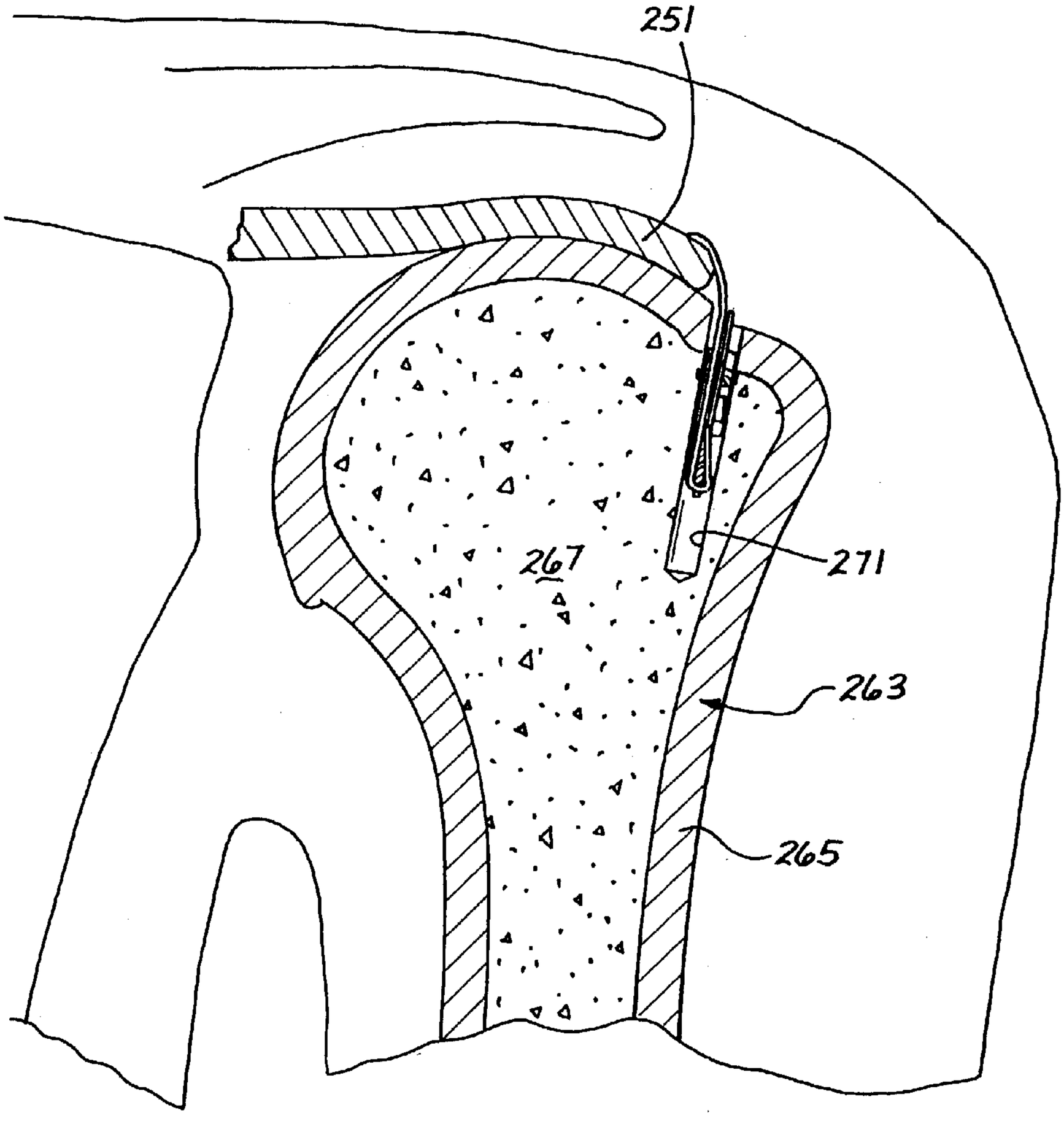


FIG. 15



METHOD AND APPARATUS FOR ATTACHING CONNECTIVE TISSUES TO BONE USING A KNOTLESS SUTURE ANCHORING DEVICE

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to methods and apparatus for attaching soft tissue to bone, and more particularly to anchors and methods for securing connective tissue, such as ligaments or tendons, to bone. The invention has particular application to arthroscopic surgical techniques for reattaching the rotator cuff to the humeral head, in order to repair the rotator cuff.

[0002] It is an increasingly common problem for tendons and other soft, connective tissues to tear or to detach from associated bone. One such type of tear or detachment is a "rotator cuff" tear, wherein the supraspinatus tendon separates from the humerus, causing pain and loss of ability to elevate and externally rotate the arm. Complete separation can occur if the shoulder is subjected to gross trauma, but typically, the tear begins as a small lesion, especially in older patients.

[0003] To repair a torn rotator cuff, the typical course today is to do so surgically, through a large incision. This approach is presently taken in almost 99% of rotator cuff repair cases. There are two types of open surgical approaches for repair of the rotator cuff, one known as the "classic open" and the other as the "mini-open". The classic open approach requires a large incision and complete detachment of the deltoid muscle from the acromion to facilitate exposure. The cuff is debrided to ensure suture attachment to viable tissue and to create a reasonable edge approximation. In addition, the humeral head is abraded or notched at the proposed soft tissue to bone reattachment point, as healing is enhanced on a raw bone surface. A series of small diameter holes, referred to as "transosseous tunnels", are "punched" through the bone laterally from the abraded or notched surface to a point on the outside surface of the greater tuberosity, commonly a distance of 2 to 3 cm. Finally, the cuff is sutured and secured to the bone by pulling the suture ends through the transosseous tunnels and tying them together using the bone between two successive tunnels as a bridge, after which the deltoid muscle must be surgically reattached to the acromion. Because of this maneuver, the deltoid requires postoperative protection, thus retarding rehabilitation and possibly resulting in residual weakness. Complete rehabilitation takes approximately 9 to 12 months.

[0004] The mini-open technique, which represents the current growing trend and the majority of all surgical repair procedures, differs from the classic approach by gaining access through a smaller incision and splitting rather than detaching the deltoid. Additionally, this procedure is typically performed in conjunction with arthroscopic acromial decompression. Once the deltoid is split, it is retracted to expose the rotator cuff tear. As before, the cuff is debrided, the humeral head is abraded, and the so-called "transosseous tunnels", are "punched" through the bone or suture anchors are inserted. Following the suturing of the rotator cuff to the humeral head, the split deltoid is surgically repaired.

[0005] Although the above described surgical techniques are the current standard of care for rotator cuff repair, they are associated with a great deal of patient discomfort and a lengthy recovery time, ranging from at least four months to one year or more. It is the above described manipulation of the deltoid muscle together with the large skin incision that causes the majority of patient discomfort and an increased recovery time.

[0006] Less invasive arthroscopic techniques are beginning to be developed in an effort to address the shortcomings of open surgical repair. Working through small trocar portals that minimize disruption of the deltoid muscle, a few surgeons have been able to reattach the rotator cuff using various bone anchor and suture configurations. The rotator cuff is sutured intracorporeally and an anchor is driven into bone at a location appropriate for repair. Rather than thread the suture through transosseous tunnels which are difficult or impossible to create arthroscopically using current techniques, the repair is completed by tying the cuff down against bone using the anchor and suture. Early results of less invasive techniques are encouraging, with a substantial reduction in both patient recovery time and discomfort.

