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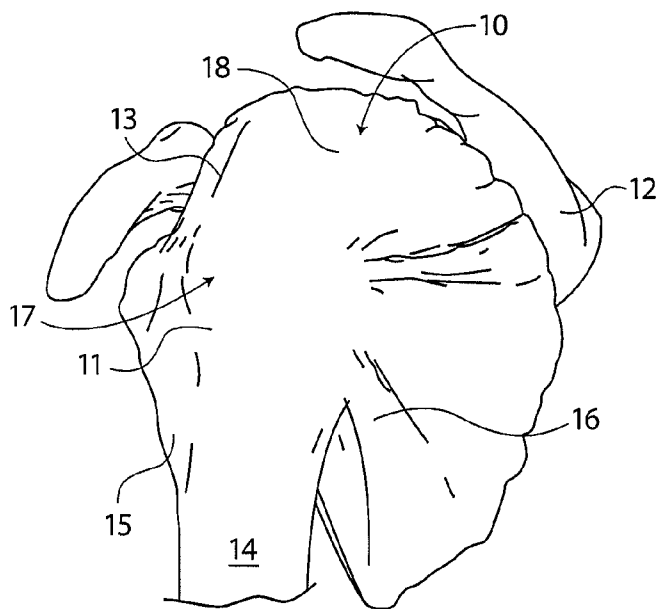


FIG. 1

(57) Abstract: Devices for attaching a sheet-like implant to a target tissue include a sheath and a staple push rod. The sheath has a distal end configured to be pressed against the target tissue. The staple push rod is disposed within at least a portion of the sheath and is slidable relative thereto. The staple push rod includes a pair of stakes. Each stake is dimensioned to abut a surface of a staple to apply pushing forces thereto. The stakes are biased to assume a bow-like shape such that an intermediate portion of a staple extends tautly between the first stake and the second stake when the stakes are extending beyond the distal end of the tubular member. Methods for attaching a sheet-like implant to a target tissue are also disclosed.

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APPARATUS HAVING BOWSTRING-LIKE STAPLE DELIVERY TO A TARGET TISSUE**CROSS REFERENCE TO RELATED APPLICATIONS**

5 [0001] The present application claims the benefit of U.S. Provisional Patent Application Serial No. 61/184,198 filed on June 4, 2009; U.S. Provisional Patent Application Serial No. 61/253,800 filed on October 21, 2009; and U.S. Provisional Patent Application No. 61/313,051 file on March 11, 2010, the disclosures of each incorporated herein by reference.

10 FIELD OF THE INVENTION

[0002] The present invention relates generally to orthopedic medicine and surgery. More particularly, the present invention relates to methods and apparatus for delivery and fixation of sheet-like materials, such as for treating articulating joints.

15 BACKGROUND OF THE INVENTION

[0003] The glenohumeral joint of the shoulder is found where the head of the humerus mates with a shallow depression in the scapula. This shallow depression is known as the the glenoid fossa. Six muscles extend between the humerus and scapula and actuate the glenohumeral joint. These six muscles include the deltoid, the teres major, and the four rotator cuff muscles. As disclosed by Ball et al. in U.S. Patent Publication No. US 2008/0188936 A1 and as illustrated in Figure 1 the rotator cuff muscles are a complex of four muscles. These four muscles are the supraspinatus, the infraspinatus, the subscapularis, and the teres minor. The centering and stabilizing roles played by the rotator cuff muscles are critical to the proper function of the shoulder. The rotator cuff muscles provide a wide variety of moments to rotate the humerus and to oppose unwanted components of the deltoid and pectoralis muscle forces.

20 [0004] The four muscles of the rotator cuff arise from the scapula 12. The distal tendons of the rotator cuff muscles splay out and interdigitate to form a common continuous insertion on the humerus 14. The subscapularis 16 arises from the anterior aspect of the scapula 12 and attaches over much of the lesser tuberosity of the humerus. The supraspinatus muscle 18 arises from the supraspinatus fossa of the posterior scapula, passes beneath the acromion and the acromioclavicular joint, and attaches to the superior aspect of the greater tuberosity 11. The infraspinatus muscle 13 arises from the infraspinous fossa of the posterior scapula and attaches to the posterolateral aspect of the greater tuberosity 11. The teres minor 15 arises from the lower lateral aspect of the scapula 12 and attaches to the lower aspect of the greater tuberosity 11.

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[0005] The mechanics of the rotator cuff muscles 10 are complex. The rotator cuff muscles 10 rotate the humerus 14 with respect to the scapula 12, compress the humeral head 17 into the glenoid fossa providing a critical stabilizing mechanism to the shoulder (known as concavity compression), and provide muscular balance. The supraspinatus and infraspinatus provide 45 percent of abduction and 90 percent of external rotation strength. The supraspinatus and deltoid muscles are equally responsible for producing torque about the shoulder joint in the functional planes of motion.

[0006] The rotator cuff muscles 10 are critical elements of this shoulder muscle balance equation. The human shoulder has no fixed axis. In a specified position, activation of a muscle creates a unique set of rotational moments. For example, the anterior deltoid can exert moments in forward elevation, internal rotation, and cross-body movement. If forward elevation is to occur without rotation, the cross-body and internal rotation moments of this muscle must be neutralized by other muscles, such as the posterior deltoid and infraspinatus. The timing and magnitude of these balancing muscle effects must be precisely coordinated to avoid unwanted directions of humeral motion. Thus the simplified view of muscles as isolated motors, or as members of force couples must give way to an understanding that all shoulder muscles function together in a precisely coordinated way--opposing muscles canceling out undesired elements leaving only the net torque necessary to produce the desired action. Injury to any of these soft tissues can greatly inhibit ranges and types of motion of the arm.

[0007] With its complexity, range of motion and extensive use, a fairly common soft tissue injury is damage to the rotator cuff or rotator cuff tendons. Damage to the rotator cuff is a potentially serious medical condition that may occur during hyperextension, from an acute traumatic tear or from overuse of the joint. With its critical role in abduction, rotational strength and torque production, the most common injury associated with the rotator cuff region is a strain or tear involving the supraspinatus tendon. A tear in the supraspinatus tendon 19 is schematically depicted in Figure 2. A tear at the insertion site of the tendon with the humerus, may result in the detachment of the tendon from the bone. This detachment may be partial or full, depending upon the severity of the injury. Additionally, the strain or tear can occur within the tendon itself. Injuries to the supraspinatus tendon 19 and recognized modalities for treatment are defined by the type and degree of tear. The first type of tear is a full thickness tear as also depicted in Figure 2, which as the term indicates is a tear that extends through the thickness of the supraspinatus tendon regardless of whether it is completely torn laterally. The second type of tear is a partial thickness tear which is further classified based on how much of the thickness is torn, whether it is greater or less than 50% of the thickness.

[0008] The accepted treatment for a full thickness tear or a partial thickness tear greater than 50% includes reconnecting the torn tendon via sutures. For the partial thickness tears greater than 50%, the tear is completed to a full thickness tear by cutting the tendon prior to reconnection. In contrast to the treatment of a full thickness tear or a partial thickness tear of greater than 50%, the treatment for a partial thickness tear less than 50% usually involves physical cessation from use of the tendon, i.e., rest. Specific exercises can also be prescribed to strengthen and loosen the shoulder area. In many instances, the shoulder does not heal and the partial thickness tear can be the source of chronic pain and stiffness. Further, the pain and stiffness may cause restricted use of the limb which tends to result in further degeneration or atrophy in the shoulder. Surgical intervention may be required for a partial thickness tear of less than 50%, however, current treatment interventions do not include repair of the tendon, rather the surgical procedure is directed to arthroscopic removal of bone to relieve points of impingement or create a larger tunnel between the tendon and bone that is believed to be causing tendon damage. As part of the treatment, degenerated tendon may also be removed using a debridement procedure in which tendon material is ablated. Again, the tendon partial tear is not repaired. Several authors have reported satisfactory early post operative results from these procedures, but over time recurrent symptoms have been noted. In the event of recurrent symptoms, many times a patient will "live with the pain". This may result in less use of the arm and shoulder which further causes degeneration of the tendon and may lead to more extensive damage. A tendon repair would then need to be done in a later procedure if the prescribed treatment for partial tear was unsuccessful in relieving pain and stiffness or over time the tear propagated through injury or degeneration to a full thickness tear or a partial thickness tear greater than 50% with attendant pain and debilitation. A subsequent later procedure would include the more drastic procedure of completing the tear to full thickness and suturing the ends of the tendon back together. This procedure requires extensive rehabilitation, has relatively high failure rates and subjects the patient who first presented and was treated with a partial thickness tear less than 50% to a second surgical procedure.

[0009] As described above, adequate treatments do not currently exist for repairing a partial thickness tear of less than 50% in the supraspinatus tendon. Current procedures attempt to alleviate impingement or make room for movement of the tendon to prevent further damage and relieve discomfort but do not repair or strengthen the tendon. Use of the still damaged tendon can lead to further damage or injury. Prior damage may result in degeneration that requires a second more drastic procedure to repair the tendon. Further, if the prior procedure was only partially successful in relieving pain and discomfort, a response may be to use the shoulder less which leads to degeneration and increased likelihood of further injury along with the need for

more drastic surgery. There is a large need for surgical techniques and systems to treat partial thickness tears of less than 50% and prevent future tendon damage by strengthening or repairing the native tendon having the partial thickness tear.

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SUMMARY OF THE INVENTION

[00010] According to aspects of the invention, devices for attaching a sheet-like implant to a target tissue are disclosed. In some embodiments, the device includes a sheath and a staple push rod. The sheath has a distal end configured to be pressed against the target tissue. The staple push rod is disposed within at least a portion of the sheath and is slidable relative thereto. The staple push rod includes a pair of stakes. Each stake is dimensioned to abut a surface of a staple to apply pushing forces thereto. The stakes are biased to assume a bow-like shape such that an intermediate portion of a staple extends tautly between the first stake and the second stake when the stakes are extending beyond the distal end of the tubular member.

[00011] In some embodiments, each stake has a distal portion and a proximal portion. Each distal portion is dimensioned to extend into a passage defined by a staple. Each proximal portion has a width larger than a width of each distal portion so that a shoulder of each proximal portion contacts a proximal surface of the staple to apply pushing forces thereto. In some embodiments, the stakes are biased to expand against an inner surface of the sheath. The intermediate portion of the staple may include a first arm, a second arm, and a bridge. The first stake and the second stake may extend away from each other when the stakes are assuming the bow-like shape.

[00012] In some embodiments, the device further comprising a sheath having a proximal end, a distal end and a lumen extending therebetween. In these embodiments, at least a portion of the staple push rod extends into the lumen and is slidable relative thereto. The first stake and the second stake may be disposed in the lumen of the sheath. In some embodiments, the sheath defines a distal opening fluidly communicating with the lumen. The staple push rod is slidably disposed in the lumen so as to urge relative movement between the stakes and the sheath. With this arrangement, the stakes can be advanced through the distal opening defined by the sheath so that the stakes are free to assume the bow-like shape.

[00013] In some embodiments, the stakes have a first lateral extent when the stakes are free to assume the bow-like shape. The lumen of the sheath has a lumen dimension smaller than the first lateral extent. In some embodiments, the sheath holds the stakes in a compact configuration. In some embodiments, the stakes are sufficiently flexible to allow the stakes to be advanced into the lumen of the sheath. A distal-most portion of each stake may extend across a leading edge of each fluke of a staple.

[00014] According to aspects of the invention, methods for attaching a sheet-like implant to a target tissue are disclosed. In some embodiments, the methods include the steps of providing a staple push rod carrying a staple, depressing the target tissue to form a depression therein, advancing a first fluke of the staple into tissue at a first side of the depression, and advancing a second fluke of the staple into tissue at a second side of the depression. In these embodiments, the staple includes first and second arms, each arm having proximal and distal ends. A bridge extends from the proximal end of the first arm to the proximal end of the second arm. A first fluke of the staple has a proximal end abutting the distal end of the first arm. A second fluke of the staple has a proximal end abutting the distal end of the second arm. The staple push rod of the device includes a shaft, a first stake and a second stake. Each stake has a distal portion and a proximal portion. A proximal end of the proximal portion of each stake is fixed to a distal end of the shaft. The distal portion of the first stake extends into a first passage defined by the first fluke of the staple. The distal portion of the second stake extends into a second passage defined by the second fluke of the staple. The stakes are biased to assume a bow-like shape such that an intermediate portion of the staple extends tautly between the first stake and the second stake.

[00015] In some embodiments, the first side of the depression and the second side of the depression are generally opposite each other. The intermediate portion of the staple may be pulled taut when the first end is advanced into tissue at the first side of the depression and the second end of the staple is advanced into tissue at the second side of the depression. In some embodiments, the intermediate portion of the staple is positioned below a tissue plane when the first end is advanced into tissue at the first side of the depression and the second end of the staple is advanced into tissue at the second side of the depression. In some embodiments, the tissue plane is defined by an outer surface of a remainder of the target tissue, and the remainder of the target tissue does not include the depression.

[00016] In some embodiments, the method further comprises the step of providing a sheath having a proximal end, a distal end and a lumen extending therebetween. The step of depressing the target tissue to form a depression therein comprises pushing on the target tissue with the distal end of the sheath.

[00017] According to aspects of the invention, methods for attaching a sheet-like implant to a target tissue are disclosed. In some embodiments, the method includes the steps of providing a staple push rod carrying a staple, advancing a first fluke of the staple in a first direction, advancing a second fluke of the staple in a second direction that is generally opposite the first direction, moving the first end and the second ends away from each other, and pulling an intermediate portion of the staple taut between the first end and the second end. In these embodiments, the staple comprises first and second arms, each arm having proximal and distal

ends. A bridge extends from the proximal end of the first arm to the proximal end of the second arm. A first fluke of the staple has a proximal end abutting the distal end of the first arm. A second fluke of the staple has a proximal end abutting the distal end of the second arm. The staple push rod of the device includes a shaft, a first stake and a second stake. Each stake has a distal portion and a proximal portion. A proximal end of the proximal portion of each stake is fixed to a distal end of the shaft. The distal portion of the first stake extends into a first passage defined by the first fluke, and the distal portion of the second stake extends into a second passage defined by the second fluke. The stakes are biased to assume a bow-like shape such that an intermediate portion of the staple extends tautly between the first stake and the second stake.

