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<p>(54) Title: TISSUE ANCHORING SYSTEM AND METHOD</p>		
<p>(57) Abstract</p>		
<p>A tissue anchoring system (10) includes a tissue anchor (30) affixed to an end of a cable (20) and supported for insertion on a delivery device (70, 800), the manipulation of which permits placement of the anchor (30) on a far side of the tissue. A tensioning, crimping and cutting tool (50, 900, 955) designed for use along the cable's longitudinal axis, thus reducing the number of incisions required. A suture anchoring system (83) is also described for introducing a loop of suture (86) into a surgical site and anchoring it, for instance, across a tear in soft tissue.</p>		

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TISSUE ANCHORING SYSTEM AND METHOD

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BACKGROUND OF THE INVENTION

The present invention relates to surgical devices and methods and, more particularly, to devices and methods for the repair of bone and soft tissue.

10 It is a common requirement in orthopedic surgical procedures to anchor two or more elements together, such as pieces of a bone, two or more bones, or a combination of soft tissue and bone. This has been accomplished by a number of devices, such as bone bolts that penetrate two pieces of bone and use a nut to draw the segments together, bone screws and interconnecting plates, wires circling at least two pieces of bone, or sutures into the tissue.

15 Often such devices require a relatively large access opening through surrounding and/or covering tissue to implant the anchoring devices. The enlarged access site may increase patient pain and lengthen recovery time. Further, in some locations it is difficult and impractical to make large access points to reach the appropriate site because of surrounding joints and vessels. Even with devices that penetrate the tissue
20 in a substantially linear manner, i.e. lag bolts, the fracture must often be reduced before drilling and insertion of the bolt. Further, some of these devices may be difficult to use since it may be hard to reduce a fracture between two bone segments and maintain that reduction while the device is inserted. This is particularly true with small bone fragments where the use of threaded implants may tend to rotate one bone
25 segment with respect to another, thereby creating a misalignment between the fragments.

Cerclage systems provide an alternative to implants that must penetrate the bone to achieve fixation. Such devices have been taught by Miller et al. (U.S. Pat. No. 5,312,410) and Songer et al. (U.S. Pat. No. 5,536,270). These systems rely on
30 passing a cable around two segments of bone and then tensioning the cable to squeeze

the bone segments together. A significant drawback of these systems is that they require access around the entire bone.

Therefore, there remains a need for a convenient and effective system for securing two segments of tissue together. Such a system should preferably be operable
5 through a relatively small insertion opening or openings to securely hold two tissue segments.

SUMMARY OF THE INVENTION

An anchor system according to the present invention can comprise an elongated flexible member having a diameter, a proximal end, a distal end and a longitudinal axis; an anchor having a proximal end, a distal end, a central portion between the proximal end and the distal end and a longitudinal axis extending between the proximal end and the distal end, the anchor including a longitudinal slot extending longitudinally from the proximal end to the central portion, the slot having a width greater than the flexible member diameter, the flexible member distal end affixed adjacent the central portion. The anchor is moveable relative to the flexible member between a first position wherein the longitudinal axes of the flexible member and the anchor are generally parallel with a portion of the flexible member adjacent the distal end residing within the slot and a second position wherein the longitudinal axes of the flexible member and the anchor are generally perpendicular.

Another embodiment of an anchoring system according to the present invention, comprises an elongated flexible member having a proximal end, a distal end and a first diameter; and an anchor affixed to the distal end, the anchor moveable between an insertion configuration adapted for insertion through a tissue opening and an anchoring configuration adapted to inhibit passage through the tissue opening, the insertion configuration having a second diameter less than twice the first diameter, and the anchoring configuration having a third diameter greater than the second diameter.

The system further includes a delivery device having a distal end, the distal end adapted to releasably receive at least the anchor proximal end for releasably retaining the anchor in the first position for insertion through at least a portion of a section of tissue, the anchor releasable from the delivery device for anchoring the flexible member in the section of tissue. The delivery device includes a mechanism for releasably exerting a longitudinal force on the flexible member in a proximal direction, for retaining the anchor proximal end in the delivery device and thereby in the first position.

In one embodiment, the insertion device comprises an inner tube having a longitudinal bore extending from a proximal end to a distal end, the inner bore sized to permit passage of an elongated flexible member and to prevent passage of an anchor attached to an elongated flexible member; an outer tube having a longitudinal bore
5 extending from a proximal end to a distal end, the outer tube bore dimensioned to permit the inner tube to pass therethrough; and a mechanism for applying tension to an elongated flexible member, the means positioned adjacent the distal end of the inner tube.

The system of the present invention further contemplates a crimping tool which
10 can comprise an outer member having an inner passage and a distal end having an outer diameter. A crimping mechanism can be disposed within the inner passage adjacent the distal end. The crimping mechanism movable with respect to the outer member between a crimping position and an open position.

An alternative embodiment of the present invention includes a suture anchoring
15 system for attaching a first section of tissue to a second section of tissue via a unitary incision having a longitudinal axis. The anchoring system comprises a suture anchor connected to a suture material having a first end, a second end, a longitudinal axis, and a diameter. The suture anchor has a longitudinal axis generally extending from a proximal end to a distal end and a first cross-sectional dimension generally along the
20 longitudinal axis greater than a second cross-sectional dimension generally perpendicular to the longitudinal axis. The system further includes a mechanism for slidably affixing a central portion of the suture material to the suture anchor, the first end and the second end of the suture material retainable outside the incision. The suture anchor is pivotable relative to the suture material between a first position
25 wherein the longitudinal axes of the incision and the suture anchor are generally parallel and a second position wherein the longitudinal axes of the incision and the suture anchor are generally perpendicular.

The present invention also contemplates a bone opening protector having a first portion defining an opening therein to receive a cable. The first portion is adapted to

engage a surface surrounding a bone opening. The protector also includes an anchoring extension, connected to the first portion, adapted to extend into bone to inhibit movement of the first portion.

The invention further contemplates a method for joining two sections of tissue.

5 The method includes providing a first anchor, an elongated member attached to the first anchor, a second anchor slidable on the elongated member and having a deformable portion adapted to engage the elongated member, and a crimping tool having an outer member and an inner member movably disposed within the outer member. The first anchor is inserted into a first section of tissue. The second anchor

10 is threaded on the elongated member. Tension is applied on the elongated member to urge the first section of tissue toward a second section of tissue. The elongated member is threaded through the crimping device, and the inner member of the crimping device is moved with respect to the outer member thereby deforming the deformable portion of the second anchor and maintaining the tension applied to the

15 elongated member.

One object of the invention is to provide an element for anchoring tissue.

Another object is to provide a system for delivering the tissue anchoring element.

A further object is to provide such a system that also tightens and ligates the anchoring element.

20 An additional object of the present invention is to provide a crimping tool.

Still another object is to provide a method for delivering a tissue anchoring element to a surgical site.

Yet another object is to provide an element for anchoring suture material.

25 Yet a further object is to provide a system for delivering the suture anchoring element.

Yet an additional object is to provide a method for delivering a suture anchoring element to a surgical site.

Still a further object of the present invention is to provide a bone opening protector.

Other objects and advantages of the present invention will be apparent from the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a perspective side view of the cable/anchor element of the present invention in an anchor position, ready to anchor tissue.

5 FIG. 1B is a perspective side view of the cable/anchor element of the present invention in an insertion position, ready for delivery by the delivery device.

FIG. 2A is a top view of the anchor of the present invention.

FIG. 2B is a side view of the anchor of FIG. 2A.

FIG. 2C is a right side view of the anchor of FIG. 2B.

10 FIG. 3A is a top view of an alternative embodiment of the anchor of the present invention.

FIG. 3B is a side cross-sectional view of the anchor of FIG. 3A.

FIG. 4 is an exploded perspective view of an alternate embodiment of a delivery device according to the present invention.

15 FIG. 5A is a side partial cross-sectional view of the delivery device of FIG. 4.

FIG. 5B is a top partial cross-sectional view of the delivery device of FIG. 5A.

FIG. 6 is a side partial cross-sectional view of still a further embodiment of a delivery device according to the present invention.

20 FIG. 7A illustrates a suture anchor according to the present invention supported by a delivery device's distal end.

FIG. 7B illustrates the suture anchor of FIG. 7A being used in repairing a soft tissue tear.

FIG. 8 illustrates the insertion step of the method of use of the system in anchoring a ligament to a bone.

25 FIG. 9 is a front perspective view of an eyelet anchor according to the present invention mounted on a delivery device.

FIG. 10 is a front perspective view of the eyelet anchor of FIG. 9 being affixed to a bone with an attached cable extending through a bone opening protector and secured by a second anchor.

FIG. 11A is a front view of a bone opening protector according to the present invention.

FIG. 11B is a side cross-sectional view of the bone opening protector of FIG. 11A.

5 FIG. 12 (A-E) illustrates a method of use of a system according to the present invention in anchoring two sections of bone together. In FIG. 12A the delivery system with anchor and attached cable are inserted through the bone. In FIG. 12B the anchor is pivoted. In FIG. 12C a washer and a ferrule are threaded onto the proximal end of the cable, and in FIG. 12D the ferrule is crimped onto the cable, and the cable is cut,
10 leaving the bone fragments anchored as shown in FIG. 12E.

FIG. 13 is a perspective side view of a tensioning, crimping and cutting tool according to the present invention.

FIG. 14A is a perspective view from the distal end of the tensioning, crimping and cutting tool of FIG. 13.

15 FIG. 14B is a perspective cross-sectional view adjacent the distal end of the tensioning, crimping and cutting tool taken along B---B' of FIG. 14A.

FIG. 15A is a side cross-sectional view of an alternative cable tensioning mechanism for use with the tool of FIG. 13.

FIG. 15B is a cross-section of the mechanism of FIG. 15A taken along line B-B.

20 FIG. 16 is a side view of an alternative embodiment of a tensioning, crimping and cutting tool according to the present invention.

FIG. 17 is a partial cross-sectional view of the tool of FIG. 15.

FIG. 18 is a top view of the tool of FIG. 15.

25 FIG. 19 is a front partial cross-sectional view of still a further embodiment of a tensioning, crimping and cutting tool according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to Fig. 1A, a tissue anchoring system 10 according to the present invention includes a cable 20 having an anchor 30 affixed to a distal end 202. A delivery device 40 is also provided for aiding in inserting the cable 20 through tissue. The term "tissue" is used herein to include any manner of body part including without limitation, bone, cartilage, ligaments, tendons, and muscle.

Referring to FIG. 1A, cable 20 may be any elongated flexible member, the choice of material and size being dependent upon the particular application. For the purposes of illustration and without limitation, the flexible member is referred to and shown as a cable, although it is within the spirit of the invention that a flexible member could similarly be a filament, thread, suture, wire, substantially flat ribbon type member, or any other flexible member suitable for implantation in the body. Cable 20 may comprise such biocompatible materials as stainless steel, titanium, nitinol, plastic, bioresorbable material, composite material, or cobalt chrome alloy. The list of possible cable compositions is provided for the purpose of illustration and is not intended as limiting, it being understood that selection of a cable may depend on the intended application. In a preferred embodiment for use in bone fracture reductions, cable 20 is a flexible multistranded metallic cable such as stainless steel as is already known in the art. In a system for affixing two sections of soft tissue together, suture material or an equivalent threadlike material can be used instead of metallic cable. Thus, it is to be assumed herein that the word "cable" should be taken

to mean any flexible material that can be used in surgical applications for affixing two sections of tissue together, and no limitations are intended thereby.

Cable Anchor

5 Attached to the cable's distal end 202 is a generally cylindrical anchor 30 (FIGS. 2A and 2B) that has a closed distal end 302, an open proximal end 304, and a partial bore 301 extending from the proximal end 304 but not through to the distal end 302. The distal end 302 is rounded to limit damage to surrounding tissue and for ease of insertion through the tissue to be anchored. Anchor 30 includes a longitudinal axis
10 303 that extends from the proximal end 304 to the distal end 302. The anchor may be constructed of a material similar to the cable or the anchor may differ from the cable. In one combination, the cable is non-resorbable while the anchor is bioresorbable such that the cable may be removed after a healing period and the anchor may remain in the body.

15 The anchor 30 has a distal portion 317 having a first cross-sectional diameter 306, or width, larger than the diameter 206 of the cable 20. In a preferred embodiment, diameter 306 is less than twice diameter 206, thus providing a relatively small insertion diameter. This first cross-sectional diameter 306 generally coincides with a cylindrical diameter. In a preferred embodiment, diameter 306 substantially
20 equals the outer diameter of delivery device 40. A second cross-sectional dimension 308, or length, is significantly larger than the width 306. This length 308 generally coincides with the length of the anchor 30 from proximal end 304 to distal end 302.

The anchor 30 also has a proximal portion 310 opposite the distal portion 317, the proximal portion 310 having a width 320, the proximal portion width 320 smaller
25 than the distal portion width 306. The proximal portion 310 includes a taper 318 tapering toward the proximal end 304 and a thickness 322. It will be understood that upon engaging a surface with cable 20 proximally tensioned, taper 318 assists the anchor in flipping to an anchoring position and in sliding under adjacent tissue during

the flipping process. There is a shoulder 311 between the proximal portion 310 and the wider distal portion 317, for engaging the distal end of the delivery device 40.

In addition, the anchor 30 has a generally longitudinal slot 314 extending from the proximal end 304 into the distal portion 317. Slot 314 has a width 312 equal to or
5 greater than the cable diameter 206. The distal end 202 of the cable 20 is affixed, for example, via crimping, within the anchor bore 301 between the anchor's distal end 302 and the slot's distal end 315 (see FIG. 1A). In a preferred embodiment, a four point crimp is applied to anchor 302 to secure cable 20 within bore 301. However, it is contemplated that an alternative crimping procedure could be performed as well as
10 welding, brazing, adhesive, etc. Additionally, cable 20 may include a loop at its distal end for attachment through an aperture in the anchor. Any attachment means may be used provided the cable is secured to the anchor with sufficient strength for the intended application.

In a preferred embodiment, the anchor outer diameter 306 is less than twice the
15 cable diameter 206. This permits the cable and anchor combination to be inserted through a relatively small hole or incision. However, the length 308 is much greater than the anchor diameter 306 thereby providing a secure anchorage for the cable.

The anchor 30 is movable in relation to the cable 20 between two positions: a first position (FIG. 1B) wherein the anchor's longitudinal axis 303 is generally parallel
20 to the cable's longitudinal axis 207 and the cable's distal portion 201 resides within anchor slot 314, and a second position (FIG. 1A) wherein the anchor's longitudinal axis 303 is at an angle to the cable's longitudinal axis 206 and a part of the cable's distal portion 201 extends outside anchor slot 314. Anchor 30 includes a curved surface 324 adjacent slot 314 for the cable to bear against and limit abrasion when in
25 the second position. By the nature of the cable-anchor connection, the anchor 30 is biased to the second position. This biasing occurs because the first position is unstable. Such biasing may be induced by a pre-set curve in distal portion 201 of cable 20 positioned within slot 314 tending to rotate anchor 30 to the second position. In addition to biasing the anchor towards the second position, taper 318 on the

proximal end of anchor 30 urges rotation of the anchor to the second position when it contacts a surface.

FIGS. 3A and 3B show an alternative embodiment of the anchor according to the present invention. The anchor 350 includes a bead 352 having a bore 360 defined therein. The distal end 362 of cable 354 is received within the bore and bead 352 is affixed to the cable. Pivoting member 356 includes a longitudinal slot 370 in communication with a longitudinal bore 364 extending to distal end 358. The bore 364 and slot 370 are sized to slidably receive cable 354 therein. The distal end 358 defines a spherical cavity for receiving a portion of bead 352. Anchor 350 is pivotable from the first insertion position shown in FIGS. 3A and 3B to an anchoring position as shown in FIG. 1A.

Delivery Device

The present invention further contemplates a delivery device for insertion of a cable and anchor combination. Although the device is illustrated for use with the above described anchor, it is contemplated that the delivery device may be used or adapted for use with a variety of cable and anchor combinations. A first embodiment of the delivery device 40 (FIGS. 1 and 2) comprises a rigid metallic cylindrical member having a length 405 sufficient to penetrate a desired surgical site and a longitudinal bore 401 extending from a proximal end 404 to a distal end 402. The bore 401 is sufficiently large to permit the anchor's proximal portion 310 to fit thereinto but too small to permit the anchor's distal portion 317 to fit thereinto. Although a preferred embodiment of the delivery device has the distal portion of anchor 30 extending distally beyond the distal end of the delivery device, it is contemplated that anchor 30 could be entirely retained within the delivery device until it is deployed. In this embodiment (not shown), cable 20 could be fixed with respect to delivery device 40 to prevent accidental deployment of the anchor.