[0007] Unfortunately, the skill level required to facilitate an entirely arthroscopic repair of the rotator cuff is inordinately high. Intracorporeal suturing is clumsy and time consuming, and only the simplest stitch patterns can be utilized. Extracorporeal knot tying is somewhat less difficult, but the tightness of the knots is difficult to judge, and the tension cannot later be adjusted. Also, because of the use of bone anchors to provide a suture fixation point in the bone, the knots that secure the soft tissues to the anchor by necessity leave the knot bundle on top of the soft tissues. In the case of rotator cuff repair, this means that the knot bundle is left in the shoulder capsule where it is able to be felt by the patient postoperatively when the patient exercises the shoulder joint. So, knots tied arthroscopically are difficult to achieve, impossible to adjust, and are located in less than optimal areas of the shoulder. Suture tension is also impossible to measure and adjust once the knot has been fixed. Consequently, because of the technical difficulty of the procedure, presently less than 1% of all rotator cuff procedures are of the arthroscopic type, and are considered investigational in nature.

[0008] Another significant difficulty with current arthroscopic rotator cuff repair techniques are shortcomings related to currently available suture anchors. Suture eyelets in bone anchors available today, which like the eye of a needle are threaded with the thread or suture, are small in radius, and can cause the suture to fail at the eyelet when the anchor is placed under high tensile loads.

[0009] There are various bone anchor designs available for use by an orthopedic surgeon for attachment of soft tissues to bone. The basic commonality between the designs is that they create an attachment point in the bone for a suture that may then be passed through the soft tissues and tied, thereby immobilizing the soft tissue. This attachment point may be accomplished by different means. Screws are known for creating such attachments, but suffer from a number of disadvantages, including their tendency to loosen over time, requiring a second procedure to later remove them, and their requirement for a relatively flat attachment geometry.

[0010] Another approach is to utilize the difference in density in the cortical bone (the tough, dense outer layer of bone) and the cancellous bone (the less dense, airy and somewhat vascular interior of the bone). There is a clear

demarcation between the cortical bone and cancellous bone, where the cortical bone presents a kind of hard shell over the less dense cancellous bone. The aspect ratio of the anchor is such that it typically has a longer axis and a shorter axis and usually is pre-threaded with a suture. These designs use a hole in the cortical bone through which an anchor is inserted. The hole is drilled such that the shorter axis of the anchor will fit through the diameter of the hole, with the longer axis of the anchor being parallel to the axis of the drilled hole. After deployment in to the cancellous bone, the anchor is rotated 90° so that the long axis is aligned perpendicularly to the axis of the hole. The suture is pulled, and the anchor is seated up against the inside surface of the cortical layer of bone. Due to the mismatch in the dimensions of the long axis of the anchor and the hole diameter, the anchor cannot be retracted proximally from the hole, thus providing resistance to pull-out. These anchors still suffer from the aforementioned problem of eyelet design that stresses the sutures.

[**0011**] Still other prior art approaches have attempted to use a "pop rivet" approach. This type of design requires a hole in the cortical bone into which a split shaft is inserted. The split shaft is hollow, and has a tapered plug leading into its inner lumen. The tapered plug is extended out through the top of the shaft, and when the plug is retracted into the inner lumen, the tapered portion causes the split shaft to be flared outwardly, ostensibly locking the device into the bone.

[**0012**] Other methods of securing soft tissue to bone are known in the prior art, but are not presently considered to be feasible for shoulder repair procedures, because of physicians' reluctance to leave anything but a suture in the capsule area of the shoulder. The reason for this is that staples, tacks, and the like could possibly fall out and cause injury during movement. As a result of this constraint, the attachment point often must be located at a less than ideal position. Also, the tacks or staples require a substantial hole in the soft tissue, and make it difficult for the surgeon to precisely locate the soft tissue relative to the bone.

[**0013**] As previously discussed, any of the anchor points for sutures mentioned above require that a length of suture be passed through an eyelet fashioned in the anchor and then looped through the soft tissues and tied down to complete the securement. Much skill is required, however, to both place the sutures in the soft tissues, and to tie knots while working through a trocar under endoscopic visualization.

[**0014**] There have been attempts to solve some of the problems that exist in current anchor designs. One such approach is disclosed in U.S. Pat. No. 5,324,308 to Pierce. In this patent, there is disclosed a suture anchor that incorporates a proximal and distal wedge component having inclined mating faces. The distal wedge component has two suture thread holes at its base through which a length of suture may be threaded. The assembly may be placed in a drilled hole in the bone, and when tension is placed on the suture, the distal wedge block is caused to ride up against the proximal wedge block, expanding the projected area within the drilled hole, and locking the anchor into the bone. This approach is a useful method for creating an anchor point for the suture, but does not in any way address the problem of tying knots in the suture to fix the soft tissue to the bone.

[**0015**] The problem of placing sutures in soft tissues and tying knots in an endoscopic environment is well known, and there have been attempts to address the problem and to simplify the process of suture fixation. One such approach is disclosed in U.S. Pat. No. 5,383,905 to Golds et al. The patent describes a device for securing a suture loop about bodily tissue that includes a bead member having a longitudinal bore and an anchor member adapted to be slidably inserted within the bore of the bead member. The anchor member includes at least two axial compressible sections which define a passageway to receive two end portions of a suture loop. The axial sections collapse radially inwardly upon insertion of the anchor member within the bore of the bead member to securely wedge the suture end portions received within the passageway.

[**0016**] Although the Golds et al. patent approach utilizes a wedge-shaped member to lock the sutures in place, the suture legs are passing through the bore of the bead only one time, in a proximal to distal direction, and are locked by the collapsing of the wedge, which creates an interference on the longitudinal bore of the anchor member. Also, no provision is made in this design for attachment of sutures to bone. The design is primarily suited for locking a suture loop, such as is used for ligation or approximation of soft tissues.

[**0017**] An approach that includes bone attachment is described in U.S. Pat. No. 5,584,835 to Greenfield. In this patent, a two part device for attaching soft tissue to bone is shown. A bone anchor portion is screwed into a hole in the bone, and is disposed to accept a plug that has been adapted to receive sutures. In one embodiment, the suture plug is configured so that when it is forced into its receptacle in the bone anchor portion, sutures that have been passed through an eyelet in the plug are trapped by friction between the wall of the anchor portion and the body of the plug portion.

[**0018**] Although there is some merit to this approach for eliminating the need for knots in the attachment of sutures to bone, a problem with being able to properly set the tension in the sutures exists. The user is required to pull on the sutures until appropriate tension is achieved, and then to set the plug portion into the bone anchor portion. This action increases the tension in the sutures, and may garrot the soft tissues or increase the tension in the sutures beyond the tensile strength of the material, breaking the sutures.

[**0019**] A disclosure that incorporates bone attachment and eliminates knot tying is set forth in U.S. Pat. No. 5,702,397 to Goble et al. One embodiment, in particular, is shown in **FIG. 23** of that patent and includes a bone anchor that has a threaded body with an inner cavity. The cavity is open to one end of the threaded body, and joins two lumens that run out to the other end of the threaded body. Within the cavity is disposed a gear, journaled on an axle. A length of suture is threaded through one lumen, around the gear, and out through the other lumen. A ball is disposed within the cavity to ride against a tapered race and ostensibly lock the suture in place. What is not clear from the patent disclosure is how the force D shown as the tension in the suture would lock the ball into the race. Although this embodiment purports to be a self-locking anchor adapted for use in blind holes for fixing sutures into bone, the construct shown is complicated, and does not appear to be adequate to reliably fixate the suture.

[**0020**] What is needed, therefore, is a new approach for repairing the rotator cuff or fixing other soft tissues to bone, wherein suture tension can be adjusted and possibly measured, the suture resides completely below the cortical bone surface, there is no requirement for the surgeon to tie a knot

to attach the suture to the bone anchor, and wherein the procedure associated with the new approach is better for the patient, saves time, is uncomplicated to use, and easily taught to practitioners having skill in the art.