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10 [00018] In some embodiments, the method further includes the step of advancing the first fluke in a distal direction through the sheet-like implant. This step may be performed before the step of advancing the first fluke of the staple in the first direction. In some embodiments, the distal direction is a generally parallel to a longitudinal axis of the shaft. In some embodiments, the distal direction is an axial direction relative to the shaft and the first direction is a lateral direction relative to the shaft.

15 [00019] Further aspects of the invention will become apparent upon review of the Detailed Description of the Invention with reference to the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

20 [00020] Figure 1 is a simplified perspective view of the human rotator cuff and associated anatomical structure.

[00021] Figure 2 is a schematic depiction of a full thickness tear in the supraspinatus tendon of the rotator cuff of Figure 1.

25 [00022] Figure 3 is a stylized anterior view of a patient with a shoulder of patient being shown in cross-section for purposes of illustration.

[00023] Figure 4 is a stylized anterior view of a shoulder including a humerus and a scapula. The head of the humerus is shown mating with the glenoid fossa of the scapula at a glenohumeral joint and a sheet-like material is fixed to the tendon.

30 [00024] Figure 5 is a stylized perspective view illustrating an exemplary procedure for treating a shoulder of a patient.

[00025] Figure 6 is a stylized perspective view of a shoulder including a supraspinatus having a distal tendon with a sheet-like material fixed thereto. A proximal end of the supraspinatus is fixed to the scapula and the distal tendon of the supraspinatus is fixed to the humerus.

35 [00026] Figure 7A, figure 7B, and figure 7C are multiple plan views illustrating an exemplary staple in accordance with the present detailed description.

[00027] Figure 8 is a perspective view further illustrating the staple shown in the previous figure.

[00028] Figure 9A and figure 9B illustrate multiple plan views of an exemplary fixation tool in accordance with the present detailed description.

5 [00029] Figure 10 is an enlarged plan view showing a distal portion of the fixation tool shown in the previous figure.

[00030] Figure 11 is an additional plan view showing the target tissue shown in the previous figure.

10 [00031] Figure 12 is an additional plan view showing the target tissue illustrated in the previous figure.

[00032] Figure 13 is a plan view showing a staple push rod including a first stake and a second stake.

[00033] Figure 14 is a plan view of an exemplary assembly in accordance with the present detailed description.

15 [00034] Figure 15A through figure 15C are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description.

[00035] Figure 16 is an exploded isometric view of an exemplary fixation tool in accordance with this detailed description.

[00036] Figure 17 is a side plan view of the fixation tool shown in figure 16.

20 [00037] Figure 18 is a top plan view of the fixation tool shown in figures 17 and 18.

[00038] Figure 19 is a plan view showing an additional exemplary embodiment of a staple in accordance with this detailed description.

[00039] Figure 20 is an isometric view further illustrating the staple shown in figure 19.

25 [00040] Figure 21A and Figure 21B illustrate multiple plan views of a fixation tool including a staple disposed in a sheath.

[00041] Figure 22A is an enlarged top view further illustrating a distal portion of the fixation tool shown in figure 21. Figure 22B is an enlarged side view further illustrating the distal portion of the fixation tool shown in figure 21.

30 [00042] Figure 23 is an isometric view showing an additional exemplary staple in accordance with the present detailed description.

DETAILED DESCRIPTION OF THE INVENTION

[00043] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are

not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[00044] As used herein, the term “tissue” refers to soft tissue, such as a tendon, and/or bone tissue, depending on the context in which it is used.

5 **[00045]** Figure 3 is a stylized anterior view of a patient 20. For purposes of illustration, a shoulder 22 of patient 20 is shown in cross-section in figure 3. Shoulder 22 includes a humerus 14 and a scapula 12. In figure 3, a head 24 of humerus 14 can be seen mating with a glenoid fossa of scapula 12 at a glenohumeral joint. With reference to figure 3, it will be appreciated that the glenoid fossa comprises a shallow depression in scapula 12. The movement of humerus 14
10 relative to scapula 12 is controlled by a number of muscles including: the deltoid, the supraspinatus, the infraspinatus, the subscapularis, and the teres minor. For purposes of illustration, only the supraspinatus 26 is shown in figure 3.

[00046] With reference to figure 3, it will be appreciated that a distal tendon 28 of the supraspinatus 26 meets humerus 14 at an insertion point. Scapula 12 of shoulder 22 includes an
15 acromium 32. In figure 3, a subacromial bursa 34 is shown extending between acromium 32 of scapula 12 and head 24 of humerus 14. In figure 3, subacromial bursa 34 is shown overlaying supraspinatus 26. Subacromial bursa 34 is one of the hundreds of bursae found in the human body. Each bursa comprises a fluid filled sac. The presence of these bursae in the body reduces friction between bodily tissues. Injury and/or infection of the bursa can cause it to become
20 inflamed. This condition is sometimes referred to as bursitis.

[00047] The exemplary methods and apparatus described herein may be used to fix tendon repair implants to various target tissues. For example, a tendon repair implant may be fixed to one or more tendons associated with an articulating joint, such as the glenohumeral joint. The tendons to be treated may be torn, partially torn, have internal micro-tears, be untorn, and/or be
25 thinned due to age, injury or overuse. Applicants believe that the methods and apparatus of the present application and related devices may provide very beneficial therapeutic effect on a patient experiencing joint pain believed to be caused by partial thickness tears and/or internal microtears. By applying a tendon repair implant early before a full tear or other injury develops, the implant may cause the tendon to thicken and/or at least partially repair itself, thereby
30 avoiding more extensive joint damage, pain, and the need for more extensive joint repair surgery.

[00048] Figure 4 is a stylized anterior view of a shoulder 22 including a humerus 14 and a scapula 12. In figure 4, a head 24 of humerus 14 is shown mating with a glenoid fossa of scapula 12 at a glenohumeral joint. A supraspinatus 26 is also shown in figure 4. This muscle (along with others) control the movement of humerus 14 relative to scapula 12. A distal tendon
35 28 of supraspinatus 26 meets humerus 14 at an insertion point 30.

[00049] In the embodiment of figure 4, distal tendon 28 includes a first damaged portion 36. A number of loose tendon fibers 40 in first damaged portion 36 are visible in figure 4. First damaged portion 36 includes a first tear 42 extending partially through distal tendon 28. First tear 42 may therefore be referred to as a partial thickness tear. With reference to figure 4, it will be appreciated that first tear 42 begins on the side of distal tendon 28 facing the subacromial bursa (shown in the previous figure) and ends midway through distal tendon 28. Accordingly, first tear 42 may be referred to as a bursal side tear.

[00050] With reference to figure 4, it will be appreciated that distal tendon 28 includes a second damaged portion 38 located near insertion point 30. In the embodiment of figure 4, second damaged portion 38 of distal tendon 28 has become frayed and a number of loose tendon fibers 40 are visible in figure 4. Second damaged portion 38 of distal tendon 28 includes second tear 44. With reference to figure 4, it will be appreciated that second tear 44 begins on the side of distal tendon 28 facing the humerus 14. Accordingly, second damaged portion 38 may be referred to as an articular side tear.

[00051] In the embodiment of Figure 4, a sheet-like implant 50 has been placed over the bursal side of distal tendon 28. With reference to figure 4, it will be appreciated that sheet-like implant 50 extends over insertion point 30, first tear 42 and second tear 44. Some useful methods in accordance with this detailed description may include placing a tendon repair implant on the bursal side of a tendon regardless of whether the tears being treated are on the bursal side, articular side or within the tendon. In some cases the exact location and nature of the tears being treated may be unknown. A tendon repair implant may be applied to the bursal side of a tendon to treat shoulder pain that is most likely caused by one or more partial thickness tears in the tendon. In the embodiment of figure 4, sheet-like implant 50 is fixed to distal tendon 28 and to humerus 14 by a plurality of staples 100, as described in detail herein.

[00052] Figure 5 is a stylized perspective view illustrating an exemplary procedure for treating a shoulder 22 of a patient 20. The procedure illustrated in figure 5 may include, for example, fixing tendon repair implants to one or more tendons of shoulder 22. The tendons treated may be torn, partially torn, have internal micro-tears, be untorn, and/or be thinned due to age, injury or overuse.

[00053] Shoulder 22 of figure 5 has been inflated to create a cavity therein. In the exemplary embodiment of figure 5A, a fluid supply 52 is pumping a continuous flow of saline into the cavity. This flow of saline exits the cavity via a fluid drain 54. A camera 56 provides images from inside the cavity. The images provided by camera 56 may be viewed on a display 58.

[00054] Camera 56 may be used to visually inspect the tendons of shoulder 22 for damage. A tendon repair implant in accordance with this disclosure may be fixed to a bursal surface of the

tendon regardless of whether there are visible signs of tendon damage. Applicants believe that the methods and apparatus of the present application and related devices may provide very beneficial therapeutic effect on a patient experiencing joint pain believed to be caused by internal microtears, but having no clear signs of tendon tears. By applying a tendon repair implant early before a full tear or other injury develops, the implant may cause the tendon to thicken and/or at least partially repair itself, thereby avoiding more extensive joint damage, pain, and the need for more extensive joint repair surgery.

[00055] A delivery system 60 can be seen extending from shoulder 22 in figure 5. Delivery system 60 comprises a sheath that is fixed to a handle. The sheath defines a lumen and a distal opening fluidly communicating the lumen. In the embodiment of figure 5, the distal opening of the sheath has been placed in fluid communication with the cavity created in shoulder 22.

[00056] A tendon repair implant is at least partially disposed in the lumen defined by the sheath of delivery system 60. Delivery system 60 can be used to place the tendon repair implant inside shoulder 22. Delivery system 60 can also be used to hold the tendon repair implant against the tendon. In some embodiments, the tendon repair implant is folded into a compact configuration when inside the lumen of the sheath. When this is the case, delivery system 60 may be used to unfold the tendon repair implant into an expanded shape.

[00057] The tendon repair implant may be fixed to the tendon while it is held against the tendon by delivery system 60. Various attachment elements may be used to fix the tendon repair implant to the tendon. Examples of attachment elements that may be suitable in some applications include sutures, tissue anchors, bone anchors, and staples. In the exemplary embodiment of figure 5, the shaft of a fixation tool 70 is shown extending into shoulder 22. In one exemplary embodiment, fixation tool 70 is capable of fixing the tendon repair implant to the tendon with one or more staples while the tendon repair implant is held against the tendon by delivery system 60.

[00058] Figure 6 is a stylized perspective view of a shoulder 22 including a supraspinatus 26 having a distal tendon 28. With reference to figure 6, it will be appreciated that a tendon repair implant 50 has been fixed to a surface of distal tendon 28. Tendon repair implant 50 may comprise, for example, various sheet-like structures without deviating from the spirit and scope of the present detailed description. In some useful embodiments, the sheet-like structure may comprise a plurality of fibers. The fibers may be interlinked with one another. When this is the case, the sheet-like structure may comprise a plurality of apertures comprising the interstitial spaces between fibers. Various processes may be used to interlink the fibers with one another. Examples of processes that may be suitable in some applications including weaving, knitting, and braiding. In some embodiment, the sheet-like structure may comprise a laminate including

multiple layers of film with each layer of film defining a plurality of micro-machined or formed holes. The sheet-like structure of the tendon repair implant may also comprise a plurality of electro-spun nanofiber filaments forming a composite sheet. Additionally, the sheet-like structure may comprise a synthetic sponge material that defines a plurality of pores. The sheet-like structure may also comprise a reticulated foam material. Reticulated foam materials that may be suitable in some applications are available from Biomerix Corporation of Fremont, California which identifies these materials using the trademark BIOMATERIAL™.

[00059] Various attachment elements may be used to fix tendon repair implant 50 to distal tendon 28 without deviating from the spirit and scope of this detailed description. Examples of attachment elements that may be suitable in some applications include sutures, tissue anchors, bone anchors, and staples. In the exemplary embodiment of figure 6, a plurality of staples 100 are fixing tendon repair implant 50 to distal tendon 28. In some exemplary methods, a plurality of staples 100 may be applied using a fixation tool. The fixation tool may then be withdrawn from the body of the patient. Distal tendon 28 meets humerus 14 at an insertion point 30. With reference to figure 6, it will be appreciated that sheet-like implant 50 extends over insertion point 30. Tendon repair implant may be applied to distal tendon 28, for example, using the procedure illustrated in the previous figure.

[00060] Figure 7A, figure 7B, and figure 7C are multiple plan views illustrating an exemplary staple 100 in accordance with the present detailed description. Figure 7A, figure 7B, and figure 7C may be collectively referred to as figure 7. A proximal direction is illustrated with an arrow P in figure 7. A distal direction is illustrated with a second arrow D in figure 7.

[00061] Staple 100 comprises a first arm 102A, a second arm 102B, and a bridge 104 extending from the proximal end of first arm 102A to the proximal end of second arm 102B. The distal end of first arm 102A abuts the proximal end of a first fluke 106A. Similarly, the distal end of second arm 102B abuts the proximal end of a second fluke 106B. In figure 7, first fluke 106A and second fluke 106B are shown extending distally from first arm 102A and second arm 102B, respectively. With reference to figure 7, it will be appreciated that first fluke 106A has a lateral extent that is larger than a lateral extent of first arm 102A. First fluke 106A is mounted eccentrically to first arm 102A in the embodiment of figure 7. Second fluke 106B is mounted eccentrically to second arm 102B and second fluke 106B has a lateral extent that is larger than a lateral extent of second arm 102B. First fluke 106A includes a first proximal surface 108A projecting at an outward angle in a proximal direction away from the distal end of first arm 102A. Second fluke 106B includes a second proximal surface 108B projecting at an outward angle in a proximal direction away from the distal end of second arm 102B.