The cable/anchor 20/30 combination is inserted into tissue with the aid of the delivery device 40, which is used to provide mechanical stiffness to the cable 20. The

cable's proximal end 204 is passed through the delivery device 40 from the distal end 402 through the bore 401 to beyond the proximal end 404. The anchor's proximal portion 310 is seated in the delivery device bore 401 adjacent the distal end 402, and tension is maintained on the cable's proximal end 204 to retain the anchor 30 in the first position. Although a preferred embodiment of the device shows proximal end 304 held within bore 401, it is contemplated that proximal end 304 may include threads and delivery device 40 may similarly have cooperable threads on the distal end such that the device may be threadedly held on delivery device 40. Alternatively, there may be a frangible connection between proximal end 304 and the distal end of the delivery device, the frangible connection breakable to permit anchor 30 to move to the second position.

In a second embodiment of a delivery device according to the present invention, (FIGS. 4, 5A, and 5B), the impelling means comprises means for releasably maintaining a longitudinal force on cable 20 in a proximal direction, for retaining the anchor 30 in the first position.

In this embodiment, the delivery device 70 comprises a body 72, which has a handle portion 720 having a proximal end 722 and a recess 728 at the distal end 724. The recess 728, which extends from the top 721 to the bottom 723 of the delivery device body 72, is rounded at its proximal end 725. A longitudinal bore 726 extends from the proximal end 722 to the distal 724 end, the bore 726 being dimensioned to permit cable 20 to pass therethrough.

A pawl housing 75 is movably affixed to the delivery device body's distal end 724 via its rounded proximal side 752, which is dimensioned to slide longitudinally within the delivery device body's recess 728. The pawl housing 75 has a pawl cavity 758 that extends from the pawl housing's top 751 through a portion of the pawl housing. The pawl housing 75 additionally has a longitudinal bore 756 that extends from the proximal side 752 to the distal side 754 through the pawl cavity 758. The bore 756 is dimensioned to permit cable 20 to pass therethrough, and is adapted for communication with the delivery device body's bore 726 when the device is assembled

for use. A spring bore 757 extends from the distal side 754 into the pawl cavity 758 and is positioned above the longitudinal bore 756.

The delivery device 70 further comprises an inner tube 73 that is affixed at its proximal end 732 to the pawl housing's distal side 754. The inner tube 73 is generally cylindrical and has a longitudinal bore 736 that extends from the proximal end 732 to the distal end 734 and is dimensioned to permit the cable 20 to pass therethrough but is too small at the distal end 734 to permit the anchor's proximal portion 310 to enter. This bore 736 is in communication with the pawl housing bore 756.

Another element of the delivery device 70 is a nose assembly 74 that is in mechanical communication with the pawl housing 75. The proximal side 742 is affixed to the distal end 724 of the delivery device body 72 with two screws (not shown). These screws are inserted through first and second screw bores 782 that extend from the tapered distal side 744 of the nose assembly 74 through to the proximal side 742. First and second screw bores 782 are positioned to meet third and fourth screw bores 727 (Fig. 10B) that extend into the body 72 from the body's distal end 724.

The nose assembly 74 has a rounded recess 748 that extends from the top 741 to the bottom 743 and is shaped to receive the rounded distal side 754 of the pawl housing 75. The two recesses 748,728 together define an enclosed elongated hole 79 that has a width 792 dimensioned to closely and slidably engage the pawl housing 75 and a length 794 greater than the length 755 of the pawl housing 75, permitting the pawl housing 75 to slide longitudinally therein from a first position against the recess proximal end 725 to a second position within the nose assembly recess 748 (dotted line, FIG. 5B).

The nose assembly 74 further has a longitudinal bore 746 that extends from the proximal side 742 to the distal side 744, this bore 746 dimensioned and positioned to permit the inner tube 73 to pass therethrough and slide relatively thereto.

Affixed to the nose assembly's distal side 744 is the proximal end 762 of a generally cylindrical outer tube 76, which has a longitudinal bore 766 that extends

from the proximal end 762 to the distal end 764. Tube 76 may be removably affixed to the nose assembly to permit different sizes and configurations of outer tube 76 to be used with delivery device 70. Alternatively, outer tube 76 may include two components (not shown) with the distal section removably attached to the proximal section such that alternative configurations and dimensions of the distal section can be attached to accommodate various anchor configurations and cable diameters. Bore 766 is dimensioned to permit the inner tube 73 to pass therethrough and the anchor proximal portion 310 to slide thereinto. In a preferred embodiment for use with the anchor of Fig. 3, bore 766 is dimensioned to prevent the anchor's distal portion 317 from passing thereinto. This bore 766 is in communication with the nose assembly bore 746. The outer tube 76 preferably has sufficient rigidity to pass through the tissue to be anchored.

The delivery device 70 additionally comprises a pawl 77 that has a longitudinal bore 776 that extends from a proximal side 772 to a distal side 774 and is dimensioned to permit the cable 20 to pass therethrough. The pawl 77 is dimensioned so that its lower portion fits within the pawl cavity 758 and is pivotally attached adjacent a lower proximal corner 759 thereto, at a position lower than the longitudinal bore 756. The pawl 77 is pivotable within the pawl housing cavity 758 between a first position against the pawl housing cavity distal side 761 and a second position against the pawl housing cavity proximal side 763.

The pawl longitudinal bore 776 is positioned in communication with the pawl housing bore 756 when the pawl 77 is in the first position thereby allowing cable 20 to pass freely therethrough. When the pawl 77 is in the second position, however, the bore 776 is positioned sufficiently off-axis to pinch the cable 20 and thereby prevent a longitudinal movement of the cable 20. Thus, placing the pawl 77 in the second position also serves to restrain the cable 20 from longitudinal movement.

The pawl 77 also has a spring bore 777 that extends from the distal side 774 in a proximal direction, but does not extend all the way through to the proximal side 772. A pawl spring 78 is affixed to the nose assembly's proximal side 742 and extends

through the pawl housing spring bore 757 and into the pawl spring bore 777 to bear against the pawl 77. This spring 78 thus positioned biases the pawl 77 into the second position, which releasably exerts a longitudinal force on the cable 20 in a proximal direction and by the spring force exerted on pawl 77 biases inner tube 73 to the second
5 position.

The delivery device member 70 elements are relatively dimensioned so that a sliding of the inner tube 73 within the outer tube 76 may be accomplished in a longitudinal direction between two positions. In the first position, the inner tube distal end 734 is in spaced relation to the anchor proximal end 304 when the anchor proximal
10 portion 310 is within the outer tube bore 766. In the second position, the inner tube distal end 734 extends to the outer tube distal end 764, which pushes the anchor proximal portion 310 out of the outer tube 76. As has been seen above, this ejection of the anchor proximal portion 310 permits the anchor 30 to flip from its first position to its second position, wherein it can anchor the cable 20 from being pulled in a proximal
15 direction. Spring 78 biases the pawl housing 75 into the first position.

Referring now to Fig. 6, a further embodiment of an anchor delivery device according to the present invention is shown. Delivery device 800 has an outer tube 810 including a series of external threads 836 adjacent the distal end that threadedly engage corresponding internal threads 834 to hold outer tube 810 to nose cone 834.
20 Inner tube 812 is slidable within outer tube 810 by a mechanism within housing 814 and controlled between a retracted position with distal end 813 spaced from distal end 811 and an extended position with distal end 813 substantially adjacent distal end 811. Specifically, inner tube 812 abuttingly engages plunger 830 which is biased to a retracted position by spring 832.

25 As with previously described embodiments, outer tube 810 is sized to receive at least a portion of anchor 30 while inner tube 812 is sized to prevent passage of an anchor such as that shown in Fig. 2. Thus, when tension is applied to a cable (not shown) connected to an anchor (not shown) positioned adjacent distal end 813, the anchor forces inner tube 812 against plunger 830. The cable extends through aperture

824 in plunger 816. As shown in Fig. 6, plunger 816 is biased into a locked position by spring 822. In this position the cable is securely held in aperture 824 to prevent movement. Thus, tension applied to the cable may be maintained in the locked position. Movement of plunger 816 in the direction of arrow 850 into an unlocked
5 position releases the cable.

Movement of plunger 830 is controlled by plunger 818 through lever 826. Movement of plunger 818 in the direction of of arrow 860 moves lever 826 about pivot pin 828 to force the lever against plunger 830 to overcome spring 832 and move plunger 830 against inner tube 812. This movement moves the anchor out of outer
10 tube 810 and permits movement to an anchoring position. In a preferred embodiment, plunger 816 includes a slot (shown in dashed lines) 820 sized to receive a distal portion 819 of plunger 818. In the locked position, shown in Fig. 6, plunger 816 blocks movement of plunger 818 and thus prevents accidental deployment of the anchor. When plunger 816 is moved in the direction of arrow 850, slot 820 is aligned with
15 plunger 818 such that distal end 819 may move into slot 820.

Crimping Tool

The present invention further contemplates a crimping tool for attachment of an anchor to a cable, suture or other elongated member. It being understood that
20 alternative crimping devices may be used to secure anchors to the above described system and that the crimping tool described below may be used or adapted for use with a variety of cabling and suturing systems. The crimping tool of the present system is desirable for the ability to crimp along the axis of a cable at a relatively distant site through a small incision.

25 Referring now to FIG. 13, crimping tool 50 of the present invention provides several advantages, including a capability of crimping along the longitudinal axis of the cable 20 and of cutting and crimping in one motion. Alternatively, cutting and crimping could be performed separately or by two separate tools with similar function and operation to the single tool shown. The crimping tool 50 comprises an outer

elongated generally cylindrical member 52 having a bore 521 from a proximal end 524 to a distal end 522. A first crimping handle 528 is affixed to and extends radially outward from the outer member's proximal end 524.

5 The crimping tool 50 additionally comprises an inner elongated generally cylindrical member 54 having a bore 541 dimensioned to permit cable 20 to pass therethrough. The inner cylindrical member 54 is dimensioned to fit within the outer cylindrical member's bore 521 and to be rotatable relatively thereto about a common longitudinal axis. A second crimping handle 548 is affixed to and extends radially outward from the inner member's proximal end 544, which extends proximal of the
10 outer member's proximal end 524.

The handles 528 and 548 are rotatable between a first, open position wherein the respective distal ends 529 and 549 are spaced apart by approximately 90 degrees to a second, crimping position wherein the distal ends 529, 549 are generally opposed. Movement of handles 528 and 548 causes inner member 54 and outer member 52 to
15 rotate with respect to each other.

The crimping means of the crimping tool 50 is illustrated in FIG. 14A, which shows the distal end 502 of the tool 50. The distal end 522 of the outer member 52 has a roughly half-moon-shaped solid portion 525 that obscures approximately half of the bore 541. A protrusion 526 positioned in spaced relation to the longitudinal axis
20 extends radially toward the opening leading to the bore 541.

The distal end 542 of the inner member 54 has a solid portion 545 that obscures the remaining portion of the bore 541 except for a bi-level stepped opening thereinto. Along the distal most portion is a first roughly semicircular cutout 552 dimensioned, together with the outer member's solid portion 525, to closely surround a ferrule 94
25 therein when the handles 528, 548 are in the open position. The outer member's protrusion 526 is positioned adjacent the cutout 552 when the handles 528, 548 are in the open position.

Longitudinally adjacent to and proximal of the solid portion 545 is a second roughly semicircular cutout 554 dimensioned to permit the cable 20 to freely slide

therethrough but too small to permit the ferrule 94 to pass thereinto. When the handles 528, 548 are moved into the crimping position, the first cutout 552 is rotated toward the solid portion 525 and protrusion 526, and a ferrule 94 residing therein is crimped onto the cable 20.

5 It can be seen that the tool 50 provides the advantage of crimping the ferrule 94 along the longitudinal axis of the cable 20, rather than at a right angle thereto, such as is common in the art, which permits the procedure to be accomplished through a small unitary incision without removing surrounding tissue.

Although a preferred embodiment of the crimping tool of the present invention is
10 shown for use with cable 20 and ferrule 94, it is contemplated that the device may be sized for a specific application. Moreover, it is contemplated that inner member 54 and outer member 52 may have removable distal portions. A variety of sizes and configurations of distal portions may be interchangeable to fit a variety of flexible member and crimp configurations and types. It is contemplated that the cabling, crimp
15 and crimping distal portions may be packaged as a unit to ensure proper use by the end user with a standard crimping tool 50.

Means are also provided for applying longitudinal tension in a proximal direction relative to the tissue to be repaired. Many devices are known for providing tension to a cable, however, many require a series of pulleys or other change of direction to
20 accomplish the desired tensioning.

In one embodiment (FIG. 13) the inner cylindrical member 54 has an externally threaded proximal portion 550. A generally cylindrical tensioner 56 has a longitudinal bore 561 therethrough from a proximal end 564 to a distal end 562 that is adapted to be mateable with the inner cylindrical member's threaded proximal portion 550. A
25 handle 565 is affixed in radially protruding relation to the tensioner 56 exterior for facilitating a rotation thereof.

The cable-affixing means comprises a cleat 51 positioned adjacent to the tensioner's proximal end 564. The cleat 51, which is analogous to such devices known in the art, is adapted to clamp the cable's proximal end 204 to restrain the cable 20

from moving in a longitudinal direction relative to the inner cylindrical member 54 when in a tightened position. When in a releasing position, the cleat 51 permits the cable 20 to slide there past.

The cable-pulling means comprises the tensioner 56 and the inner cylindrical member proximal end 544, which are relatively movable via a screwing motion therebetween, which serves to change the tension on the cable 20. For example, in use the inner cylindrical member 54 and tensioner 56 are mated, and a cable 20 is inserted through the inner cylindrical member bore 541 and through the tensioner bore 561, and a proximal portion of the cable is clamped by tightening the cleat 51. Unscrewing the tensioner 56 relative to the inner cylindrical member 54 serves to pull the cable 20 in a proximal direction, increasing the tension thereon. The nut could be urged to prevent twisting of cable 20.

A cutting mechanism is also provided within the tool 50 whereby, when the handles 528, 548 are moved from the open to the crimping position, the cable 20 is cut at a location proximal to or through the ferrule 94. Referring to FIG. 14B, the cutting mechanism comprises two jaws 527, 547, respectively, affixed within the bores 521, 541 of the outer cylindrical member 52 and the inner cylindrical member 54, and are placed into opposition when the arms 528, 548 are closed, cutting the cable 20.

In a particular embodiment the ferrule 94 is typically formed of a metal, such as stainless steel, titanium, or cobalt-chrome alloy. However, in an alternate embodiment the ferrule 94 may be made of a resorbable or non-resorbable polymer material.

The tensioning mechanism shown in FIG. 13 may be replaced with the alternative tensioning mechanism of FIG. 15. The alternative tensioning mechanism 590 attaches to the distal end 584 of the inner member 54. Outer tube 575 is positioned about distal end 584 with spring 577 positioned between the distal end and internal shoulder 585. Inner member 54 includes at least one slot 582 adapted to receive a retaining pin 581 to slidably connect the tensioning mechanism 590. Also disposed on the outer surface of distal end 584 are a series of grooves 583 or other markings to indicate the position of the outer tube 575 with respect to inner member

54. Inner tube 586 includes a cleat 574 pivotally mounted thereon by pivot pin 576. Cleat 574 pivots between a clamping position clamping a cable positioned in channel 580 and a non-clamping position, and extends through slot 578 in the outer tube. Inner tube 586 further includes an externally threaded portion 579. A handle 570
5 having an internally threaded bore is pivotally mounted on outer tube 575 and is held in place by retaining spring 572. Rotation of handle 571 urges outer tube 575 against spring 577, thereby tensioning a cable (not shown) disposed within channel 580. It will be understood that the tension applied to a cable may be estimated by calibrating the spring force applied as outer tube 575 is adjacent each index marking 583.