SUMMARY OF THE INVENTION

[0021] The present invention solves the problems outlined above by providing innovative bone anchor and connective techniques which permit a suture attachment which lies entirely beneath the cortical bone surface. In the present state of the art, the sutures which are passed through the tissues to be attached to bone typically are threaded through a small eyelet incorporated into the head of the anchor and then secured by tying knots in the sutures. Endoscopic knot tying is an arduous and technically demanding task. Therefore, the present invention discloses devices and methods for securing sutures to a bone anchor without the requirement of knot tying.

[0022] In one embodiment, the suture legs, after having been placed into soft tissues to be anchored to bone, are threaded through the anchor and then through a floating wedge block located at the distal end of the anchor. The wedge block is configured such that it has a hollow lumen through the center, and a conically tapered outer surface. The distal end of the wedge block is the wider end of the cone, and the transition from the inside diameter created by the hollow lumen and the outside diameter created by the conical surface includes smooth radii for dressing the sutures threaded through the hollow lumen. The sutures are passed back around the outside of the wedge block such that they rest on the conical surface. They are then re-threaded in the opposite direction back through the anchor, exiting the anchor at the proximal end thereof. The anchor is then inserted into the bone, and secured. The distal end of the anchor is tapered to match the taper of the conical surface on the wedge block. When tension is placed on the legs of the suture passing back out of the anchor, the suture is drawn through the hollow center lumen, around the distal end of the wedge block, and back out of the anchor. This tension tends to cause the wedge block to force its way back up into the anchor body, and a means to prevent this may be employed. Such means may include any structure that selectively holds the wedge block separate from the anchor body.

[0023] At this juncture, by pulling on the suture legs, any slack in the sutures is removed, and the soft tissues are drawn toward the anchor. When the soft tissues are in the desired orientation, relative to the bone to which they are to be attached, the structure holding the wedge block is removed, and the back tension on the sutures pulls the wedge block into the matching taper in the anchor body, maintaining the compressive force on the suture legs.

[0024] In another embodiment, the wedge block may be adapted to have a U-shaped channel along one side of the wedge, and a tapered face along the opposite side of the wedge. The U-shaped channel communicates with the tapered face via a large radius surface that transitions and blends the channel face to the tapered face. The wedge is configured such that it may be placed inside of a hollow cylinder with a tapered face that protrudes into the interior of the cylinder and is configured to mate with the taper of the wedge. The wedge is adapted to permit two legs of the suture to be threaded through the anchor body, and along the U-shaped channel to the distal end of the anchor, wherein the sutures are drawn around the radiused surface and onto the tapered surface of the wedge on the opposite side. The sutures then pass back out of the proximal end of the anchor. As before, the suture legs may pass freely around the tapered wedge block until such time as tension in the bound legs pulls the wedge block back up into the tapered body of the anchor, and locks the suture in place.

[0025] Thus, with the above-described suture locking system, suture failure rates are dramatically reduced over conventional techniques because of the increased radius over which the suture is loaded, and the inventive procedures are significantly easier to perform than conventional techniques because of the elimination of knot tying.

[0026] More particularly, there is provided a bone anchor device for attaching connective tissue to bone, which comprises an outer body, and a lumen extending axially through the outer body. Inner walls which define the lumen in a proximal portion of the outer body extend inwardly relative to inner walls which define the lumen in a portion of the outer body distal to the proximal portion. A wedge member is advantageously disposed in a distal end of the lumen, distal to the inwardly extending lumen wall portion, which has outer walls that taper inwardly in a proximal direction therealong. The wedge member is axially movable in the lumen distal end.

[0027] In one preferred embodiment, a lumen extends axially through the wedge member, for receiving a suture therein. The wedge member preferably comprises a distal end having a curved surface, and the tapered proximal surface of the wedge member and the inwardly extending lumen internal wall together define a tapered distal lumen which communicates with the lumen.

[0028] A suture extends through the lumen and around the distal curved surface of the wedge member, and includes a free end extending proximally out of the bone anchor device and a bound end attached to soft tissue to be secured to the bone, wherein when the free end is placed in tension by a proximally directed force, the suture travels about the wedge member until increased tension on the bound end causes the suture to move the wedge member axially in a proximal direction, the proximal axial travel of the wedge member continuing until the proximal surface of the wedge member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of the suture in the tapered distal lumen.

[0029] In another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises an outer body and a lumen extending axially through the outer body. Inner walls which define the lumen taper in a proximal portion of the outer body extend inwardly relative to inner walls which define the lumen in a portion of the outer body distal to the proximal portion. A suture clamping member, consisting of a wedge member, is axially movable in the lumen.

[0030] In still another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises an outer body having a lumen extending axially therethrough. Inner walls which define the lumen in a proximal portion of the outer body extend inwardly relative to inner walls which define the

lumen in a portion of the outer body distal to the proximal portion. A suture clamping member comprising a wedge member is axially movable in the lumen distal portion. A suture extends through the lumen and around a distal surface of the wedge member, which includes a free end extending proximally out of the bone anchor device and a bound end attached to soft tissue to be secured to the bone. When the free end is placed in tension by a proximally directed force, the suture travels about the wedge member until increased tension on the bound end causes the suture to move the wedge member axially in a proximal direction, the proximal axial travel of the wedge member continuing until the proximal surface of the wedge member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of the suture therebetween.

[**0031**] In another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises an outer body having an open distal end, and a lumen extending axially through the outer body. Inner walls which define the lumen in a proximal portion of the outer body extend inwardly relative to inner walls which define the lumen in a portion of the outer body distal to the proximal portion. A suture clamping member having an outer surface is disposed in the lumen distal end and is axially movable therein. Advantageously, complementary engaging structure is disposed on each of the suture clamping member outer surface and the lumen inner surface for retaining the suture clamping member in the lumen distal end when the bone anchor device is not in a portion of bone. This complementary engaging structure preferably comprises a pin disposed on one of the suture clamping member outer surface and the lumen inner surface, and a recess for receiving the pin disposed on the other of the suture clamping member outer surface and the lumen inner surface.

[**0032**] In yet another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises an outer body having an outer surface, and a lumen extending axially through the outer body. Inner walls which define the lumen in a proximal portion of the outer body extend inwardly relative to inner walls which define the lumen in a portion of the outer body distal to the proximal portion. A suture clamping member is disposed in the lumen distal portion and is axially movable therein. Additionally, at least one outwardly extendable rib is disposed on the outer body outer surface for anchoring the outer body into surrounding bone.

[**0033**] In still another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises a distal wedge anchor portion comprising an outer body having an outer surface, on which a outwardly deployable anchoring element is situated. Additionally, a proximal driver portion is connected to the distal wedge anchor portion at a proximal end thereof, which includes an actuator for deploying the anchoring element outwardly. Advantageously, the connection between the proximal driver portion and the distal wedge anchor portion is releasable once the anchoring element has been deployed. In a preferred embodiment, this is accomplished because of a designed failure point in the connection between the proximal driver portion and the distal wedge anchor portion, so that upon deployment of the anchoring element outwardly, additional force may be applied to separate the driver portion from the anchor portion so that only the driver portion may be proximally removed from the patient's body.