[00062] With reference to figure 7A, it will be appreciated that first fluke 106A includes a first point 120A and a first barb 122A. Second fluke 106B includes a second point 120B and a second barb 122B. In figure 7, first point 120A and second point 120B are shown generally pointing in the distal direction indicated by arrow D. Also in figure 7, first barb 122A and second barb 122B are shown generally pointing in the proximal direction indicated by arrow P.

[00063] With reference to figure 7A it will be appreciated that first fluke 106A defines a first passageway 124A and second fluke 106B defines a second passageway 124B. In the exemplary embodiment of figure 7, first passageway 124A extends through first fluke 106A and second passageway 124B extends through second fluke 106B. It will be appreciated, however, that first passageway 124A may extend through other portions of staple 100 in some embodiments.

Similarly, second passageway 124B may extend through other portions of staple 100 in some embodiments. With reference to figure 7B it will be appreciated that, first passageway 124A and second passageway 124B each have a generally square cross-sectional shape. It will be appreciated, however, that first passageway 124A and second passageway 124B may have various cross-sectional shapes without deviating from the spirit and scope of the present detailed description. It will also be appreciated that each passageway can extend partially through the length of each fluke rather than completely through the length of each fluke. When this is the case, each passageway will provide a blind hole rather than a through hole.

[00064] With reference to figure 7C, it will be appreciated that first barb 122A of first fluke 106A defines a first notch 126A. In the exemplary embodiment of figure 7, first notch 126A divides first barb 122A into a first sub-barb and a second sub-barb. Second barb 122B of second fluke 106B defines a second notch 126B. In the exemplary embodiment of figure 7, second notch 126B divides second barb 122B into a first sub-barb and a second sub-barb.

[00065] Figure 8 is a perspective view showing staple 100 shown in the previous figure. Staple 100 comprises a first arm 102A, a second arm 102B, and a bridge 104 extending from the proximal end of first arm 102A to the proximal end of second arm 102B. The distal end of first arm 102A abuts the proximal end of a first fluke 106A. With reference to figure 8 it will be appreciated that first fluke 106A defines a first passageway 124A. In the exemplary embodiment of figure 8, first passageway 124A has a generally square cross-sectional shape. It will be appreciated, however, that first passageway 124A may have various cross-sectional shapes without deviating from the spirit and scope of the present detailed description.

[00066] A second fluke 106B extends distally from second arm 102B with the proximal end of second fluke 106B abutting the distal end of second arm 102B. With reference to figure 8, it will be appreciated that second fluke 106B has a lateral extent that is larger than a lateral extent of second arm 102B. Second fluke 106B is mounted eccentrically to second arm 102BA in the

embodiment of figure 8. Similarly, first fluke 106A is mounted eccentrically to first arm 102A and first fluke 106A has a lateral extent that is larger than a lateral extent of first arm 102A.

[00067] A proximal direction is illustrated with an arrow P in figure 8. A distal direction is illustrated with a second arrow D in figure 8. With reference to figure 8A, it will be appreciated that first fluke 106A of first arm 102A includes a first point 120A and a first barb 122A. Second fluke 106B includes a second point 120B and a second barb 122B. In figure 8, first point 120A and second point 120B are shown generally pointing in the distal direction indicated by arrow D. Also in figure 8, first barb 122A and second barb 122B are shown generally pointing in the proximal direction indicated by arrow P. With reference to figure 8, it will be appreciated that first fluke 106A includes a first proximal surface 108A projecting at an outward angle in a proximal direction away from the distal end of first arm 102A. Second fluke 106B includes a second proximal surface 108B projecting at an outward angle in a proximal direction away from the distal end of second arm 102B.

[00068] Figure 9A and figure 9B illustrate multiple plan views of an exemplary fixation tool 144 in accordance with the present detailed description. Figure 9A and figure 9B may be referred to collectively as figure 9. It is customary to refer to multi-view projections using terms such as front view, top view, and side view. In accordance with this convention, figure 9A may be referred to as a top view of fixation tool 144 and figure 9B may be referred to as a side view of fixation tool 144. The terms top view and side view are used herein as a convenient method for differentiating between the views shown in figure 9. It will be appreciated that the elements shown in figure 9 may assume various orientations without deviating from the spirit and scope of this detailed description. Accordingly, the terms top view and side view should not be interpreted to limit the scope of the invention recited in the attached claims.

[00069] In the embodiment of figure 9, fixation tool 144 includes a fixation tool sheath 146 that is attached to a handle 148. Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. In figure 9, a staple 100 can be seen residing in lumen 152 of fixation tool sheath 146. For purposes of illustration, a distal portion of fixation tool sheath 146 is enlarged in figure 9 to better show staple 100. Staple 100 comprises a first arm 102A, a second arm 102B, and a bridge 104 extending from the proximal end of first arm 102A to the proximal end of second arm 102B. The distal end of first arm 102A abuts the proximal end of a first fluke 106A. Similarly, the distal end of second arm 102B abuts the proximal end of a second fluke 106B. In figure 9, first fluke 106A and second fluke 106B are shown extending distally from first arm 102A and second arm 102B, respectively.

[00070] In the embodiment of figure 9, fixation tool 144 includes a staple push rod 130 that is slidingly received in lumen 152 defined by fixation tool sheath 146. Staple push rod 130

includes a shaft 132 and a pair of stakes 134 that are coupled to shaft 132. Stakes 134 include a first stake 134A and a second stake 134B. First stake 134A and second stake 134B each have a distal portion 138 and a proximal portion 140. In figure 9, the distal portion 138 of each stake 134 can be seen extending through a passageway defined by staple 100. In the embodiment of figure 9, a trigger 160 is pivotably coupled to handle 148 of fixation tool 144. Trigger 160 is operatively coupled to staple push rod 130. In operation, staple push rod 130 will be advanced and/or retracted in an axial direction when trigger 160 is pivoted relative to handle 148. With reference to figure 9, it will be appreciated that staple 100 is disposed on a distal portion of staple push rod 130. Accordingly, staple 100 can be moved distally and/or proximally by pivoting trigger 160 relative to handle 148 of fixation tool 144.

[00071] Figure 10 is an enlarged plan view showing a distal portion of fixation tool 144. For purposes of illustration, a portion of fixation tool sheath 146 is cut-away in figure 10.

Accordingly, staple 100 and staple push rod 130 can be seen residing in a distal portion of fixation tool sheath 146. In figure 10, the distal end of fixation tool sheath 146 is pushing against a sheet-like implant 50 and a target tissue 178. The pushing force applied by fixation tool 144 has caused a depression 176 to form in target tissue 178. Depression 176 lies below a plane defined by an outer surface 184 of the remainder of target tissue 178. The remainder of target tissue 178 is a portion of target tissue not including depression 176.

[00072] Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. In figure 10, fixation tool sheath 146 is shown in partial cross-section. Accordingly, a staple 100 can be seen residing in lumen 152 of fixation tool sheath 146. Staple 100 comprises a first arm 102A, a second arm 102B, and a bridge 104 extending from the proximal end of first arm 102A to the proximal end of second arm 102B. The distal end of first arm 102A abuts the proximal end of a first fluke 106A. Similarly, the distal end of second arm 102B abuts the proximal end of a second fluke 106B. In figure 10, first fluke 106A and second fluke 106B are shown extending distally from first arm 102A and second arm 102B, respectively.

[00073] Fixation tool 144 of figure 10 includes a staple push rod 130 that is slidably disposed in lumen 152 defined by fixation tool sheath 146. Staple push rod 130 includes a shaft 132 and a pair of stakes 134 that are coupled to shaft 132. Stakes 134 include a first stake 134A and a second stake 134B. In figure 10, a distal portion of each stake 134 can be seen extending through a passageway defined by staple 100.

[00074] Figure 11 is an additional plan view showing target tissue 178 shown in the previous figure. In the embodiment of figure 11, first fluke 106B of staple 100 has been advanced into target tissue 178 at one side of depression 176. Second fluke 106B of staple 100 has been advanced into the tissue at a second side of depression 176. With reference to figure 11, it will

be appreciated that first fluke 106A and second fluke 106B have been advanced in generally opposite directions. In figure 11 an intermediate portion 180 of staple 100 is shown extending along a generally straight path between first fluke 106A and second fluke 106B. In the exemplary embodiment of figure 11, intermediate portion 180 of staple 100 comprises first arm 102A, second arm 102B and bridge 104. Some methods in accordance with the present detailed disclosure include the step of pulling the intermediate portion of a staple taut between a first fluke and a second fluke.

[00075] With reference to figure 11, it will be appreciated that staple push rod 130 comprises a distal bow 182 formed of first stake 134A and second stake 134B. In figure 11, intermediate portion 180 of staple 100 is shown extending across distal bow 182 like a bowstring. In the embodiment of figure 11, intermediate portion 180 of staple 100 is disposed below a plane defined by an outer surface 184 of the remainder of target tissue 178. The remainder of target tissue 178 is the portion of target tissue 178 that does not include depression 176.

[00076] With reference to the two figures discussed immediately above, it will be appreciated that one exemplary method in accordance with the present detailed description may include providing a staple having a first fluke, a second fluke, and an intermediate portion extending therebetween; moving the first fluke and the second fluke away from one another; and pulling the intermediate portion taut between the first fluke and the second fluke.

[00077] An additional exemplary method may include providing a staple having a first fluke, a second fluke, and an intermediate portion extending therebetween; advancing the first fluke of the staple in a first direction; and advancing the second fluke of the staple in a second direction. In some cases the first direction and the second direction may be generally opposite directions.

[00078] Figure 12 is an additional plan view showing the target tissue 178 illustrated in the previous figure. In the embodiment of figure 12, the first fluke 106A and the second fluke 106B of staple 100 are disposed in target tissue 178. In the exemplary embodiment of figure 12, a depression 176 is formed in target tissue 178. First fluke 106A is disposed near a first side of depression 176. Second fluke 106B is disposed near a second side of depression 176 that is generally opposite the first side of depression 176. With reference to figure 12, it will be appreciated that first fluke 106A and second fluke 106B are generally pointing away from each other.

[00079] In figure 12, an intermediate portion of staple 100 is shown extending between first fluke 106A and second fluke 106B. In the embodiment of figure 12, intermediate portion 180 of staple 100 is disposed below a plane defined by an outer surface 184 of the remainder of target tissue 178. The remainder of target tissue 178 is the portion of target tissue 178 that does not

include depression 176. In the embodiment of figure 12, sheet-like implant 50 is fixed to target tissue 178 by staple 100.

[00080] A method of treating a target tissue in accordance with the present detailed description may include depressing the target tissue 178o form a depression therein. The first end of a staple may be advanced into tissue at a first side of the depression. The second end of the staple may be advanced into tissue at a second side of the depression. In some cases, the first side of the depression and the second side of the depression are generally opposite one another. An intermediate portion of the staple may be pulled taut when the first end is advanced into tissue at the first side of the depression and the second end of the staple is advanced into tissue at the second side of the depression. Additionally, the intermediate portion of the staple may be positioned below a tissue plane when the first end is advanced into tissue at the first side of the depression and the second end of the staple is advanced into tissue at the second side of the depression.

[00081] Figure 13 is a plan view showing a staple push rod 130. In the embodiment of figure 13, staple push rod 130 comprises a first stake 134A and a second stake 134B. First stake 134A and second stake 134B form a distal bow 182. In the embodiment of figure 13, distal bow 182 has a shape analogous to the shape of recurve bows traditionally used in archery. In figure 13, first stake 134A and second stake 134B are in a substantially unstressed state. With reference to the figures discussed above, it will be appreciated that first stake 134A and second stake 134B can be resiliently urged to assume shapes other than the shape shown in figure 13. For example, first stake 134A and second stake 134B can be placed inside a fixation tool sheath.

[00082] In the embodiment of figure 13, each stake 134 has a distal portion 138 and a proximal portion 140. In some useful embodiments, each distal portion 138 is dimensioned to extend into a passage defined by a staple. In the embodiment of figure 13, each proximal portion 140 has a width larger than a width of each distal portion 138 so that a shoulder of each proximal portion 140 contacts a proximal surface of the staple to apply pushing forces thereto. First stake 134A comprises a first shoulder 142A and second stake 134B comprises a second shoulder 142B. In the embodiment of figure 13, proximal portion 140 of first stake 134A and the proximal portion 140 of second stake 134B diverge from one another as they extend in distal direction D away from shaft 132.

[00083] Figure 14 is a plan view of an exemplary assembly in accordance with the present detailed description. The assembly of figure 14 comprises a staple push rod 130 and a staple 100. Staple push rod 130 comprises a first stake 134A and a second stake 134B. In figure 14, a distal portion 138 first stake 134A is shown extending into a first passageway 124A defined by a first fluke 106A of staple 100. Also in figure 14, a distal portion 138 of second stake 134B is

shown extending into a second passageway 124B defined by a second fluke 106B of staple 100. In some useful embodiments, an intermediate portion 180 of staple 100 extends tautly between first stake 134A and second stake 134B when the stakes are forming the bow-like shape shown in figure 14.

5 **[00084]** First fluke 106A of staple 100 defines a first passageway 124A. In figure 14, a distal portion 138 of first stake 134A of staple push rod 130 can be seen extending through first passageway 124A defined by first fluke 106A. A distal portion 138 of second stake 134B of staple push rod 130 can be seen extending through a second passageway 124B defined by second fluke 106B of staple 100.

10 **[00085]** In figure 14, a first shoulder 142A of first stake 134A is shown contacting proximal surface 108 of first fluke. Distal portion 138 of first stake 134A extends distally of first shoulder 142A and proximal portion 140 of first stake 134A extends proximally of first shoulder 142A. Proximal portion 140 of second stake 134B extends proximally of second shoulder 142B and distal portion 138 of second stake 134B extends distally of second shoulder 142B. In the
15 embodiment of figure 14, proximal portion 140 of second stake 134B has a width larger than the width of distal portion 138 of second stake 134B so that the shoulder 142 of second stake 134B contacts proximal surface 108 of second fluke 106B to apply pushing forces thereto. Similarly, proximal portion 140 of first stake 134A has a width larger than the width of distal portion 138 of first stake 134A so that the shoulder 142 of first stake 134A contacts proximal surface 108 of
20 first fluke 106A to apply pushing forces thereto.

