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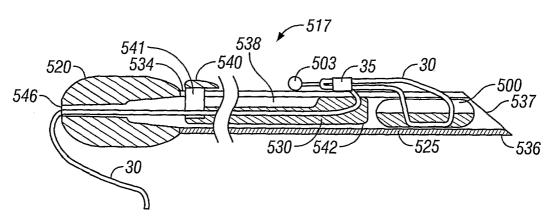
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(54) Title: SOFT TISSUE ATTACHMENT AND REPAIR



(57) Abstract: A surgical assembly includes a fastener, a retainer, and a flexible member. The fastener is configured to be secured within bone tissue. The flexible member connects the fastener to the retainer and is movably attached to the retainer such that pulling on a free end of the flexible member shortens a length of the flexible member between the fastener and the retainer. A method includes positioning a fastener within bone tissue, positioning a retainer against soft tissue to be attached to the bone tissue, and pulling a free end of a flexible member. The fastener and the retainer are connected by the flexible member, the flexible member is movably attached to the retainer, and pulling on the free end of the flexible member shortens a length of the flexible member between the fastener and the retainer.





# Soft Tissue Attachment And Repair

#### RELATED APPLICATIONS

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This application is a continuation-in-part of co-pending U.S. Application Serial No. 09/886,367, filed June 22, 2001, entitled CLOSURE DEVICE AND METHOD FOR TISSUE REPAIR, which is a continuation of co-pending U.S. Application Serial No. 09/704,926, filed November 2, 2000, entitled CLOSURE DEVICE FOR AND METHOD FOR TISSUE REPAIR, and a continuation-in-part of co-pending U.S. Application Serial No. 09/453,120, filed December 2, 1999, entitled WOUND CLOSURE DEVICES AND METHODS, all of which are incorporated herein by reference.

# **BACKGROUND**

This invention relates to devices and methods for attaching soft tissue to bone and for repairing torn soft tissue.

One area in the body where soft tissue is surgically reattached to bone is the attachment of a rotator cuff tendon to the humerus. The rotator cuff tendons have areas of low blood supply. With an increased blood supply, a tissue, such as a tendon, can repair and maintain itself better and faster. Thus, areas of poor blood supply in the rotator cuff make these tendons difficult and slow to heal following an injury, such as a tear to the supraspinatus muscle or the subscapularis muscle. In such a tear, part of the tendon is pulled away from the bone. Because of the poor blood supply, rather than attempting to allow an injured rotator cuff to heal on its own, a physician will often recommend that the tendon be surgically repaired to better fix the position of the cuff to the bone to prevent further damage and improve the environment for healing. For example, the physician may attempt to fix the tendon to the bone using a suture anchor. One example of a suture anchor is disclosed in Hayhurst, U.S. Patent No. 4,741,330, which is incorporated herein by reference.

Other areas in the body also have tissue that can be surgically reattached to bone when torn from the bone or can be surgically repaired when a tear forms in the tissue. These areas include, for example, the biceps tendon, the lateral collateral ligament in the knee, the

medial collateral ligament in the knee, the meniscus in the knee, the popliteal ligament in the leg, and the labrum tendon in the knee.

#### **SUMMARY**

In one general aspect, a surgical assembly includes a fastener configured to be secured within bone tissue, a retainer for engaging tissue, and a flexible member. The flexible member connects the fastener to the retainer and is movably attached to the retainer such that pulling on a free end of the flexible member shortens a length of the flexible member between the fastener and the retainer to urge the tissue against the bone tissue.

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Embodiments of the surgical assembly may include one or more of the following features. For example, the movable attachment of the flexible member to the retainer is configured to enable the length of the flexible member between the fastener and the retainer to be shortened, but not lengthened. The movable attachment includes a knot formed in the flexible member, and the knot is a slip knot. The flexible member is a suture.

The retainer includes a smooth first surface and a second surface having a length and protrusions that are transverse to the length of the second surface. The retainer has a low profile such that the retainer does not protrude sufficiently from the tissue to impinge against adjacent tissue. The retainer has a thickness of between approximately 0.5 and 2.5 millimeters.

The fastener is a screw. The screw has a threaded shank and a head, and the head defines at least one opening through which the flexible member passes. The head defines a through hole for receiving the flexible member. The screw includes a ridge between the shank and the head.

The surgical assembly further includes a delivery device for delivering the fastener and retainer to a surgical site. The delivery device includes a cannula defining a lumen for receiving the fastener and retainer. The delivery device also includes a retractable needle positioned within the lumen and connected to a switch in the delivery device for advancing and retracting the needle.

In another general aspect, a surgical method includes positioning a fastener within bone tissue, positioning a retainer against soft tissue to be attached to the bone tissue, and pulling a free end of a flexible member connecting the fastener and the retainer. The flexible

member is movably attached to the retainer, and pulling on the free end of the flexible member shortens a length of the flexible member between the fastener and the retainer to urge the soft tissue against the bone tissue.

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Embodiments of the method may include one or more of the following features. For example, the movable attachment of the flexible member to the retainer enables shortening but not lengthening of the length of the flexible member between the fastener and the retainer. The movable attachment includes a slip knot formed in the flexible member and pulling the free end moves the slip knot along the flexible member. Positioning the fastener within bone tissue includes rotatably inserting the fastener into bone tissue.

Positioning the retainer against soft tissue includes locating the retainer within a needle, passing the needle through the soft tissue such that a protrusion on the retainer passes through at least a portion of the soft tissue, and withdrawing the needle from the soft tissue such that the retainer is pulled from the needle by the interaction of the protrusion and the soft tissue.

The surgical method further includes positioning a second retainer against the tissue on a side of the tissue opposite that of the first retainer. The second retainer is positioned within the needle. The flexible member connects the second retainer to the first retainer and the fastener. Withdrawing the needle from the tissue causes the flexible member to be under tension such that the second retainer is pulled from the needle. Pulling the free end of the flexible member moves a slip knot along the flexible member, the slip knot being positioned between the free end of the flexible member and the second retainer.

The retainer has a low profile such that the retainer does not protrude sufficiently from the soft tissue to impinge against adjacent tissue when the retainer is positioned against soft tissue. The retainer has a thickness of between approximately 0.5 and 2.5 millimeters. The retainer has a thickness of approximately 2 millimeters.

In another general aspect, a surgical assembly includes a first screw, a second screw, and a flexible member. The flexible member connects the first screw to the second screw. The flexible member is movably attached to the second screw such that pulling on a free end of the flexible member shortens a length of the flexible member between the first screw and the second screw.

Embodiments of the surgical assembly may include one or more of the following features. For example, the surgical assembly further includes a cannula for receiving the first and second screws. The cannula has a lumen and a distal end and the first screw is received within the lumen and the second screw is located at the distal end. The first screw and the cannula are configured to limit relative rotation therebetween.

The surgical assembly further includes a pusher rod extending into the cannula for advancing the first screw to the distal end of the cannula.

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In another general aspect, a surgical assembly includes a delivery device and a surgical device. The delivery device includes a handle and a cannula. The cannula extends from the handle and includes a longitudinal channel and a longitudinal slot along at least a portion of the length of the channel. The surgical device includes a first retainer, a second retainer, and a flexible member. The flexible member couples the first retainer and the second retainer. The flexible member is movably attached to the first retainer such that pulling on a free end of the flexible member shortens a length of the flexible member between the first retainer and the second retainer. The first retainer is positioned within the longitudinal channel, the second retainer is positioned adjacent to an outer surface of the cannula, and the flexible member passes from the longitudinal channel through the longitudinal slot.

Embodiments of the surgical assembly may include one or more of the following features. For example, the surgical assembly includes a pusher tube slidably positioned within the cannula and a thumb switch extending through the longitudinal slot for advancing and retracting the pusher tube. The movable attachment of the flexible member to the first retainer is a slip knot. The slip knot is positioned within the longitudinal channel or, alternatively, outside of the longitudinal channel.

In another general aspect, a surgical method includes drilling a channel through bone tissue and soft tissue, pulling a first flexible member to pull a fastener in a first direction through the channel such that the fastener passes through the bone tissue and the soft tissue, pulling a second flexible member to pull the fastener in a second direction against the soft tissue, and pulling a free end of the second flexible member to shorten a length of the second flexible member between the fastener and a retainer. The second flexible member connects

the fastener to the retainer. Pulling the free end of the second flexible member positions the retainer against the bone.

In another general aspect, a surgical method includes positioning a fastener within bone tissue, positioning a first retainer movably attached to the fastener by a flexible member against soft tissue to be attached to the tone tissue, positioning a second retainer movably attached by the flexible member to the first retainer and the fastener against soft tissue to be attached to the bone tissue, and pulling a free end of the flexible member to shorten a length of the flexible member between at least any two of the fastener, the first retainer and the second retainer.

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Embodiments of the surgical method may include one or more of the following features. For example, the movable attachment of the flexible member to the retainer enables shortening but not lengthening of the length of the flexible member between any two of the fastener, the first retainer and the second retainer. Pulling the free end of the flexible member moves a slip knot along the flexible member, the slip knot being positioned between the free end of the flexible member and the second retainer. Positioning the fastener within bone tissue includes rotatably inserting the fastener into bone tissue.

Positioning either of the first retainer and the second retainer against soft tissue includes locating the retainer within a needle, passing the needle through the soft tissue such that a protrusion on the retainer passes through at least a portion of the soft tissue, and withdrawing the needle from the soft tissue such that the retainer is pulled from the needle by the interaction of the protrusion and the soft tissue.

Pulling a free end of the flexible member includes moving a slip knot positioned between a free end of the flexible member and the second retainer along the flexible member to shorten a length of the flexible member between at least any two of the fastener, the first retainer and the second retainer.

In another general aspect, a surgical method includes positioning a fastener within bone tissue, advancing a delivery device including a needle under a first soft tissue member, advancing the curved delivery device through a second soft tissue member, and positioning a retainer against the second soft tissue member. The fastener and retainer are connected by a flexible member, the flexible member being movably attached to the retainer. Pulling a free

end of the flexible member shortens a length of the flexible member between the fastener and the retainer.

Embodiments of the surgical method may include one or more of the following features. For example, the movable attachment of the flexible member to the retainer enables shortening but not lengthening of the length of the flexible member between the fastener and the retainer. Pulling the free end moves the slip knot along the flexible member, the slip knot being formed in the flexible member. Positioning the fastener within bone tissue comprises forcibly inserting the fastener into bone tissue.

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Positioning the retainer against the second soft tissue further includes locating the retainer within the needle, passing the needle through the second soft tissue such that a protrusion on the retainer passes through at least a portion of the second soft tissue, and withdrawing the needle from the second soft tissue such that the retainer is pulled from the needle by the interaction of the protrusion and the second soft tissue.

The delivery device is advanced under the first soft tissue member and the retainer is positioned against the second soft tissue member prior to positioning the fastener within the bone tissue.

In another general aspect, a surgical method for repairing a meniscal tear includes positioning a delivery device that includes a needle against a first position on soft tissue, advancing the needle through the soft tissue, withdrawing the needle from the soft tissue, positioning the delivery device against a second position on the soft tissue, advancing the delivery device and the needle through the soft tissue a second time, and withdrawing the delivery device from the soft tissue. A first retainer is positioned within a longitudinal channel of a lumen of the needle and includes a protrusion extending from the first retainer through a longitudinal slot in the needle. The needle is withdrawn from the soft tissue such that the first retainer is pulled from the needle by the interaction of the protrusion and the soft tissue, a second retainer is positioned within the longitudinal channel of the lumen. The second retainer includes a protrusion extending from the second retainer through the longitudinal slot in the needle. The delivery device is withdrawn from the soft tissue a second time such that the second retainer is pulled from the needle by the interaction of the protrusion and the soft tissue.

Embodiments of the surgical method may include one or more of the following features. For example, positioning the first retainer and the second retainer may include positioning the first retainer and the second retainer on opposite sides or the same side of the meniscal tear.

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The surgical assembly, the surgical device, the delivery device, and the surgical methods described herein can provide considerable advantages. In particular, the physician does not need to tie any knots and the retainer has a low profile, which limits protrusion of the retainer into the joint capsule. For example, the device and methods provide an optimal repair and reattachment of soft tissue to bone by first providing optimal fixation when the devices are placed and then providing an easily manipulated slip knot that fixes the position of the devices against the bone and tissue. Because the system uses optimal fixation prior to tightening the slip knot, a fastener or fasteners can be used in bone tissue that has a less than optimal tissue condition, such as osteoporotic bone.

Moreover, the procedure is simple and easy. For example, in one embodiment the fastener is rotatably positioned within the bone, the delivery device is withdrawn, a knot pusher is used to tighten the slip knot to place the retainer against the tendon, and the proximal end of the suture is cut. Thus, the physician does not need to tie any knots or reach through tissue to manipulate any of the components used in the procedure.

The details of one or more embodiments of the systems and methods of repair are set forth in the accompanying drawings and the description below. Other features and advantages of the systems and methods of repair will be apparent from the description, the drawings, and the claims.

#### **DESCRIPTION OF DRAWINGS**

- Fig. 1 is a surgical device attaching soft tissue to bone.
- Fig. 2 is a fastener, a suture, and a retainer of the device of Fig. 1.
- Fig. 3 is a side view of the device of Fig. 1 and a delivery device for delivering the surgical device to a surgical site.
  - Fig. 4 is a perspective view of a slip knot in the suture of the surgical device of Fig. 1.
  - Fig. 5 is a side view of the fastener of the surgical device of Fig. 1.
  - Fig. 6 is a top view of the fastener of Fig. 5.