[**0034**] In yet another aspect of the invention, there is disclosed a method for securing connective tissue to bone, which comprises securing a first end of a length of suture to a portion of soft tissue to be attached to a portion of bone. A second end of the length of suture is threaded through a lumen in an outer body of a bone anchor device and about an axially movable suture clamping member disposed in a distal portion of the lumen. The outer body is placed in a blind hole disposed in the portion of bone, and the second end of the length of suture is pulled proximally, so that the suture travels about the axially movable suture clamping member and draws the first end of the length of suture toward the bone anchor device, thereby securing the portion of soft tissue snugly to the portion of bone. Advantageously, when the tension on the first end of the length of suture increases, as the portion of soft tissue is bound to the portion of bone, the suture clamping member is pulled proximally toward inwardly extending walls defining a portion of the lumen, thereby clamping a portion of the length of suture between the inwardly extending lumen walls and the suture anchoring device.

[**0035**] Additional steps in the preferred method include anchoring the outer body in the blind hole, preferably by deploying ribs disposed on an outer surface of the outer body to an outwardly extended position, into surrounding cancellous bone, and cutting a portion of the suture second end to complete the procedure.

[**0036**] In another aspect of the invention, there is disclosed a method for securing connective tissue to bone, which comprises securing a first end of a length of suture to a portion of soft tissue to be attached to a portion of bone, and threading a second end of the length of suture through a lumen in an outer body of a bone anchor device and about an axially movable suture clamping member disposed in a distal portion of the lumen. The bone anchor device is inserted into a blind hole disposed in the portion of bone, and a deployable anchoring member disposed on an outer surface of the outer body is extended outwardly to secure the bone anchor device in surrounding bone. Following this step, a driver portion of the bone anchor device is separated from the outer body and withdrawn from the patient's body. Then, the second end of the length of suture is pulled proximally, to secure the portion of soft tissue properly to the portion of bone and to anchor the suture in the outer body by moving the suture clamping member axially to a suture clamping position.

[**0037**] In still another aspect of the invention, there is provided a bone anchor device for attaching connective tissue to bone, which comprises a body having a longitudinal axis, a distal end, and a proximal end. A surface on the body distal end slopes inwardly toward the longitudinal axis from a distal portion of the surface toward a proximal portion thereof. A suture anchoring member which is movable axially toward and away from sloping surface forms a part of the bone anchor device. The suture anchoring member s a distal end surface and opposing axial surfaces, wherein the distal end and opposing axial surfaces all comprise suture receiving surfaces for contacting suture material wrapped thereabout. In essence, this means that in use, a length of

suture material will be wrapped about the suture anchoring member in such a manner that the length of suture material will be in physical contact with all of the distal end surface and opposing side surfaces. In preferred embodiments, one of the opposing axial surfaces is sloped so that a width of the suture anchoring member (i.e. a dimension of the suture anchoring member which is transverse to the longitudinal axis) tapers from a distal end to a proximal end thereof.

[**0038**] As has been discussed supra, the sloped axial surface and the inwardly sloped body distal end surface together define a tapered distal lumen.

[**0039**] Now, it is to be understood that the above described invention is particularly suited to locking sutures that have been passed through soft tissues and are to be anchored to bone. The creation of an anchor point within the bone is outside the scope of this invention, although many alternative methods of anchoring suture to bone are contemplated. For example, some currently preferred methods are discussed in U.S. patent application Ser. No. 09/616,802, entitled Method & Apparatus for Attaching Connective Tissues to Bone Using a Suture Anchoring Device, filed on Jul. 14, 2000. The referenced application is commonly assigned with the present application, and is incorporated by reference in its entirety herein. Other prior art anchors, such as screws, moly bolts, and pop rivets may be adapted for use with the present invention as well.

[**0040**] The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

[**0041**] **FIG. 1** is a cross-sectional view of one embodiment of a portion of a bone anchor having a suture lock constructed in accordance with the principles of the present invention;

[**0042**] **FIG. 2** is a plan view of a second embodiment of a bone anchor having a suture lock similar to that shown in **FIG. 1**;

[**0043**] **FIG. 2A** is a cross-sectional view taken along lines **2**A-**2**A of **FIG. 2**;

[**0044**] **FIG. 2B** is a view taken along lines **2**B-**2**B of **FIG. 2**;

[**0045**] **FIG. 3** is a plan view similar to that of **FIG. 2**, illustrating a first step in a preferred method for using the embodiment of **FIG. 2**;

[**0046**] **FIG. 3A** is a cross-sectional view taken along lines **3**A-**3**A of **FIG. 3**;

[**0047**] **FIG. 3B** is a distal end view taken along lines **3**B-**3**B of **FIG. 3**;

[**0048**] **FIG. 4** is a plan view similar to that of **FIG. 3**, illustrating a second step in a preferred method for using the embodiment of **FIG. 2**;

[**0049**] **FIG. 4A** is a cross-sectional view taken along lines **4**A-**4**A of **FIG. 4**;

[**0050**] **FIG. 4B** is a distal end view taken along lines **4**B-**4**B of **FIG. 4**;

[**0051**] **FIG. 5** is a plan view similar to those of **FIGS. 3 and 4**, illustrating a third step in a preferred method for using the embodiment of **FIG. 2**;

[**0052**] **FIG. 5A** is a cross-sectional view taken along lines **5**A-**5**A of **FIG. 5**;

[**0053**] **FIG. 6** is a plan view similar to those of FIGS. **3-5**, illustrating a fourth step in a preferred method for using the embodiment of **FIG. 2**;

[**0054**] **FIG. 6A** is a cross-sectional view taken along lines **6**A-**6**A of **FIG. 6**;

[**0055**] **FIG. 6B** is a view taken along lines **6**B-**6**B of **FIG. 6**;

[**0056**] **FIG. 6C** is a cross-sectional view of one type of suture material which may be used in the present invention;

[**0057**] **FIG. 6D** is a cross-sectional view illustrating the suture of **FIG. 6C** after it has been clamped and compressed by the wedge clamp of the present invention;

[**0058**] **FIG. 7** is a plan view similar to those of FIGS. **3-6**, illustrating a fifth step in a preferred method for using the embodiment of **FIG. 2**;

[**0059**] **FIG. 8** is a schematic view illustrating a first step in a preferred method for using a suture lock and bone anchor constructed in accordance with the present invention to repair a tom rotator cuff arthroscopically;

[**0060**] **FIG. 9** is an enlarged schematic view illustrating the distal end of the instrument shown in **FIG. 8**;

[**0061**] FIGS. **10-14** are views similar to **FIG. 9** illustrating sequential steps in the aforementioned method; and

[**0062**] **FIG. 15** is a schematic view similar to **FIG. 8** illustrating the repaired rotator cuff at the conclusion of the aforementioned method.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[**0063**] Referring now more particularly to the drawings, there is shown in **FIG. 1 a** bone anchor **10** constructed in accordance with an embodiment of the present invention, comprising a body **12** which includes threads **14** on an outside surface thereof, a proximal lumen **16**, and a tapered distal lumen **18** that communicates with the proximal lumen **16**. A wedge body **20** includes a tapered end **22** and a lumen **24** through the wedge body **20**. The lumen terminates in a large blend radius **26** at the distal end of the wedge body **20**. A suture **28** which includes a bound leg **30** and a free leg **32** is threaded through the proximal lumen **16** and the wedge body lumen **24**, passes around the large blend radius **26**, and is redirected back through the proximal lumen **16**. The bound leg **30** is considered bound because in practice, this leg of the suture is "bound" to the soft tissues to be attached to bone by virtue of passing the sutures through the tissues using conventional suturing techniques known in the art. The free leg **32** is considered "free" because the surgeon, in practice, has control over this leg of the suture with his or her hands.