[00086] Figure 15A through figure 15C are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description. Figure 15A through figure 15C may be referred to collectively as figure 15. A distal direction is illustrated with an arrow D in figure 15. The exemplary method of figure 15 may be used, for example, to fix a
25 sheet-like implant to a target tissue.

[00087] Each of these figures shows a fixation tool sheath 146 disposed about a distal portion of a staple push rod 130. Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. Staple push rod 130 is slidingly disposed in lumen 152 in the embodiment of figure 15. For purposes of illustration, a portion of wall 150 is cut away in each figure, making the interior of
30 lumen 152 visible. Staple push rod 130 of fixation tool 144 includes a shaft 132 and a pair of stakes 134 that are coupled to shaft 132. Stakes 134 include a first stake 134A and a second stake 134B. In figure 15, a distal portion of each stake 134 can be seen extending through a passageway defined by staple 100.

[00088] In figure 15A, staple 100 can be seen residing in a distal portion lumen 152. Staple
35 100 comprises a first arm 102A, a second arm 102B, and a bridge 104 extending from the

proximal end of first arm 102A to the proximal end of second arm 102B. The distal end of first arm 102A abuts the proximal end of a first fluke 106A. Similarly, the distal end of second arm 102B abuts the proximal end of a second fluke 106B. In figure 15, first fluke 106A and second fluke 106B are shown extending distally from first arm 102A and second arm 102B,

5 respectively.

[00089] Figure 15B illustrates an exemplary configuration in which staple push rod 130 has been moved in a distal direction D relative to fixation tool sheath 146. With reference to figure 15B, it will be appreciated that staple 100 is now extending through a distal opening 186 defined by fixation tool sheath 146. Additionally, first fluke 106A of staple 100 has been moved in a
10 first lateral direction L. Similarly, second fluke 106B of staple 100 has been moved in a second lateral direction R. With reference to figure 15B, it will be appreciated that first fluke 106A and second fluke 106B have moved laterally away from each other.

[00090] Figure 15C illustrates an exemplary embodiment in which staple 100 is disposed outside of lumen 152 defined by fixation tool sheath 146. By comparing figure 15B and figure
15 15C, it will be appreciated that first fluke 106A of staple 100 has been moved further in the first lateral direction L and second fluke 106B has been moved further in the second lateral direction R. Additionally, it will be appreciated that first fluke 106A and second fluke 106B have moved laterally away from each other.

[00091] In figure 15C an intermediate portion 180 of staple 100 is shown extending along a
20 generally straight path between first fluke 106A and second fluke 106B. In the exemplary embodiment of figure 15, intermediate portion 180 of staple 100 comprises first arm 102, second arm 102 and bridge 104. Some methods in accordance with the present detailed disclosure include the step of pulling the intermediate portion of a staple taut between a first fluke and a second fluke. With reference to figure 15, it will be appreciated that staple push rod 130
25 comprises a distal bow 182 formed of first stake 134A and second stake 134B. In figure 15, intermediate portion 180 of staple 100 is shown extending across distal bow 182 like a bowstring.

[00092] Figure 16 is an exploded isometric view of an exemplary fixation tool 144 in
30 accordance with this detailed description. In the embodiment of figure 16, fixation tool 144 comprises a fixation tool sheath 146 and a handle 148. In figure 16, handle 148 is exploded into two pieces. A proximal portion of fixation tool sheath 146 is fixed to handle 148 when fixation tool 144 is in an assembled state. Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. When fixation tool 144 is in an assembled state a staple push rod 130 extends into lumen 152 of fixation tool sheath 146. Staple push rod 130 comprises a bow 180 and a shaft
35 132. Bow 180 comprises a first stake 134A and a second stake 134B. Shaft 132 and a wire 190

are coupled between bow 180 and a lever 174. Lever 174 is coupled to a trigger 160. Trigger 160 is pivotably coupled to handle 148 of fixation tool 144 when fixation tool 144 is in an assembled state. In operation, staple push rod 130 will be advanced and/or retracted in an axial direction when trigger 160 is pivoted relative to handle 148.

5 [00093] Figure 17 is a side plan view of fixation tool 144 shown in the previous figure. In figure 17, one piece of handle 148 is removed so that lever 174 can be seen residing in handle 148. Handle 148 of fixation tool 144 is fixed to a proximal portion of fixation tool sheath 146. Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. A staple push rod 130 extends into lumen 152 of fixation tool sheath 146. Staple push rod 130 comprises a bow 180 and a shaft 132. Bow 180 comprises a first stake 134A and a second stake 134B. Shaft 132 and a wire 190 are coupled between bow 180 and a lever 174. Lever 174 is coupled to a trigger 160. Trigger 160 is pivotably coupled to handle 148 of fixation tool 144. In operation, staple push rod 130 will be advanced and/or retracted in an axial direction when trigger 160 is pivoted relative to handle 148.

15 [00094] Figure 18 is a top plan view of fixation tool 144 shown in the previous figure. Handle 148 of fixation tool 144 is shown in cross-section in figure 18 so that lever 174 can be seen residing in handle 148. Handle 148 of fixation tool 144 is fixed to a proximal portion of fixation tool sheath 146. Fixation tool sheath 146 comprises a wall 150 defining a lumen 152. A staple push rod 130 extends into lumen 152 of fixation tool sheath 146. Staple push rod 130 comprises a bow 180 and a shaft 132. Bow 180 comprises a first stake 134A and a second stake 134B. Shaft 132 and a wire 190 are coupled between bow 180 and lever 174. Lever 174 is coupled to a trigger 160. Trigger 160 is pivotably coupled to handle 148 of fixation tool 144. In operation, staple push rod 130 will be advanced and/or retracted in an axial direction when trigger 160 is pivoted relative to handle 148.

25 [00095] Figure 19 is a plan view showing an additional exemplary embodiment of a staple 123 in accordance with this detailed description. Staple 123 of figure 19 comprises a first arm 125A, a second arm 125B, and an intermediate portion 127 that extends between first arm 125A and second arm 125B. First arm 125A comprises a portion of a wall 129 defining a first lumen 133A. Second arm 125B comprises a portion of wall 129 defining a second lumen 133B.

30 [00096] With reference to figure 19, it will be appreciated that first arm 125A of staple 123 includes a first point 135A and a first barb 137A. Second arm 125B of staple 123 has a second point 135B and a second barb 137B. In the embodiment of figure 19, first point 135A and second point 135B are pointing in a distal direction D. Also in the embodiment of figure 19, first barb 137A and second barb 137B are pointing in a proximal direction P. Intermediate portion

127 of staple 123 is shown extending along an arcuate path between first arm 125A and second arm 125B in figure 19.

[00097] Figure 20 is an isometric view showing staple 123 shown in the previous figure. In the embodiment of figure 20, staple 123 comprises a wall 129 defining a first lumen 133A, a second lumen 133B, and a channel 139. A first arm 125A of staple 123 is formed of the portion of wall 129 defining first lumen 133A. The portion of wall 129 defining second lumen 133B forms a second arm 125B. Channel 139 is defined by an intermediate portion 127 of staple 123.

[00098] In figure 20, intermediate portion 127 of staple 123 is shown extending along an arcuate path between first arm 125A and second arm 125B. First arm 125A defines a first notch 143A that fluidly communicates with first lumen 133A. With reference to figure 20, it will be appreciated that first notch 143A defines a first barb 137A of first arm 125A. Second arm 125B defines a second notch 143B that fluidly communicates with second lumen 133B. Second notch 143B defines a second barb 137B of second arm 125B in the embodiment of figure 20.

[00099] In some embodiments, staples such as staple 123 described above may have an internal lumen diameter of about 0.025 inches, and outside diameter of about 0.039 inches, and an overall length of about 0.450 inches. In some embodiments, staples may have a nominal diameter of less than about 0.039 inches. In some embodiments, staples may have a nominal diameter of between about 0.001 and 0.1 inches.

[000100] Figure 21A and Figure 21B illustrate multiple plan views of a fixation tool 145 including staple 123 shown in the previous figure. Figure 21A and Figure 21B may be referred to collectively as Figure 21. It is customary to refer to multi-view projections using terms such as front view, top view, and side view. In accordance with this convention, Figure 21A may be referred to as a top view of fixation tool 145 and Figure 21B may be referred to as a side view of fixation tool 145. The terms top view and side view are used herein as a convenient method for differentiating between the views shown in Figure 21. It will be appreciated that the elements shown in Figure 21 may assume various orientations without deviating from the spirit and scope of this detailed description. Accordingly, the terms top view and side view should not be interpreted to limit the scope of the invention recited in the attached claims.

[000101] In the embodiment of figure 21, fixation tool 145 comprises a handle 147 and a fixation tool sheath 149 that is coupled to handle 147. In figure 21, staple 123 can be seen residing in a distal portion of fixation tool sheath 149. For purposes of illustration, the distal portion of fixation tool sheath 149 is enlarged in figure 21 to better show staple 123.

[000102] In the embodiment of figure 21, a trigger 153 is pivotably coupled to handle 147. Trigger 153 is operatively coupled to a staple pusher 155. In operation, staple pusher 155 is advanced and/or retracted when trigger 153 is pivoted relative to handle 147. With reference to

figure 21, it will be appreciated that staple 123 is disposed on a distal portion of staple pusher 155. Accordingly, staple 123 can be moved distally and/or proximally by pivoting trigger 153 relative to handle 147 of fixation tool 145.

[000103] Figure 22A is a further enlarged top view of the distal portion of fixation tool 145 shown in the previous figure. Figure 22B is an additional side view showing the distal portion of fixation tool 145. For purposes of illustration, a portion of fixation tool sheath 149 is cut-away in figure 22A and figure 22B. Accordingly, staple 123 can be seen residing in the distal portion of fixation tool sheath 149. Figure 22A and figure 22B may be referred to collectively as figure 22.

[000104] With reference to figure 22, it will be appreciated that staple 123 comprises a first arm 125A, a second arm 125B, and an intermediate portion 127 that extends between first arm 125A and second arm 125B. First arm 125A comprises a portion of a wall 129 defining a first lumen 133A. Second arm 125B comprises a portion of wall 129 defining a second lumen 133B. Staple 123 is disposed on a staple pusher 155 of fixation tool 145 that extends into fixation tool sheath 149. In the exemplary embodiment of figure 22, staple pusher 155 comprises a first strut 157A and a second strut 157B. In figure 22, first strut 157A can be seen extending into first lumen 133A defined by first arm 125A. Second strut 157B extends into second lumen 133B defined by second arm 125B.

[000105] Figure 23 is an isometric view showing an additional exemplary staple 323 in accordance with the present detailed description. Staple 323 of figure 23 comprises a first arm 325A, a second arm 325B, and an intermediate portion 327 that extends between first arm 325A and second arm 325B. First arm 325A comprises a portion of a wall 329 defining a first lumen 333A. With reference to figure 23, it will be appreciated that first arm 325A includes a first point 335A and a first barb 337A. In the embodiment of figure 23, first barb 337A is defined by a first notch 343A.

[000106] Second arm 325B comprises a portion of wall 329 defining a second lumen 333B. Second arm 325B defines a second notch 343B that fluidly communicates with second lumen 333B. With reference to figure 23, it will be appreciated that second notch 343B defines second barb 337B of second arm 325B. A second point 335B of second arm 325B is also visible in figure 23. In figure 23, intermediate portion 327 of staple 323 is shown extending between first arm 325A and second arm 325B. Intermediate portion 327 of staple 323 defines a channel 339 that fluidly communicates with first lumen 333A and second lumen 333B.

[000107] While exemplary embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims and

subsequently filed claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

CLAIMS

What is claimed is:

1. A device for attaching a sheet-like implant to a target tissue, comprising:
a sheath having a distal end configured to be pressed against the target tissue; and
5 a staple push rod disposed within at least a portion of the sheath and slidable relative thereto, the staple push rod including a pair of stakes, each stake dimensioned to abut a surface of a staple to apply pushing forces thereto;
wherein the stakes are biased to assume a bow-like shape such that an intermediate portion of a staple extends tautly between the first stake and the second stake when the stakes are
10 extending beyond the distal end of the tubular member.
2. The device of claim 1, wherein each stake has a distal portion and a proximal portion, each distal portion being dimensioned to extend into a passage defined by a staple, each proximal portion having a width larger than a width of each distal portion so that a shoulder of
15 each proximal portion contacts a proximal surface of the staple to apply pushing forces thereto.
3. The device of claim 1, wherein the stakes are biased to expand against an inner surface of the sheath.
- 20 4. The device of claim 1, wherein the intermediate portion of the staple includes a first arm, a second arm, and a bridge.
5. The device of claim 1, wherein the first stake and the second stake extend away from each other when the stakes are assuming the bow-like shape.
- 25 6. The device of claim 1, further comprising a sheath having a proximal end, a distal end and a lumen extending therebetween, at least a portion of the staple push rod extending into the lumen and slidable relative thereto.
- 30 7. The device of claim 6, wherein the first stake and the second stake are disposed in the lumen of the sheath.
8. The device of claim 6, wherein:
the sheath defines a distal opening fluidly communicating with the lumen; and

the staple push rod is slidably disposed in the lumen so as to urge relative movement between the stakes and the sheath such that the stakes can be advanced through the distal opening defined by the sheath so that the stakes are free to assume the bow-like shape.

5 9. The device of claim 6, wherein:
 the stakes have a first lateral extent when the stakes are free to assume the bow-like shape; and
 the lumen of the sheath has a lumen dimension smaller than the first lateral extent such that the sheath holds the stakes in a compact configuration.

10 10. The device of claim 1, wherein:
 the stakes have a first lateral extent when the stakes are free to assume the bow-like shape; and
 the lumen of the sheath has a lumen dimension smaller than the first lateral extent; and
15 the stakes are sufficiently flexible to allow the stakes to be advanced into the lumen of the sheath.