Fig. 7 is a cross-sectional side view of the delivery device of Fig. 3.

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- Fig. 8 is an end view of the delivery device of Fig. 7 taken at section lines 8-8 of Fig. 7.
- Fig. 9 is a cross-sectional side view of the distal end of the delivery device illustrating the surgical device of Fig. 1 positioned within the delivery device.
- Figs. 10-13 are top, bottom, side, and end views, respectively, of the retainer of the surgical device of Fig. 1.
- Fig. 14 is a perspective view of the retainer illustrating the passage of the suture through channels or openings in the retainer.
- Figs. 15-17 are perspective bottom, perspective top, and cross-sectional side views, respectively, of an alternative embodiment of a retainer having a tissue contacting surface with protrusions.
- Fig. 18 is a perspective bottom view of an oblong retainer having a smooth bottom surface.
- Figs. 19-21 are perspective bottom views of oblong retainers having bottom surfaces with protrusions.
- Figs. 22-25 illustrate an arthroscopic procedure to repair a rotator cuff injury using the device of Fig. 3.
- Fig. 26 is a cross-sectional side view of an alternative embodiment of a surgical assembly for placing a fastener and one or more retainers.
- Figs. 27 and 28 are side and top views of a retractable needle and handle of a delivery device of the surgical assembly of Fig. 26.
- Fig. 29 shows a distal region of the surgical assembly of Fig. 26 illustrating the fastener and two barbed retainers positioned in the delivery device.
- Fig. 30 illustrates the arrangement of the fastener, barbed retainers, and suture of the surgical device of Fig. 26.
  - Figs. 31-38 illustrate a tissue repair procedure using the surgical assembly of Fig. 26.
- Figs. 39 and 40 are an alternative embodiment of a surgical assembly including a fastener and a barbed retainer connected by a suture having a slip knot.
- Fig. 41 illustrates an alternative embodiment of a surgical assembly including a pair of fasteners connected by a suture having a slip knot.

Figs. 42 and 43 illustrate top and bottom views, respectively, of the fastener of Fig. 41.

- Figs. 44 and 45 illustrate end views of two implementations of a cannula of a delivery device of the surgical assembly of Fig. 41.
- Fig. 46 illustrates an alternative embodiment of a surgical device that includes two retainers, a suture, and a slip knot.

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- Fig. 47 illustrates the surgical device of Fig. 46 used to repair a meniscal tear.
- Fig. 48 is a cross-sectional side view of the surgical device of Fig. 46 shown positioned within the delivery device for delivering the surgical device to a surgical site.
  - Fig. 49 is a top view of the surgical device and delivery device of Fig. 48.
- Figs. 50-53 illustrate the surgical device and delivery device of Fig. 48 in use repairing a tear in meniscal tissue.
- Fig. 54 is a cross-sectional side view of an alternative embodiment of a delivery device for the surgical device of Fig. 46.
- Fig. 55 is a cross-sectional side view of another alternative embodiment of a delivery device for the surgical device of Fig. 46.
- Fig. 56 is a side view of a knee joint in which there is laxity in the lateral collateral ligament.
- Fig. 57 is a top view of a surgical assembly that includes a delivery device and a surgical device for repairing laxity in the lateral collateral ligament of Fig. 56.
  - Fig. 58 is a side view of the surgical assembly of Fig. 57.
- Fig. 59 is a cross-sectional side view of the distal end of the surgical device of Fig. 57.
- Figs. 60-64 illustrate the surgical device of Fig. 57 in use repairing laxity in the lateral collateral ligament of Fig. 56.
- Fig. 65 is a cross-sectional side view of the distal end of a modified version of the surgical device of Fig. 57.
- Figs. 66 and 67 illustrate the surgical device of Fig. 65 in use repairing laxity in the lateral collateral ligament of Fig. 56.
  - Fig. 68 illustrates a surgical device having a button-shaped fastener.
  - Figs. 69 and 70 illustrate the drilling of a channel through the tibia and femur.

Fig. 70 is a side view of a drill.

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Figs. 71-73 illustrate the placement of the surgical device of Fig. 68 in the knee joint to repair a torn meniscus.

Figs. 74-77 illustrate the placement of the surgical device of Fig. 68 in the shoulder joint to repair a torn rotator cuff.

Fig. 78 is a side view of a surgical device for repairing a meniscal tear.

Fig. 79 is a cross-sectional side view of a delivery device for delivering the surgical device of Fig. 78.

Figs. 80-82 illustrate a first placement of the surgical device of Fig. 78 in the meniscus to repair a meniscal tear.

Fig. 83 illustrates a second placement of the surgical device of Fig. 78 in the meniscus to repair a meniscal tear.

## **DETAILED DESCRIPTION**

Referring to Figs. 1 and 2, a surgical device 18 for reattaching soft tissue, e.g., tendon, ligament, or cartilage 10, that is torn partially or completely from a bone 15 to the bone 15, includes a fastener 20, a retainer 25, and a flexible member, such as a suture 30. The suture 30 couples the fastener 20 and the retainer 25, and is tied in a slip knot 35 such that the distance between the fastener 20 and the retainer 25 can be shortened by pulling on a free end 115 of the suture 30.

Referring to Fig. 3, a surgical assembly 5 includes surgical device 18 and a delivery device 100. The delivery device 100 includes a handle 105 and a cannula 110, and is configured to receive the fastener 20, the retainer 25, and the suture 30. The suture 30 passes through the cannula 110 and the handle 105. The handle 105 includes a circumferential slot 106, a longitudinal slot 107, and a connecting member 108 that connects the handle 105 to the cannula 110. When the fastener 20, the retainer 25, and the suture 30 are received in the cannula 100, the suture 30 is passed out of the handle 105. To ensure that the fastener 20 and the retainer 25 remain within the cannula 110 prior to use, the physician pulls the suture 30 through the longitudinal slot 107 until the suture 30 is within the circumferential slot 106 and then wraps the suture 30 around the connecting member 108. In this manner, the fastener 20

and the retainer 25 cannot be withdrawn from the cannula 110 without first loosening the suture 30 from the connecting member 108.

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Referring to Fig. 4, the suture 30 is tied in a slip knot 35 or other type of movable attachment or knot. The movable attachment of the suture 30 to the retainer 25 is one-way such that the length of the suture 30 between the fastener 20 and the retainer 25 can be shortened, but not lengthened. The slip knot 30 is formed, for example, by using the suture 30 to make one or more loops 112 around itself and then tightening the loops 112 against the segment of suture 30 that they encircle. As illustrated in Figs. 3 and 4, the suture 30 extends from the slip knot 35, through the retainer 25, through the fastener 20, back through the retainer 25, and through the slip knot 35. If the fastener 20 is in a fixed position, such as within bone 15, pulling the free end 115 of the suture 30 in a first direction A pulls the slip knot 35 along the suture 30 in a generally opposite direction B, which is in the direction of the fastener 20. As long as the free end 115 is pulled, the slip knot 35 will continue to slide along the suture 30 in the direction B until the slip knot's movement is obstructed by the retainer 25. In one application of the surgical device 18, the slip knot's movement is obstructed by the retainer 25 when soft tissue 10 is compressed between the retainer 25 and the fastener 20.

As shown in Fig. 1, the surgical assembly 5 is generally used, for example, to reattach tissue torn from bone, by placing the fastener 20 through the tissue and into bone, and then tightening the slip knot 35 to push the retainer 25 against the torn tissue. In this manner, the tissue is forced against the bone and the torn edge of the tissue may be placed in apposition to promote healing and prevent further trauma to the tissue.

Referring to Figs. 5 and 6, the fastener 20 is, e.g., a screw including a head 135 and a shank 140 with threads 145. The head 135 is shaped to mate with the cannula 110. For example, the outer surface 146 of the head 135 has a hexagonal shape and the cannula 110 has a hexagonally shaped opening 155 (Fig. 8) that receives the head 135. The head 135 is separated from the shank 140 by a ridge 147 for purposes discussed below. The head 135 includes one or more openings 150 through which one or more sutures 30 pass. Generally, only one suture will be used and therefore only one of the openings 150 will include a suture 30 passing through it. Nonetheless, one or more sutures 30 can be passed through each opening 150 and couple to one or more retainers 25. The threads 145 are of any

configuration, such as a set of parallel threads of different pitch, angle, and/or diameter. The screw 20 is made of a biocompatible metal, polymer, or bioabsorbable polymer, such as titanium, stainless steel, polyethylene, polypropylene, polyglycolic acid, or polylactic acid. The screw 20 is made by one or more of many methods, including machining, molding, casting, or cutting. Alternatively, the fastener 20 can be a push-in type fixation member such as described in the Hayhurst patent, *supra*.

Referring also to Figs. 7-9, the hexagonal opening 155 for receiving the screw head 135 is at the distal region 156 of a lumen or longitudinal channel 157 having a hexagonally shaped bore 159 that extends between the hexagonal opening 155 and a proximal hexagonal opening 160 of the cannula 110. The lumen 157 extends from the cannula 110 through the handle 105 and terminates at an opening 161. The suture 30, the slip knot 35, the retainer 25, and the head 135 of the fastener 20 are placed within the cannula lumen 157 with the slip knot 35 placed proximal to the retainer 35 and the head 135 of the fastener 20 placed distal to the retainer. The threaded shank 140 of the fastener 20, however, is not positioned within the cannula lumen 157 but instead extends beyond the cannula 110. The free end 115 of the suture 30 passes out of the proximal opening 161 in the handle 105 such that the physician can grasp the suture 30 and gently pull on the suture 30 to apply tension to the suture 30. Pulling on the suture 30 applies tension to the suture 30 because the ridge 147 prevents the physician from pulling the fastener 20 further into the lumen 157. By applying tension to the suture 30, the physician ensures that the fastener 20 will not accidentally fall out of the lumen 157 during delivery of the surgical device.

When the assembly 18 is positioned in the longitudinal channel 155, the retainer 25 and the fastener 20 are separated by a tube or block 158 of a rapid absorbing material, such as thrombin, a dry salt, or dry saline. The tube 158 provides a separation between the fastener 20 and the retainer 25 such that the fastener 20 can be delivered without the retainer 25 accidentally being removed or otherwise dislodged from the cannula lumen 157 with the fastener. If the separation between the fastener 20 and the retainer 25 is not sufficient, when the physician delivers the fastener 20 the retainer 25 may be dislodged from the lumen 157. The tube 158 also can be used as a drug or therapeutic agent delivery device to provide a drug or therapeutic agent to the surgical site. For example, the tube 158 includes a wound healing agent, an anti-bacterial agent, or an anti-inflammatory agent. The tube 158 is

expelled from the cannula 110 when the retainer 25 is advanced forward in the cannula 110, as described below.

The suture 30 is made of any suture material, such as, for example, polyethylene or polypropylene. The handle 105 and cannula 110 likewise are made of a biocompatible polymer such as, for example, polyethylene or polypropylene, or a biocompatible metal, or a combination of these.

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Although the absorbable tube 158 is described as being pulled from the needle and/or cannula by the tension in the suture as the suture pulls on the adjacent retainer or screw, the absorbable tube can include a barb or other protrusion to actively catch onto tissue and fix the position of the tube 158 when the cannula or needle is withdrawn.

As illustrated in Figs. 10-14, the retainer 25 includes one or more channels or openings 162, sides 163, an upper surface 165, and a lower surface 170. The channels or openings 162 receive the suture 30 and therefore are smooth or tapered to limit any sharp edges that could damage the suture. The sides 163 and the upper surface 165 likewise are smooth to provide atraumatic tissue contacting surfaces. Passing between the channels 160 on the upper surface 165 is a groove 166 such that when the slip knot 35 is tightened the suture 30 is recessed in the groove 166. In this manner, less of the suture 30 is exposed to mechanical forces associated with body movement. The lower surface 170 preferably includes one or more longitudinally-oriented protrusions 175 that contact the tissue being reattached when the retainer 25 is implanted. The protrusions 175 provide traction against the tissue to limit movement of the retainer 25 relative to the tissue.

The retainer 25 has a low profile to limit protrusion from the soft tissue 10 so that the retainer 25 does not extend from the soft tissue surface e.g., to avoid impingement against other tissue surfaces. For example, if the low profile retainer 25 is used to repair the rotator cuff, the thickness of the retainer 25 is selected to prevent impingement of the retainer 25 against the boney surface of the accromium. Other considerations that can be used in determining the thickness of the retainer 25 include (1) the strength of the retainer relative to the suture passing through the retainer, (2) the depth into the soft tissue that the retainer is seated, and (3) the cosmetic appearance caused by protrusion against the skin (e.g., repair of the lateral collateral ligament). In general, the low profile retainer has dimensions that prevent protrusion of the retainer beyond the tissue in which it is placed. Although some

protrusion beyond the overall surface of the soft tissue is satisfactory, if the low profile retainer is positioned flush with the overall surface of the soft tissue (e.g., by tightening the slip knot against the retainer to "bury" the retainer into the soft tissue) there is a reduced likelihood of impingement and/or contact with other tissue surfaces.

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With respect to determining the thickness of the retainer 25 based on the strength of the suture, the thickness can be determined such that the retainer 25 has the same approximate strength as the suture. The principle behind this consideration is that the retainer 25 does not inherently need to have an increased thickness and, as such, one guide to determining thickness is to provide the minimum thickness necessary to have a similar strength as the suture. In this manner, the retainer 25 provides adequate strength without protruding too much. With respect to the cosmetic appearance caused by the retainer 25, if the retainer is implanted close to the skin surface, a relatively thin retainer will protrude less from the skin than a relatively thick retainer. As such, the recipient of the retainer is less likely to notice the retainer or find the retainer to be a source of irritation.