[**0064**] In operation, as the surgeon pulls on the free leg **32** of the suture **28**, the bound leg **30** of the suture follows through the bone anchor until such time as the tissues binding in the bound leg **30** of the suture **28** creates a tension

in the suture **28**. At this point, tension in the suture **28** tends to urge the wedge body **20** up into the tapered distal lumen **18**, pinching the suture **28** between the tapered distal lumen **18** and the tapered end **22** of the wedge body **20**. As the tension in the bound leg **30** of the suture **28** increases, the force on the wedge body **20** increases. In turn, the pinching force on the suture **28** also increases, creating a self-locking mechanism. The threads **14** on the exterior surface of the body **12** function to secure the bone anchor in surrounding bone material.

[**0065**] Referring now to **FIGS. 2, 2A**, and **2**B, a second modified embodiment of the inventive bone anchor device **110** is illustrated, wherein like elements to those shown in **FIG. 1** are designated by like reference numerals, preceded by the numeral "1". The bone anchor device **110** comprises a distal wedge anchor portion **135** and a proximal driver portion **137**, which are secured together mechanically in a coaxial arrangement by crimped segments **139** or other suitable means. As in the **FIG. 1** embodiment, the distal wedge anchor portion **135** includes a body **112** which comprises a proximal lumen **116**, a tapered distal lumen **118**, and a wedge body **120** having a tapered end **122** and a large blend radius **126**. A pin **141** may be disposed in a groove **142** on the wedge body **120**, which is complementary to a groove **143** on an interior surface of the body **112** of the distal wedge anchor portion **135**. When the pin **141** is disposed in the groove **142** and the groove **143**, it functions as a retainer to keep the wedge body **120** in position in the distal lumen **118** of the device **110**. This arrangement is particularly convenient when there is no suture threaded through the device, so that the device, though formed of separable elements, tends to remain unitary, thereby easing the already complicated job of the practitioner performing the repair procedure.

[**0066**] A crimped flat **145** on the surface of the distal portion of the body **112** creates the progressive proximal tapering in the tapered distal lumen **118**, discussed supra in connection with the **FIG. 1** embodiment, which is important to ensure that the suture becomes pinched between the wedge body **120** and the interior surface of the bone anchor body **112** in the tapered distal lumen **118** as the wedge body **120** moves proximally under tension, as will be described more fully hereinbelow.

[**0067**] Also on the outer surface of the body **112** of the bone anchor portion **135** are a plurality of slots **147**, which are distributed in a spaced configuration about the entire circumference of the cylindrical body **112**. These slots **147** are illustrated as being disposed at an acute angle with respect to a longitudinal axis **149** of the instrument **110**, although in other preferred embodiments the slots are oriented parallel to the axis **149**. Such slots and their function are more fully described in U.S. patent application Ser. No. 09/616,802, which has already been expressly incorporated herein by reference. Their function will also be described in greater detail hereinbelow.

[**0068**] Now with reference in particular to FIGS. **3-7**, a method for using the bone anchor device **110** of **FIGS. 2, 2A**, and **2**B to secure soft tissue to bone, for example, will be described. Initially, a suture **128**, and particularly a bound leg **130** of the suture **128**, is stitched in a suitable manner to a portion of soft tissue **151**, such as a tendon, which is to be secured to a bone (not shown). The stitching process may be accomplished by any known means, and any known suture stitch may be employed, the objective being to ensure a secure stitch so that the suture is not inadvertently separated from the tendon after completion of the repair procedure, necessitating reentry to the surgical site. In preferred approaches, the suture is attached to the soft tissue using a "mattress stitch", which is well known in the art as being a particularly secure stitch which is unlikely to fail postoperatively. Of course, as discussed supra, the preferred repair procedure discussed herein is an arthroscopic procedure, wherein an initial access incision is made to the repair site, such as a shoulder, and a trocar is inserted into the access incision to provide access to the repair site for surgical instruments as well as optical instruments. Preferably, a suturing instrument is inserted into the trocar to perform the aforementioned suturing step. Of course, the inventive devices may also be utilized in an open surgical procedure, if desired, wherein the sutures are manually placed.

[**0069**] Once the suturing process is completed, a free end **132** of the suture **128** is removed proximally through the trocar from the patient's body, together with the suturing instrument. The free end **132** of the suture is then threaded through a lateral port **153** and then through the proximal lumen **116** of the bone anchor instrument **110** (**FIGS. 3, 3A**, and **3**B). It is threaded distally through the tapered distal lumen **118** and around the distal end surface (large blend radius) **126** of the wedge body **120**, then proximally back through the tapered distal lumen **118** and through the lumen **116** to the proximal end of the driver portion **137**. It is noted that, in this embodiment, the wedge body **120** does not include a wedge lumen, as in the **FIG. 1** embodiment. Rather, the suture is threaded about the wedge body, so that it is in physical contact with the large blend radius **126**, as well as with each opposing side surface **154***a, b* (**FIG. 4A**) of the wedge body. However, the wedge body could be modified to include a wedge lumen, and the suture could be threaded therethrough, as in the **FIG. 1** embodiment, if desired.

[**0070**] Once the threading process is completed, the bone anchor instrument **110** is returned through the trocar (not shown) to the repair site, and the distal wedge anchor portion **135** is placed into a blind hole (not shown) which has been made, preferably by drilling, into the bone to which the soft tissue **151** is to be secured.

[**0071**] With reference now to **FIGS. 4, 4A**, and **4**B, once the distal wedge anchor portion **135** is satisfactorily disposed within the bone (not shown), the driver portion is actuated to radially outwardly deploy a plurality of ribs **157** which comprise the portions of the body **112** which lie between the aforementioned spaced slots **147**. This procedure is more fully described in co-pending U.S. patent application Ser. No. 09/616,802, already incorporated herein by reference, but, essentially, the deployment is made by axially compressing the distal wedge anchor portion to thereby force the ribs **157** radially outward. In a preferred embodiment, wherein, as mentioned supra, the slots **147** lie at an angle with the longitudinal axis **149** of the device **110**, the resulting "petals" formed by the radially outwardly extending ribs **157** take on a semi-circular shape, with the "petals" overlapping one another to create an extraordinarily strong anchor body. The soft cancellous bone into which the anchor body is radially extended tends to flow between the "petals" as well, further strengthening the achieved anchoring effect both axially and radially. The anchor should be

radially deployed beneath the cortical bone surface, so that it is virtually impossible to retract the distal wedge anchor portion from the bone proximally past the cortical outer surface thereof without breaking the native bone.

[**0072**] A unique and important feature of the present invention is the provision of a stress point **159** in the junction between the distal wedge anchor portion **135** and the proximal driver portion **137**. The reason for this is that, once the driver portion has been utilized to position the wedge anchor portion, and then actuated to axially compress the wedge anchor portion, so that the anchor ribs **157** are radially extended, there is no more purpose for the driver portion. As mentioned supra, the wedge anchor portion **135** and driver portion **137** are mechanically joined by, for example, a plurality of crimped segments **139**, which create an interfering fit between the axially overlapping cylindrical bodies of each of the two portions **135**, **137**. Of course, many other equivalent joinder means may be employed as well, and these means will be well known to those of ordinary skill in the art. In the presently preferred embodiment, however, the stress point **159** is co-located with the crimped segments **139**, and designed so that, as the compressing force is applied by the driver portion **137** to the wedge anchor portion **135**, to radially deform and extend the ribs **157**, when it reaches a level somewhat above the force level required to complete the anchor deployment, the stress point which is a pre-designed point of weakness or "failure point", will break, physically separating the driver portion **137** from the anchor portion **135**. **FIGS. 5 and 5**A illustrate the device **110** after the driver portion **137** has been separated from the wedge anchor portion **135** and withdrawn proximally from the patient's body through the trocar (not shown).