10 A further embodiment of a tensioning, crimping and cutting tool according to the present invention is disclosed in FIG. 15. The crimping tool 900 includes an outer tube 902 attached to a nose 904. This nose is attached to a front housing 922 which is interconnected with rear housing 924. As shown in the partial cross-section view of FIG. 16, inner tube 901 is disposed within outer tube 902 and includes a bore 917 for
15 receiving cable 908. The position of cable 908 within inner tube 901 is maintained with respect to movement toward the distal end 905 by trigger pawl 906. Trigger pawl 906 is pivotally connected to front housing 922 by pivot pin 939. As shown in FIG. 16, spring 938 biases trigger pawl 906 into the cable retaining position with engaging end 907 engaging cable 908 adjacent the proximal end of inner tube 901. Trigger pawl
20 906 may be moved to a disengaged position by overcoming the force of spring 938 and moving trigger pawl 906 within slot 940 such that engaging end 907 disengages cable 908.

Rear housing 924 includes a cable tensioner assembly 926 for applying tension to cable 908 towards the proximal end 913. Tensioning assembly 926 is operable
25 between a tensioning position and the released position shown in FIG. 16, by movement of handle 910 with respect to handle 912. Handle 910 is pivotally attached to rear housing 924 by pivot pin 918. A linking bar 915 is joined to handle 910 by pivot pin 916 and interconnects the handle with tensioning assembly 926 through

pivot pin 924. Movement of handle 910 towards handle 912, fixedly connected to rear housing 924, causes tensioning assembly 926 to move proximally.

Referring now to FIG. 16, tensioning assembly 926 includes a pair of pawls that grip cable 908 when tensioning assembly 926 is displaced proximally and that allow
5 passage of the cable when tensioning assembly is moving distally. Pawl 941 is pivotally connected to the tensioning assembly 926 by pivot pin 942. The pawl is urged into a locking position by spring 943. The pawl opposing pawl 941 is identical. Tensioning assembly 926 further includes a set of belleville springs 944 that may be adjusted by movement of threaded shaft 945 to increase or decrease the pressure
10 applied to the cable when the gripping teeth of the pawls are disengaged with the wire as the tensioning assembly is drawn forward. Springs 944 maintain the position of pin 924 within slot 932. Spring 914 disposed between handles 910 and 912 in openings 928 and 930 respectively, urges handle 910 forward. This movement also urges tensioning assembly pawls against front wall 937 which in turn urges the pawls into a
15 disengaged position shown in FIG. 16.

In operation, tensioning assembly 926 is moved to apply proximal tension to cable 908. As previously described, trigger pawl 906 permits proximal movement of the cable. Once proximal tension is released by the tensioning assembly, trigger pawl 906 engages cable 908 to prevent distal movement and thereby maintain the tension
20 while the pawls of the tensioning assembly are disengaged to permit the assembly to return to a forward position. This process may be continued until the desired amount of cable tension has been achieved.

Cable tensioner, crimper and cutter 900 also includes crimping and cutting handles 934 and 936. Referring to FIG. 17, handle 936 is fixedly attached to rear
25 housing 924 while handle 924 is connected by pivot pin 946 to front housing 922. The handles are biased into a separated position by spring 949 mounted on projection 950 of handle 934 and received within opening 951 in the rear housing. Handle 934 includes a slot 948 for receiving an inner tube extension 947 (FIG. 16). Linear movement of handle 934 toward handle 936 is translated into rotation of inner tube 901

by the engagement of inner tube extension 947 in slot 948. The distal end 905 of inner and outer tubes 901 and 902 are configured as shown in FIGS. 14A and 14B such that rotation of the inner tube in relation to the outer tube results in crimping a ferrule and cutting a cable.

5 Still a further embodiment of a tensioning, crimping and cutting tool according to the present invention relies on longitudinal movement of the components rather than rotational movement. Referring to FIG. 18, a tensioning, crimping and cutting tool 955 includes an inner member 959, an outer member 958 and a cable retaining assembly 975. Cable retaining assembly 975 is preferably received within inner
10 member 959 and includes a cleat 977 pivotally mounted to be moveable between a disengaged position and an engaged position securely holding cable 956. Retaining assembly 975 further includes a threaded section 976. Inner member 959 includes a flange 972. An internally threaded nut 973 is disposed about flange 972 and engages threaded section 976. Nut 973 is rotatably maintained in position by mounting pins
15 974.

Inner member 959 includes an externally threaded section 971 adjacent flange 972 and at an opposite end, a pair of spaced branches 978 and 979, each having a flared section 980 and 981, respectively. Branch 978 includes a cutting blade 962 and a crimping projection 964 while branch 979 includes a corresponding cutting anvil 963
20 and crimping depression 965. It is contemplated that inner member 959 may include more than two branches and may have multiple projections disposed adjacent distal end 967.

Inner member 959 is disposed within a preferably tubular outer member 958. Outer member 958 includes an inclined surface 960 adjacent distal end 966. Opposite
25 the inclined surfaces is a flange 968. Nut 969 is disposed about flange 968 and pivotally retained there by mounting pins 970.

In operation, cable 956, having a distal end anchored in a tissue section (not shown), is threaded through inner member 959 and cable retaining assembly 975. A ferrule 957, slidable along cable 956, is positioned within branches 978 and 979

adjacent crimping projection 964 and crimping depression 965. Cleat 977 is rotated to engage cable 956. Nut 973 is rotated about external threads 976 to move the cable retaining assembly with respect to the inner member, which bears against a section of tissue (not shown), and thereby applies tension to cable 956. Once the desired amount
5 of tension is applied, nut 969 is rotated with respect to threads 971 to urge outer member 958 downward toward ferrule 957. As outer member 958 advances, branches 978 and 979 are urged toward each other by acting against inclined surface 960. Thus, cutting blade 962 and cutting anvil 963 cooperate to cut cable 956 while crimping projection 964 and crimping depression 965 crimp ferrule 957 to securely engage cable
10 956.

While threaded engagements have been illustrated for applying cable tension and for moving the outer member, it is contemplated that other mechanisms known to those skilled in the art may be applied to the device described herein. Moreover, nut 973 may be engaged by a torque wrench to provide the user with an estimate of the tension
15 applied to cable 956.

Variations of the present longitudinal crimping tool are within the spirit of the present invention, such tools utilizing movement preferably occurring within the outer tube such that the opening in the tissue is not significantly enlarged beyond the diameter of the outer tube as a result of the crimping process.

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Alternative Anchor Embodiments

An alternate form of a tissue anchor comprises an eyelet anchor 32, the structure and function of which are illustrated in FIGS. 9 and 10. The eyelet anchor 32 is affixed at a proximal end 324 to the cable distal end 202, and the eyelet anchor 32 has
25 an eyelet hole 321 at a distal end 322 for receiving an anchoring screw 79. The eyelet anchor 32 also has a cable bore 323 adjacent the proximal end 324 adapted to permit cable 20 to pass therethrough and to be crimped therein.

The delivery devices of FIGS. 1, 4 or 6 are also usable with the eyelet anchor 32 described above. In this case, the eyelet anchor 32 has a central portion 325 that is

dimensioned larger than the distal portion of the delivery device member cylindrical portion bore 401 or 766. The eyelet anchor 32 further has a proximal portion 326 that is dimensioned to reside within the distal portion of the delivery device member cylindrical portion bore 401 or 766. Thus, as above, the eyelet anchor proximal portion 326 is retainable within the bore 401 or 766 when the cable 20 to which it is attached is under longitudinal tension in a proximal direction. Alternatively, it is contemplated that eyelet anchor 32 is formed of a deformable material which tends to resume its original shape. It will be understood that an eyelet anchor 32 formed of such a material may be deformed to be received within outer tube 76, such that inner tube 73 will force eyelet anchor 32 out of outer tube 76. The anchor may then resume its larger original dimensions.

The present invention also contemplates the use of a bone opening protector 150 as shown in FIGS. 10 and 11. Opening protector includes a surface engaging portion 152 adapted to engage the exterior surface of the bone adjacent the opening to prevent advancement into the bone. Opening protector 150 also includes a cylindrical portion 151 that extends into the bone opening and provides a lumen for passage of cable 20. Preferably, the exterior surface of the cylindrical portion 151 includes a roughened surface to engage the surrounding bone to prevent dislodgement. While it is contemplated that the roughened surface may be threads such that the protector may be screwed into the opening, preferably, the surface includes a series of circular projections 153 having an inclined leading edge for ease of insertion and a cavity adjacent the trailing edge to inhibit removal. Also, it is contemplated that cylindrical portion 151 could be substantially eliminated and anchoring elements could extend through, or be a part of, surface engaging portion 152.

It is intended that the surface engaging position 152 lie substantially flush with the surface of the bone. Thus, for openings created perpendicular to the surface of the bone, cylindrical portion 151 and surface engaging portion 152 will be perpendicular. In a preferred embodiment, the corner 154 between the cylindrical portion 151 and surface engagement portion 152 is rounded. This is intended to limit the abrasion and

wear on the anchoring member as it slides across the corner. The protector is particularly useful in applications where the cable or suture will be pulled against the corner of the bone opening. As shown in FIG. 10, eyelet anchor 32 secured by bone screw 79 and cable 20 extends through opening protector 150. Tension is applied to cable 20 and is maintained by crimped ferrule 94 bearing against washer 14. Without opening protector 150, cable 20 would have a tendency to cut through the edge of the bone opening causing damage to surrounding tissue and reducing the tension on cable 20.

10 Tissue Anchoring Method

The method for utilizing the above-described system comprises the following steps, as shown in FIGS. 12A-E, for anchoring two sections of bone together. It is obvious to one skilled in the art that the same technique is applicable to a method for anchoring two different bones together, for anchoring other types of tissue together, or for anchoring another type of tissue to bone [see, e.g., FIG. 8, illustrating the anchoring of a ligament 92 (here, a medial collateral ligament) to a bone 90 (here, the tibia)]. Therefore, no limitations are intended by the presentation of this exemplary embodiment.

Two holes 115 and 116 are drilled through the bone sections 90 and 91, the cable/anchor/delivery device 20/30/40 combination is inserted through the holes 115, 116 until the anchor 30 is completely through the distal hole 115 (FIG. 12A). Although drilled holes are illustrated, it is contemplated that anchor 30 may include a sharp tip such that the anchor may be pushed through unprepared bone or other tissue. The cable tension is released, which permits the anchor 30 to rotate and be restrained on the distal side of the distal hole 115 (FIG. 12B). In addition to the anchor disclosed herein, it is contemplated that the insertion device could also be used with an anchor designed to be embedded within the bone, i.e. the anchor would not exit the distal cortical bone and instead would be deployed in the cancellous bone.

The delivery device 30 is removed from the cable 20, and a washer 93 and ferrule 94 are threaded onto the cable to a position adjacent the proximal hole 912 (FIG. 12C). The cable 20 is then inserted into the crimping tool 50 sufficiently far that the ferrule 94 is positioned within the first cutout 552 adjacent the second cutout 554. The cable 20 is clamped with the cleat 51 and pulled to a desired tension (FIG. 5 12D). Tensioner 56 may be unscrewed with respect to inner cylindrical member 54 while cleat 51 securely holds cable 20, thereby pulling the bone fragments together and applying measurable compression between the fragments. The crimping tool 50 is closed to crimp the ferrule 94 onto the cable 20 and also to cut the cable 20 (FIG. 10 12E). Alternatively, the crimp may be made first, and then a separate cable cutting tool (not shown) can be used for thicker types of cable.

If desired, an eyelet anchor 60, such as shown in FIGS. 9, may also be used. In this case, the eyelet anchor 60 is threaded onto the cable 20 via cable bore 602, which is at the proximal end 601, before the ferrule 94 is threaded on, and, after the crimp is made, a screw 61 is inserted through the screw hole 604, which forms the eyelet, and 15 into the bone 90 to attach the eyelet anchor 60 (FIG. 9).

The method described above may be performed utilizing any combination of the delivery devices and tensioning, crimping and cutting tools described herein.

20 Suture Material Anchoring System and Method

A suture material anchor system 83, as shown in FIG. 7A for repairing soft tissue, comprises a suture anchor 84 for use with a delivery device, such as either of the delivery devices 40, 70 or 800 as described above.

The suture anchor 84 is an elongated member having a longitudinal axis 25 extending from a proximal end 844 to a distal end 842. The suture anchor 84 also has a pair 845, 846 of cross-bores extending from a first side 847 through to a second, opposed side 848. Cross-bores 845, 846 are dimensioned to permit suture material 86 to pass therethrough. In use suture material 86 is threaded through bore 845 from the

first side 847 to the second side 848 and then through the other bore 846 from the second side 848 to the first side 847.

The suture anchor 84 has a narrowed proximal portion 843 at the proximal end 844, proximal of the cross-bores 845, 846, that is dimensioned to be insertable into and supported by the impeller bore 401 or the outer tube bore 766, as previously
5 described for the pivotable anchor 30. The central portion 848 is dimensioned too large to be insertable into the impeller bore 401 or the outer tube bore 766. The suture anchor 84 has a first cross-sectional dimension generally along the longitudinal axis greater than a second cross-sectional dimension generally perpendicular to the
10 longitudinal axis, as before for the pivotable anchor 30.

The suture anchor 84 is manipulable and pivotable by pulling the ends of the suture material, which can accomplish a bracing of the suture anchor 84 against the distal side of the tissue 85 to be repaired. In use, the ends of the suture material 86 are retainable outside the incision, or, alternatively, one end 862 can be retained outside
15 the introducing incision 88, and a second end 864 can be pulled through a second incision 89, as shown in FIG. 7B.

A method of using the system 83 to repair a soft tissue tear such as a meniscal tear T comprises the steps of piercing the tissue 85 across the tear T, inserting the delivery device/suture material/anchor system into the pierced hole 834, manipulating
20 the delivery device so that the anchor 84 emerges from the far end of the tear T and rotates so that the anchor 84 has its length generally perpendicular to the tear T and thus will not slip out. The surgeon can then manipulate the suture material 86 and tie it off as desired to secure the repair. Alternatively, a second incision 835 may be made at an adjacent site across the tear T, as shown in FIG. 7B, and the two pieces of
25 suture material then joined together to strengthen the repair. The anchor 84 can either be inserted into the body of the tissue 84, as shown in FIG. 7B, or it can be impelled completely through the tissue (not shown), depending upon the application, to anchor the suture material 86.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the
5 spirit of the invention are desired to be protected.

What is claimed is:

1. An anchor system, comprising:

an elongated flexible member having a diameter, a proximal end, a distal end and
5 a longitudinal axis; and

an anchor having a proximal end, a distal end, a central portion between said
proximal end and said distal end and a longitudinal axis extending between said
proximal end and said distal end, said anchor including a longitudinal slot extending
longitudinally from said proximal end to said central portion, the slot having a width
10 greater than the flexible member diameter, said flexible member distal end
interconnected with said anchor;

said anchor moveable relative to said flexible member between a first position
wherein the longitudinal axes of said flexible member and said anchor are generally
parallel with a portion of the flexible member adjacent the distal end residing within
15 said slot and a second position wherein the longitudinal axes of said flexible member
and said anchor are generally perpendicular.

2. The anchor system of claim 1, wherein said anchor includes a partial
longitudinal bore extending between a closed distal end and an open proximal end, said
20 bore in communication with said slot; and

said flexible member distal end affixed within said bore.

3. The anchor system of claim 2, wherein said flexible member is affixed in
said bore by adhesive.

25

4. The anchor system of claim 2, wherein said flexible member is affixed in
said bore by crimping said anchor adjacent said bore.

5 5. The anchor system of claim 1, wherein the proximal end of said anchor is angled with respect to said longitudinal axis, the proximal end opposite said slot extending more proximally than the proximal end adjacent said slot, whereby engagement of said angled proximal end with a surface tends to rotate said anchor toward said second position.

10 6. The anchor system of claim 1, wherein said flexible member is fixedly attached to said anchor and said flexible member deforms to permit movement between said first position and said second position.

15 7. The anchor system of claim 1, wherein said anchor is biased toward said second position.

20 8. The anchor system of claim 7, wherein said flexible member is a cable and said cable is bent adjacent said anchor to create said bias towards said second position.

25 9. The anchor system of claim 1, wherein said anchor distal end is larger than said anchor proximal end.

30 10. The anchor system of claim 9, wherein said smaller proximal end is adapted for releasable engagement with a delivery device.

35 11. The anchor system of claim 10, further including a delivery device sufficiently rigid to advance said anchor through tissue, said delivery device having a distal end adapted to releasably engage said proximal end of said anchor, the distal end of said anchor extending distally beyond the distal end of said delivery device.