For example, in one embodiment the retainer 25 has a thickness, t, of between approximately 0.5 and 2.5 mm and, preferably, approximately 2 mm. The length, l, of the retainer 25 is between approximately 6 mm and 10 mm and, preferably, approximately 8 mm. The width, w, of the retainer 25 is between approximately 1.5 and 3 mm and, preferably, between approximately 2 mm and 2.5 mm.

Referring to Figs. 15-17, in an alternative embodiment of the retainer, a retainer 25a is a low profile implant that has a lower surface 170a with transverse protrusions 175a. The protrusions 175a provide traction against a tissue to limit movement of the retainer 25a relative to the tissue. The retainer 25a has two channels 162a extending between a generally smooth upper surface 165a and the lower surface 170a. The channels 162a are oppositely oriented at an angle,  $\alpha$ , to surfaces 165a, 170a. The angle,  $\alpha$ , is between about 30° and 60°. By angling the channels 162a, the force vector associated with the sutures 30 passing through the channels 162a is optimized to achieve optimal repair stability when used with the slip knot 35. In particular, by angling the channels 162a the slip knot 35 has a reduced likelihood of loosening because the suture 30 on the upper surface 165a is under tension in a different direction than that of the suture 30 that passes through the channels 162a. Angling the channels 162a also beneficially causes the two lengths of suture 30 that pass from the retainer

25a to the fastener 20 to be adjacent to each other. By keeping the two lengths of suture 30 adjacent to each other, the channel through the soft tissue through which the suture 30 passes is smaller than it would be if the two lengths of suture was spread apart. Finally, the channels 162a have a tapered opening 176 to accommodate suture 30 passing through the openings 162a and resting against the smooth upper surface 165a. The tapered openings 176 limit damage to the suture 30 that can be caused by sharp edges.

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Referring to Figs. 18-21, less oblong shaped retainers 25b, 25c, 25d, and 25e include an upper surface 165b, 165c, 165d, 165e, a lower surface 170b, 170c, 170d, 170e, and channels 162b, 162c, 162d, 162e, respectively, through the retainer 25b, 25c, 25d, 25e. Referring to Fig. 18, the lower surface 170b and/or the upper surface 165b are smooth. Referring to Fig. 19, the lower surface 170c has protrusions in the form of dimples 188. Referring to Fig. 20, the lower surface 170d has protrusions in the form of ridges 189. Referring to Fig. 21, the lower surface 170e has protrusions in the form of ridges and teeth 190. The channels 162b, 162c, 162d, and 162e are angled relative to the surface 170 and also have a tapered or flared opening as described with respect to Figs. 15-17.

The retainers 25 and 25a-e are made of a bioabsorbable material, a biocompatible plastic, or a biocompatible metal and are made using any well-known technique, including, for example, injection molding, casting, machining, cutting, and stamping. They can be coated with a therapeutic material that, for example, promotes healing of torn tissue and/or prevents infections.

Referring again to Fig. 9, the delivery device 100 is loaded with the suture 30, the retainer 25, and the fastener 20 in the opposite order in which these items are deployed. The tube or block 158 is optionally inserted between the retainer 25 and the fastener 20. The free, proximal end 115 of the suture 30 is inserted into the open, distal end 155 of the cannula 110 and threaded through the lumen 157 until the free, proximal end 115 extends through the proximal opening 161 of the handle 105. The slip knot 35 followed by the retainer 25 is manipulated into the lumen 157 while gently pulling the proximal end of the suture 30. The tube 158 is then inserted into the lumen 157. In the last step, the head 135 is positioned within the bore 159 of the lumen 157 until the ridge 147 is pressed against the distal end 156 of the cannula 110. The proximal end 115 of the suture 30 is then given a final gentle pull to ensure that the fastener 20 is securely positioned within the lumen 157.

Referring to Fig. 22, the surgical assembly 5 is used in an arthroscopic procedure with an arthroscope 190 to repair, e.g., a rotator cuff injury. In this procedure, two small incisions are made into the shoulder joint and the arthroscope 190 is inserted through one incision and the delivery device 100 is inserted through the second incision. The delivery device 100 optionally is placed through a cannula in the second incision. The arthroscope 190 provides a video means of viewing the inside of the shoulder joint throughout the procedure. Prior to inserting the delivery device 100, the physician initially removes any unhealthy or degenerated rotator cuff tissue. Then, the physician prepares the area of the humerus bone 15 where the tendon 10 tore away from the bone 15. For example, the physician gently roughens the bone's cortex to enhance healing by decorticating the cortical surface of the bone to prepare a fresh bed or bleeding surface to encourage tissue to heal. The decortication of the bone results in a slight trough, known as a decorticated trough, to which the tendon is attached.

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Following the initial preparatory work, the physician passes the delivery device 100 through the tendon tissue 10 until the fastener 20 is in contact with the bone 15. The physician then screws the fastener 20 into the bone 15 by grasping the handle 105 and rotating it. The fastener 20 has either left-handed or right-handed threads and the physician rotates the handle in the appropriate direction based on the threads to insert the fastener 20 into the bone 15. Because the cannula 110 has the hexagonal bore 159 and the fastener 20 has the hexagonal head 135, rotating the handle transfers the rotational force to the head 135 and fastener 20 and thereby screws the fastener 20 into the bone tissue.

As illustrated in Fig. 23, the physician then withdraws the delivery device 100 from the tendon 10. Because the fastener 20 is inserted into the bone 15, withdrawing the delivery device 100 pulls the suture 30, the slip knot 35, and the retainer 25 out of the lumen 155. If the physician has inserted the tube 158 into the cannula 110, the tube 158 is also pulled out of the cannula 110 when the retainer 25 is pulled out.

Referring to Fig. 24, the physician then threads the free end 115 of the suture 30 through a knot pusher 192, advances the knot pusher 192 over the suture 30 to slip knot 35, and, while pulling the free end 115, pushes the slip knot 35 against the retainer 25, and presses the retainer 25 and the slip knot 35 against the tendon tissue 10 to firmly position the tendon 10 against the bone 15. The knot pusher can be, for example, the knot pusher

component of the Smith & Nephew FasT-Fix Meniscal Repair System (Smith & Nephew, Andover, MA).

Referring to Fig. 25, the physician then cuts the suture 30 at a position adjacent to the slip knot 35. After examining the repair through the arthroscope, the physician determines whether additional tissue repair is necessary and, if so, places one or more additional fasteners 20 and retainers 25.

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Other embodiments are within the scope of the following claims. For example, referring to Figs. 26-30, a surgical assembly 202 includes a delivery device 200 and a surgical device 205. The surgical device includes the fastener 20, the suture 30, and the slip knot 35 of Fig. 1, and, rather than a single retainer, a pair of low-profile retainers 208a, 208b. One or more absorbable tubes 158 are between the retainers 208a and 208b, and between the distal retainer 208a and the fastener 20. The delivery device 200 and surgical device 205 are used in procedures in which there is, for example, insufficient tissue to grasp or poor quality tissue such that a single fastener 20 and retainer 25 would not adequately reattach the tissue 10 to the bone 15. As described in more detail below, using the surgical device 205 allows the physician to bridge a gap between an area of poor or insufficient tissue and an area of better quality tissue and pull the better quality tissue in the direction of the fastener 20 to attach the better quality tissue to the bone 15. For example, there may be insufficient tissue to grasp when the patient's shoulder is in abduction and there is not sufficient space to manipulate the delivery device 200 to deliver the retainers 208a, 208b through the tissue. There also may be poor quality tissue and insufficient tissue to grasp when the tear has a fraved end that must be trimmed. There may be poor quality tissue when the patient is elderly and the tissue has degenerated. In these situations, the surgical device 205 is used to bridge the gap between the better quality tissue and the bone to which the tissue is to be attached. The pair of retainers 208a, 208b also beneficially helps to distribute the load on the suture 30.

Delivery device 200 includes a handle 210, a cannula 215, and a retractable needle 220. The needle 220 includes a thumb pad 225 at the proximal end 226 of the needle 220 and a sharpened tip 230 at the distal end 227 of the needle 220. The thumb pad 225 protrudes out of an open region 231 in the handle 210 to provide access to the thumb pad 225 for the surgeon to advance or retract the needle 220. The open region 231 is configured to be

slightly wider than the thumb pad 225 such that the thumb pad 225 will slide within the open region 231 with minimal lateral play. The open region 231 has a length, I, that provides sufficient play for the needle 220 to be fully extended by moving the thumb pad 225 in one direction, arrow A, and completely retracted by moving the thumb pad in the opposite direction, arrow B.

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The needle 220 includes a longitudinal slot 235 that opens into a channel 240 defined within the needle 220. The needle 220 slides within a lumen 245 of the cannula 215 and can be advanced to extend distally from the cannula 215 or can be retracted to be wholly contained within the cannula 215. As described in more detail below, the retainers 208a, 208b are positioned within the channel 240 because to deliver the retainer 208a, the needle 220 is extended to pass through the soft tissue. Like the needle 220, the cannula 215 includes a slot 250 that opens into the lumen 245. The physician positions the suture 30 such that it passes through the slots 250, 235 rather than passing over the sharpened tip 230 of the needle 220, thereby preventing the sharpened tip 230 from damaging the suture 125 (Fig. 34). As described in more detail below, the purpose of the needle 220 is to create an opening to pass the cannula 215 through the tissue 10 to place the retainers 208a, 208b. Because the suture 30 is passed through the slots 250, 235, the suture 30 will not pass over the sharpened tip 230 and thereby be cut by the sharpened tip 230 when pressing the sharpened tip 230 against the tissue 10 to create the opening with the needle 220. Thus, one purpose of the slots 235, 250 is to provide a location in which to pass the suture 30 such that the suture 30 is away from the sharpened tip 230.

The retainers 208a, 208b each include a barb or protrusion 223 that extends from a surface 251 of the retainer 208a, 208b and passes through the slots 235, 250. As described in more detail below, the barb 223 catches on the tissue 10 when the delivery device 200 is being withdrawn. By catching the tissue 10, the barb 223 acts to withdraw the retainer 208a from the needle 220 and cannula 215.

As illustrated in Fig. 31, the delivery device 200 is used to reattach soft tissue to bone in, for example, the rotator cuff. Initially, the surgical site is prepared as described above, including the physician forming a decorticated trough 253. The physician then passes the cannula 215 and the fastener 20 through the tendon tissue 10 until the fastener 20 is in contact with the bone 15. In the same manner as described above, the physician inserts the

fastener 20 into the bone 15 by grasping and rotating the handle 210. In particular, because the lumen 245 of the cannula 215 is shaped, for example, to have a hexagonal shape, and the fastener 20 has the mating hexagonal head 135, as described above with respect to Figs. 7-9, rotating the handle transfers the rotational force to the head 135 and fastener 20 and thereby screws the fastener 20 into the bone tissue 15. Fig. 31 illustrates a situation in which there is an insufficient amount of tendon tissue 10 that is accessible by the physician, and the physician has inserted the fastener 20 through the tendon tissue 10 into the decorticated trough 253 approximately where he or she wants to reattach the tendon tissue 10. As described below, subsequent placement of the pair of retainers 208a, 208b, further away from the tear, pulls the better quality tendon tissue 10 into the decorticated trough 253 to reattach the tissue 10 to the bone 15.

As illustrated in Fig. 32, the physician then withdraws the delivery device 200 from the tendon tissue 10, leaving the fastener 20 in the bone 15. At this step, the suture 30 passes from the fastener 20 through the tendon tissue 10 to the retainer 208a. Referring to Fig. 33, the physician then advances the retractable needle 220 out of the cannula 215 by pushing the thumb pad 225 from its retracted position to its extended position. To avoid having the suture 30 extending from the delivery device 200 such that it is surrounded by the sharpened tip 230, the physician changes the position of the suture 30 relative to the sharpened tip 230 such that it passes through the slots 235, 250. For example, the physician can gently grasp the free end 115 of the suture 30 and apply tension to the suture 30 while slightly rotating the handle 210 around its longitudinal axis until the suture 30 moves along the circumference of the sharpened tip and enters the slots 235, 250.

To manipulate the suture 30 through the slots 235, 250, the physician can instead rotate the handle 210 until the suture 30 is lined up with the slots 235, 250. By advancing the delivery device 200 and extending the needle 220 such that the suture 30 passes into the slots 235, 250, the physician clears the suture 30 away from the sharpened tip 230. The physician then positions the sharpened tip 230 of the needle 220 against the tendon tissue 10 with the suture 30 moved away from the sharpened tip 230. In this position, the suture 30 is not between the sharpened tip 230 and the tendon tissue 10 and will not thereby be damaged (e.g., cut by the sharpened tip 230) when the needle is pressed into the tendon tissue 10. The physician places the needle 220 adjacent to the better quality tendon tissue 10.

Referring to Fig. 34, the physician grasps the handle 210 and pushes the delivery device 200 in the direction of the tendon tissue 10 to drive the needle 220 through the tendon tissue 10 until the first barbed retainer 208a has completely passed through the tendon tissue 10. In particular, the barb 223 of the retainer 208a is positioned within or through the tendon tissue 10. The suture 30 now extends from the fastener 20 through the tendon tissue 10, and back into the tendon tissue 10 to the retainer 208a and back to the delivery device 200.

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Referring also to Figs. 35 and 36, the physician withdraws the needle 220 after placing the first retainer 208a. By withdrawing the needle 220, the barb 223 catches the tendon tissue 10 and remains caught against the tendon tissue 10 after the needle 220 is withdrawn. The first retainer 208a is flush against the tendon tissue 10, or alternatively, within the tendon tissue 10. As the physician further withdraws the needle 220, tension in the suture 30 pulls the second retainer 208b and the slip knot 35 out of the needle 220.