 11. The device of claim 1, wherein a distal-most portion of each stake extends across a leading edge of each fluke of a staple.

20 12. A method for attaching a sheet-like implant to a target tissue, comprising the steps of:
 providing a staple push rod carrying a staple, the staple comprising a first arm having a proximal end and a distal end, and a second arm having a proximal end and a distal end with a
25 bridge extending from the proximal end of the first arm to the proximal end of the second arm, a first fluke of the staple having a proximal end abutting the distal end of the first arm, and a second fluke of the staple having a proximal end abutting the distal end of the second arm;
 the staple push rod of the device including a shaft, a first stake and a second stake, each stake having a distal portion and a proximal portion, a proximal end of the proximal portion of
30 each stake being fixed to a distal end of the shaft, the distal portion of the first stake extending into a first passage defined by the first fluke, and the distal portion of the second stake extending into a second passage defined by the second fluke, the stakes being biased to assume a bow-like shape such that an intermediate portion of the staple extends tautly between the first stake and the second stake;
35 depressing the target tissue to form a depression therein;

advancing the first fluke of the staple into tissue at a first side of the depression; and
advancing the second fluke of the staple into tissue at a second side of the depression.

5 13. The method of claim 12, wherein the first side of the depression and the second
side of the depression are generally opposite each other.

10 14. The method of claim 13, wherein the intermediate portion of the staple is pulled
taut when the first end is advanced into tissue at the first side of the depression and the second
end of the staple is advanced into tissue at the second side of the depression.

15 15. The method of claim 13, wherein the intermediate portion of the staple is
positioned below a tissue plane when the first end is advanced into tissue at the first side of the
depression and the second end of the staple is advanced into tissue at the second side of the
depression.

16. The method of claim 15, wherein the tissue plane is defined by an outer surface of
a remainder of the target tissue and the remainder of the target tissue does not include the
depression.

20 17. The method of claim 15, further comprising the step of providing a sheath having
a proximal end, a distal end and a lumen extending therebetween; and
wherein the step of depressing the target tissue to form a depression therein comprises
pushing on the target tissue with the distal end of the sheath.

25 18. A method for attaching a sheet-like implant to a target tissue, comprising the
steps of:

30 providing a staple push rod carrying a staple, the staple comprising a first arm having a
proximal end and a distal end, and a second arm having a proximal end and a distal end with a
bridge extending from the proximal end of the first arm to the proximal end of the second arm, a
first fluke of the staple having a proximal end abutting the distal end of the first arm, and a
second fluke of the staple having a proximal end abutting the distal end of the second arm;

35 the staple push rod of the device including a shaft, a first stake and a second stake, each
stake having a distal portion and a proximal portion, a proximal end of the proximal portion of
each stake being fixed to a distal end of the shaft, the distal portion of the first stake extending
into a first passage defined by the first fluke, and the distal portion of the second stake extending

into a second passage defined by the second fluke, the stakes being biased to assume a bow-like shape such that an intermediate portion of the staple extends tautly between the first stake and the second stake;

advancing the first fluke of the staple in a first direction;

5 advancing the second fluke of the staple in a second direction that is generally opposite the first direction;

moving the first end and the second end away from each other; and

pulling the intermediate portion taut between the first end and the second end.

10 19. The method of claim 18, further comprising the step of advancing the first fluke in a distal direction through the sheet-like implant.

15 20. The method of claim 19, wherein the step of advancing the first fluke in the distal direction through the sheet-like implant is performed before the step of advancing the first fluke of the staple in the first direction.

21. The method of claim 19, wherein the distal direction is a generally parallel to a longitudinal axis of the shaft.

20 22. The method of claim 19, wherein:
the distal direction is an axial direction relative to the shaft; and
the first direction is a lateral direction relative to the shaft.

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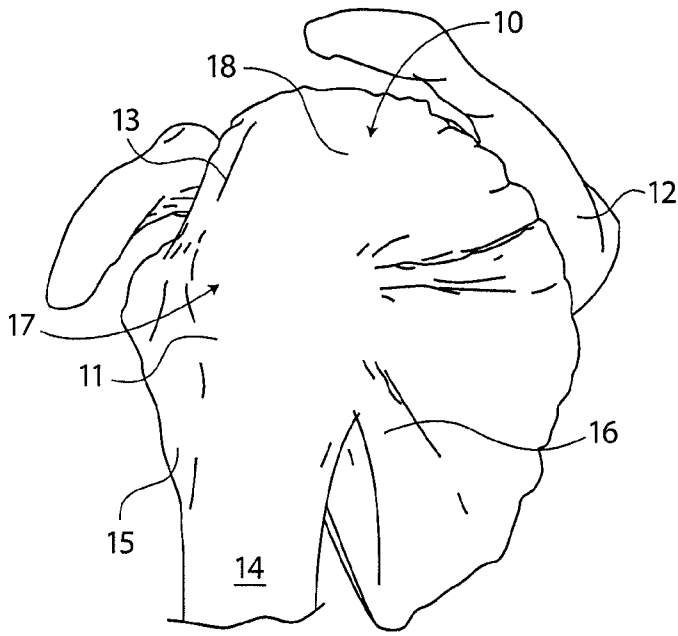


FIG. 1

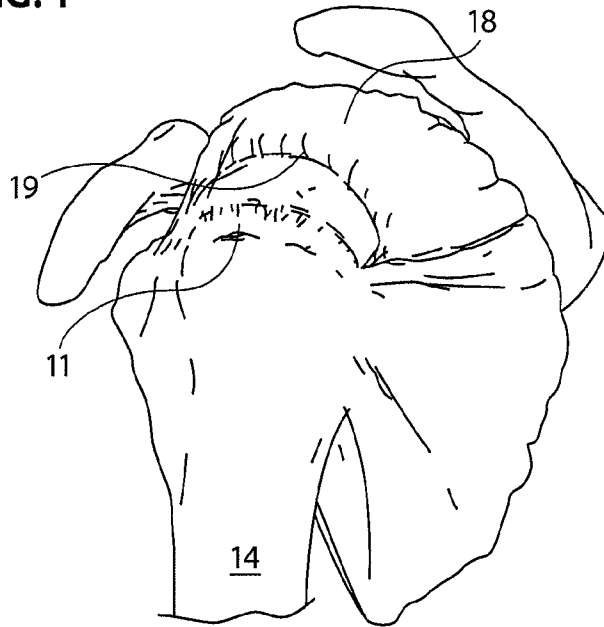


FIG. 2

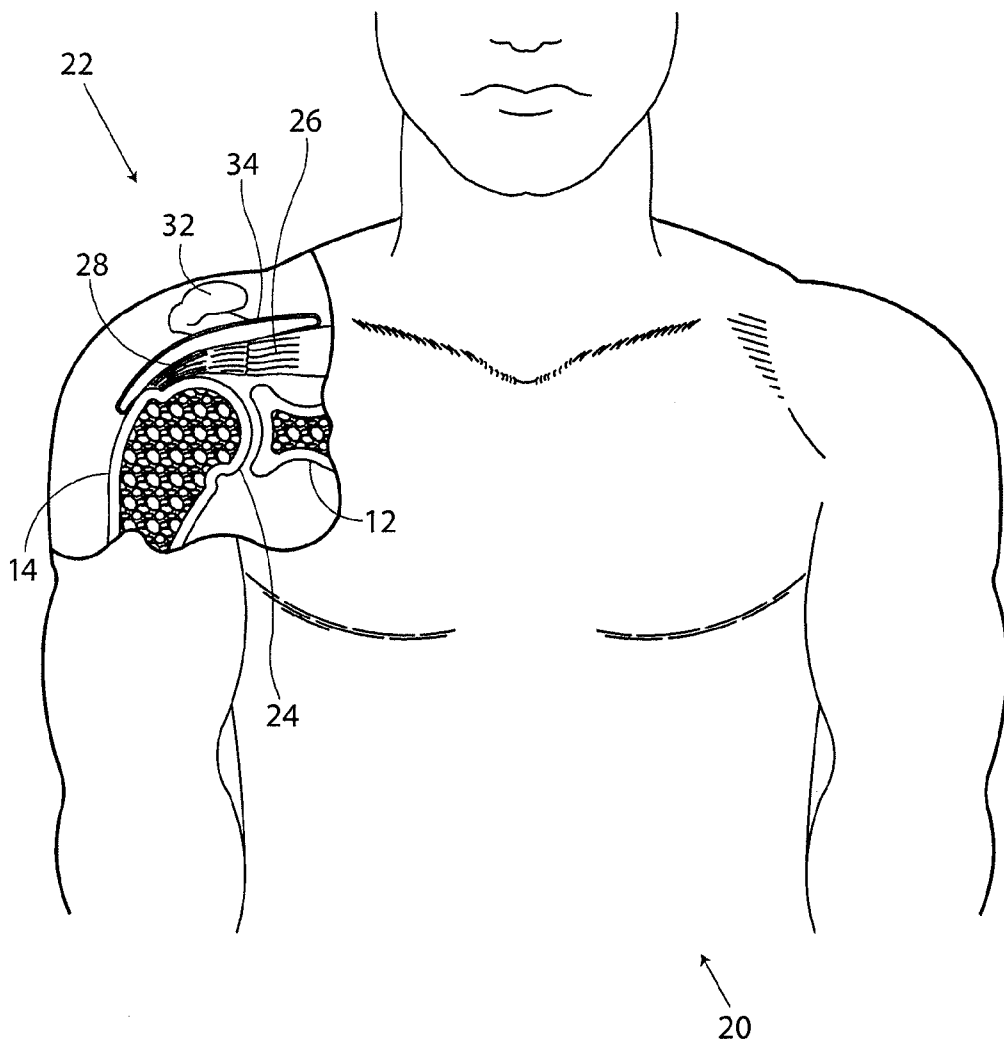


FIG. 3

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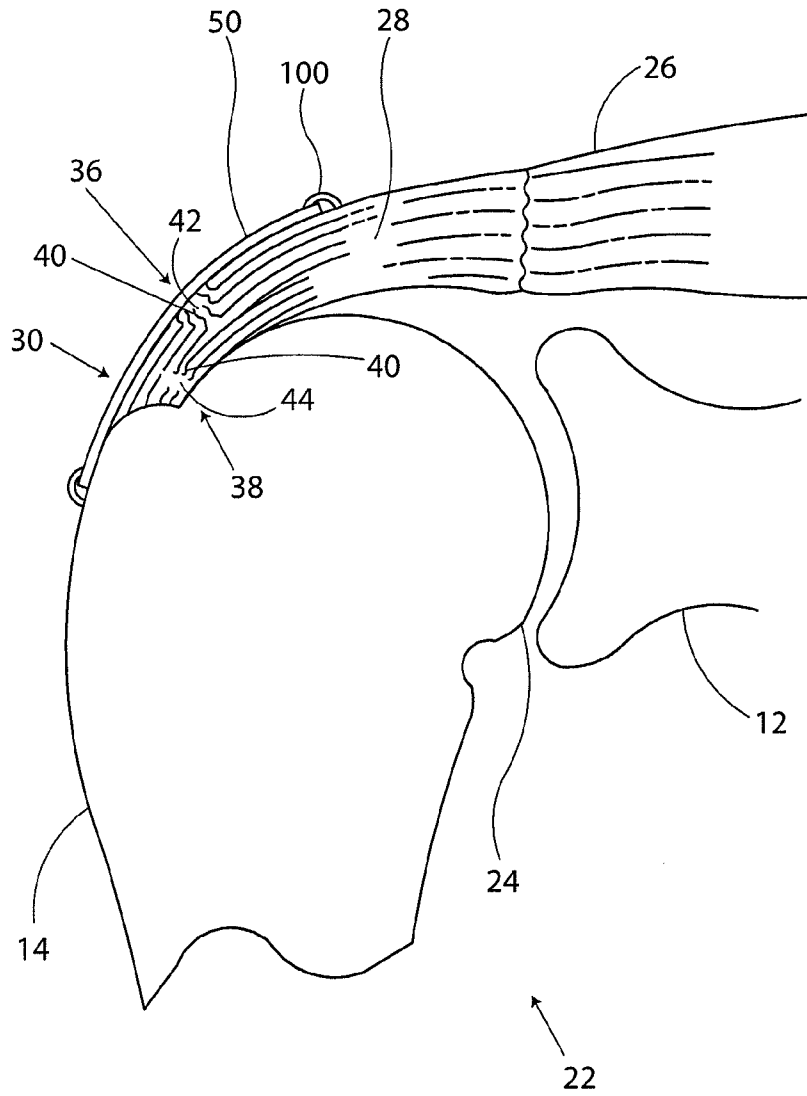