12. The anchor system of claim 1, wherein said flexible member is formed of bioresorbable material.

13. The anchor system of claim 1, wherein said anchor is formed of
5 bioresorbable material.

14. The anchor system of claim 1, wherein said flexible member and said anchor are formed of bioresorbable material.

10 15. The anchor system of claim 1, wherein said anchor is substantially cylindrical and has a second diameter, said second diameter being less than twice the diameter of said flexible member.

15 16. The anchor system of claim 1, further including a second anchoring element adapted to fixedly engage said flexible member adjacent said proximal end to maintain said flexible member in tension across a tissue section when said anchor is in said second position.

17. The anchoring system of claim 16, wherein said second anchor includes a
20 deformable portion, said deformable portion deformable to fixedly engage said flexible member.

18. The anchoring system of claim 17, wherein said second anchor comprises a washer and a ferrule.

25

19. The anchoring system of claim 16, wherein said second anchor comprises an eyelet anchor having a first aperture for receiving said flexible member and second aperture for receiving a fixation member adapted to extend into adjacent bone.

20. The anchoring system of claim 19, further including a deformable ferrule for fixedly engaging said flexible member, said ferrule sized larger than said eyelet first aperture to inhibit movement of said flexible member through said eyelet first aperture in at least one direction.

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21. An anchoring system, comprising:

an elongated flexible member having a proximal end, a distal end and a first diameter; and

an anchor affixed to said distal end, said anchor moveable between an insertion configuration adapted for insertion through a tissue opening and an anchoring configuration adapted to inhibit passage through the tissue opening, said insertion configuration having a second diameter less than twice said first diameter, and said anchoring configuration having a third diameter greater than said second diameter.

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22. The anchoring system of claim 21, wherein said anchor is biased toward said anchoring configuration.

15

23. The anchoring system of claim 21, wherein said anchor is substantially rigid.

20

24. The anchoring system of claim 21, wherein said third diameter is at least twice said second diameter.

25. The anchoring system of claim 21, wherein said anchor includes a proximal portion defining a channel, said channel having a diameter at least as large as said first diameter, a portion of said flexible member adjacent said distal end received within said channel in said insertion configuration.

25

26. The anchoring system of claim 21, wherein said tissue is bone.

27. An anchoring system, comprising:

an elongated flexible member having a distal end, a proximal end and a longitudinal axis;

5 an anchor affixed to said distal end, said anchor having reduced size insertion configuration and an expanded size anchoring configuration;

said anchor moveable relative to said flexible member between a first position wherein the longitudinal axes of said flexible member and said anchor are generally parallel and a second position wherein the longitudinal axes of said flexible member
10 and said anchor are generally perpendicular;

a delivery device having a distal end, said distal end adapted to releasably receive at least said anchor proximal end for releasably retaining the anchor in said first position for insertion through at least a portion of a section of tissue, said anchor releasable from said delivery device for anchoring said flexible member in said section
15 of tissue; and

a means for releasably exerting a longitudinal force on said flexible member in a proximal direction, for retaining the anchor proximal end in said delivery device and thereby in said first position.

20 28. The anchoring system of claim 27, wherein said flexible member has a diameter and said anchor is a generally cylindrical element having:

a longitudinal slot extending longitudinally from the proximal end to a central portion, the slot having a width greater than said flexible member diameter; and

the flexible member distal end affixed adjacent said central portion;

25 wherein in the first position a portion of said distal end of said flexible member is positioned within said slot.

29. The anchoring system recited in claim 28, wherein:

said delivery device comprises a member having an elongated generally cylindrical distal portion having a longitudinal bore extending through at least a portion thereof from a proximal end to a distal end, the bore dimensioned to permit the cable to pass therethrough, the cylindrical distal portion having sufficient rigidity to pass through the tissue;

the anchor central portion is dimensioned larger than a distal portion of the delivery device member cylindrical portion bore; and

said anchor proximal end is dimensioned to slide within the distal portion of the delivery device member cylindrical portion bore, the anchor proximal end retainable within said cylindrical portion bore.

30. The anchoring system of claim 29, wherein said anchor distal end is rounded and extends distally beyond the distal end of said delivery device.

31. The anchoring system of claim 29, wherein the delivery device member comprises:

a generally cylindrical inner tube having a longitudinal bore extending from a proximal end to a distal end, the inner tube bore dimensioned to permit the cable to pass therethrough and further dimensioned smaller than the anchor proximal portion;

a generally cylindrical outer tube having a longitudinal bore extending from a proximal end to a distal end, the outer tube bore dimensioned to permit the inner tube to pass therethrough and the anchor proximal portion to pass thereinto but dimensioned too small to permit the anchor central portion to pass thereinto; and

means for sliding the inner tube within the outer tube in a longitudinal direction between a first position wherein the inner tube distal end is in spaced relation to the anchor proximal end when the anchor proximal portion is within the outer tube bore and a second position wherein the inner tube distal end extends to at least the outer tube distal end, thereby pushing the anchor proximal portion out of the outer tube.

32. The anchoring system recited in claim 31, wherein the delivery device member further comprises:

a pawl housing movably affixable to a distal end of the delivery device body affixed to the proximal end of the inner tube, and having:

5 a pawl cavity extending from a top of the pawl housing;

a bore from a proximal side to a distal side through the pawl cavity dimensioned to permit the cable to pass therethrough, the inner tube bore in communication with the pawl housing bore; and

a spring bore extending from the distal side into the pawl cavity;

10 a nose assembly in mechanical communication with the pawl housing and having a bore from a proximal side to a distal side, the nose assembly bore dimensioned and positioned to permit the inner tube to pass therethrough, the nose assembly distal side affixed to the outer tube proximal end, the outer tube bore in communication with the nose assembly bore;

15 a pawl having:

a lower portion dimensioned to fit within the pawl cavity and pivotably affixed thereto, the pawl pivotable between a first position against the pawl housing distal side and a second position against the pawl housing proximal side, a movement of the pawl to the first position causing the pawl housing to move in a distal direction relative to the nose assembly, thereby causing the inner tube to move in a distal direction relative to the outer tube;

20 a longitudinal bore extending from a proximal side to a distal side, the pawl longitudinal bore dimensioned to permit the cable to pass therethrough and positioned in communication with the pawl housing bore when the pawl is in the first position and positioned sufficiently off-axis when the pawl is in the second disposition to prevent a longitudinal movement of the cable; and

a spring bore extending from a distal side into a central portion;

a pawl spring affixed to the proximal side of the nose assembly and extending through the pawl housing spring bore and into the pawl spring bore to bear against the

pawl, thereby biasing the pawl into the second position, for releasably exerting a longitudinal force on the cable in a proximal direction, thereby biasing the inner tube to the second position, and for preventing a longitudinal movement of the cable.

- 5 33. A system for joining tissue segments, comprising:
 an elongated flexible member having a distal portion and a proximal portion;
 a first anchor fixedly attached to said distal portion, said anchor adapted to
engage a first tissue section;
 a second anchor having an aperture for slidably receiving said elongated flexible
10 member, said second anchor including a deformable portion adjacent said aperture,
said deformable portion deformable to securely engage said elongated flexible member,
said second anchor adapted to engage a second tissue section; and
 a crimping tool having:
 an outer member with an inner passage and a distal end; and
15 a crimping mechanism disposed within said inner passage adjacent said distal
end, said crimping mechanism having an inner chamber sized to receive said
deformable portion, whereby actuation of said crimping mechanism deforms said
deformable portion to securely engage said flexible member.

- 20 34. The anchoring system recited in claim 33, wherein said flexible member
is a cable and said second anchor includes a washer and a ferrule slidable over the
cable.

35. The anchoring system of claim 34, wherein said crimping mechanism
25 comprises:
 an inner cylindrical member having a bore dimensioned to permit the cable to
slide therethrough;

said outer cylindrical member positioned in surrounding relation to the inner cylindrical member and rotatable relative thereto about a common longitudinal axis between a holding position and a crimping position; and

the inner and outer cylindrical member have cooperating distal ends adapted to
5 hold a ferrule in the holding position and to crimp the ferrule in the crimping position.

36. The anchoring system of claim 35, wherein:

the inner cylindrical member distal end has a depression therein dimensioned to admit the ferrule; and

10 the outer cylindrical member distal end has a protrusion directed toward the depression and positioned to apply pressure to the ferrule when in the crimping position.

37. The anchoring system recited in claim 36, wherein the crimping
15 mechanism further includes a cutter for cutting the cable proximal of the ferrule.

38. The anchoring system recited in claim 36, wherein said cutter includes cooperating cutting surfaces affixed to the inner and the outer members proximal of the depression and the protrusion.

20

39. The anchoring system of claim 35, further comprising:

a first handle affixed adjacent a proximal end of the inner tube; and

a second handle affixed adjacent a proximal end of the outer tube member;

the first handle and the second handle for facilitating a relative rotation of the
25 inner cylindrical member and the outer cylindrical member.

40. The anchoring system of claim 35, further including means for applying longitudinal tension to the cable in a proximal direction.

41. The anchoring system of claim 40, wherein the tension applying means comprises:

means for affixing a proximal section of cable thereto; and

means for pulling the affixed cable in a proximal direction relative to the tissue.

5

42. The anchoring system recited in claim 40, wherein:

the inner cylindrical member has an externally threaded proximal portion; and

the tension applying means comprises a generally cylindrical tensioner member having a longitudinal bore from a distal end to a proximal end dimensioned to permit the cable to pass therethrough, the bore having a threaded distal portion adapted to be screwable relative to the inner cylindrical member threaded proximal portion.

10

43. The anchoring system recited in claim 42, wherein the affixing means comprises a clamp positioned in cable-retaining relation to the tensioner member bore, said clamp movable between a releasing position wherein the cable is slidable there past and a tightened position wherein the cable is retained there against.

15

44. The anchoring system recited in claim 42, wherein the tension-applying means further comprises handle means affixed to an exterior of the tensioner member for facilitating a screwing motion thereof.

20

45. An anchoring system, comprising:

an elongated flexible member having a distal end, a proximal end, a longitudinal axis, and a diameter;

25

an eyelet anchor affixed at a proximal end to the cable distal end, the eyelet anchor having an eyelet hole at a distal end for receiving an anchoring screw; and

means for impelling the cable-eyelet anchor combination through tissue, the impelling means having means for receiving a proximal portion of the anchor for releasably retaining the anchor for insertion through the first section of tissue and then

through the second section of tissue, the eyelet anchor for anchoring the cable at a distal side of the second section of tissue with an anchoring screw.

46. The anchoring system recited in claim 45, wherein the eyelet anchor has a
5 cable bore adjacent the proximal end adapted to permit said cable to pass therethrough and to be crimped therein.

47. The anchoring system recited in claim 46, wherein:
the impelling means comprises a delivery device member having an elongated
10 generally cylindrical distal portion having a longitudinal bore extending from a proximal end to a distal end, the bore dimensioned to permit the cable to pass therethrough, the cylindrical portion having sufficient rigidity to pass through the tissue to be anchored;
the eyelet anchor has a central portion dimensioned larger than a distal portion of
15 the delivery device member cylindrical portion bore; and
eyelet anchor has a proximal portion dimensioned to reside within the distal portion of the delivery device member cylindrical portion bore, the eyelet anchor proximal portion retainable therein when the cable is under longitudinal tension in a proximal direction.

20

48. The anchoring system recited in claim 47, wherein the impelling means comprises means for releasably exerting a longitudinal force on the cable in a proximal direction, for retaining the eyelet anchor within the distal portion of the delivery device member cylindrical portion bore.

25

49. The anchoring system recited in claim 47, wherein said eyelet of anchor is formed of a deformable material.

50. An insertion device for inserting an anchor and an elongated flexible member combination, comprising:

an inner tube having a longitudinal bore extending from a proximal end to a distal end, the inner bore sized to permit passage of an elongated flexible member and to prevent passage of an anchor attached to an elongated flexible member;

an outer tube having a longitudinal bore extending from a proximal end to a distal end, the outer tube bore dimensioned to permit the inner tube to pass therethrough; and

a means for applying tension to an elongated flexible member, said means positioned adjacent the distal end of said inner tube.

51. The anchor insertion device of claim 50, further including a pawl housing affixed to the proximal end of the inner and having:

a pawl cavity extending from a top of the pawl housing;

a bore from a proximal side to a distal side through the pawl cavity dimensioned to permit the cable to pass therethrough, the inner tube bore in communication with the pawl housing bore; and

a spring bore extending from the distal side into the pawl cavity;

a nose assembly in mechanical communication with the pawl housing and having a bore from a proximal side to a distal side, the nose assembly bore dimensioned and positioned to permit the inner tube to pass therethrough, the nose assembly distal side affixed to the outer tube proximal end, the outer tube bore in communication with the nose assembly bore;

a pawl having:

a lower portion dimensioned to fit within the pawl cavity and pivotably affixed thereto, the pawl pivotable between a first position against the pawl housing distal side and a second position against the pawl housing proximal side, a

movement of the pawl to the first position causing the pawl housing to move in a distal direction relative to the nose assembly, thereby causing the inner tube to move in a distal direction relative to the outer tube;

a longitudinal bore extending from a proximal side to a distal side, the pawl
5 longitudinal bore dimensioned to permit the cable to pass therethrough and positioned in communication with the pawl housing bore when the pawl is in the first position and positioned sufficiently off-axis when the pawl is in the second position to prevent a longitudinal movement of the cable; and

a spring bore extending from a distal side into a central portion;

10 a pawl spring affixed to the proximal side of the nose assembly and extending through the pawl housing spring bore and into the pawl spring bore to bear against the pawl, thereby biasing the pawl into the second position, for releasably exerting a longitudinal force on the cable in a proximal direction, thereby biasing the inner tube to the second position, and for preventing a longitudinal movement of the cable.

15

52. A crimping tool, comprising:

an outer member having an inner passage and a distal end having an outer diameter; and

a crimping mechanism disposed within said inner passage adjacent said distal end
20 said crimping mechanism movable with respect to said outer member between a crimping position and an open position.

53. The crimping tool of claim 52, wherein said crimping mechanism
comprises an inner member having a bore dimensioned to permit an elongated member
25 to slide therethrough, said outer member positioned in surrounding relation to the inner member; and

said inner member and said outer member having cooperating distal ends adapted to receive a ferrule in the open position and to crimp the ferrule in the crimping position.

54. The crimping tool of claim 53, wherein:
the inner member distal end has a depression therein dimensioned to admit the ferrule; and
- 5 the outer member distal end has a protrusion directed toward the depression, whereby upon rotation of said inner member relative to said outer member, said protrusion applies pressure to the ferrule when in the crimping position.
55. The crimping tool of claim 54, further including a cutter for cutting the
10 cable proximal to the ferrule.
56. The crimping tool of claim 55, wherein the cutter includes cooperating cutting surfaces affixed to the inner and the outer members adjacent the depression and the protrusion.
- 15
57. The crimping tool of claim 54, further comprising:
a first handle affixed adjacent a proximal end of the inner member; and
a second handle affixed adjacent a proximal end of the outer member;
the first handle and the second handle for facilitating a relative rotation of the
20 inner member and the outer member.
58. The crimping tool of claim 53, further including means for applying longitudinal tension to the cable in a proximal direction.
- 25
59. The crimping tool of claim 58, wherein the tension applying means comprises:
means for affixing a proximal section of cable thereto; and
means for pulling the affixed cable in a proximal direction relative to the tissue.

60. The crimping tool of claim 58, wherein:
said inner member has an externally threaded proximal portion; and
the tension applying means comprises a generally cylindrical tensioner member
having a longitudinal bore from a distal end to a proximal end dimensioned to permit
5 the cable to pass therethrough, the bore having a threaded distal portion adapted to be
screwable relative to the inner cylindrical member threaded proximal portion.

61. The crimping tool of claim 60, wherein said affixing means comprises a
clamp positioned in cable-retaining relation to the tensioner member bore, the clamp
10 movable between a releasing position wherein the cable is slidable there past and a
tightened position wherein the cable is retained there against.