[**0073**] Thus, the wedge anchor portion **135** is now permanently deployed in the bone, to thereby securely anchor the suture **128** therein, and thus permanently secure the soft tissue **151** to the bone.

[**0074**] With reference now to **FIGS. 6, 6A**, and **6**B, it will be seen that, once the distal anchor portion **135** is secured within the bone, it is time for the practitioner to pull the free ends **132** of the suture **128** proximally, to draw the soft tissue **151** toward the bone until it is snugly situated in desired proximity thereto, thereby creating a tight and secure connection between the soft tissue and the bone. As discussed supra, with respect to the **FIG. 1** embodiment, the bound leg **130** of the suture follows through the bone anchor, about the wedge body **120**, until such time as the tissues **151** binding in the bound leg **130** of the suture **128** create a tension in the suture **128**. This will occur when the soft tissue **151** has been drawn toward the bone and is snugly situated with respect thereto. At this point, tension in the suture **128** tends to urge the wedge body **120** proximally, up into the tapered distal lumen **118**, as shown in **FIG. 6**A, pinching the suture **128** between an inwardly sloping surface **161 (FIG. 4A)** on the body **112** and the sloping axial surface **154***a* on the tapered end **122** of the wedge body **120**, within the tapered distal lumen **118**. As the tension in the bound leg **130** of the suture **128** increases, the proximal force on the wedge body **120** increases. In turn, the pinching force on the suture **128** also increases, creating a self-locking mechanism.

[**0075**] It may be helpful to discuss in some detail this self-locking suture mechanism. One of the significant advantages of this mechanism is its reversibility; i.e. its ability to permanently lock the bound end of the suture in position, but to permit continued adjustability of the suture loop by applying a tensile force to the free end of the suture. This is important, because a practitioner will often find that, during the course of a procedure, after the tendon/soft tissue **151** has been brought into what is believed to be a desired position relative to the bone to which it is being secured, and the suture has been locked into place to retain the tendon in that orientation, a further adjustment is necessary or desired to optimize the outcome. Using existing prior art solutions, though, wherein the suture is knotted into position and fixed at a particular length, it would be necessary to either forego the desired adjustment or, alternatively, to cut the suture and resuture the tendon. In some instances, it may be necessary to abandon the suture anchor, leaving the useless (and expensive) anchor in position, and locating a new anchor in the bone to re-suture the tendon.

[**0076**] On the other hand, in the present invention, after the free end **132** has been pulled, as described above, sufficiently that a tension is created in the bound end **130** (due to approximation of the tendon **151** to the bone), and the suture **128** has been clamped in the tapered distal lumen **118**, only the bound end **130** is anchored in a fixed position. This ensures that the tendon is not movable relative to the bone after completion of the procedure, which, of course, is desirable. On the other hand, the free end **132** continues to be movable, to thereby permit adjustment of the size of the suture loop through the tendon **151**, which in turn permits adjustment or "fine tuning" of the position of the tendon **151** with respect to the bone.

[**0077**] To understand this advantageous feature, it may be helpful to review in a bit more detail the functionality of the inventive device and method. Again with reference to FIGS. **2-6**B, it may be seen that, in the early procedural steps, both the free and bound suture legs are freely movable to slide the suture **128** about the free-floating anchor wedge **120**. However, once tension develops in the bound leg **130** as the tendon **151** approximates the bone, the wedge **120** is pulled proximally to clamp a length of the suture **128** within the tapered distal lumen **118**, as discussed in detail supra. Applying a tensile force to the bound leg at this juncture only enhances the clamping effect by proximally pulling the wedge **120** even more tightly against the clamped length of suture **128**. **FIGS. 6C and 6D** illustrate the effect of this clamping force on the clamped length of suture **128**, as observed by the inventor. In the case where #2 round suture is utilized, having a cross-sectional width of 0.023 inches, as shown in **FIG. 6**C, the clamping force exerted by the wedge block **120** against the clamped length of suture causes it to flatten and compress to a width of approximately 0.011 inches.

[**0078**] On the other hand, now the free leg **132** of the suture **128** may continue to be manipulated to adjust the size of the suture loop at the bound end. Applying a tensile force to the free leg **132**, once the suture is clamped by the wedge **120**, causes the wedge **120** now to move again in a distal direction, thereby increasing the cross-sectional area of the tapered lumen **118**, so that the clamped length of suture may slide to adjust the positioning of the bound suture end. There are two apparent reasons for this response. One is that, when the free end **132** is pulled, the clamped length of suture **128** wants to straighten out, so that it pushes against the angled inner lumen wall which forms, in part, the tapered distal

lumen **118**. Since this wall is fixed in position, a reactive force pushes against the tapered face of the wedge **120**, pushing it a modest distance distally. Another reason is that continued tension on the free end of the suture results in a return of the cross-sectional area of the clamped suture portion from a reduced flat cross-section to the original larger round cross-section. This rounding effect reduces the surface contact of the suture with the adjacent lumen walls (and resultant frictional interface), making it easier for the suture to slide through the tapered lumen. Also, the increased suture diameter pushes the wedge **120** a slight distance distally. The resultant larger tapered lumen permits free sliding of the suture **128** until a desired adjustment has been made, after which the tendon **151** is again clamped as explained supra.

[**0079**] Now referring to **FIG. 7**, the final step in the sequence of permanently anchoring the soft tissue **151** to bone is illustrated, wherein, once the suture is locked in place by virtue of the proximal positioning of the wedge body **120** within the anchor portion **135**, the free end **132** is cut off near the proximal end of the anchor portion **135**, and the incision is closed. The free end **132** is only cut off after all final adjustments have been made, as discussed above, so that the tendon is precisely positioned as desired.

[**0080**] FIGS. **8-15** illustrate a procedure similar to that shown in FIGS. **2-7**, but specifically adapted for repair of a patient's rotator cuff, arthroscopically. Accordingly, like elements to those illustrated in previous figures will be designated by the same reference numerals, preceded by the numeral "2".

[**0081**] Thus, there is shown in **FIG. 8 a** shoulder **261**, which comprises a humeral head **263**, including an outer cortical bone layer **265**, which is hard, and inner cancellous bone **267**, which is relatively soft. As is typically the case for rotator cuff injuries, in this instance the supraspinatus tendon **251** has become separated from the humeral head **263**, and the objective of the rotator cuff repair procedure is to reattach the tendon **251** to the humeral head **263**.

[**0082**] Alternate rotator cuff repair procedures are also discussed in co-pending U.S. patent application Ser. No. 09/475,495, filed on Dec. 30, 1999, and entitled Method and Apparatus for Attaching Connective Tissues to Bone Using a Knotless Suture Anchoring Device, which is herein expressly incorporated by reference.

[**0083**] To effect the rotator cuff repair, the practitioner will first create an incision in the patient's shoulder **261**, into which will be inserted a trocar **269**, as shown in **FIG. 8**. The trocar permits access to the procedural site for visualization instruments, as well as working instruments, and permits the procedure to be completed arthroscopically.