FIG. 4

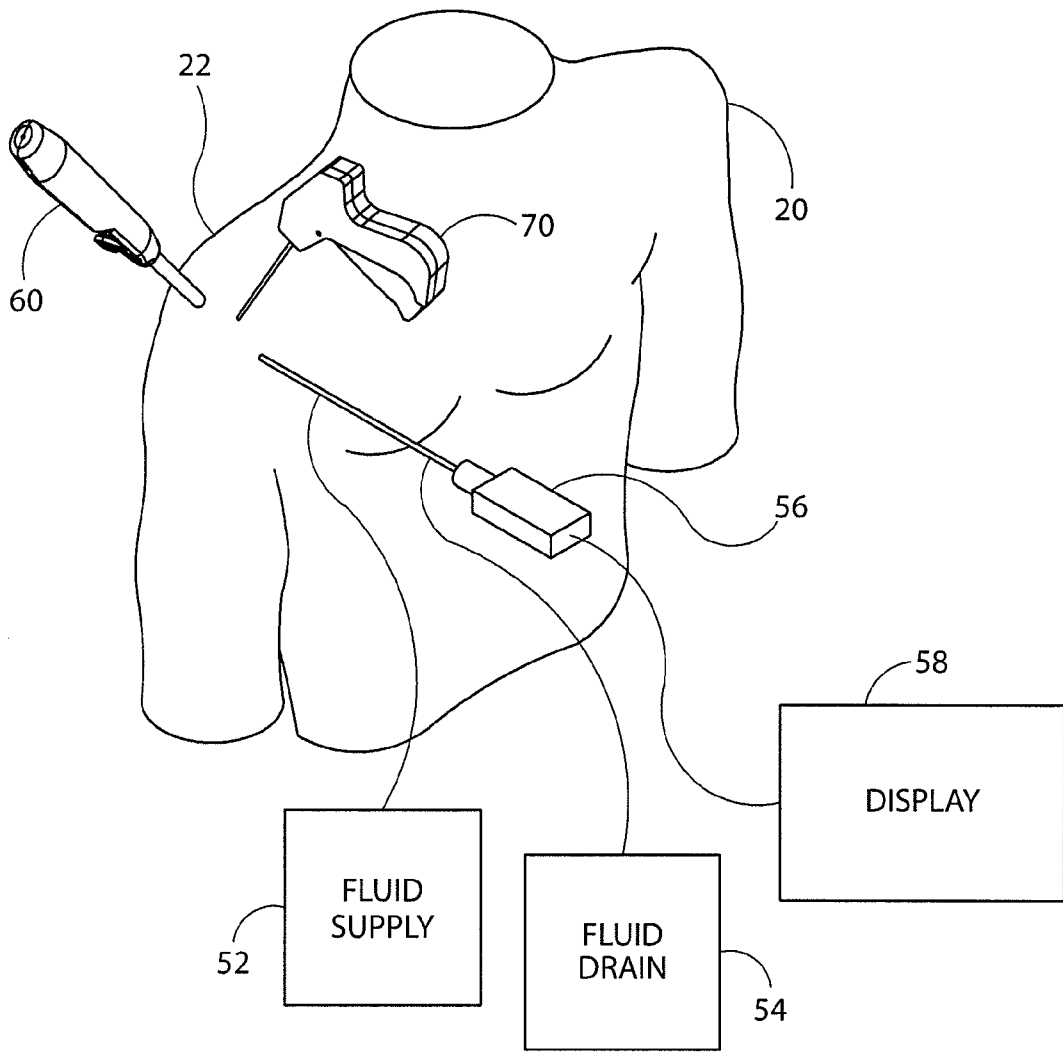


FIG. 5

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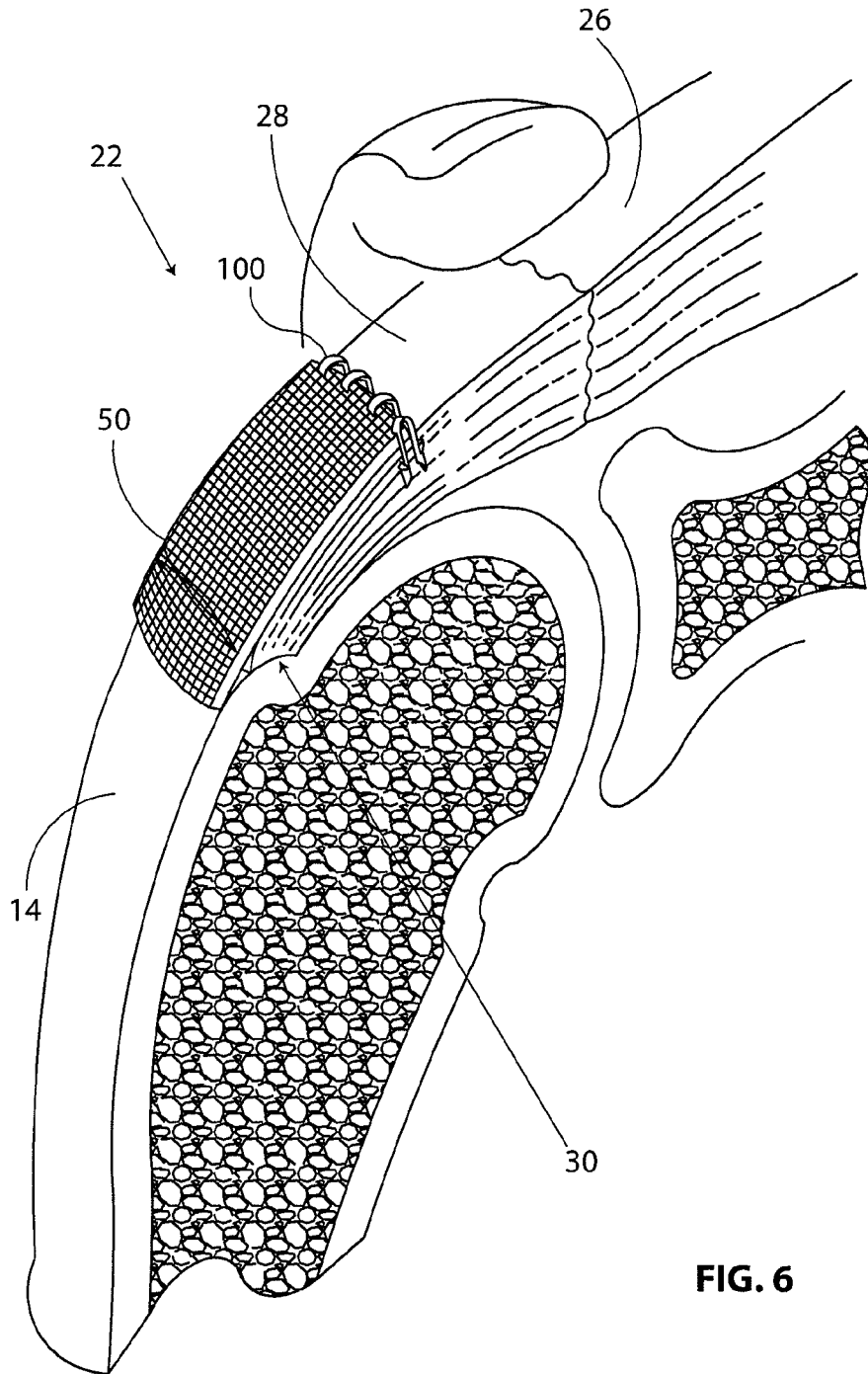
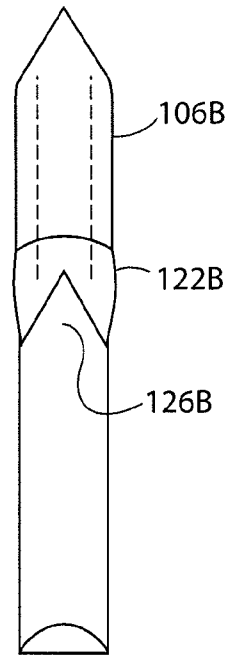
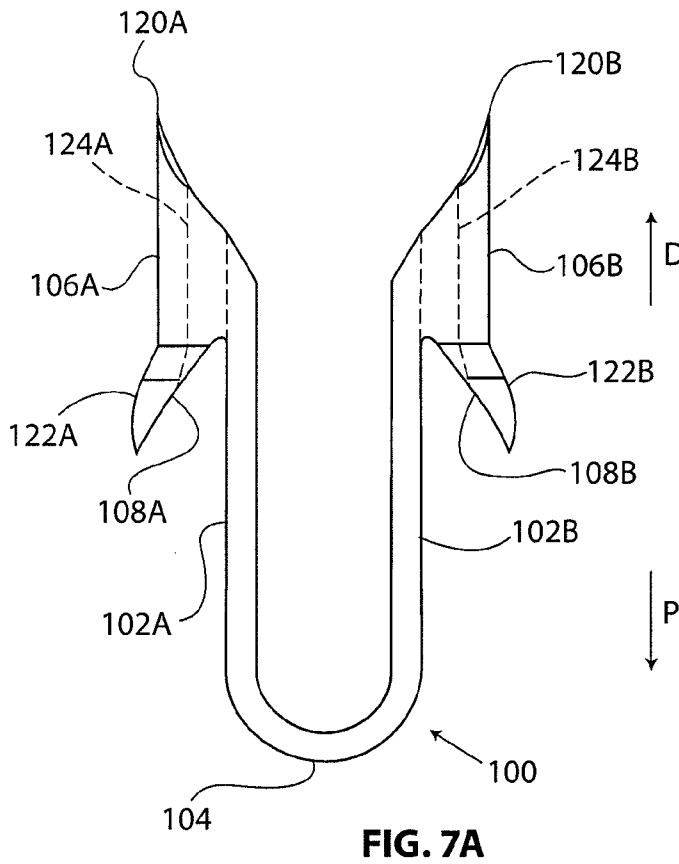
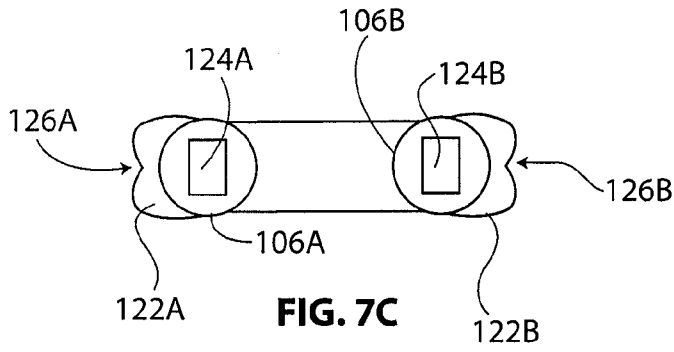


FIG. 6

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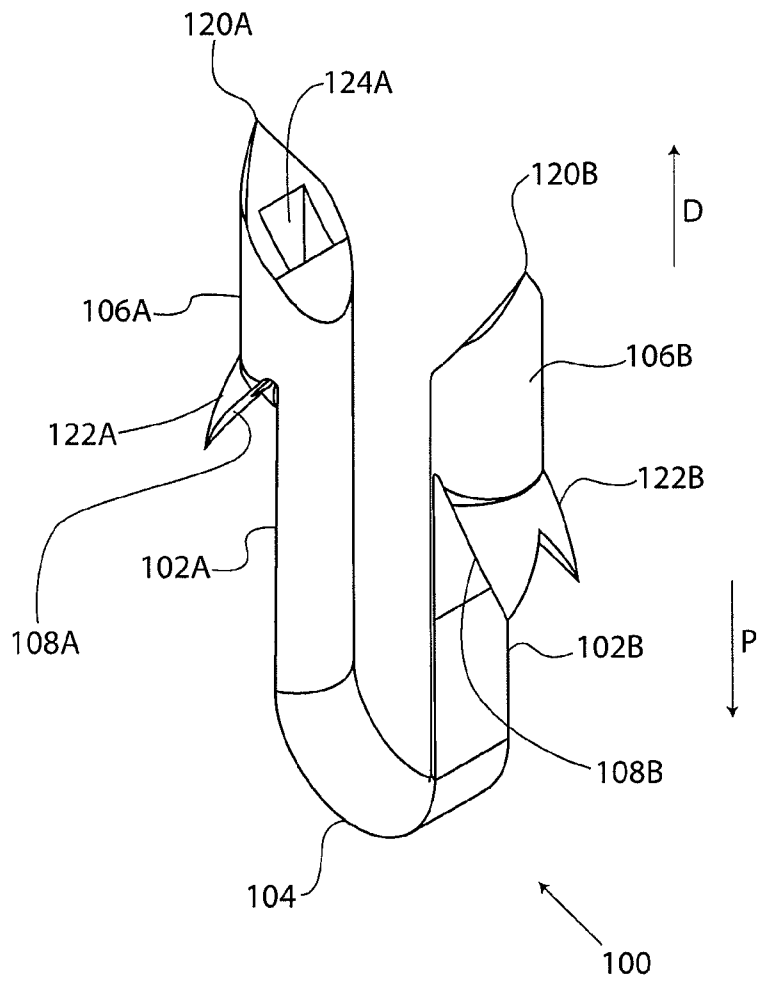


FIG. 8

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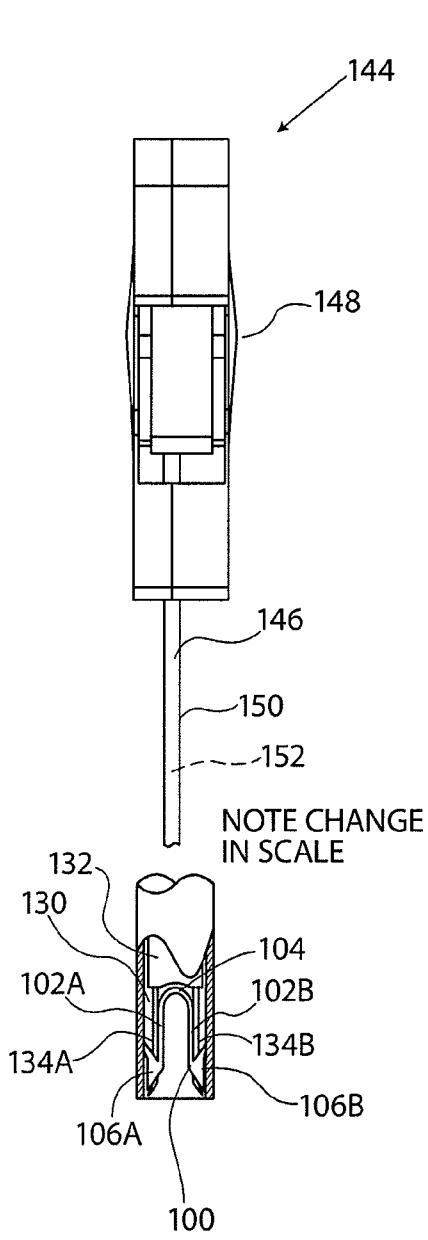