Although both retainers 208a, 208b are illustrated as having the barb 223, it is not necessary in all circumstances to provide the second retainer 208b with a tissue-catching member such as the barb 223. Because the first retainer 208a is positioned against the tissue 10, withdrawing the needle 220 from the first retainer 208 causes tension in the suture 30 that pulls the second retainer 208b from the needle 220 without the barb 223 being used. However, to reduce manufacturing costs and inventory costs, for example, the second retainer 208b can be barbed such that it is the same part as the first retainer 208a.

Moreover, the barb 223 can be made of a bioabsorbable material such that it is absorbed by the tissue and does not remain as a potential tissue irritant. The bioabsorbable materials can include a therapeutic agent to treat the injury, promote healing, or provide a preventative anti-bacterial effect. If the physician has placed an absorbable tube 158 between the fastener 20 and the first retainer 208a, when the physician withdraws the needle 220 the tube 158 also is pulled out of the needle 220 by the interaction of the retainer 208a and the tissue 10 such that the tube 158 is positioned in proximity to the first retainer 208a. If the physician has also placed an absorbable tube 158 between the two retainers 208a, 208b, when the physician further withdraws the needle 220, the tension in the suture 30 that pulls the second retainer 208b out of the needle 220 also pulls the second absorbable tube 158 out of the needle 220.

Referring to Figs. 37 and 38, the physician tightens the slip knot 35, optionally using a knot pusher, as discussed above, to press the second retainer 208b firmly against the tendon 10, which presses the tendon tissue 10 firmly against the bone 15 within the decorticated trough to which it is being reattached. As the slip knot 35 is tightened, the distance between the retainers 208a, 208b is reduced and the distance between the fastener 20 and the retainers 208a, 208b is reduced. In reducing these distances, the tendon tissue 10 is pulled into the decorticated trough 253 and into contact with the bone tissue adjacent to the fastener 20. Moreover, the retainers 208a, 208b are pressed flush against the tendon tissue 10 to have a low profile, t. In this manner, even if there initially was insufficient tendon tissue or insufficient quality tendon tissue near the bone, the surgical assembly 205 pulls the detached tendon tissue 10 into the decorticated trough 253 such that quality tendon tissue 10 is reattached. After tightening the slip knot 35, the physician cuts the suture 30 adjacent to the slip knot 130 and removes the delivery device 200.

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Referring to Figs. 39 and 40, a delivery device 300 is used to place the fastener 20 and a single barbed retainer 208a instead of two barbed retainers 208a, 208b. In this embodiment, both the fastener 20 and the retainer 208a are placed between the bone 15 and the tissue that is being reattached to the bone 15 (as illustrated in Fig. 35). The suture 30 passes though and over the tissue between the fastener 20 and the retainer 208a to compress the tissue against the bone 15. Because there is only one retainer 208a, which is positioned under the tendon, only the slip knot 35 remains on the outer or upper surface of the tendon 10.

Referring to Fig. 41, a delivery device 400 for placing fasteners 405, 410 joined by the suture 30 and the slip knot 35 includes a cannula 420, a handle 425, and a thumb activated pusher rod 430. The cannula 420 and the fastener 410 are keyed to limit relative rotation. For example, a bore 433 of the cannula 420 is hexagonal and the fastener 410 is hexagonal along its entire length. To provide the hexagonal shape to the shaped fastener 410, the threads are machined to have hexagonal sides. The fastener 405 has a hexagonal head 434.

Referring to Figs. 42-44, rather than being hexagonally shaped, the fastener 410 and the bore 433 each have a pair of generally straight parallel walls 435, 440 and a pair of curved, oppositely placed walls 445, 450. The straight walls 435 of the fastener 410 are

aligned with the straight walls 440 of the cannula 420 to prevent rotation of the fastener 410 when it is positioned within the shaped bore 433 of the shaped cannula 420. The threads are flattened, cut or otherwise shaped along the entire length of the shank or along only a portion of the length of the shank. The fastener 410 has a slightly smaller cross-sectional profile such that the fastener 410 slides smoothly within the bore 433 of the cannula 420. As illustrated in Fig. 45, the cannula 420 includes a slot 455 along its length through which the suture 30 passes.

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To place the fasteners 405 and 410, the physician places the first fastener 405 through the tendon tissue 10 into the bone 15 in an analogous manner as described above. The physician advances the shaped fastener 410 in the shaped bore 433 of the cannula 420 by advancing the thumb-activated pusher rod 430 from a first retracted position to a second extended position. In the second, extended position the shaped fastener 410 is advanced such that the distal end of the fastener 410 extends out of the cannula 420 and a portion of the shank remains keyed within the shaped bore 433. The physician then presses the shaped fastener 410 through the tendon tissue 10 and screws it into the bone 15, as described above. Because the fastener 410 is keyed to the shaped bore 433 of the cannula 420 because of the mating shape, the shaped fastener 410 will not rotate relative to the cannula 420. The ability of the shaped fastener 410 not to rotate relative to the cannula 420 limits the amount of twisting that is imparted in the suture 30 as well as allows the shaped fastener 410 to be advanced within the cannula 420 and be rotated with the cannula 420. The physician then withdraws the delivery device 400, which pulls the slip knot 35 from the cannula 420, tightens the slip knot 35 against the tissue 10 using an optional knot pusher, and cuts the suture 30 at a position adjacent proximal to the slip knot 35.

Referring to Figs. 46 and 47, a surgical device 502 for repairing a tear 505 in soft tissue, e.g., meniscal tissue 510, includes a first retainer 500 and a second retainer 503 connected by suture 30 that is tied in slip knot 35 such that the distance between the retainers 500, 503 can be shortened but not lengthened. The slip knot 35 is moved to shorten the distance between the retainers 500, 503 to appose the two edges 511, 512 of the meniscal tear 505. Unlike the surgical device 18 (Fig. 2) in which the retainer 25 is positioned between the slip knot 35 and the fastener 20, the slip knot 35 of Fig. 46 is positioned between the first retainer 500 and the second retainer 503. As such, when the surgical device 18 is implanted

the slip knot 35 is positioned against the retainer 25, as illustrated in Fig. 1. In contrast, when the surgical device 502 is implanted the slip knot 35 is positioned within tissue between the first retainer 500 and the second retainer 503.

The retainer 500 is positioned on an anterior surface 545 of the meniscal tissue 510 and the retainer 503 is positioned on a posterior surface 544 of the meniscal tissue 510. The free end 115 of the suture 30 extends out of the posterior surface 544 and the slip knot is within the meniscal tissue 510. When the slip knot 35 is moved to appose the two edges 511, 512, the slip knot 35 remains within the meniscal tissue 510.

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Referring to Figs. 48 and 49, the retainer 500, the retainer 503, the suture 30, and the slip knot 35 (shown as a block for simplicity) are delivered to a surgical site in a delivery device 517 that includes a handle 520, a needle 525, and a pusher tube 530. The needle 525 extends from the handle 520 and includes a longitudinal slot 535 extending along the length of the needle 525 except for a proximal portion 534 of the needle. The needle 525 includes a distal end 536 that tapers to a sharp distal point 537. The pusher tube 530 is positioned within a lumen 538 of the needle 525 and includes a proximal thumb switch 540 that is positioned outside of the needle 525 but is connected to the tube 530 by a connecting plate 541 that passes through the slot 535. The pusher tube 530 also includes a distal end 542 for contacting and pushing the retainer 500. The thumb switch 540 is used to advance and retract the pusher tube 530. For example, the thumb switch is advanced to contact and dislodge the retainer 500 from the needle 525. The needle 525 can be withdrawn from the pusher tube 530 such that the pusher tube 530 can function alone as a knot pusher.

In use, the first retainer 500 is positioned within the needle lumen 538 in a position adjacent to the distal end 542 of the pusher tube 530. The slip knot 35 and the second retainer 503 are positioned outside of the needle 525. The suture 30 extends from the slip knot 35 through the slot 535 into the needle lumen 538 and passes proximally through a lumen 543 in the pusher tube 530 and a channel 546 in the handle 520.

Referring to Figs. 50-53, the meniscal tear 505 is repaired in a simple insertion and removal operation in which the needle 525 is inserted into and through the meniscal tissue 510, the first retainer 500 is deployed, and the needle 525 is withdrawn. Referring specifically to Figs. 50 and 51, initially the needle 525 is passed from the posterior surface 544 of the meniscus 510 to the anterior surface 545 of the meniscus 510. The suture 30 and

the slip knot 35 are pulled into the meniscus 510 with the needle 525 such that the slip knot 35 is positioned within the meniscal tissue 510. The second retainer 503 remains positioned outside of the meniscus 510 against the posterior surface 544. The physician then advances the pusher tube 530 to dislodge the first retainer 500 from the needle 525 to a position adjacent to the anterior surface 545 of the meniscus 510. This action further pulls the slip knot 35 such that the slip knot remains in the meniscal tissue 510.

Referring to Fig. 52, the physician withdraws the needle 525 from the meniscus 510 leaving the pusher tube 530 within the meniscus 510. By next advancing the pusher tube 530 while holding the suture 30 to apply tension to the suture 30, the physician uses the pusher tube 530 as a knot pusher to push or advance the slip knot 35 to shorten the length of the suture 30 between the first retainer 500 and the second retainer 503, closing the meniscal tear 505. Using the pusher tube 530 as a knot pusher aids the physician in seating the knot 35 deep within the tissue. Referring to Fig. 53, the physician next withdraws the pusher tube 530 from the meniscus 510 and, to complete the repair, cuts the suture 30 adjacent to the posterior surface 544 of the meniscus 510. If necessary, the physician inserts additional retainers 500 and 503 to further repair the tear.

Referring to Fig. 54, an atraumatic device 550 for delivering a surgical device 502 has a needle 525a with a curved distal end 555 rather than the tapered distal end 536 of the needle 525a. The needle 525a also has a slot 535a. The curved delivery device 550 is used to deliver the first retainer 500, the second retainer 503, the suture 30, and the slip knot 35. The curved distal end 555 is used to avoid neuromuscular tissue, e.g., in the knee joint when inserting the needle 525a. The curved delivery device 550 is loaded with the retainers 500, 503, the suture 30, and the slip knot 35 in a different manner than the delivery device 517. In particular, while the second retainer 503 remains positioned external to the needle 525a, the slip knot 35 is placed within the needle 525a and the suture 30 extends from the slip knot 35 through the slot 535a to the second retainer 503 and back through the slot 535a to the slip knot 35 and proximally through the pusher tube 530. Positioning the slip knot 35 within the needle 525a advantageously reduces the profile of the device 550 and also protects the slip knot 35 from contacting any surfaces that could possibly damage the slip knot 35. The slip knot 35 and the first retainer 500 are separated by the block 158, having features described above.

If there is no block 158 positioned between the retainer 500 and the slip knot 35, the physician can accidentally dislodge the slip knot 35 prematurely if he or she pushes the pusher tube 530 too far distally. By including the block 158 to separate the retainer 500 and the slip knot 35, the physician has more distance that he or she can push the pusher tube 530 forward without accidentally dislodging the slip knot with the retainer 500. When the pusher tube 530 is advanced to an extended position, the block 158 is pushed out of the needle 525 with the first retainer 500. Because the block 158 is bioabsorbable, it will be absorbed and thereby not remain adjacent to the tissue as a long-term irritant.

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The delivery device 555 is used to deliver the first retainer 500, the second retainer 503, the slip knot 35, and the suture 30 in the same manner as the delivery device 517. A primary difference in the manner of delivery is the ability to direct the curved distal end 555 around neuromuscular tissue. Although the slip knot 35 is delivered within the needle 525, this does not affect the manner in which the physician delivers the first retainer 500 or the second retainer 503. Although shown having a curved distal end 555, the needle 525a also will function with a straight end.

Referring to Fig. 55, as an alternative to the block 158, a delivery device 550a includes a pusher tube 570 having a narrow distal section 575 and a wider middle section 580. Like the block 158 described above with respect to Fig. 54, the narrow distal section 575 is used to increase the distance that the physician can advance the pusher tube without accidentally dislodging the slip knot 35. The slip knot 35 is positioned on the narrow distal section 575 at a position adjacent to the wider middle section 580. In use, the physician advances the pusher tube 570 to push the first retainer 500 out of the needle 525. By advancing the pusher tube 570 further, the middle section 580 aids in pushing the slip knot 35 out of the needle 525a. Although the slip knot 35 will be pulled out by merely retracting the needle 525 after placing the first retainer 500, the middle section 580 provides the physician extra control in placing the slip knot. Moreover, the middle section 580 functions as a knot pusher to push or advance the slip knot 35 deeper into the meniscal tissue. Otherwise, the first retainer 500, the second retainer 503, and the slip knot 35 are delivered in the same manner as described above. Namely, the needle 525a is inserted through the meniscus 510 and the meniscal tear 505, the pusher tube 570 is advanced to an extended position to place the first retainer 500 against the anterior surface 545 of the meniscus 510, thereby advancing

the wider section 580. Finally, the needle 525a is withdrawn, which leaves the slip knot 35 in the meniscal tissue 510 and the second retainer 503 positioned against the posterior surface 544 of the meniscus 510. The pusher tube 570 then is advanced to use the wider section 580 as a knot pusher to push the slip knot 35 to shorten the length of suture 30 between the first retainer 500 and the second retainer 503, which apposes the edges of the tear 505. The pusher tube 570 then is withdrawn and the suture 30 is cut proximally to the slip knot 35.