[**0084**] Again, as in the embodiment shown in FIGS. **3-7**, once the trocar has been inserted, the first procedural step is to suture the tendon **251**, using desired techniques which are beyond the scope of this patent application, creating a bound suture end **230** (**FIGS. 8 and 9**). Once this suturing step is completed, as with the FIGS. **3-7** embodiment, the free end **232** (**FIG. 9**) of the suture **228** is removed proximally through the trocar from the patient's body, together with the suturing instrument (not shown). The free end **232** of the suture is then threaded through the proximal lumen **216** of the bone anchor instrument **210** through a lateral port **253**, distally through the tapered distal lumen **218** and around the large blend radius **226** of the wedge body **220**, then proximally back through the tapered distal lumen **218** and through the lumen **216** to the proximal end of a driver portion **237**. Once the threading process is completed, the bone anchor instrument **210** is returned through the trocar **269** to the repair site, and the distal wedge anchor portion **235** is placed into a blind hole **271** which has been made, preferably by drilling, into the bone **263** to which the soft tissue tendon **251** is to be secured.

[**0085**] With reference now to **FIG. 10**, once the distal wedge anchor portion **235** is satisfactorily disposed within the bone **263**, beneath the cortical layer **265**, the driver portion **237** is actuated to radially outwardly deploy a plurality of ribs **257** to create a "flower" comprised of a plurality of "petals", which have a diameter substantially larger than the diameter of the hole **271**, thereby preventing "backout" of the anchor portion **235** from the hole **271**. Although many different actuation mechanisms may be employed, the illustrated embodiment shows a handle portion **273** (**FIG. 8**) including a trigger **275**, which may be squeezed by the practitioner to axially compress the anchor portion **235** and thereby deploy the "flower" anchor. This procedure is the same as that employed in the FIGS. **3-7** embodiment.

[**0086**] As in the FIGS. **3-7** embodiment, a stress point **259** is provided in the junction between the distal wedge anchor portion **235** and the proximal driver portion **237**. Referring now to **FIG. 11**, then, as in the prior embodiment, once the wedge anchor portion has been fully compressed to fully radially extend the anchor ribs **257**, the trigger **275** continues to be squeezed for a period of time to exert continuing axial compression force on the column of the wedge anchor portion **235**. This continued force application will cause the column to fail at its designed failure point, namely, the stress point **259**, so that the driver portion **237** becomes physically separated from the anchor portion **235**. As shown in **FIG. 11**, once the driver portion **237** is physically separated from the anchor portion **235**, it is withdrawn proximally through the trocar **269**, out of the patient's body. In **FIG. 11**, the driver portion **237** is shown partially withdrawn, and in **FIG. 12** it is fully withdrawn. It is noted that, in this embodiment, a suture channel **277** is disposed coaxially about the driver portion **237**, as shown.

[**0087**] Thus, the wedge anchor portion **235** is now permanently deployed in the bone **263**, to thereby securely anchor the suture **228** therein, and thus permanently secure the soft tissue **251** to the bone **263**.

[**0088**] With reference now to **FIGS. 12 and 13**, it will be seen that, once the distal anchor portion **235** is secured within the bone **263**, it is time for the practitioner to pull the free end **232** of the suture **228** proximally, to draw the tendon **251** toward the bone **263** until it is snugly situated in desired proximity thereto, thereby creating a tight and secure connection between the tendon and the bone. As discussed supra, with respect to prior embodiments, the bound leg **230** of the suture follows through the bone anchor, about the wedge body **220**, until such time as the tendon **251** binding in the bound leg **230** of the suture **228** creates a tension in the suture **228**. At this point, tension in the suture **228** tends to urge the wedge body **220** proximally, up into the tapered distal lumen **218**, as shown in **FIG. 12**, pinching the suture

228 between the tapered distal lumen **218** and the tapered end **222** of the wedge body **220**. As the tension in the bound leg **230** of the suture **228** increases, the proximal force on the wedge body **220** increases. In turn, the pinching force on the suture **228** also increases, creating a self-locking mechanism.

[**0089**] Now referring to **FIG. 13**, once the suture **228** is locked in place within the bone anchor portion **235**, the suture channel **277** is proximally withdrawn through the trocar **269**. Then, as shown in **FIGS. 14 and 15**, the excess suture material on the free leg **232** is cut off, the trocar is removed, and the incision is closed to complete the procedure.

[**0090**] Accordingly, although an exemplary embodiment of the invention has been shown and described, it is to be understood that all the terms used herein are descriptive rather than limiting, and that many changes, modifications, and substitutions may be made by one having ordinary skill in the art without departing from the spirit and scope of the invention. In particular, it is noted that the procedures, while oriented toward the arthroscopic repair of the rotator cuff, are applicable to the repair of any body location wherein it is desired to attach or reattach soft tissue to bone, particularly using an arthroscopic procedure.

What is claimed is:

1. A bone anchor device for attaching connective tissue to bone, comprising:

an outer body;

a lumen extending axially through said outer body, wherein inner walls which define said lumen in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion; and

a wedge member disposed in a distal end of said lumen, said wedge member having outer walls which taper inwardly in a proximal direction therealong, said wedge member being axially movable in said lumen distal end.

2. The bone anchor device as recited in claim 1, said outer body having an outer surface and having a protrusion thereon extending outwardly to anchor said outer body in a bone.

3. The bone anchor device as recited in claim 2, wherein said protrusion comprises a thread.

4. The bone anchor device as recited in claim 2, wherein said protrusion comprises a plurality of outwardly extendable ribs.

5. The bone anchor device as recited in claim 1, and further comprising a lumen extending axially through said wedge member, for receiving a suture therein.

6. The bone anchor device as recited in claim 1, wherein said wedge member comprises a distal end having a curved surface.

7. The bone anchor device as recited in claim 1, wherein the tapered proximal surface of said wedge member and said inwardly extending lumen internal wall together define a tapered distal lumen which communicates with said lumen.

8. The bone anchor device as recited in claim 7, and further comprising a suture extending through said lumen and around a distal curved surface of said wedge member, said suture including a free end extending proximally out of said bone anchor device and a bound end attached to soft tissue to be secured to said bone, wherein when said free end is placed in tension by a proximally directed force, the suture travels about said wedge member until increased tension on said bound end causes said suture to move said wedge member axially in a proximal direction, the proximal axial travel of said wedge member continuing until the proximal surface of the wedge member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of said suture in said tapered distal lumen.

9. A bone anchor device for attaching connective tissue to bone, comprising:

an outer body;

a lumen extending axially through said outer body, wherein inner walls which define said lumen taper in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion; and

a suture clamping member consisting of a wedge member which is axially movable in said lumen.

10. The bone anchor device as recited in claim 9, and further comprising a lumen extending axially through said wedge member, for receiving a suture therein.

11. The bone anchor device as recited in claim 9, wherein said wedge member comprises a distal end having a curved surface.

12. The bone anchor device as recited in claim 9, and further comprising a suture extending through said lumen and around a distal curved surface of said wedge member, said suture including a free end extending proximally out of said bone anchor device and a bound end attached to soft tissue to be secured to said bone, wherein when said free end is placed in tension by a proximally directed force, the suture travels about said wedge member until increased tension on said bound end causes said suture to move said wedge member axially in a proximal direction, the proximal axial travel of said wedge member continuing until the proximal surface of the wedge member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of said suture therebetween.

13. A bone anchor device for attaching connective tissue to bone, comprising:

an outer body;

a lumen extending axially through said outer body, wherein inner walls which define said lumen in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion;

a suture clamping member comprising a wedge member which is axially movable in said lumen distal portion; and

a suture extending through said lumen and around a distal surface of said wedge member, said suture including a free end extending proximally out of said bone anchor device and a bound end attached to soft tissue to be secured to said bone, wherein when said free end is placed in tension by a proximally directed force, the suture travels about said wedge member until increased

tension on said bound end causes said suture to move said wedge member axially in a proximal direction, the proximal axial travel of said wedge member continuing until the proximal surface of the wedge member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of said suture therebetween.