FIG. 9A

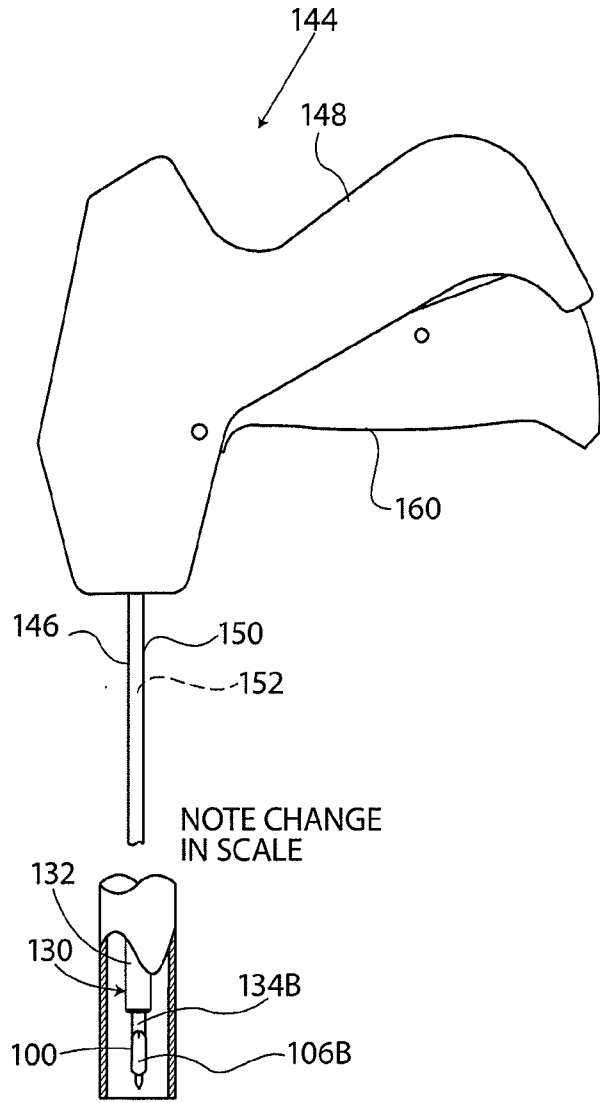


FIG. 9B

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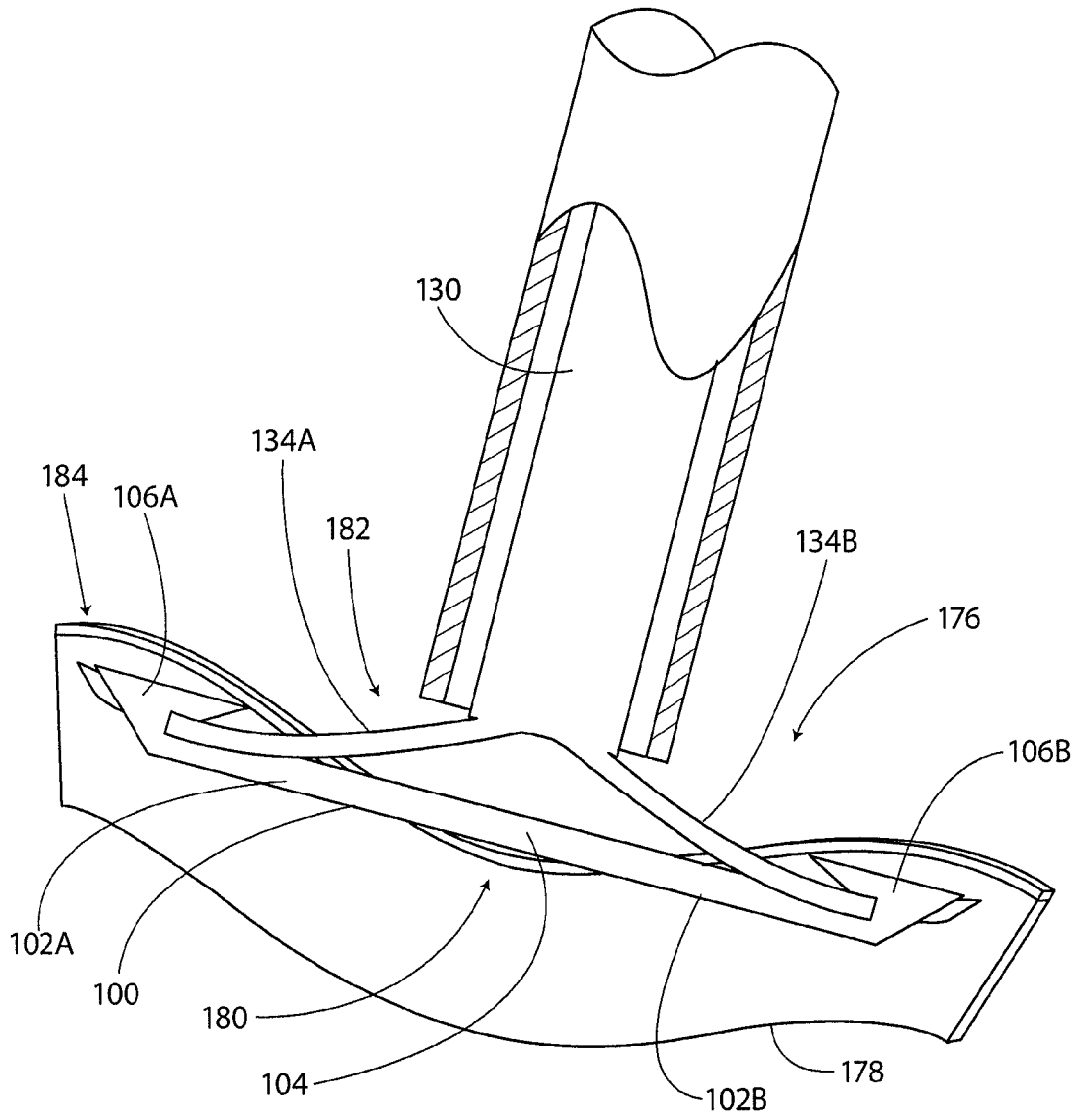


FIG. 11

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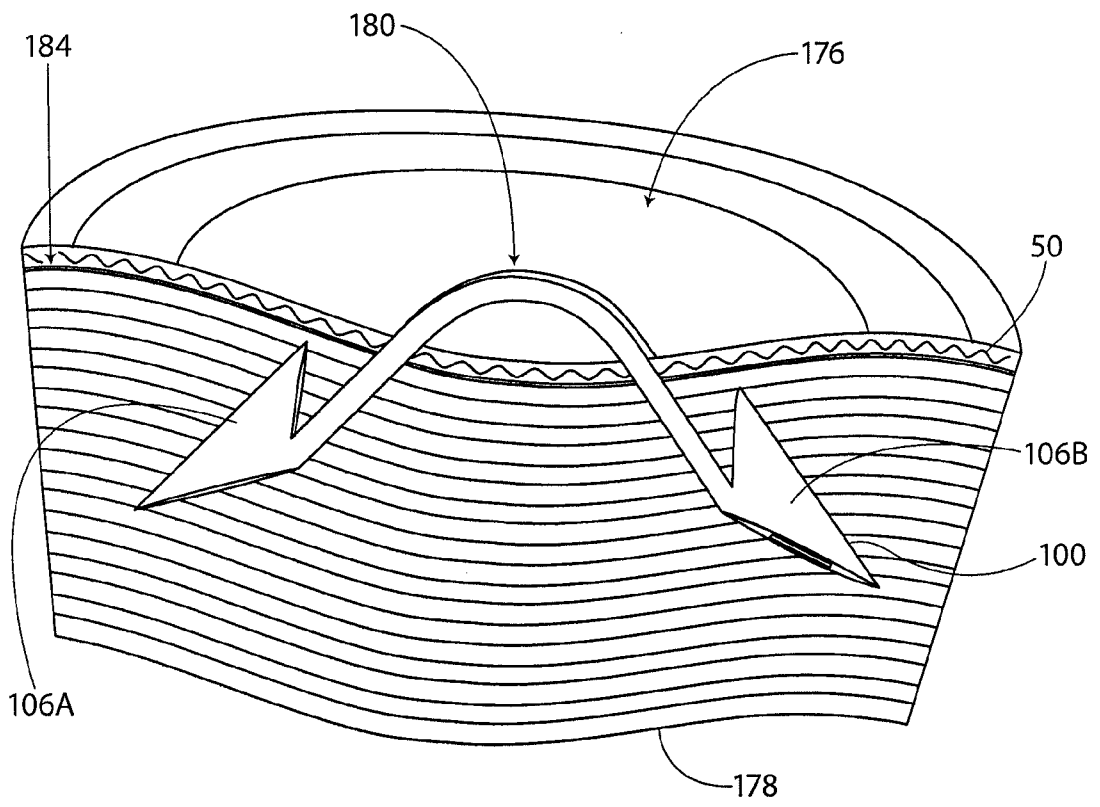


FIG. 12

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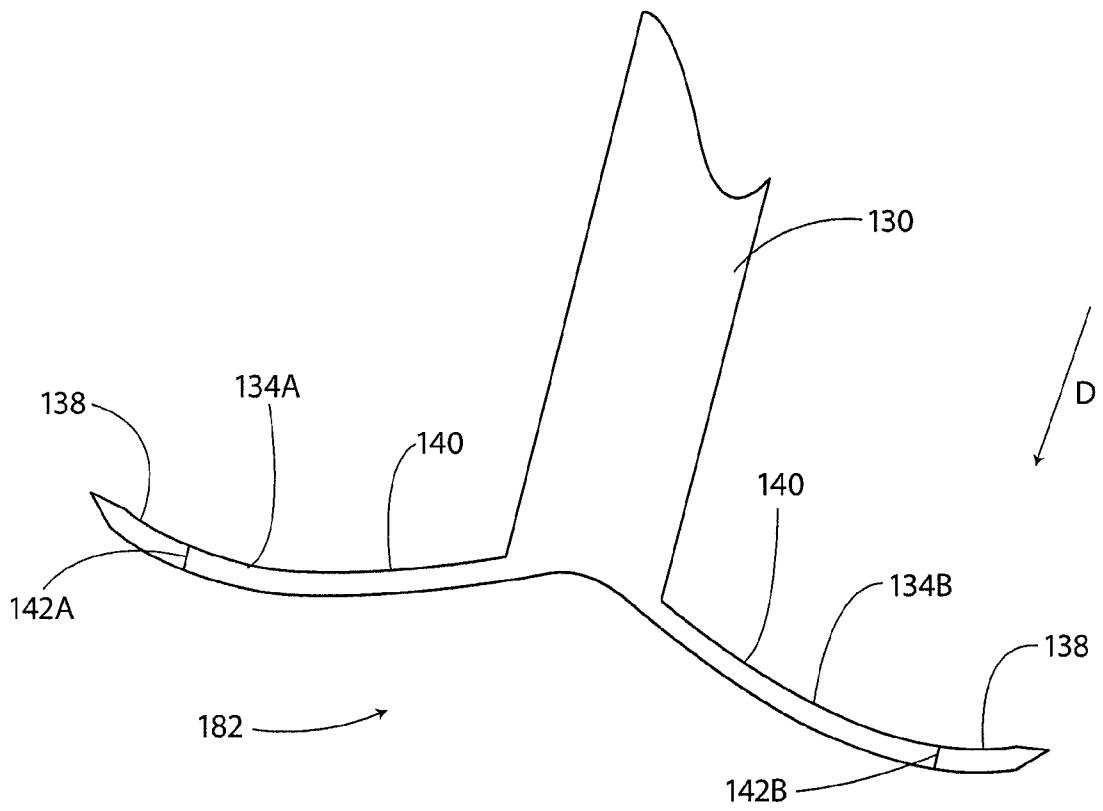