62. A suture anchoring system for attaching a first section of tissue to a
second section of tissue via a unitary incision having a longitudinal axis, the anchoring
15 system comprising:

suture material having a first end, a second end, a longitudinal axis, and a
diameter;

a suture anchor having:

a longitudinal axis generally extending from a proximal end to a distal end;

20 a first cross-sectional dimension generally along the longitudinal axis greater than
a second cross-sectional dimension generally perpendicular to the longitudinal axis;
and

means for slidably affixing a central portion of the suture material to the suture
anchor, the first end and the second end of the suture material retainable outside the
25 incision;

wherein the suture anchor is pivotable relative to the suture material between a
first position wherein the longitudinal axes of the incision and the suture anchor are
generally parallel and a second position wherein the longitudinal axes of the incision
and the suture anchor are generally perpendicular; and

means for impelling the suture material-suture anchor combination through tissue, the impelling means having means for receiving a proximal portion of the suture anchor for releasably retaining the suture anchor in the first position for insertion through the first section of tissue and then through the second section of tissue, the suture anchor for anchoring the central portion of the suture material at a distal side of the second section of tissue.

63. The suture anchoring system recited in claim 60, wherein the suture anchor has a pair of cross-bores generally perpendicular to the longitudinal axis, a first cross-bore generally perpendicular to the longitudinal axis, a first cross-bore adapted to receive the suture material distal end therethrough from a first side to a second side, a second cross-bore adapted to receive the suture material distal end therethrough from the second side to the first side, the suture material distal end and proximal end retainable outside the incision, the suture anchor pivotable by a manipulation of the suture material distal end and proximal end.

64. A method for attaching a first section of tissue to a second section of tissue via a unitary incision, the method comprising the steps of:

providing an anchor member having a first dimension larger than a second dimension;

movably affixing the anchor member to a first end of a cable, the anchor member first dimension generally aligned with a longitudinal axis of the cable;

inserting the cable-anchor member combination into a bore of a delivery device, a distal end of the anchor member retained outside the delivery device bore, a proximal end of the anchor member inserted into an supported by the bore of the delivery device;

maintaining tension on the cable with the delivery device to retain the anchor member proximal end within the delivery device bore;

impelling the cable-anchor member combination through the first tissue section and then through the second tissue section;

releasing the tension on the cable;

pivoting the anchor to a position wherein the anchor member first dimension is
5 generally aligned with the cable longitudinal axis;

applying tension to a second end of the cable to force the anchor against a distal side of the second tissue section and to force the first tissue section into close opposition with the second tissue section;

affixing a retainer to the cable adjacent a proximal side of the first tissue section;
10 and

cutting the cable proximal of the retainer.

65. A method for joining two sections of tissue, comprising;

providing a first anchor, an elongated member attached to the first anchor, a
15 second anchor slidable on the elongated member and having a deformable portion adapted to engage the elongated member, and a crimping tool having an outer member and an inner member movably disposed within the outer member;

inserting the first anchor into a first section of tissue;

threading the second anchor on the elongated member;

20 applying tension on the elongated member to urge the first section of tissue toward a second section of tissue;

threading the elongated member through the crimping device; and

moving the inner member with respect to the outer member thereby deforming the deformable portion of the second anchor and maintaining the tension applied to the
25 elongated member.

66. A bone opening protector, comprising:

a first portion having an opening therein, said first portion adapted to engage a surface surrounding a bone opening; and

an anchoring extension connected to said first portion, said anchoring extension adapted to extend into bone to inhibit movement of said first portion.

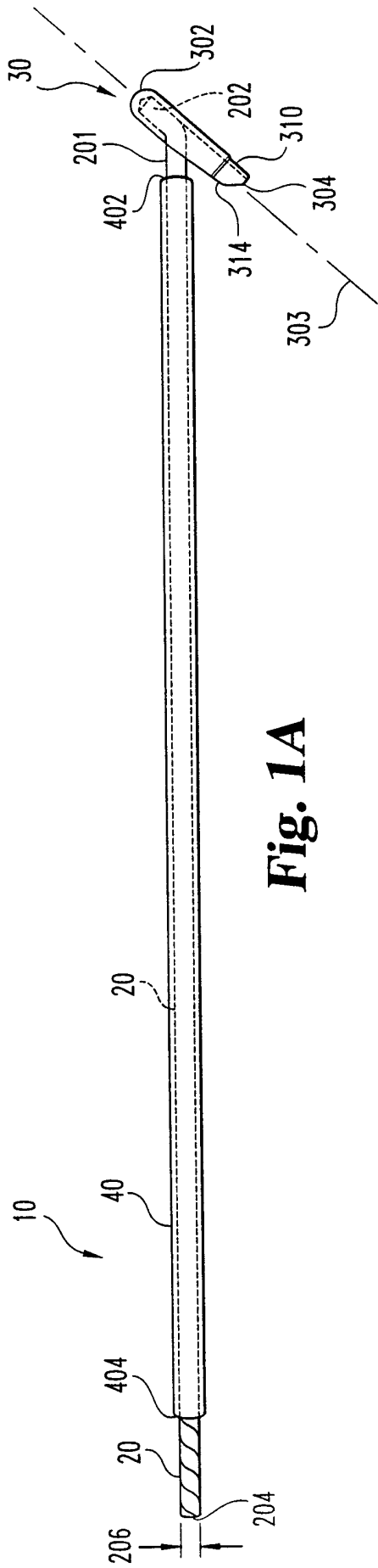


Fig. 1A

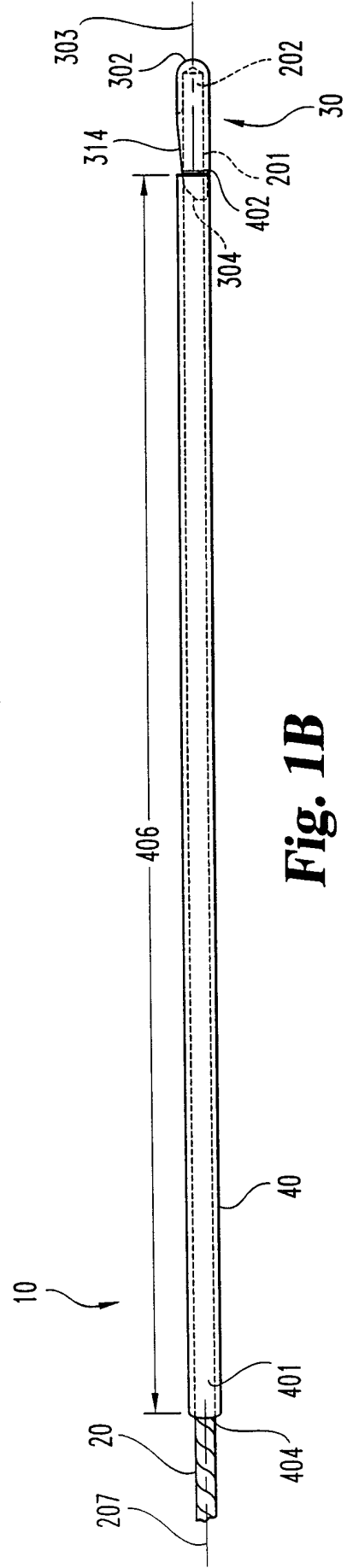


Fig. 1B

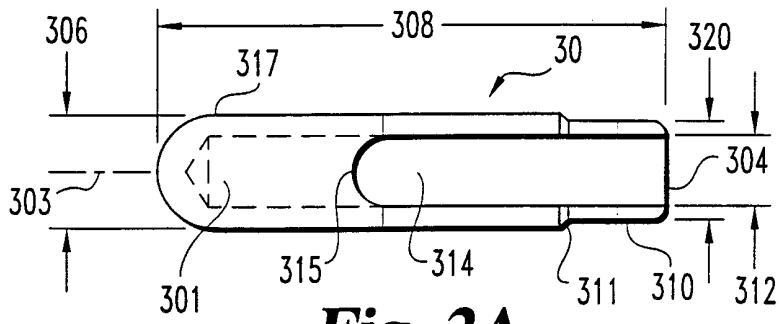


Fig. 2A

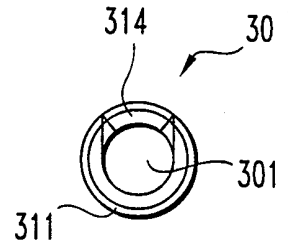


Fig. 2C

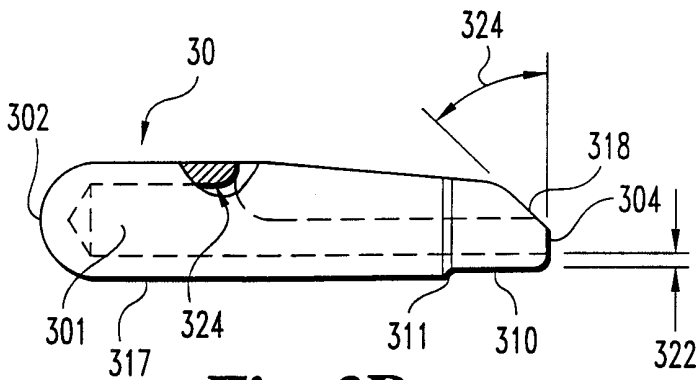


Fig. 2B

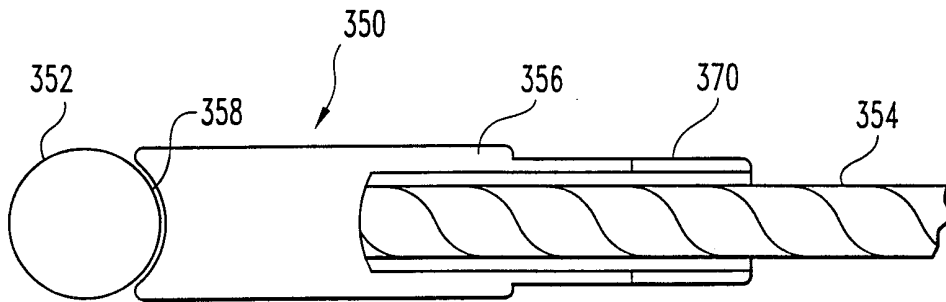


Fig. 3A

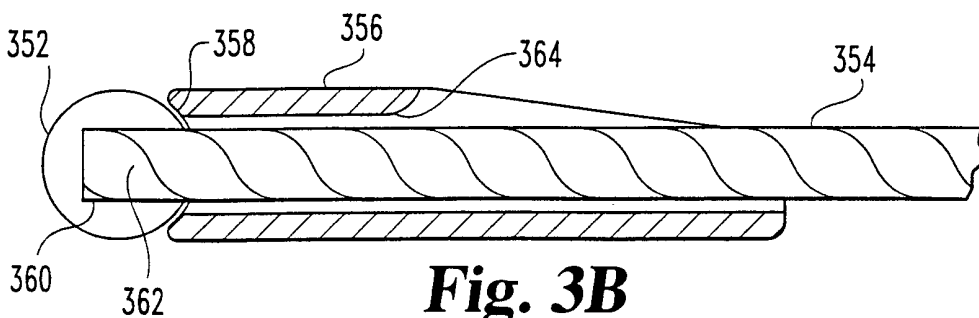
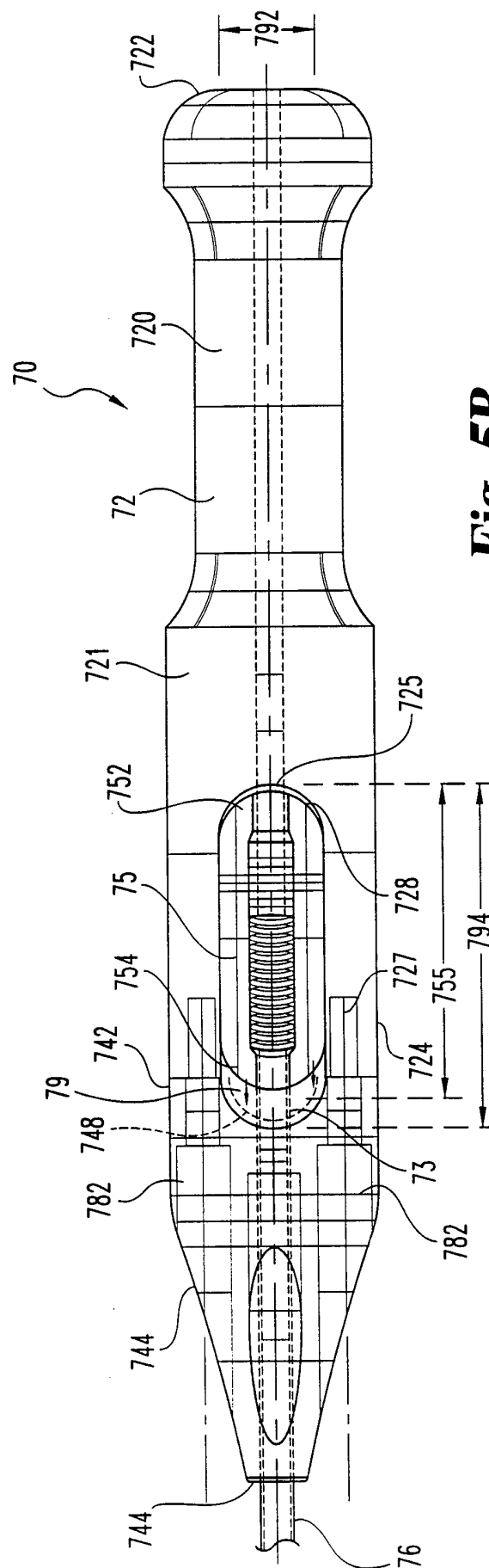
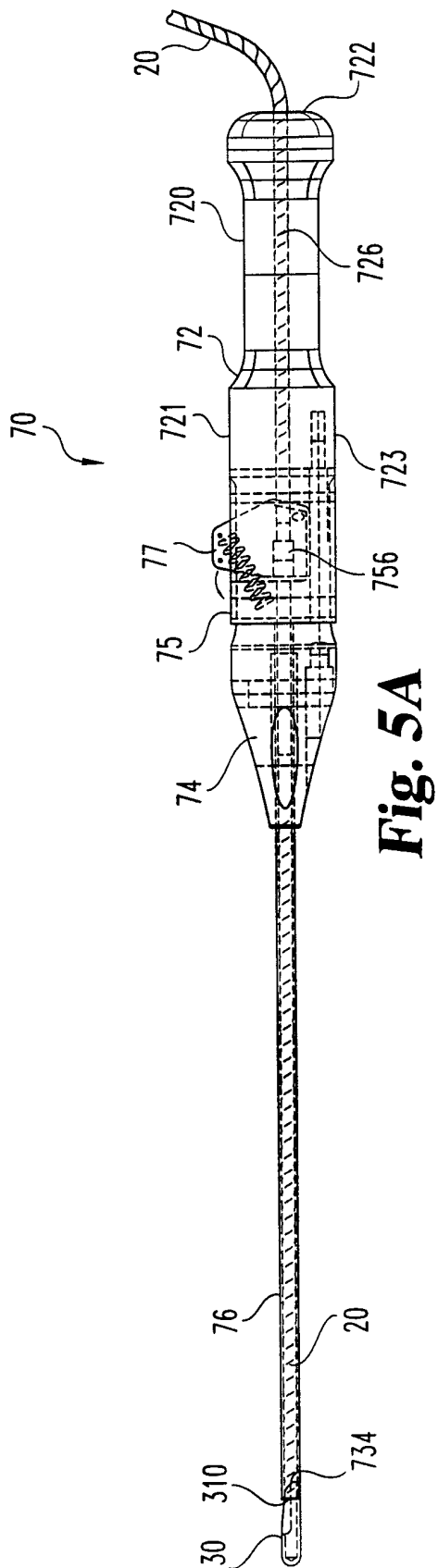