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Referring to Fig. 56, a knee joint 600 includes a first meniscus 605, a second meniscus 610, a first ligament 615, and a second ligament 620, the lateral collateral ligament. The first meniscus 605 and the first ligament 615 illustrate the normal position of the meniscus and ligament relative to each other and to an upper surface 625 of the tibia 630. In contrast, the second ligament 620 extends outwardly from its normal position due to laxity in the ligament 620. As a result of the laxity in the second ligament 620, the second meniscus 610 is dislodged from its normal position relative to the upper surface 625 of the tibia 630.

Referring to Figs. 57-59, a surgical assembly 640 used to correct laxity in the ligament 620 includes a surgical device 645 and a delivery device 650. The surgical device 645 includes a fastener 655, a retainer 660, and a flexible member, such as a suture 665. The suture 665 couples the fastener 655 and the retainer 660, and is tied in a slip knot 670 such that the distance between the fastener 655 and the retainer 660 can be shortened but not lengthened by pulling on a free end 675 of the suture 665. The fastener 655 includes a head 680 and a shank 685. The head 680 includes an opening 690 through which the suture 665 passes. The shank 685 includes circumferential ridges 695 that resist pullout of the fastener 655 when the fastener 655 is implanted in bone. The retainer 660 includes a pair of openings 700 through which the suture passes and a tab 705 that extends from the retainer 660. The retainer 660 is a low profile retainer and has a thickness of between approximately 0.5 and 2.5 millimeters, and more particularly of approximately 2 millimeters.

The delivery device 650 includes a handle 710 and a cannula 715 which extends from the handle 710. The handle 650 includes an opening 720 in which a thumb switch 725 slides to advance and retract a pusher tube 730 that is connected to the thumb switch 725. The cannula 715 includes an inner lumen 735 that extends from the opening 720 in the handle 650 to a sharp, distal tip 740 at a curved distal end 742. A longitudinal slot 745 opens from outside the cannula 715 into the inner lumen 735. The inner lumen 735 receives the fastener

655, the retainer 660, the suture 665, and the slip knot 670. The suture 665 is placed first within the inner lumen 735 and pulled through the handle 710. The slip knot 670 is placed next within the inner lumen 735. The fastener 665 is placed next within the inner lumen 735 in an orientation with the shank 685 distal to the head 680. Finally, the retainer 660 is placed within the inner lumen 735 with the tab 705 passing through the longitudinal slot 745.

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The suture 665 extends through the cannula 715 and the handle 710 such that the free end 675 passes outside of the delivery device 650. The cannula 715 also includes a stop 750 positioned within the inner lumen 735 between the fastener 655 and the retainer 660. Referring particularly to Fig. 59, the stop 750 is cut from the cannula and can be pressed down in a first direction, a, by the exertion of force against the stop, such as by advancing the fastener 655 distally over the stop 750. The necessity to apply force to pass the fastener 655 over the stop 750 prevents the fastener 655 from being accidentally dislodged. Although the stop 750 can be pressed forward in the first direction, a, the stop 750 cannot easily, if at all, be pressed backward in a second opposite direction, b.

To dislodge the fastener 655 from the cannula 715, the physician advances the thumb switch 725, which advances the pusher tube 730 and forces the fastener 655 over and past the stop 750. The stop 750 prevents the fastener 655 from being pushed back into the cannula 715 once it is pushed distal of the stop 750. Because the stop 750 prevents backwards movement of the fastener 655, the delivery device 650 can be used to press the fastener 655 into bone tissue, as described in more detail below.

Referring to Fig. 60, the physician initially accesses the knee joint 600, for example, using arthroscopic techniques, and drills a guide hole 755 into the upper surface 625 of the bone 630 into which the fastener 655 is to be placed. The physician then advances the delivery device 650 into the knee joint 600 and positions the cannula 715 underneath the second meniscus 610 until the sharp, distal tip 740 is pressed against the ligament 620. The physician then advances the cannula 715 into the second ligament 620 by forcing the sharp, distal tip 740 through the ligament 620. The physician continues to advance the cannula 715 sufficiently such that the retainer 660 is pushed completely through the ligament 620. The physician then retracts the delivery device 650 enough to pull the cannula 715 out of the ligament 620. In pulling back the cannula 715, the tab 705 that extends from the retainer 660 catches the ligament 620, thereby dislodging the retainer 660 from the cannula 715.

Referring to Fig. 61, the physician next positions the delivery device 650 within the knee joint 600 such that the sharp, distal tip 740 is brought up to or inserted into the guide hole 755. With the tip 740 in this position, the physician advances the thumb switch 725 to push the fastener 655 out of the lumen 735 and into the guide hole 755.

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Referring to Fig. 62, the physician then presses the fastener 655 deeper into the guide hole 755. To press the fastener 655 into the guide hole 755, the physician rests the stop 750 against the head 680 of the fastener 655 and applies force to the delivery device 650. Because the stop 750 will not bend backwards, the force applied to the stop 750 will be transmitted to the fastener 655 and will thereby force the fastener 655 into the guide hole 755. The physician may need to further advance the thumb switch 725 to advance the pusher rod 730 to ensure that the fastener 655 is completely within the guide hole 755.

Referring to Fig. 63, after placing the fastener 665, the physician withdraws the delivery device 650 from the knee joint 600, leaving the fastener 655 within the bone 630 and the retainer 660 against the ligament 620. The slip knot 670 is positioned underneath the meniscus 610 between the retainer 660 and the fastener 655 and the remainder of the suture 665 extends out of the knee joint 600. The fastener 655 is positioned within the bone 630 at an angle,  $\delta$ , that is at ninety degrees or less relative to the suture 665 that passes between the retainer 660 and the fastener 655. An angle  $\delta$  of ninety degrees or less opposes a force that would tend to pull the fastener 655 out of the bone 630. The physician next pulls the free end 675 of the suture 665 in a direction, F, which shortens the distance between the fastener 655 and the retainer 660 as the slip knot 670 is pulled toward the fastener 655. Referring to Fig. 64, shortening the distance between the fastener 655 and the retainer 660 pulls the retainer 660 in the direction of the fastener 655, thus, moving the ligament 620 and the meniscus 610 inward, which corrects the misplacement of the meniscus 610. The physician then cuts the suture 665 at a position adjacent to, but proximal of, the slip knot 670, which tends to remain underneath the meniscus 610.

Figs. 56-64 illustrate a method of repairing the laxity in the ligament 620 and the displaced meniscus 610 by placing the retainer 660 before the fastener 655. Nonetheless, the order in which the retainer 660 and the fastener 655 are placed can be reversed. For example, by modifying the cannula 715 and placing the retainer 660 in the cannula 715 before the fastener 655 is placed in the cannula 715, the fastener 655 can be placed in the

bone 630 before the retainer 660 is placed against the ligament 620. In particular, referring to Fig. 65, a cannula 715a has a stop 750a positioned closer to a sharp, distal tip 740a than to stop 750 of the cannula 715. By placing the stop 750a in a more distal position, the stop 750a limits the likelihood that the fastener 655 will retract into the cannula 715a when it is forcibly inserted into the guide hole 755.

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Referring to Fig. 66, in the manner described above, the physician initially accesses the knee joint 600 and drills a guide hole 755 into the upper surface 625 of the bone 630 into which the fastener 655 is to be placed. The physician then advances the delivery device 650a into the knee joint 600 and positions the delivery device 650a within the knee joint 600 such that the fastener 655 and the sharp, distal tip 740a are inserted into the guide hole 755. With the tip 740a in this position, the physician advances the delivery device 650a to further press the fastener 655 into the guide hole 755. The physician then retracts the delivery device 650a from the guide hole 755. Because the fastener 655 includes circumferential ridges 695 that are wedged into the bone 630 surrounding the guide hole 755, the fastener 655 will resist pullout when the delivery device 650a is retracted. To ensure that the fastener 655 is placed sufficiently within the guide hole 755, the physician presses the fastener 655 deeper into the guide hole 755. Because the stop 750a will not bend backwards, the force applied to the stop 750a will be transmitted to the fastener 655 and will thereby force the fastener 655 further into the guide hole 755.

Referring to Fig. 67, the physician next positions the cannula 715a underneath the second meniscus 610 and advances the cannula until the sharp, distal tip 740a is pressed against the ligament 620. The physician then advances the cannula 715a into the ligament 620 by forcing the sharp, distal tip 740a through the ligament 620 while pressing the thumb switch 725a forward to advance the pusher rod 730a and pass the retainer 660 over the stop 750a. The physician continues to advance the cannula 715a sufficiently such that the retainer 660 is pushed completely through the ligament 620. The physician then retracts the delivery device 650a enough to pull the cannula 715a out of the ligament 620. In pulling back the cannula 715a, the tab 750a that extends from the retainer 660 catches the ligament 620, thereby dislodging the retainer 660 from the cannula 715a.

As described above with respect to Fig. 63, after placing the retainer 660, the physician withdraws the delivery device 650a from the knee joint 600, leaving the fastener

655 within the bone 630 and the retainer 660 against the ligament 620. The fastener 655 is positioned within the bone 630 at an angle,  $\delta$ , that is at ninety degrees or less relative to the suture 665 that passes between the retainer 660 and the fastener 655. The slip knot 670 is positioned underneath the meniscus 610 between the retainer 660 and the fastener 655 and the remainder of the suture 665 extends out of the knee joint 600. The physician next pulls the free end 675 of the suture 665 in a direction, F, which shortens the distance between the fastener 655 and the retainer 660 as the slip knot 670 is pulled toward the fastener 655. As described above with respect to Fig. 64, shortening the distance between the fastener 655 and the retainer 660 pulls the retainer 660 in the direction of the fastener 655. Pulling the retainer 660 pulls the ligament 620 and the meniscus 610 inwardly, which corrects the misplacement of the meniscus 610. The physician then cuts the suture 665 at a position adjacent to, but proximal of, the slip knot 670, which tends to remain underneath the meniscus 610.

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Referring to Figs. 68-73, the fastener can be shaped like a button and passed through a channel for repairing a tear in soft tissue. Referring to Fig. 68, a surgical device 800 includes a fastener 805 in the shape of a button, a retainer 810, and a flexible member, such as a suture 815. The suture 815 couples the fastener 805 and the retainer 810, and is tied in a slip knot 820 such that the distance between the fastener 805 and the retainer 810 can be shortened but not lengthened by pulling on a free end 825 of the suture 815. The fastener 805 includes a pair of width edges 830, a pair of length edges 835, an upper surface 840, a lower surface 845, a pair of inner openings 850 passing between the upper surface 840 and the lower surface 845, and a pair of outer openings 855 passing between the upper surface 840 and the lower surface 845. The fastener has a length, L, of between approximately 18-22 mm and a width, W, of between approximately 2-6 mm. The suture 815 passes through the inner openings 850. A pair of sutures 860 pass through each of the outer openings 855 and are used to flip the fastener 805, as described below. The retainer 810 includes a pair of openings 865 through which the suture 815 passes. The retainer 810 is a low profile retainer and has a thickness, T, of between approximately 0.5 and 2.5 millimeters, and more particularly of approximately 2 millimeters.

Referring to Figs. 69 and 70, the physician uses the surgical device to repair, for example, a tear in the meniscus 870 of the knee joint 875. Initially, the physician makes a surgical incision on the anterior surface of the lower leg 880 and passes a drill 883 through

the tibia 885, the meniscus 870, and the femur 890 to form a channel 895 through the tibia 885, the meniscus 870, and the femur 890. The drill 883 includes a head 897 and a shank 900. The head 897 includes an opening 905 for receiving sutures 860 and the shank 900 includes a cutting section 910 and a smooth section 915.

Referring also to Fig. 71, once the physician passes the cutting section 910 through the femur 890 and the skin 920, the physician removes the drill 883 from the handle or other device used to advance the drill 883. The physician then passes the free ends of the sutures 860 coupled to fastener 805 through the opening 905 and advances the drill 883 along the channel 895 until the drill 883 is completely advanced through and out of the channel 895. The sutures 860 now extend between a first opening 925 of the channel 895 and a second opening 930 of the channel 895. Specifically, free ends 935 of the sutures 860 extend from the second opening 930. The mid-section of the sutures 860 extend from the first opening 925 and pass through the outer openings 855 of the fastener 805. The physician then inserts the fastener 805 lengthwise into the channel 895 and pulls the free ends 935 of the sutures 860 to pull the fastener 805 into the channel 895. The physician continues to pull the free ends 935 until the fastener 805 passes through the tibia 885 and the meniscus 870, and is within the knee joint 875.

Referring to Fig. 72, to position the fastener 805 against the meniscus 870 within the knee joint 875, the physician pulls on the suture 815, which pulls the fastener 805 back in the direction of the meniscus 870 and the tibia 885. To ensure that the fastener 805 is not pulled back into the channel 895, the physician changes the orientation of the fastener 805 to be transverse to the channel 895 by pulling on the sutures 860. The physician pulls on one of the sutures 860 more than the other suture 860 to rotate the fastener 805 within the joint. The physician then pulls the free end 825 of the suture 815, which moves the slip knot 820 to shorten the distance between the fastener 805 and the retainer 810. The physician continues to pull on the free end 825 until the retainer 810 is pressed against the first opening 925, which presses the fastener 805 against the meniscus 870 to repair the tear in the meniscus 870. Referring to Fig. 73, to complete the procedure, the physician cuts the suture 815 adjacent to the slip knot 820 and pulls one free end 935 of each suture 860, which pulls the sutures 860 out of the fastener 805.