14. The bone anchor device as recited in claim 13, wherein said wedge member distal surface is curved.

15. The bone anchor device as recited in claim 13, wherein said outer body has an outer surface, said outer surface having outwardly extendable ribs disposed thereon for anchoring said outer body in bone.

16. The bone anchor device as recited in claim 13, and further comprising a lumen extending axially through said wedge member for receiving a suture therein.

17. A bone anchor device for attaching connective tissue to bone, comprising:

an outer body having an open distal end;

a lumen extending axially through said outer body, wherein inner walls which define said lumen in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion;

a suture clamping member having an outer surface, said suture clamping member being disposed in said lumen distal end and being axially movable therein; and

complementary engaging structure disposed on each of said suture clamping member outer surface and said lumen inner surface for retaining said suture clamping member in said lumen distal end when the bone anchor device is not in a portion of bone.

18. The bone anchor device as recited in claim 17, wherein said complementary engaging structure comprises a pin disposed on one of said suture clamping member outer surface and said lumen inner surface, and a recess for receiving the pin disposed on the other of said suture clamping member outer surface and said lumen inner surface.

19. A bone anchor device for attaching connective tissue to bone, comprising:

an outer body having an outer surface;

a lumen extending axially through said outer body, wherein inner walls which define said lumen in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion;

a suture clamping member disposed in said lumen distal portion and being axially movable therein; and

at least one outwardly extendable rib disposed on said outer body outer surface for anchoring said outer body into surrounding bone.

20. The bone anchor device as recited in claim 19, wherein said at least one outwardly extendable rib comprises a plurality of outwardly extendable ribs.

21. The bone anchor device as recited in claim 19, said suture clamping member comprising a wedge member having outer walls which taper inwardly in a proximal direction therealong.

22. The bone anchor device as recited in claim 19, and further comprising a suture extending through said lumen and around a distal surface of said suture clamping member, said suture including a free end extending proximally out of said bone anchor device and a bound end attached to soft tissue to be secured to said bone, wherein when said free end is placed in tension by a proximally directed force, the suture travels about said suture clamping member until increased tension on said bound end causes said suture to move said suture clamping member axially in a proximal direction, the proximal axial travel of said suture clamping member continuing until a proximal surface of the suture clamping member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of said suture in a tapered distal lumen disposed between said suture clamping member proximal surface and the inwardly extending internal lumen wall.

23. The bone anchor device as recited in claim 19, wherein said outer body comprises a distal anchor portion and said device further comprises a proximal driver portion connected to a proximal end of said distal anchor portion.

24. The bone anchor device as recited in claim 23, wherein said proximal driver portion comprises an actuator for outwardly extending said at least one outwardly extendable rib.

25. The bone anchor device as recited in claim 24, wherein the connecting joint between said distal anchor portion and said proximal driver portion includes a designed failure point, so that upon deployment of said at least one outwardly extendable rib to its extended position, additional force may be applied to separate the driver portion from the anchor portion so that only the driver portion may be proximally removed from the patient's body.

26. A bone anchor device for attaching connective tissue to bone, comprising:

a distal wedge anchor portion comprising an outer body having an outer surface, on which a outwardly deployable anchoring element is situated; and

a proximal driver portion connected to said distal wedge anchor portion at a proximal end thereof, said driver portion including an actuator for deploying said anchoring element outwardly, wherein the connection between said proximal driver portion and said distal wedge anchor portion is releasable once the anchoring element has been deployed.

27. The bone anchor device as recited in claim 26, and further comprising a designed failure point in the connection between the proximal driver portion and the distal wedge anchor portion, so that upon deployment of said anchoring element outwardly, additional force may be applied to separate the driver portion from the anchor portion so that only the driver portion may be proximally removed from the patient's body.

28. The bone anchor device as recited in claim 26, said distal wedge anchor portion further comprising a lumen extending axially through said outer body, wherein inner walls which define said lumen in a proximal portion of said outer body extend inwardly relative to inner walls which define said lumen in a portion of said outer body distal to said proximal portion; and

a suture clamping member disposed in said lumen distal portion and being axially movable therein.

29. The bone anchor device as recited in claim 28, and further comprising a suture extending through said lumen and around a distal surface of said suture clamping member, said suture including a free end extending proximally out of said bone anchor device and a bound end attached to soft tissue to be secured to said bone, wherein when said free end is placed in tension by a proximally directed force, the suture travels about said suture clamping member until increased tension on said bound end causes said suture to move said suture clamping member axially in a proximal direction, the proximal axial travel of said suture clamping member continuing until a proximal surface of the suture clamping member has moved into sufficient proximity to the inwardly extending internal lumen wall to pinch a length of said suture in a tapered distal lumen disposed between said suture clamping member proximal surface and the inwardly extending internal lumen wall.

30. A method for securing connective tissue to bone, comprising:

securing a first end of a length of suture to a portion of soft tissue to be attached to a portion of bone;

threading a second end of the length of suture through a lumen in an outer body of a bone anchor device and about an axially movable suture clamping member disposed in a distal portion of said lumen;

placing said outer body in a blind hole disposed in said portion of bone; and

pulling the second end of the length of suture proximally, so that the suture travels about the axially movable suture clamping member and draws the first end of the length of suture toward the bone anchor device, thereby securing the portion of soft tissue snugly to the portion of bone;

wherein when the tension on the first end of the length of suture increases, as the portion of soft tissue is bound to the portion of bone, the suture clamping member is pulled proximally toward inwardly extending walls defining a portion of said lumen, thereby clamping a portion of the length of suture between the inwardly extending lumen walls and the suture anchoring device.

31. The method as recited in claim 30, and further comprising a step of anchoring said outer body in said blind hole.

32. The method as recited in claim 31, wherein said anchoring step is accomplished by deploying ribs disposed on an outer surface of said outer body to an outwardly extended position.

33. The method as recited in claim 30, and further comprising a step of cutting a portion of the suture second end to complete the procedure.

34. A method for securing connective tissue to bone, comprising:

securing a first end of a length of suture to a portion of soft tissue to be attached to a portion of bone;

threading a second end of the length of suture through a lumen in an outer body of a bone anchor device and about an axially movable suture clamping member disposed in a distal portion of said lumen;

inserting said bone anchor device into a blind hole disposed in said portion of bone;

extending a deployable anchoring member disposed on an outer surface of said outer body outwardly to secure said bone anchor device in surrounding bone;

separating a driver portion of said bone anchor device from said outer body and withdrawing said driver portion from the patient's body; and

pulling the second end of the length of suture proximally, to secure the portion of soft tissue properly to the portion of bone and to anchor the suture in said outer body by moving the suture clamping member axially to a suture clamping position.

35. A bone anchor device for attaching connective tissue to bone, comprising:

a body having a longitudinal axis, a distal end, and a proximal end;

a surface on said body distal end which slopes inwardly toward said axis from a distal portion of said surface toward a proximal portion thereof; and

a suture anchoring member which is movable axially toward and away from said sloping surface, said suture anchoring member having a distal end surface and opposing axial surfaces, said distal end and opposing axial surfaces all comprising suture receiving surfaces for contacting suture material wrapped thereabout.

36. The bone anchor device as recited in claim 35, and further comprising a length of suture material wrapped about said suture anchoring member, said length of suture material being in physical contact with each of said distal end and opposing axial surfaces.

37. The bone anchor device as recited in claim 35, wherein one of said opposing axial surfaces is sloped so that a width of said suture anchoring member tapers from a distal end to a proximal end thereof.

38. The bone anchor device as recited in claim 37, wherein said sloped axial surface and said inwardly sloped body distal end surface together define a tapered distal lumen.

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