Fig. 3B



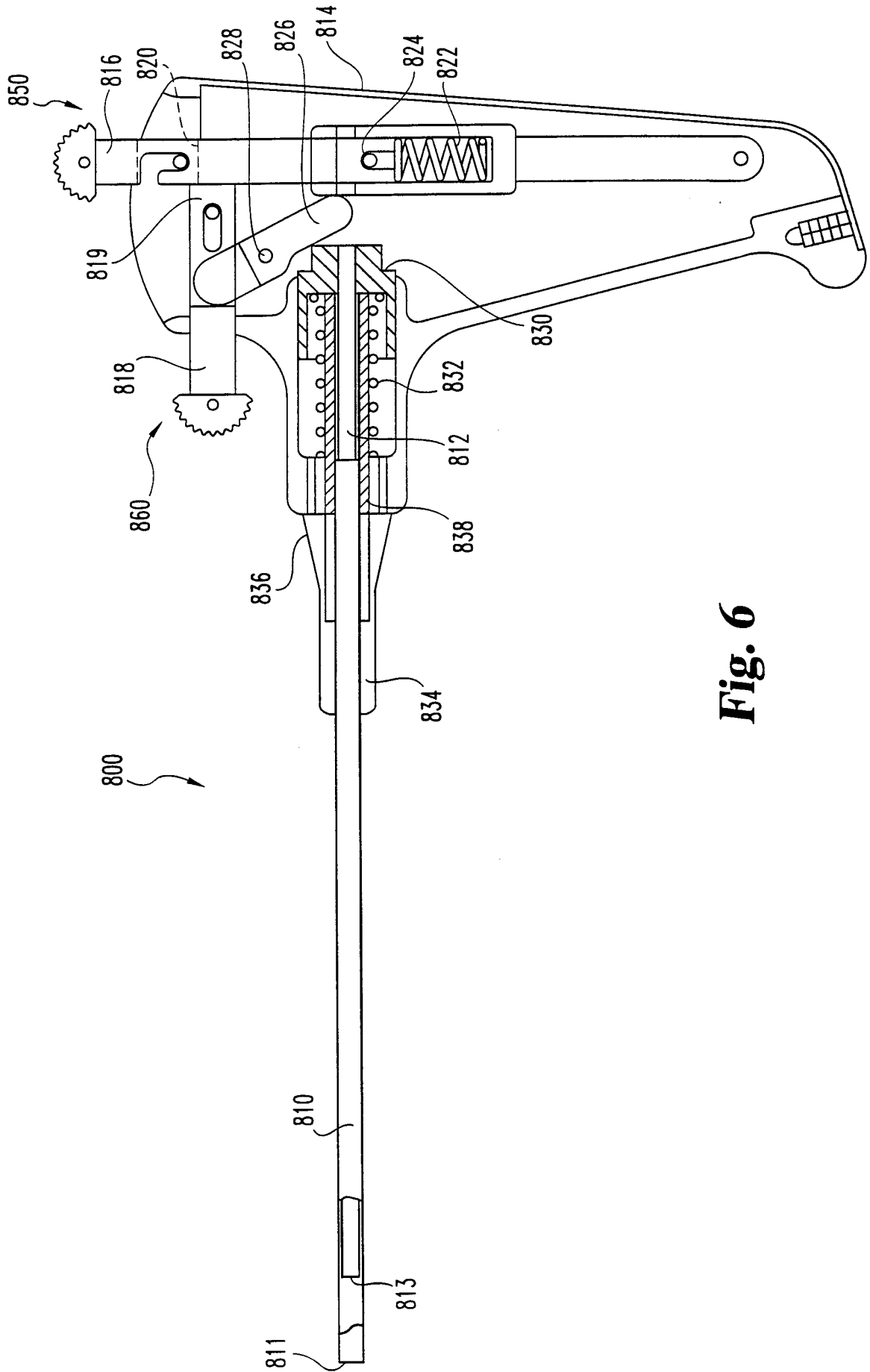


Fig. 6

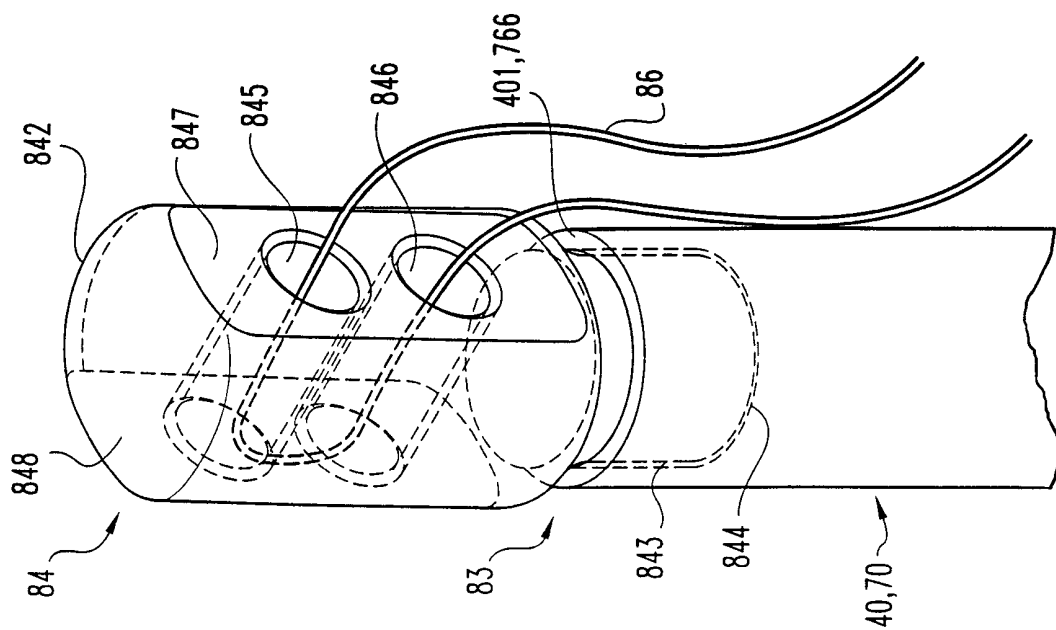


Fig. 7A

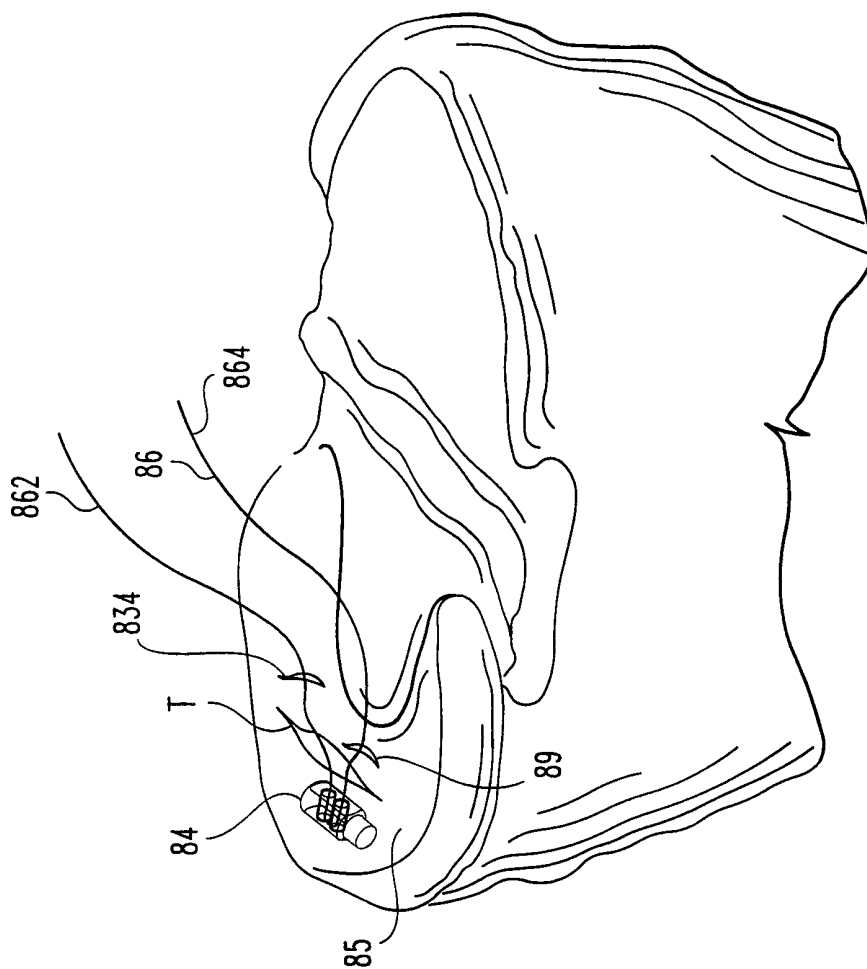


Fig. 7B

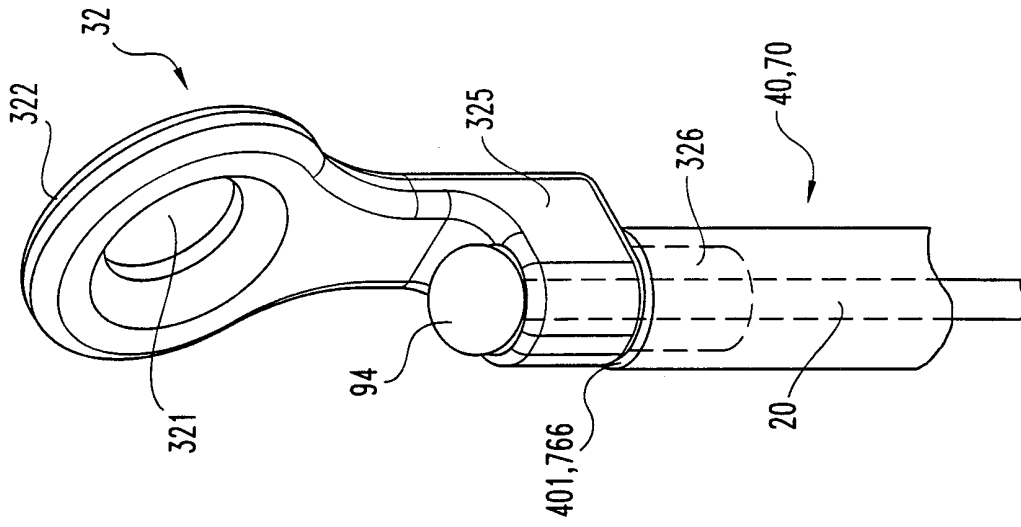


Fig. 9

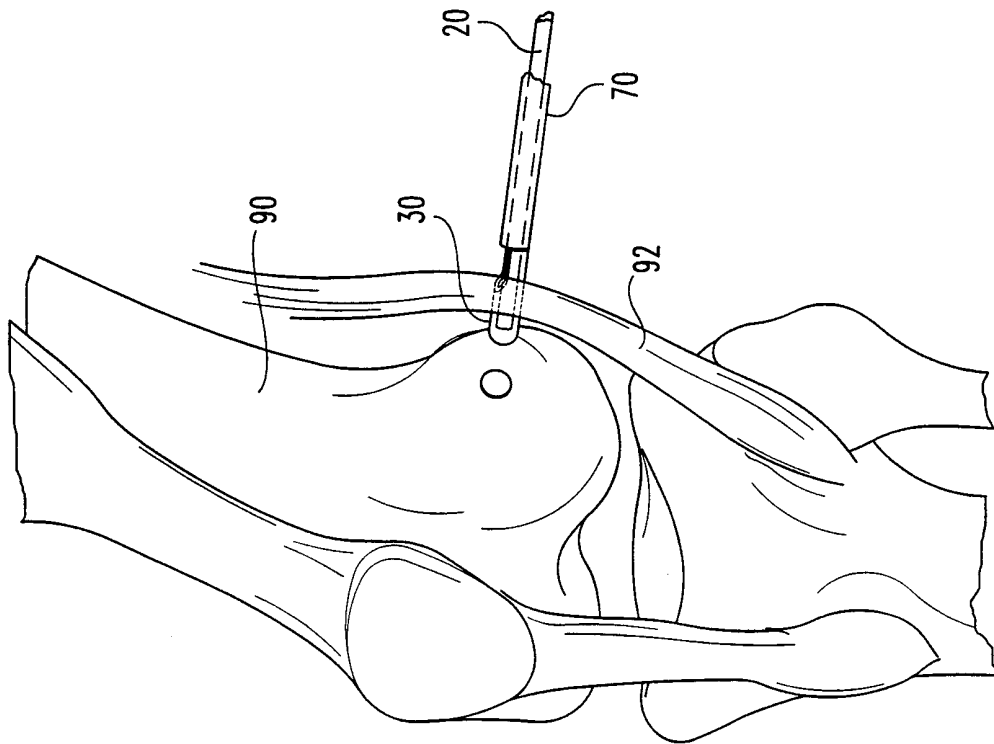


Fig. 8

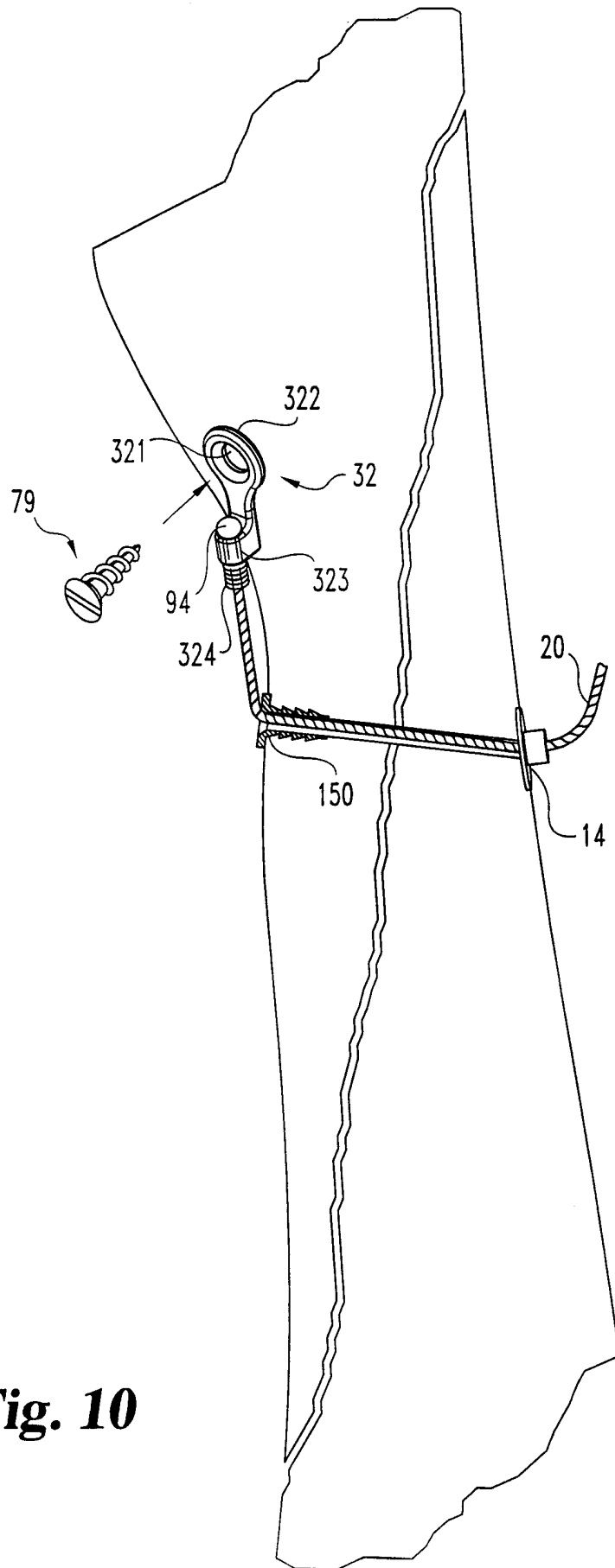


Fig. 10

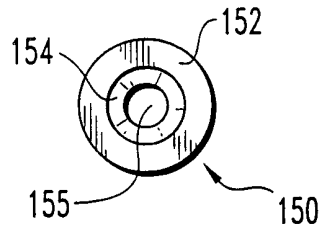


Fig. 11A

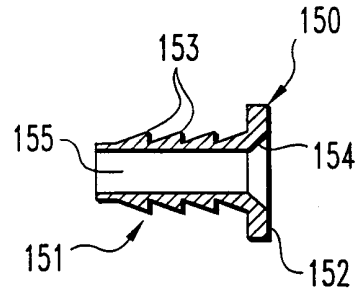


Fig. 11B

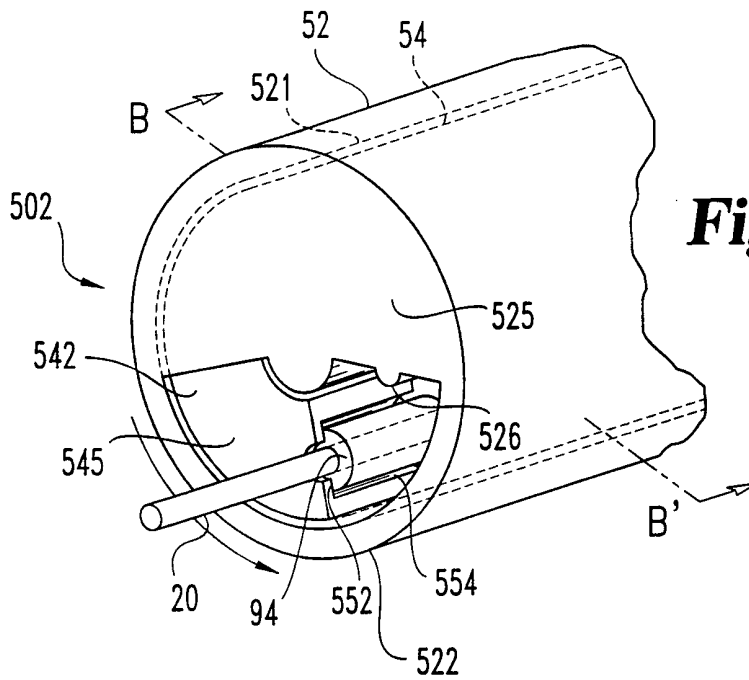
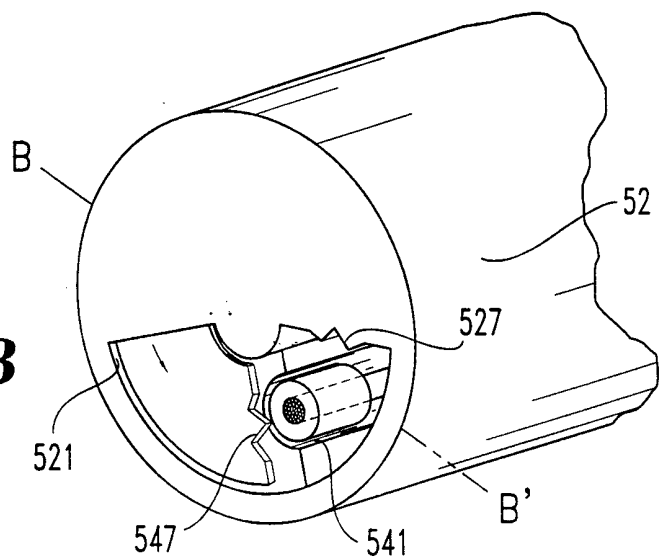