The surgical device 800 also can be used in a similar manner to repair other tissue within the body. For example, referring to Figs. 74-77, the surgical device 800 can be used to repair a torn rotator cuff 950 in the shoulder joint 953. Referring to Fig. 74, the physician initially makes an incision to access the rotator cuff 950 and then uses the drill 883 to drill a channel 955 through the rotator cuff 950, the humerus head 957, and the skin 960. When the cutting section 910 passes through the skin 960, the physician removes the tool (e.g., handle) used to drive the drill 883 and passes the sutures 860 through the opening 905.

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Referring to Fig. 75, the physician then advances the drill 883 completely through the channel 955 pulling the free ends of the sutures 860 couple to openings 855 of fastener 805 through the skin 960. The sutures 860 extend between a first opening 962 of the channel 955 and a second opening 965 of the channel 955. The second opening 965 is in the skin 960. Specifically, free ends 935 of the sutures 860 extend from the second opening 930. The physician then inserts the fastener 805 lengthwise into the channel 955 and pulls the free ends 935 of the sutures 860 to pull the fastener 805 through the channel 955. The physician continues to pull the free ends 935 until the fastener 805 passes through the rotator cuff 950 and the humerus head 957 and is positioned between the skin 960 and the humerus head 957.

Referring to Fig. 76, to position the fastener 805 against the humerus head 957, the physician pulls on the suture 815, which pulls the fastener 805 in the direction of the humerus head 957. To ensure that the fastener 805 is not pulled back into the channel 955, the physician changes the orientation of the fastener 805 to be transverse to the channel 955 by pulling on the sutures 860. To change the orientation, the physician can pull on one of the sutures 860 more than the other suture 860 to rotate the fastener 805. The physician then pulls the free end 825 of the suture 815, which moves the slip knot 820 to shorten the distance between the fastener 805 and the retainer 810. The physician continues to pull on the free end 825 until the retainer 810 is pressed against the first opening 962, which presses the fastener 805 against the rotator cuff 950 to repair the tear.

Referring to Fig. 77, to complete the procedure the physician cuts the suture 815 adjacent to the slip knot 820 and pulls one free end 935 of each suture 860, which pulls the sutures 860 out of the fastener 805.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and

scope of the invention. For example, although in certain embodiments the fastener is generally described and illustrated as a screw, other implementations of the fastener include an anchor, pound-in screw, or any other configuration that is insertable and retained within bone. The screw and cannula can be coupled by other than hexagonal shapes.

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Although in some embodiments, a pair of retainers, or a retainer and a fastener, are connected by a slip knot, in other embodiments the retainers or the retainer and the fastener may be connected by a suture or flexible member without a slip knot. For example, referring to Fig. 78, a surgical device 1000 includes a first retainer 1005, a second retainer 1010, and a flexible member, such as a suture 1015. The suture 1015 couples the first retainer 1005 and the second retainer 1010, and has a knot 1020 formed at each end 1025 of the suture 1015 to prevent the respective retainer from being separated from the suture 1015. The first retainer 1005 includes a longitudinal channel 1030 and a fin 1035. The longitudinal channel 1030 is open to a side 1033 of the retainer. As described in more detail below, the fin 1035 is used to catch tissue to release the first retainer 1005 from a delivery device when the delivery device is withdrawn from a tissue site during a surgical procedure. The second retainer 1010 includes a longitudinal channel 1040 that opens to a side 1045. As described in more detail below, the openings to the sides 1033, 1045 allow the first retainer 1005, the second retainer 1010, and the suture 1015 to be placed under tension and cause the retainers to shift relative to the suture to be aligned generally perpendicularly to the suture. In this manner, the retainers 1005, 1010 resist pullback through tissue.

Referring also to Fig. 79, the surgical device 1000 is delivered into tissue, such as meniscal tissue, using a delivery device 1050 that includes a needle 1055, a handle 1060, and a thumb-activated pusher rod 1065. The needle 1055 includes a longitudinal slot 1070 through which the fin 1035 extends. The thumb-activated pusher rod 1065 can be used to maintain the position of the retainers 1005, 1010 within the needle 1055 during delivery and to assist in delivering the second retainer 1010.

Referring to Figs. 80-82, the surgical device 1000 and delivery device 1050 are used to repair a meniscal tear 1075. The knee joint is accessed anteriorly and the needle is inserted into an anterior portion 1085 of the meniscus 1080 through a first insertion point 1087 and pushed through the meniscus to a posterior portion 1090 of the meniscus 1080 such that the first retainer 1005 extends from the meniscus at a first exit point 1092. While

pushing the needle through the meniscus, the physician optionally can apply a force to the thumb-activated finger switch 1065 to prevent tissue from pressing the fin 1035 further back into the needle. Of course, the longitudinal slot 1070 can be fabricated to a length that is slightly longer than the length of the fin 1035 to provide an automatic limitation on the retrograde movement of the first retainer 1005.

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The physician next pulls back on the delivery device 1050 and pulls the needle 1055 out of the meniscus 1080, although not out of the knee joint. The physician then moves the needle 1055 to a second insertion point 1093 adjacent to the first insertion point 1087. The physician then inserts the needle 1055 a second time into the meniscus 1080 from the anterior portion 1085 of the meniscus through the second insertion point 1093 and pushes the needle through the meniscus to the posterior portion 1090 of the meniscus such that the second retainer extends from the opposite side of the meniscal tear 1075 at a second exit point 1094. A length 1096 of suture 1015 spans the meniscus between the first insertion point 1087 and the second insertion point 1093. The physician next uses the thumb-activated pusher rod to dislodge the second retainer 1010 from the needle 1055.

Proper placement of the second retainer 1010 relative to the first retainer 1005 will cause the suture 1015 to be in tension. Proper placement is ensured by setting the second insertion point 1093 far enough from the first insertion point 1087 such that there is little play in the suture prior to placing the second retainer 1010. As noted above, the retainers 1005, 1010 are placed such that there is tension in the suture. To relieve some of the tension, the retainers 1005, 1010 will shift position to be generally perpendicular to the suture 1015. This advantageously limits the likelihood that the retainers 1005, 1010 will be pulled back into the channels created by the needle during insertion. The tension in the suture 1015 also advantageously apposes the edges of the meniscal tear 1075 to heal the tear.

Referring to Fig. 83, the surgical device 1000 also can be implanted in a different position relative to the tear than illustrated in Figs. 80-83. For example, instead of placing the retainers 1005, 1010 on opposite sides of the meniscal tear 1075, the retainers 1005, 1010 can be placed on the same side of the tear and the suture 1015 used to appose the edges of the tear. In this positioning of the retainers 1005, 1010, the needle 1055 is advanced anteriorly to distally through the meniscal tear 1075, the first retainer 1005 placed, and the needle 1055 withdrawn. The physician next moves the needle 1055 laterally to create a length 1097 of

suture that extends along the anterior surface 1085 of the meniscus. The needle 1055 then is advanced anteriorly to distally through the meniscal tear 1075, the pusher rod 1065 advanced to dislodge the second retainer 1010, and the needle withdrawn. Again, the tension in the suture 1015 causes the retainers 1005, 1010 to shift to be perpendicular to the suture. The tension in the suture tends to pull the retainers 1005, 1010 in the direction of the length 1095 of suture that extends along the meniscus, which apposes the edges of the meniscal tear.

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The devices and techniques described above can be applied to other anatomical regions to reattach tissue to bone or repair a tear in soft tissue, such as the biceps tendons, the lateral collateral ligament, the medial collateral ligament, the popliteal ligament, and the hip. Accordingly, other embodiments are within the scope of the following claims.

#### WHAT IS CLAIMED IS:

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1. A surgical assembly comprising:

a delivery device comprising a handle and a cannula, the cannula extending from the handle and including a longitudinal channel and a longitudinal slot in the cannula along at least a portion of the length of the channel; and

a surgical device comprising a first retainer, a second retainer, a flexible member coupling the first retainer and the second retainer, the flexible member being movably attached to the first retainer such that pulling on a free end of the flexible member shortens a length of the flexible member between the first retainer and the second retainer,

wherein the first retainer is positioned within the longitudinal channel, the second retainer is positioned adjacent to an outer surface of the cannula, and the flexible member passes from the longitudinal channel through the longitudinal slot.

- 2. The surgical assembly of claim 1 further comprising a pusher tube slidably positioned within the cannula and including a thumb switch extending through the longitudinal slot for advancing and retracting the pusher tube.
- 3. The surgical assembly of claim 2 wherein the pusher tube is positioned within the longitudinal channel proximal to the first retainer.
- 20 4. The surgical assembly of claim 2 wherein the pusher tube includes a distal end that contacts the first retainer.
  - 5. The surgical assembly of claim 2 wherein the thumb switch is at a proximal end of the pusher tube.
  - 6. The surgical assembly of claim 2 wherein a portion of the thumb switch is positioned outside the longitudinal channel.
- 7. The surgical assembly of claim 2 wherein the pusher tube includes a distal section that extends from a middle section that is wider than the distal section.

8. The surgical assembly of claim 7 wherein the movable attachment is positioned on the distal section at a position adjacent the wider middle section.

- 5 9. The surgical assembly of claim 7 wherein the distal section contacts the first retainer.
  - 10. The surgical assembly of claim 1 wherein the movable attachment comprises a slip knot.
  - 11. The surgical assembly of claim 10 wherein the movable attachment is positioned within the longitudinal channel.

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- 12. The surgical assembly of claim 11 wherein the surgical device comprises a block positioned between the movable attachment and the first retainer.
  - 13. The surgical assembly of claim 12 wherein the block is bioabsorbable.
- 14. The surgical assembly of claim 11 wherein the movable attachment is positioned outside of the longitudinal channel.
  - 15. The surgical assembly of claim 1 wherein the cannula is a needle.
- 16. The surgical assembly of claim 15 wherein the needle includes a distal end that tapers to a sharp distal point.
  - 17. The surgical assembly of claim 1 wherein the needle includes a distal end that is curved.
- 30 18. A surgical assembly comprising: a fastener configured to be secured within bone tissue;

a retainer for engaging tissue; and

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a flexible member connecting the fastener to the retainer, the flexible member being movably attached to the retainer such that pulling on a free end of the flexible member shortens a length of the flexible member between the fastener and the retainer to urge the tissue against the bone tissue.

- 19. The surgical assembly of claim 18 wherein the movable attachment of the flexible member to the retainer is configured to enable the length of the flexible member between the fastener and the retainer to be shortened, but not lengthened.
- 20. The surgical assembly of claim 19 wherein the movable attachment includes a knot formed in the flexible member.
  - 21. The surgical assembly of claim 20 wherein the knot comprises a slip knot.
- 22. The surgical assembly of claim 18 wherein the flexible member comprises a suture.
- 23. The surgical assembly of claim 18 wherein the retainer includes a smooth first surface and a second surface that includes protrusions.
  - 24. The surgical assembly of claim 18 wherein the retainer includes a smooth first surface and a second surface having a length and protrusions that are transverse to the length of the second surface.
  - 25. The surgical assembly of claim 18 wherein the retainer has a low profile such that the retainer does not protrude sufficiently from the tissue to impinge against adjacent tissue.
- 30 26. The surgical assembly of claim 18 wherein the retainer has a thickness of between approximately 0.5 and 2.5 millimeters.

27. The surgical assembly of claim 18 wherein the retainer has a thickness of approximately 2 millimeters.

- 28. The surgical assembly of claim 18 wherein the fastener comprises a screw.
- 29. The surgical assembly of claim 27 wherein the screw comprises a threaded shank and a head, and the head defines at least one opening and the flexible member passes through the opening.

30. The surgical assembly of claim 29 wherein the screw comprises a ridge between the shank and the head.

- 31. The surgical assembly of claim 18 further comprising a delivery device for delivering the fastener and retainer to a surgical site.
  - 32. The surgical assembly of claim 31 wherein the delivery device includes a cannula defining a lumen for receiving the fastener and retainer.
- 20 33. The surgical assembly of claim 31 further comprising a retractable needle positioned within the lumen and connected to a switch in the delivery device for advancing and retracting the needle.
  - 34. A surgical assembly comprising:
  - a first screw;

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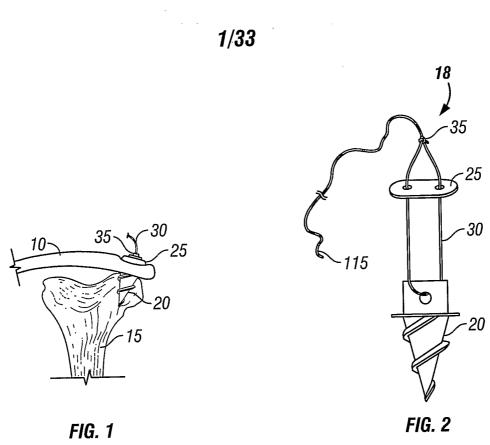
- a second screw; and
- a flexible member connecting the first screw to the second screw, the flexible member being movably attached to the second screw such that pulling on a free end of the flexible member shortens a length of the flexible member between the first screw and the second screw.

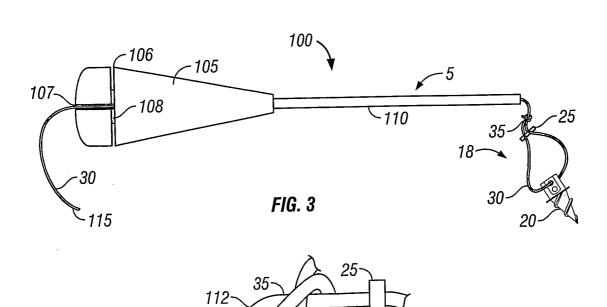
35. The surgical assembly of claim 34 further comprising a cannula for receiving the first and second screws, the cannula having a lumen and a distal end, the first screw being received within the lumen and the second screw being located at the distal end, the first screw and the cannula being configured to limit relative rotation therebetween.