Fig. 14A

Fig. 14B



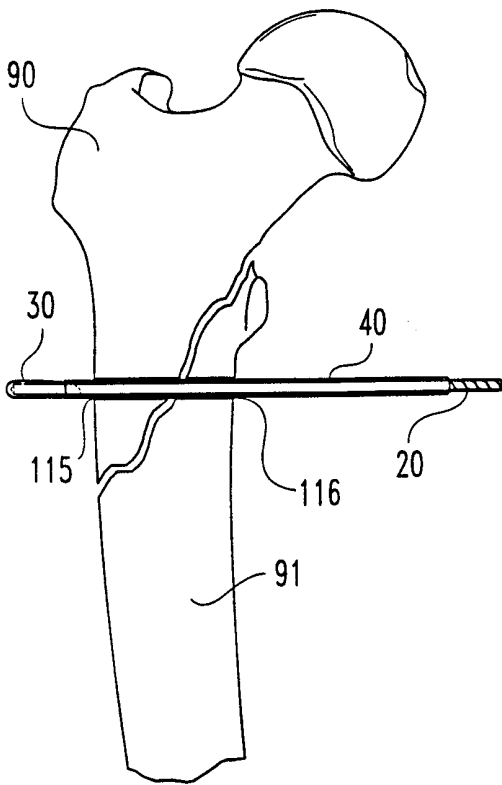


Fig. 12A

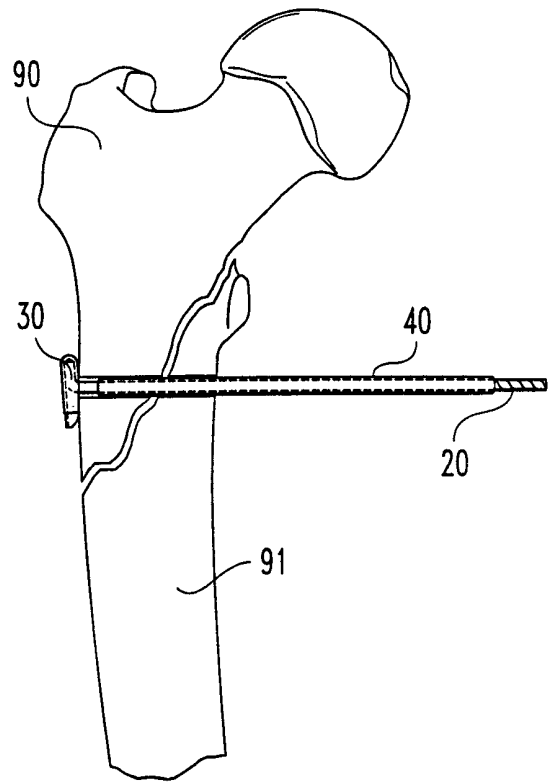


Fig. 12B

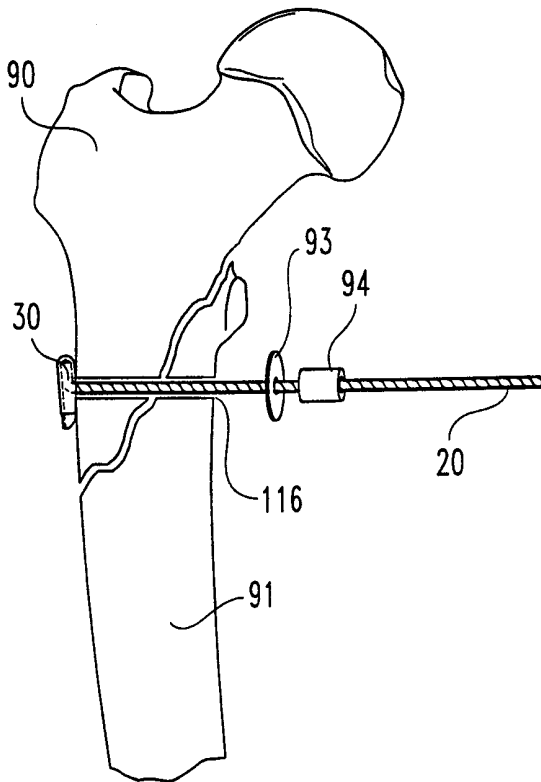


Fig. 12C

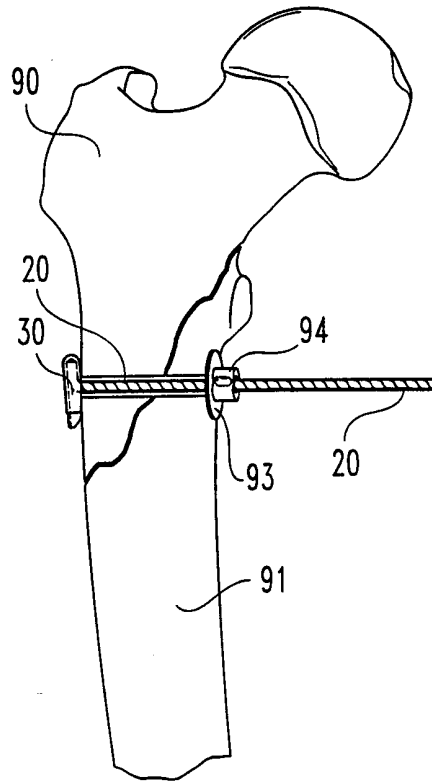


Fig. 12E

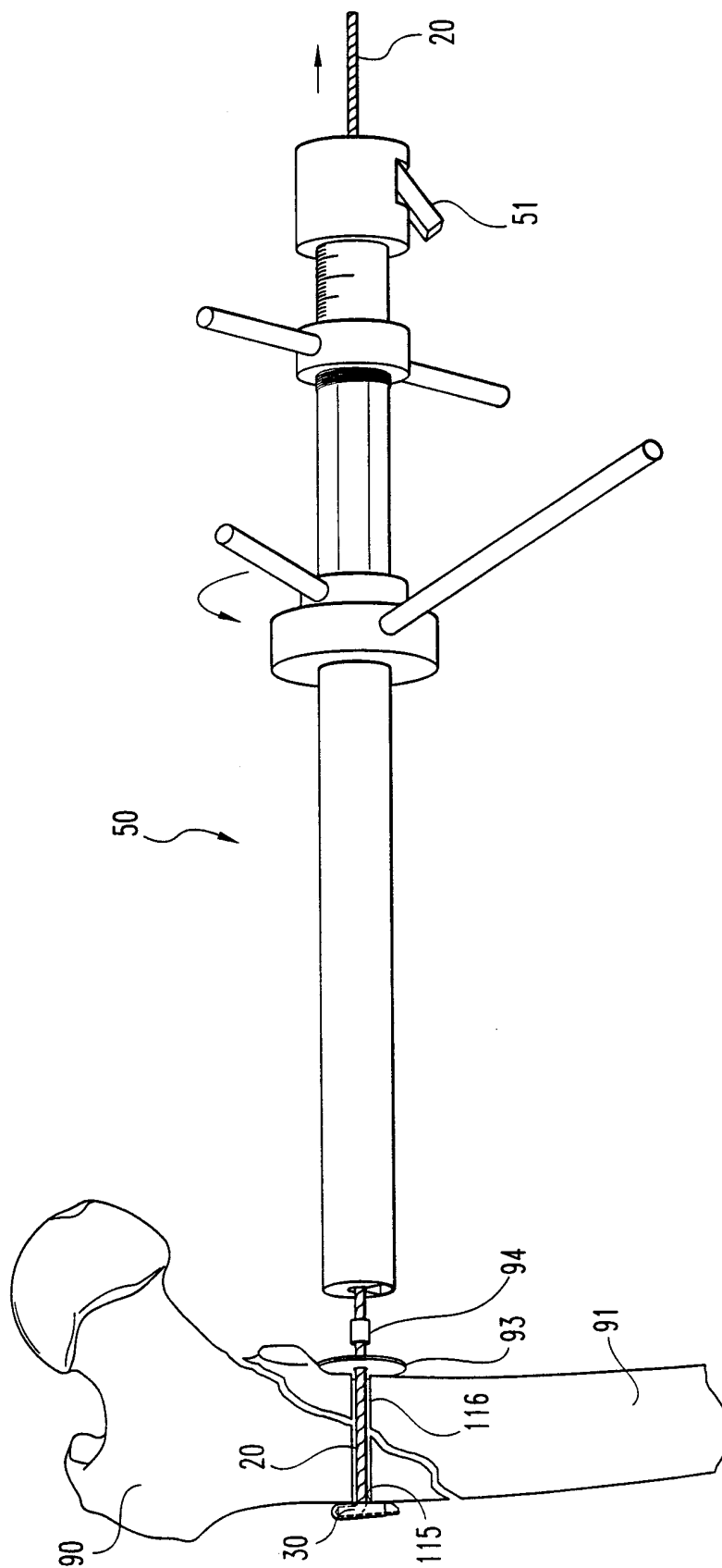


Fig. 12D

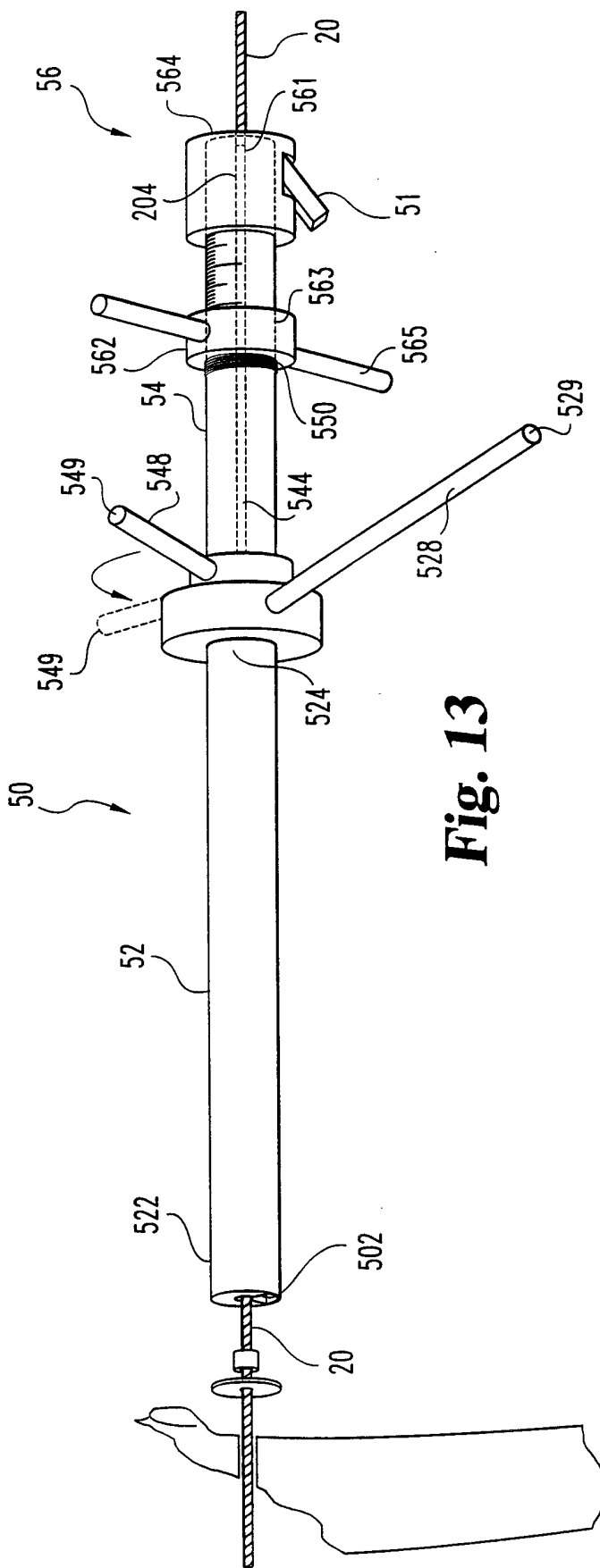


Fig. 13

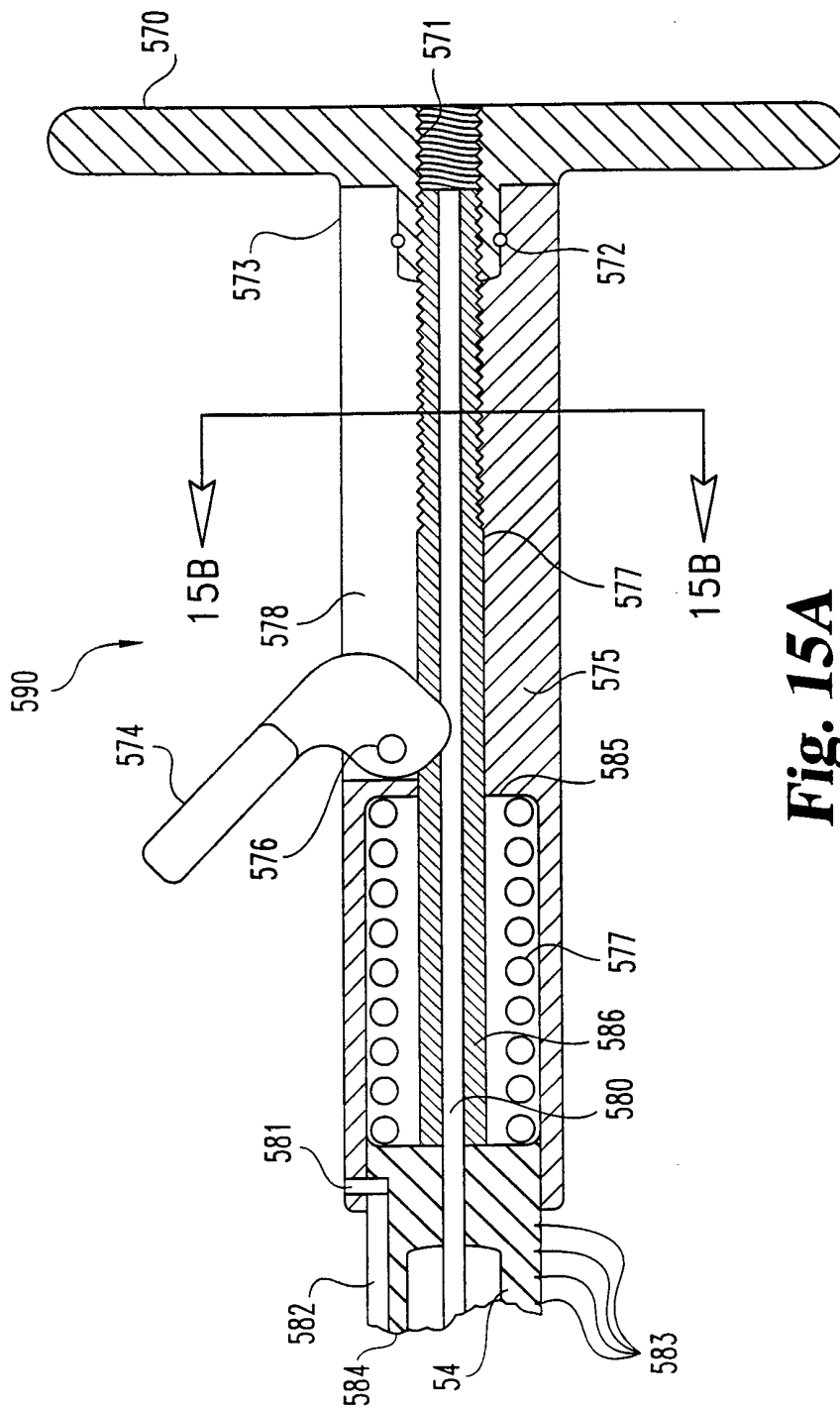


Fig. 15A

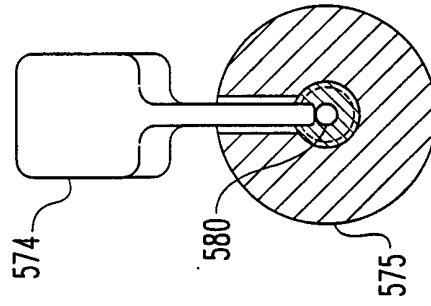


Fig. 15B

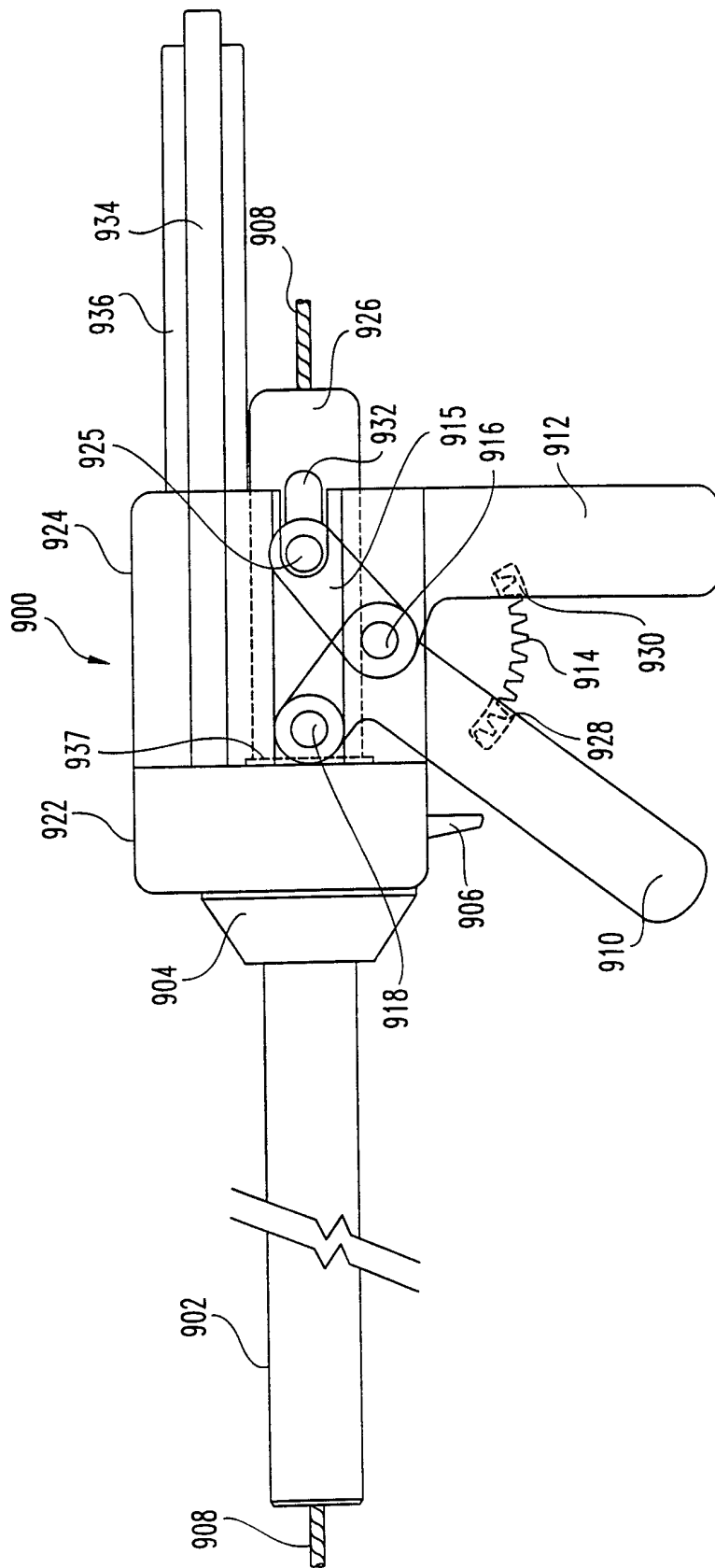


Fig. 16

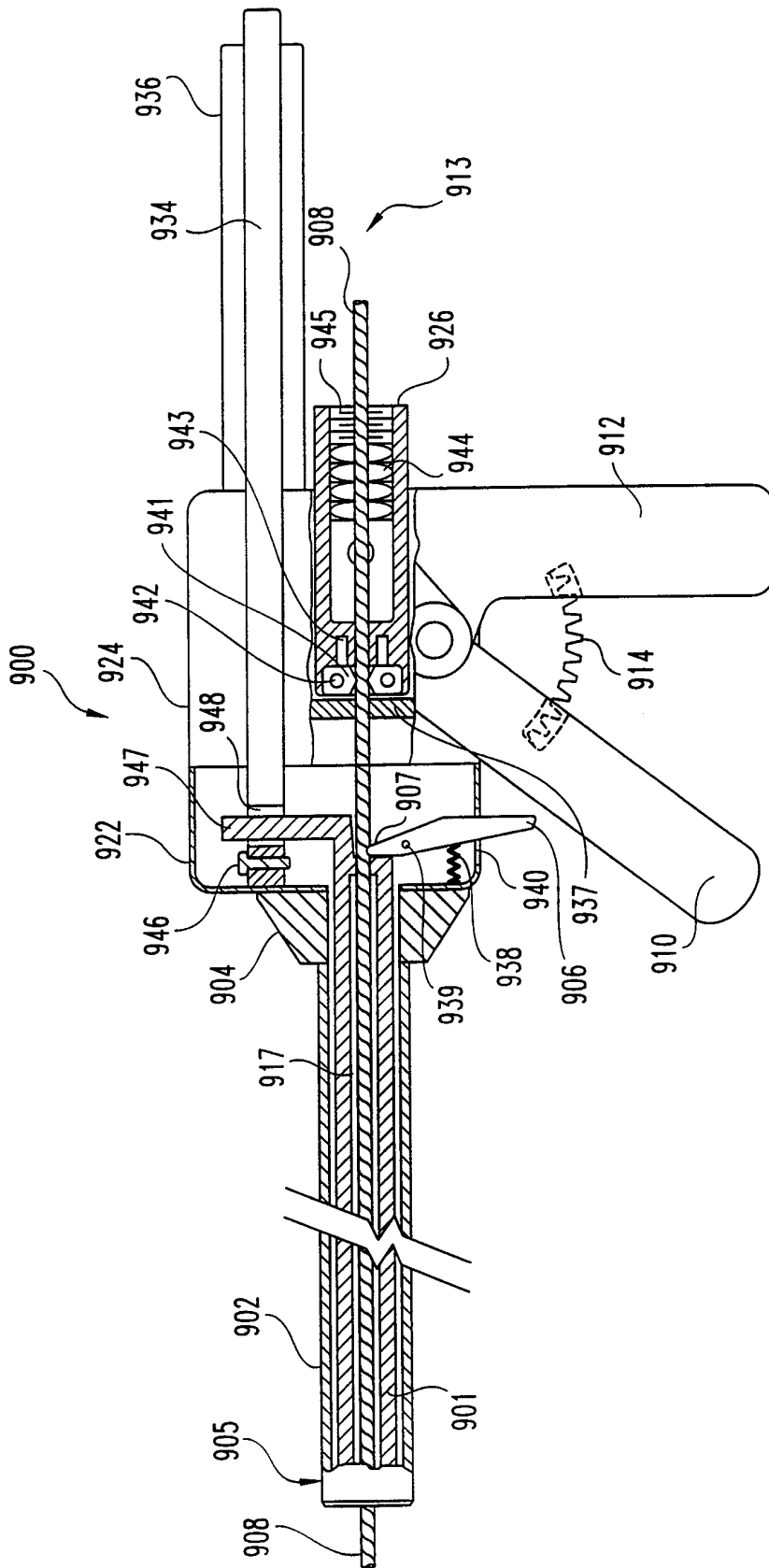


Fig. 17

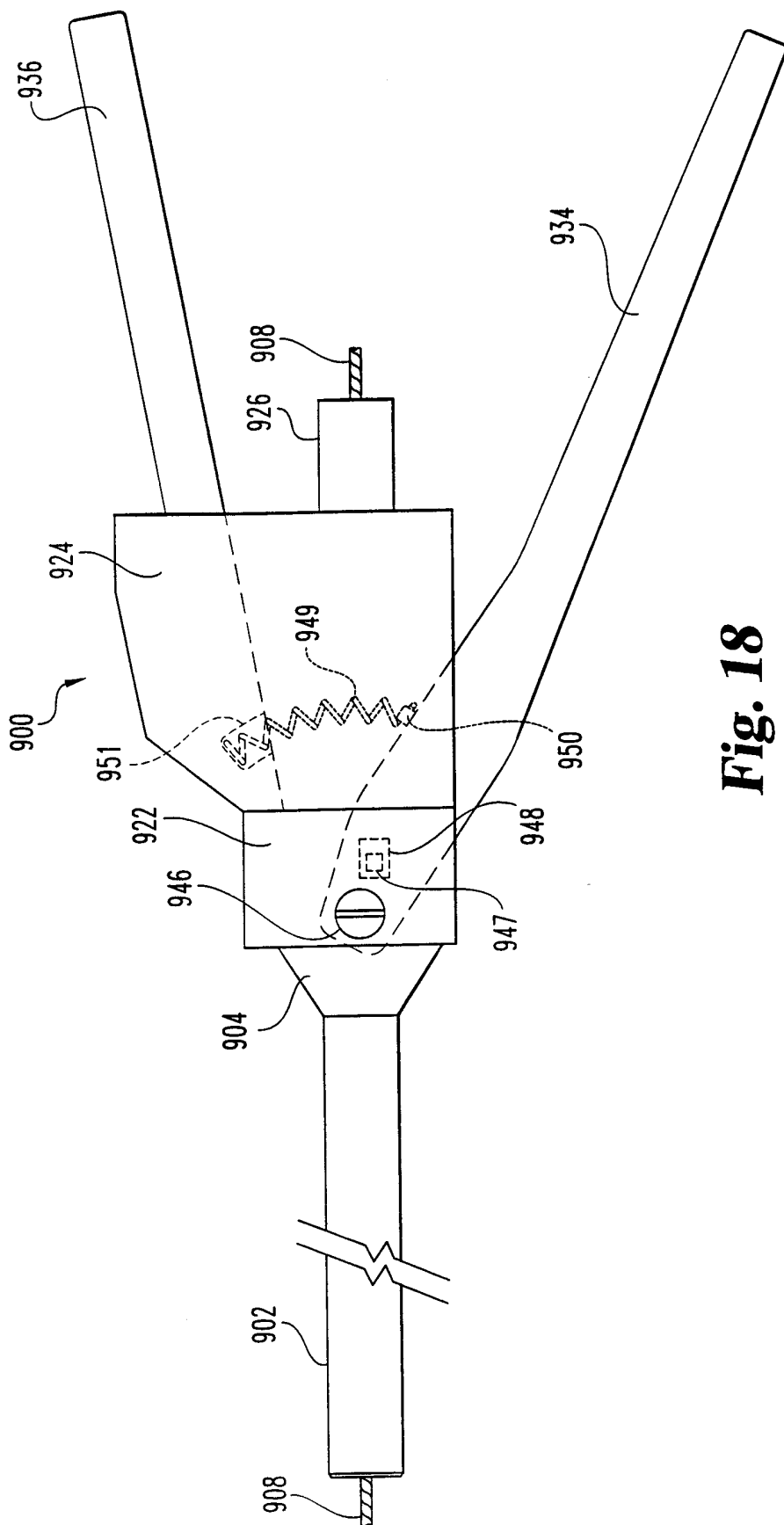


Fig. 18

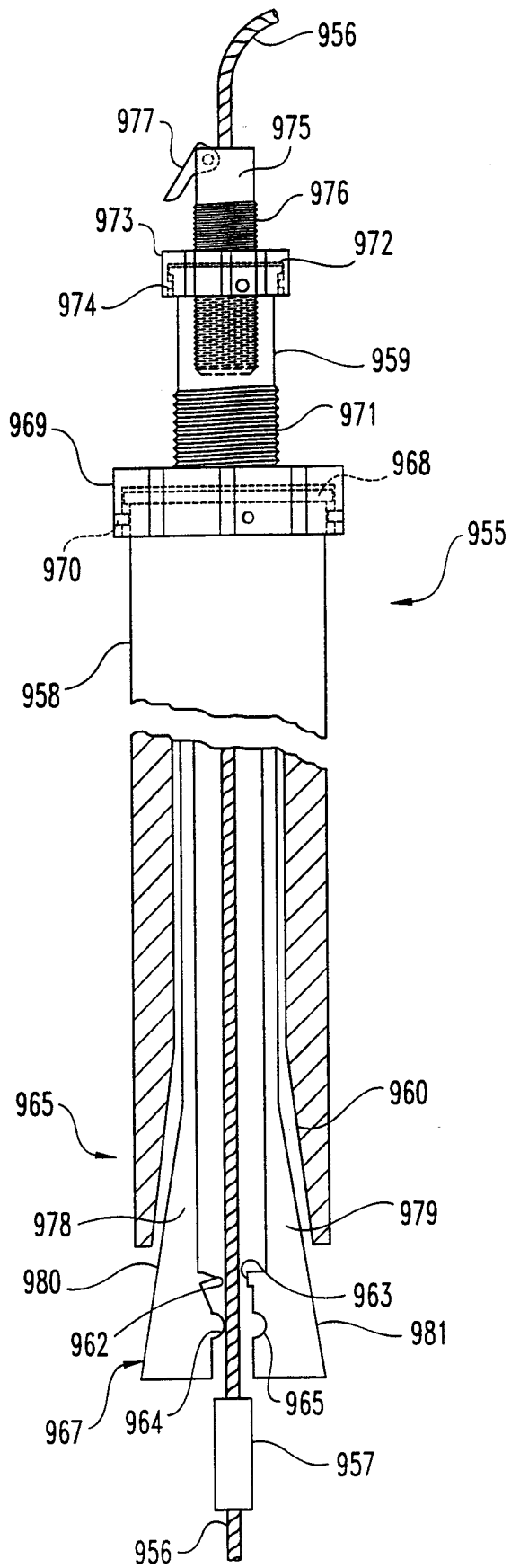


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/01203

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(6) : A61B 17/10
 US CL : 606/139
 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)
 U.S. : 606/53, 54, 72, 75, 138, 139, 151, 228, 233

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,041,129 A (HAYHURST et al.) 20 August 1991, Figs. 1 and 2	1-31
Y	US 4,738,255 A (GOBLE et al.) 19 April 1988, Figs. 1-11.	32-66

Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document 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 13 MARCH 1999	Date of mailing of the international search report 01 APR 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized Officer <i>Andie Robinson</i> LIEN NGO Telephone No. (703) 305-0294