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36. The surgical assembly of claim 35 further comprising a pusher rod extending into the cannula for advancing the first screw to the distal end of the cannula.









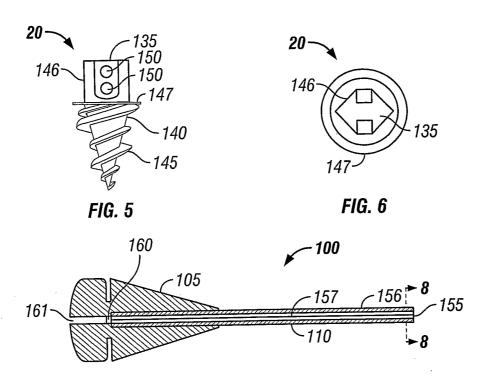
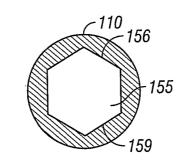


FIG. 7



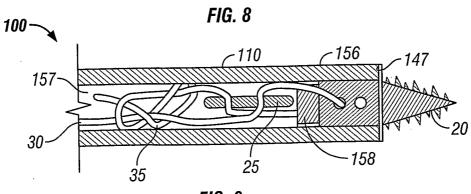
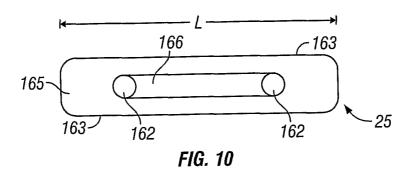
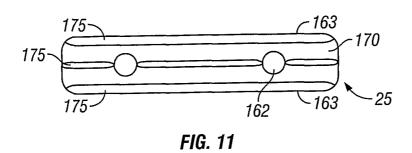
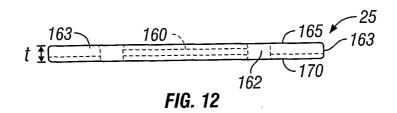


FIG. 9







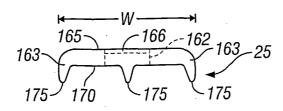


FIG. 13

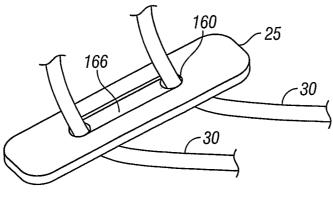


FIG. 14

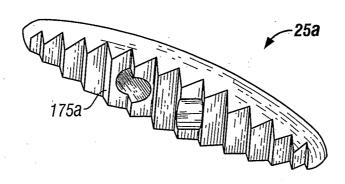


FIG. 15

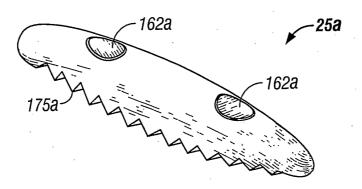


FIG. 16

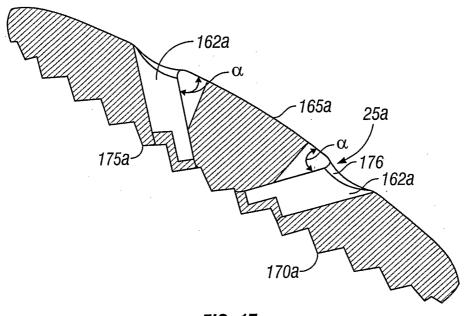
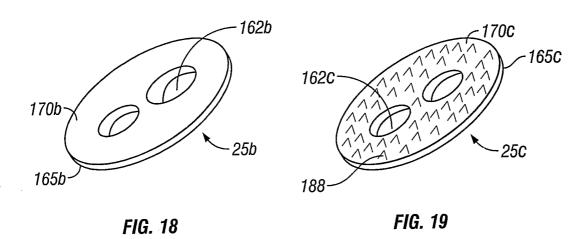
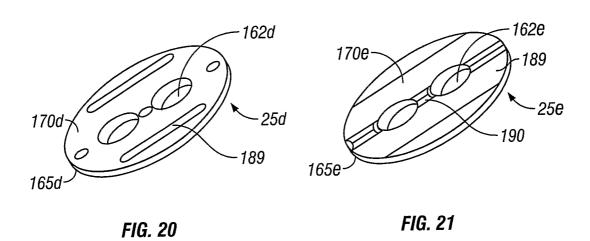


FIG. 17







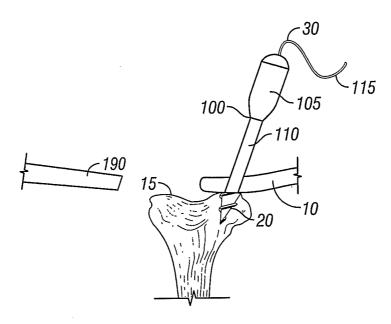


FIG. 22

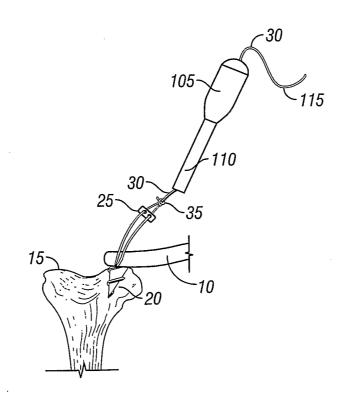


FIG. 23

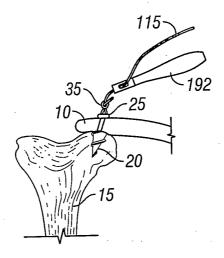


FIG. 24

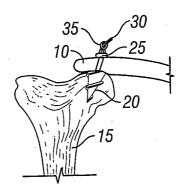
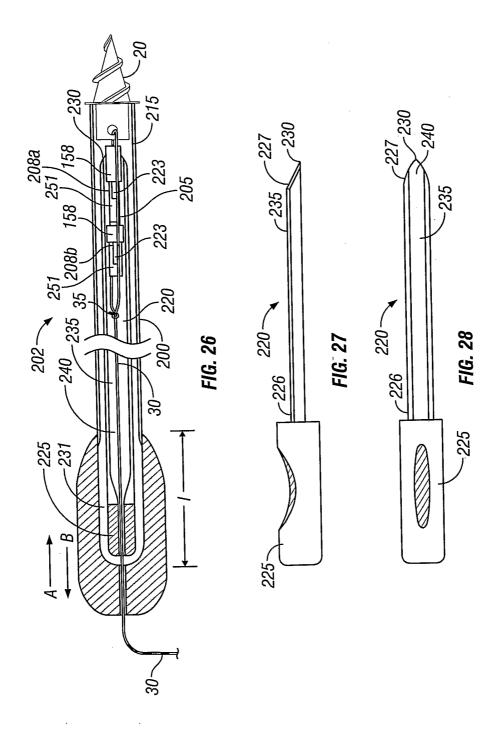
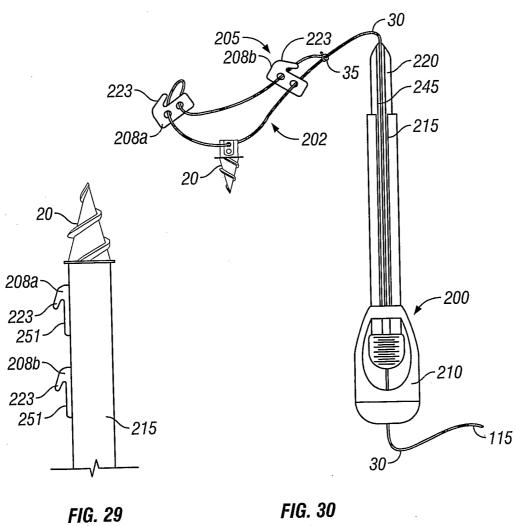


FIG. 25





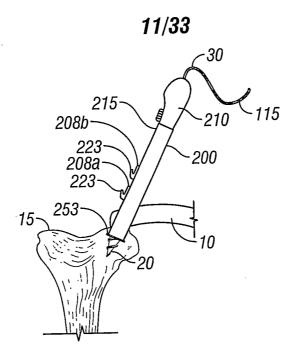


FIG. 31

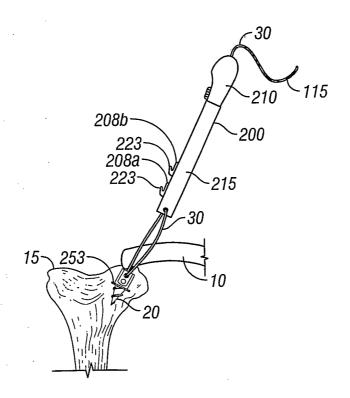


FIG. 32

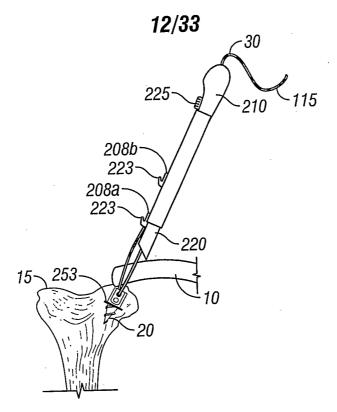


FIG. 33

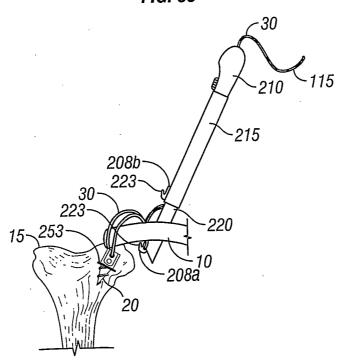


FIG. 34

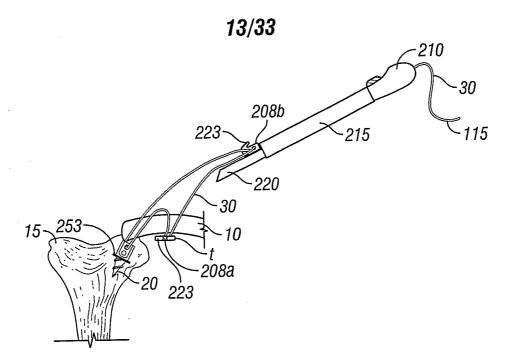


FIG. 35

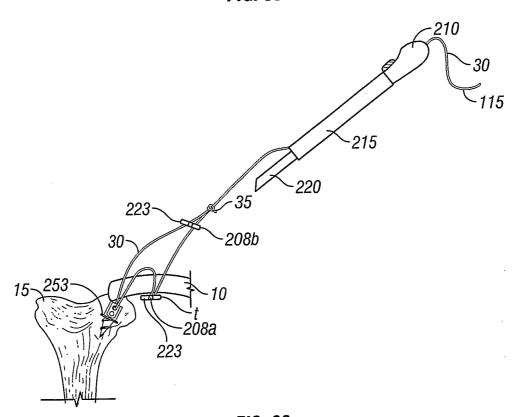


FIG. 36

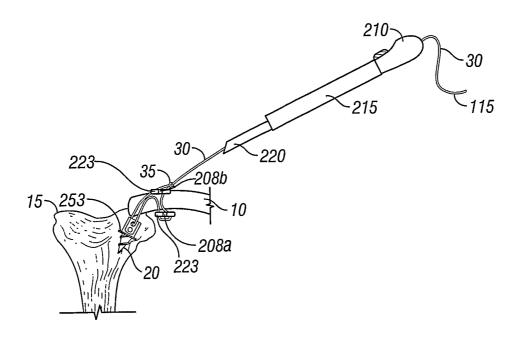


FIG. 37

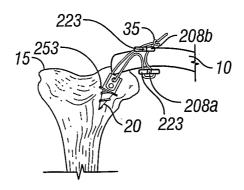


FIG. 38

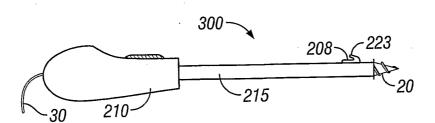


FIG. 39

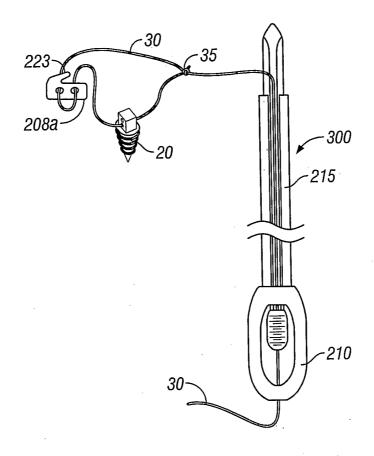
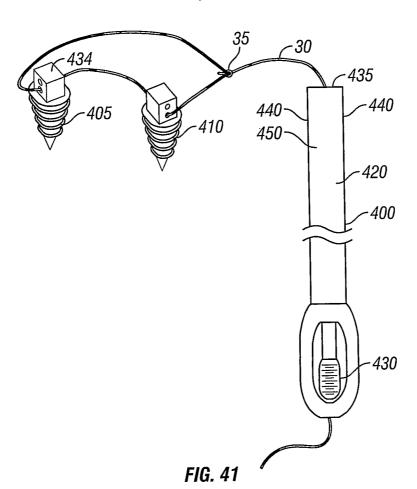


FIG. 40





435 435 435 445

FIG. 42

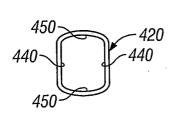
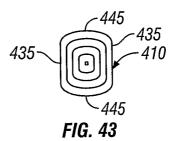


FIG. 44



455
440
450

FIG. 45

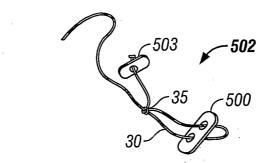


FIG. 46

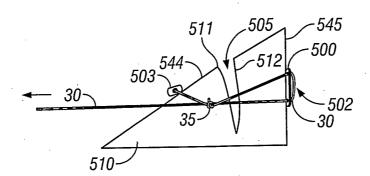
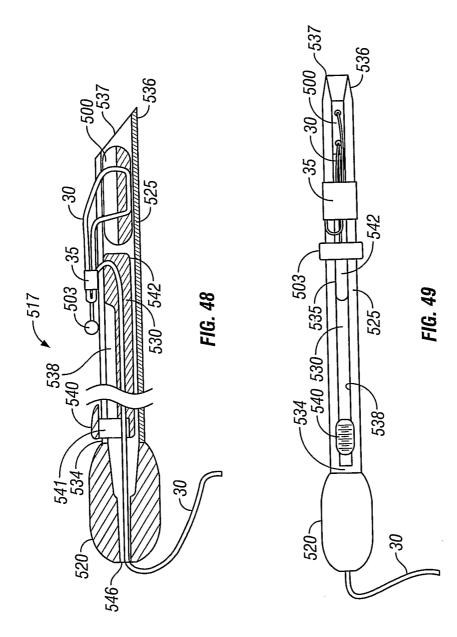


FIG. 47



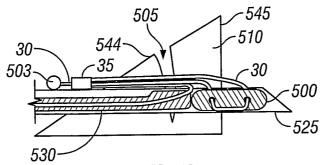
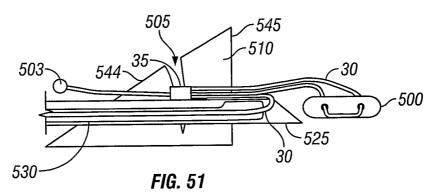


FIG. 50



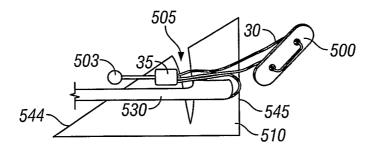


FIG. 52

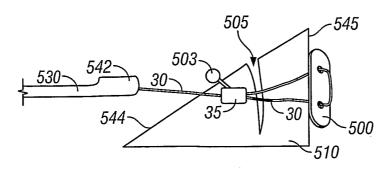
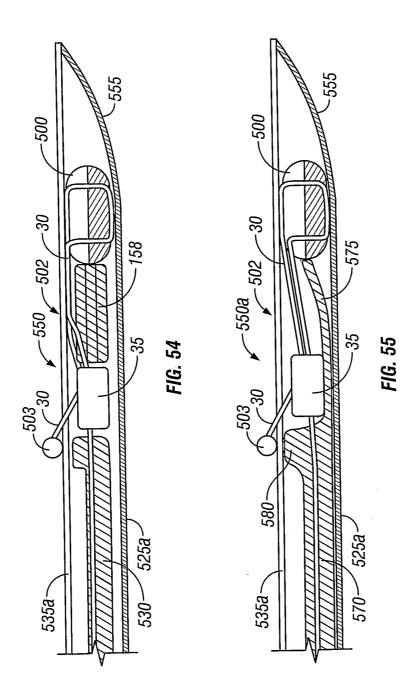


FIG. 53



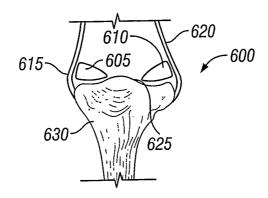


FIG. 56

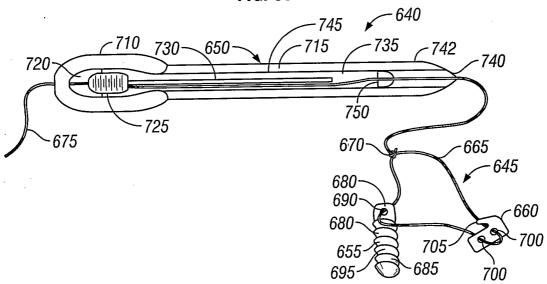


FIG. 57

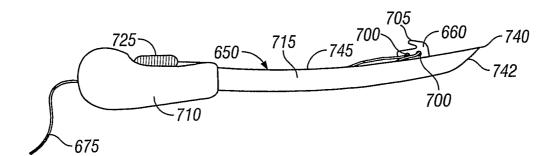


FIG. 58

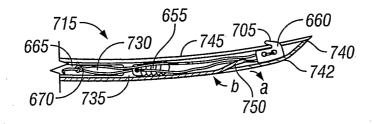


FIG. 59

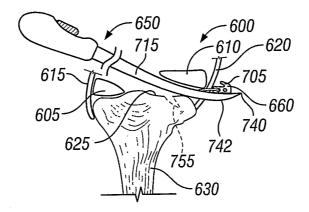


FIG. 60

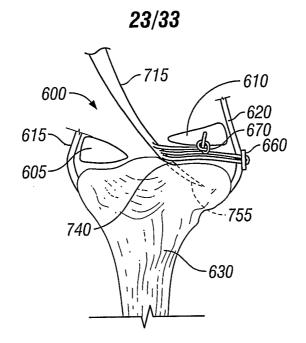


FIG. 61

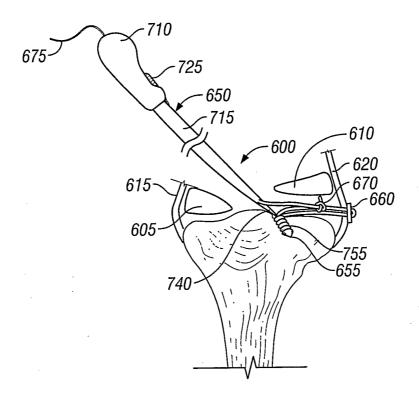


FIG. 62

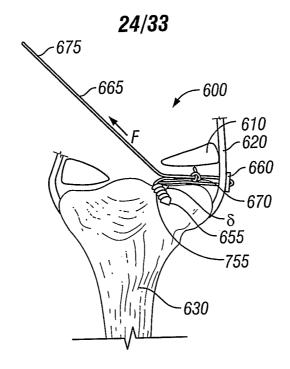
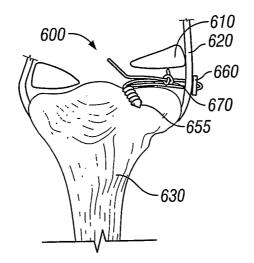


FIG. 63



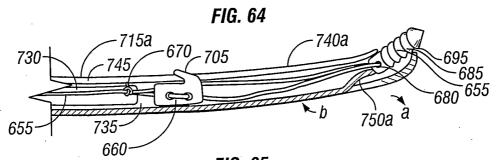


FIG. 65

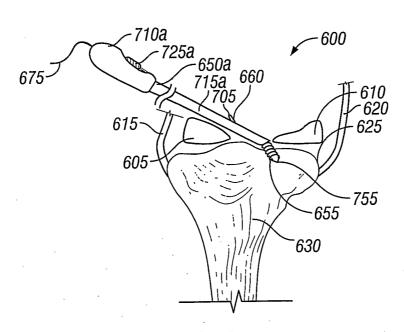


FIG. 66

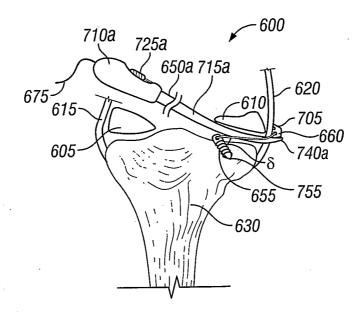
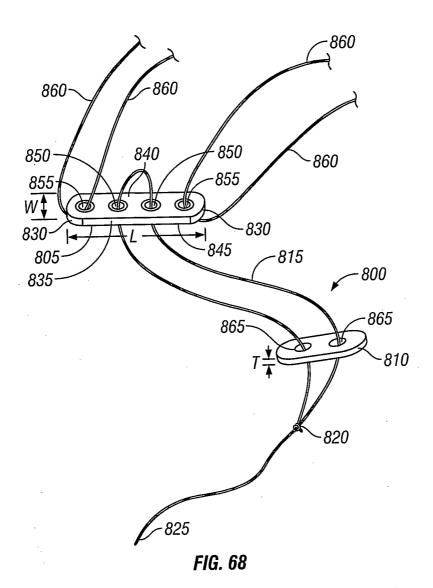


FIG. 67



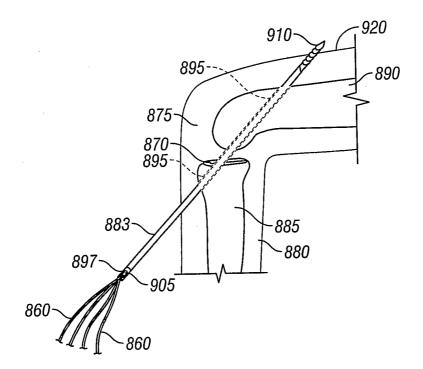


FIG. 69

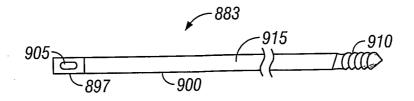


FIG. 70

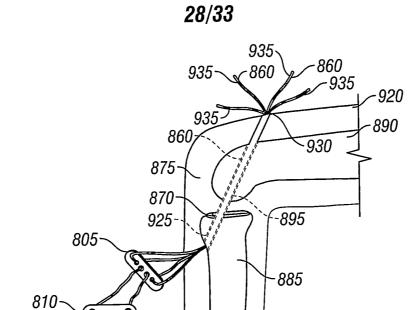


FIG. 71

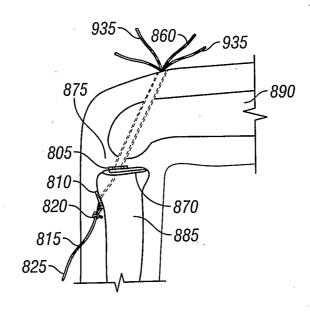


FIG. 72

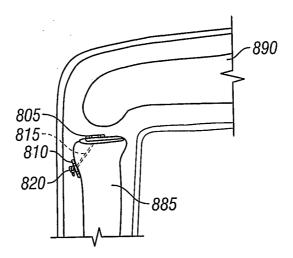


FIG. 73

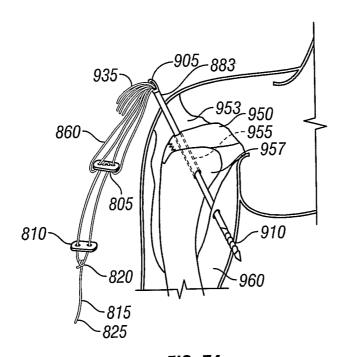


FIG. 74

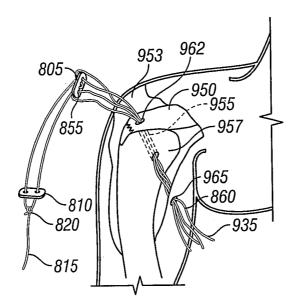


FIG. 75

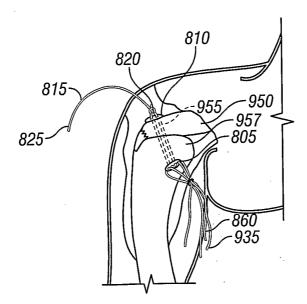


FIG. 76

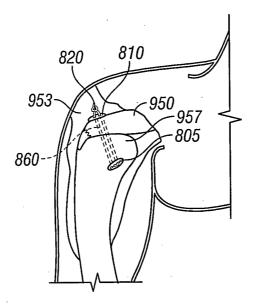
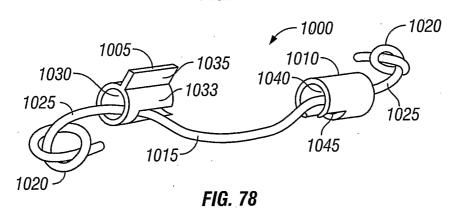


FIG. 77



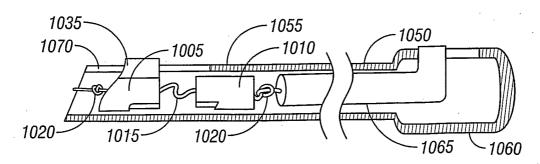


FIG. 79

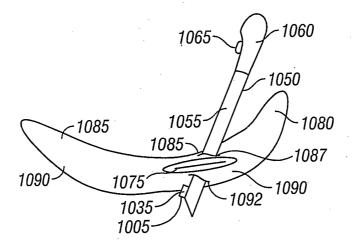


FIG. 80

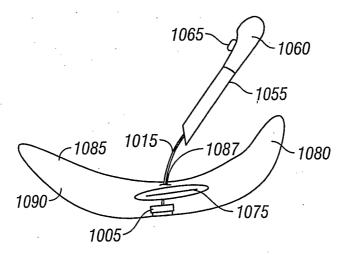


FIG. 81

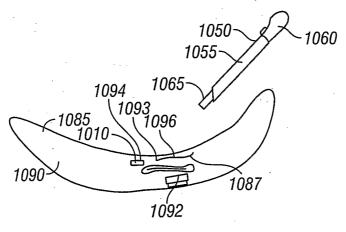


FIG. 82

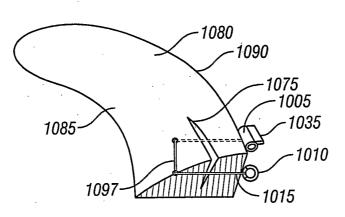


FIG. 83