FIG. 13

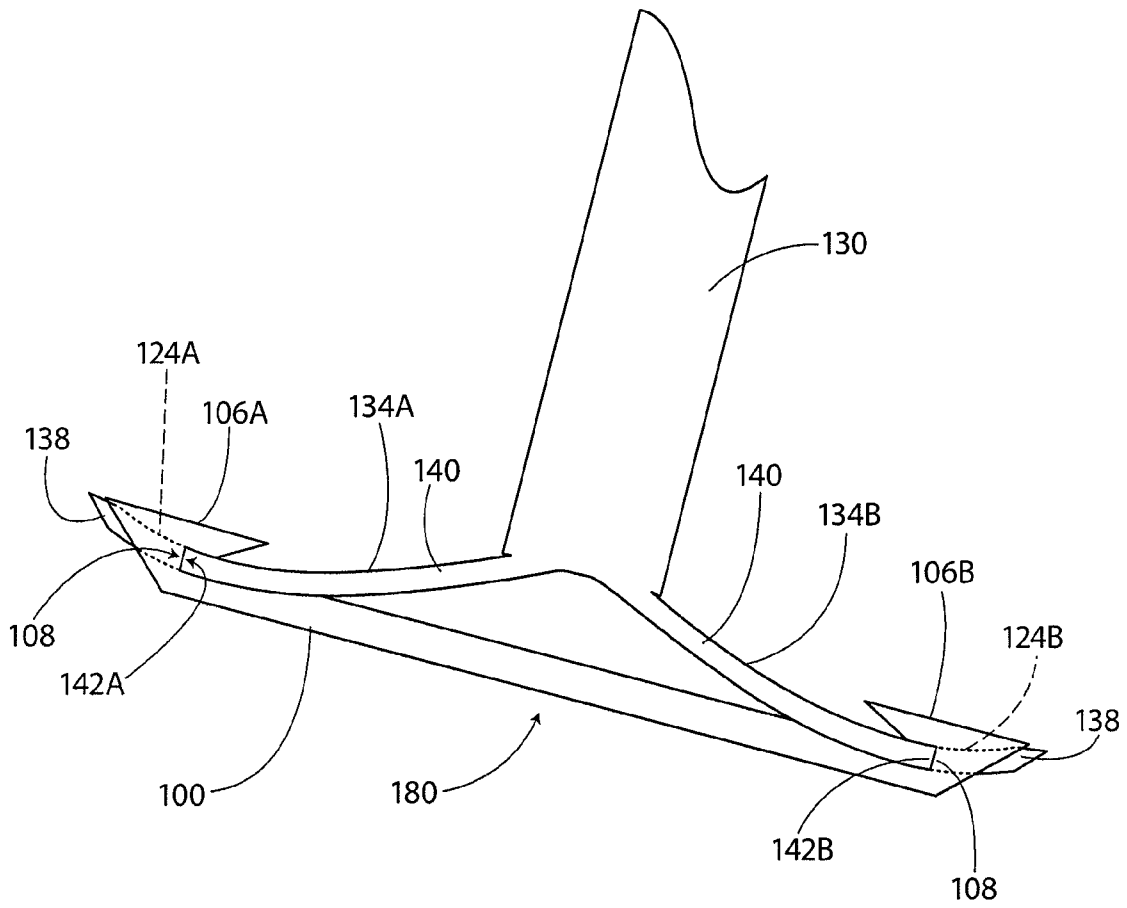


FIG. 14

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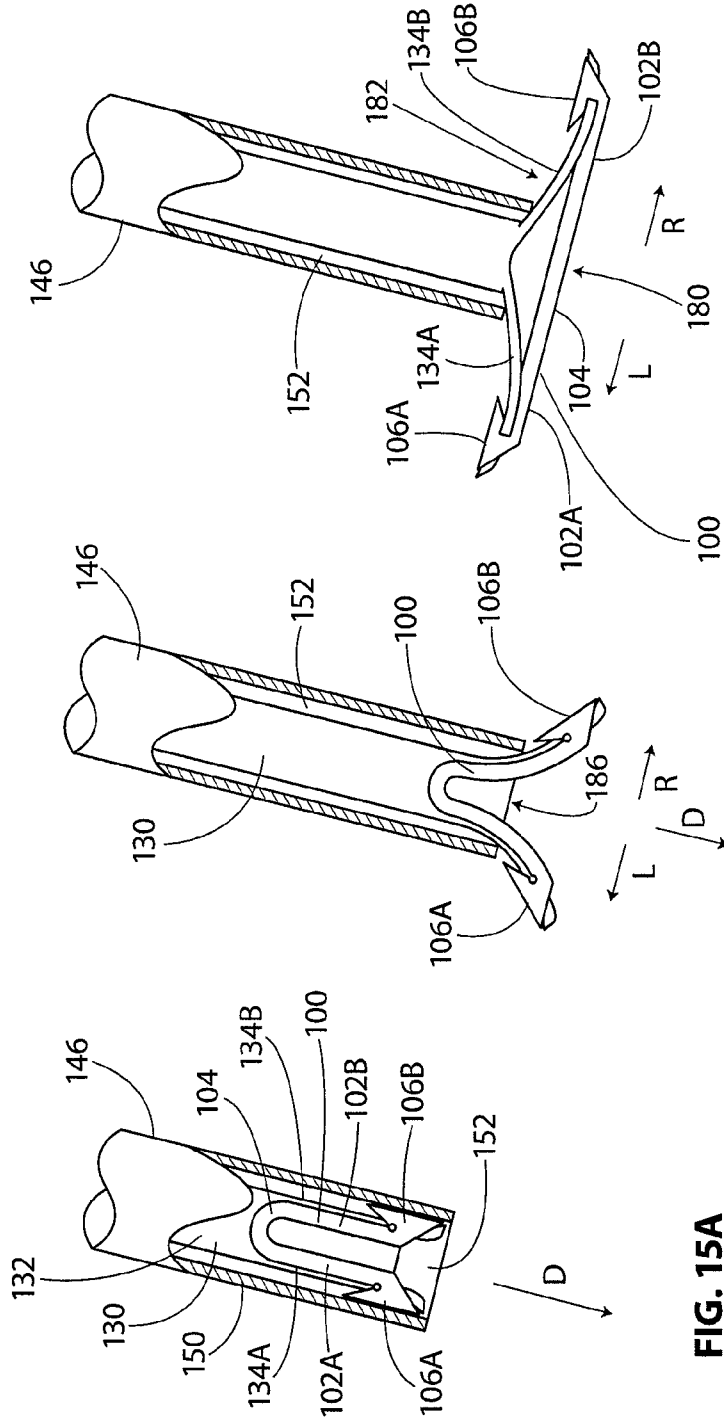


FIG. 15C

FIG. 15B

FIG. 15A

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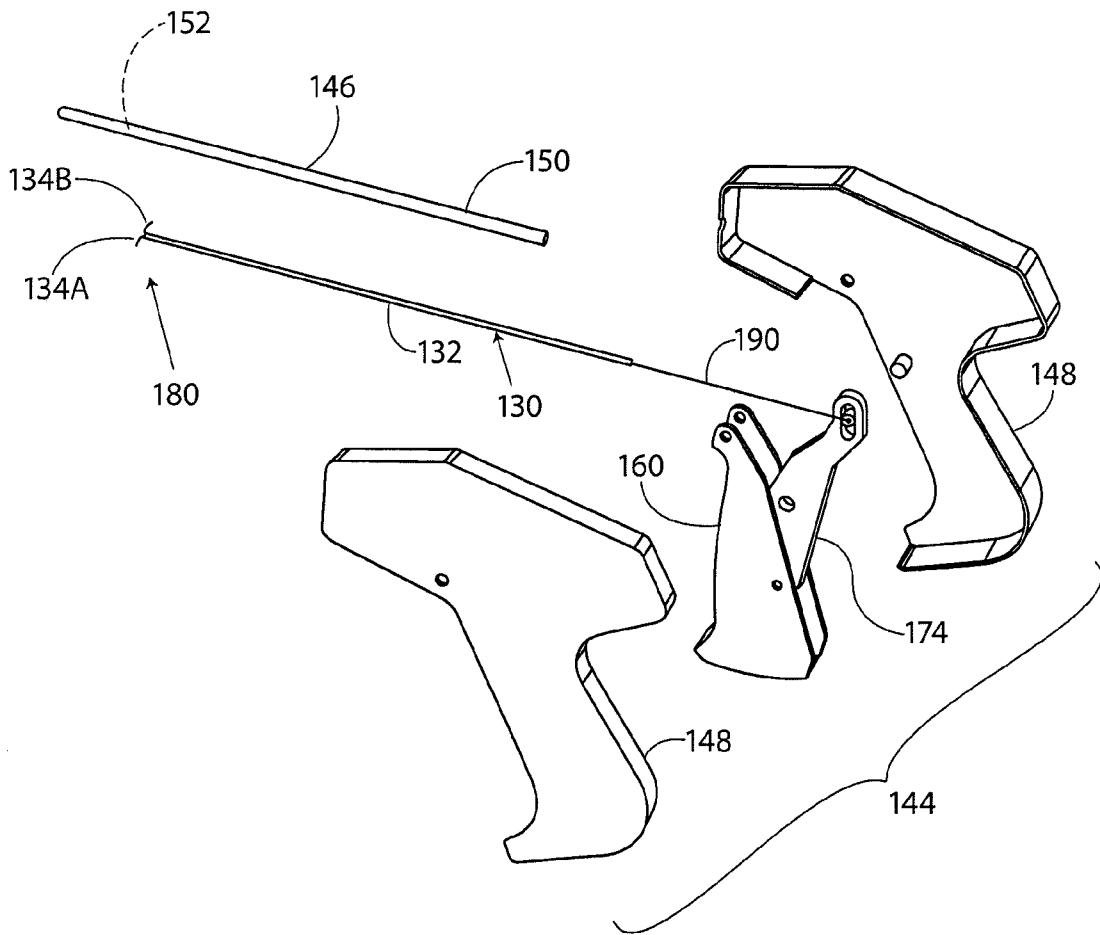


FIG. 16

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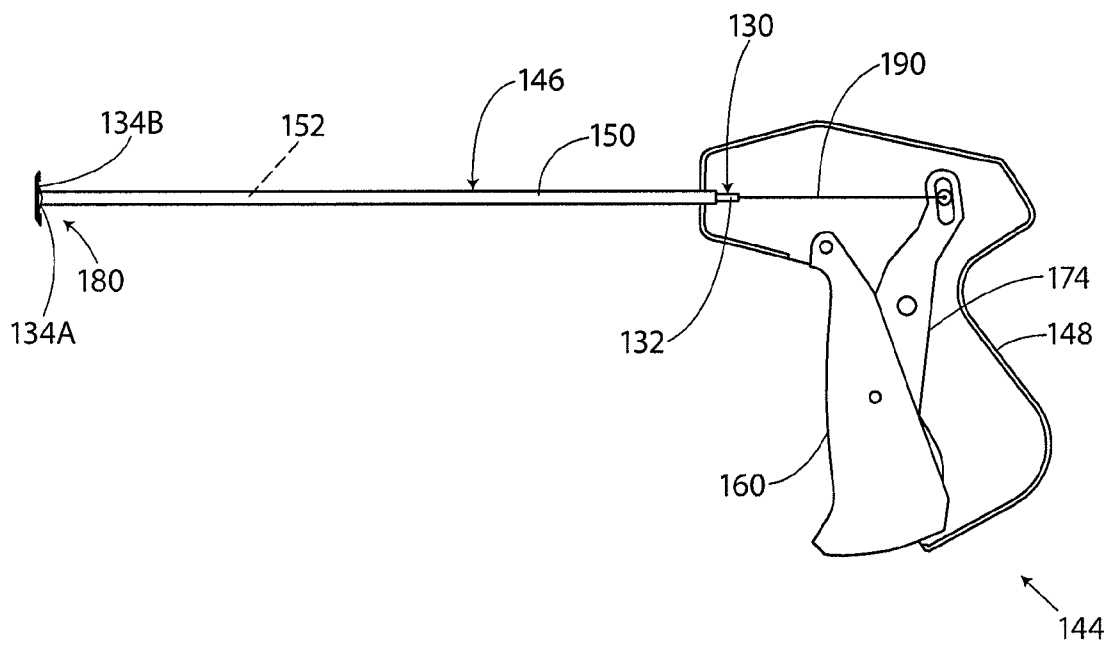


FIG. 17

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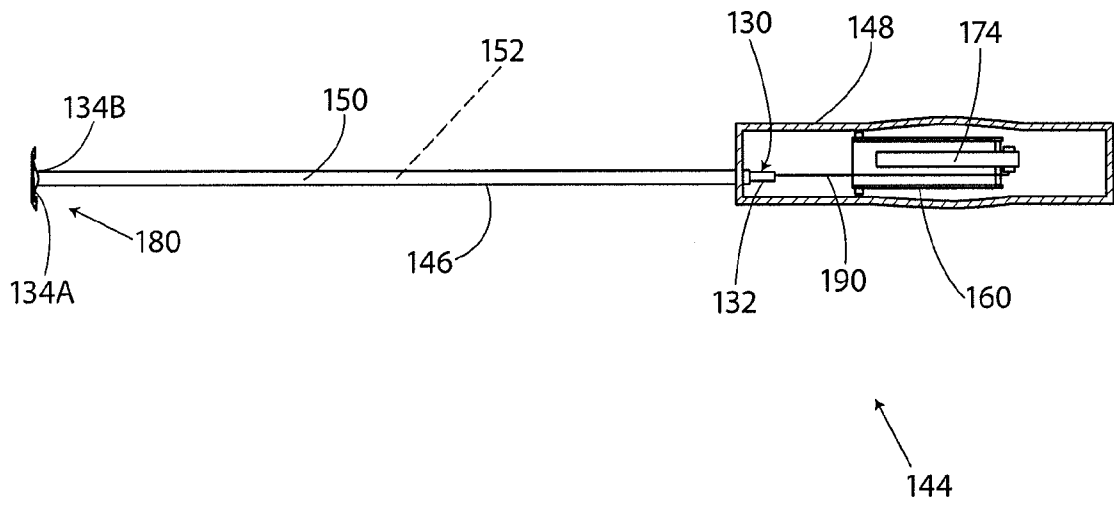


FIG. 18

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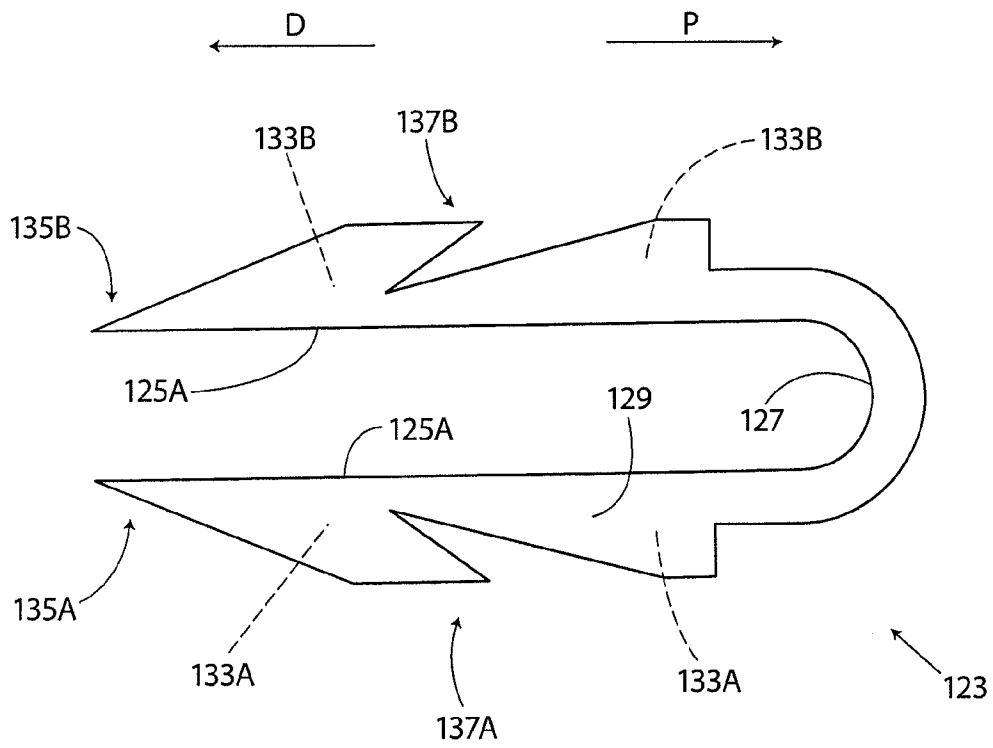


FIG. 19

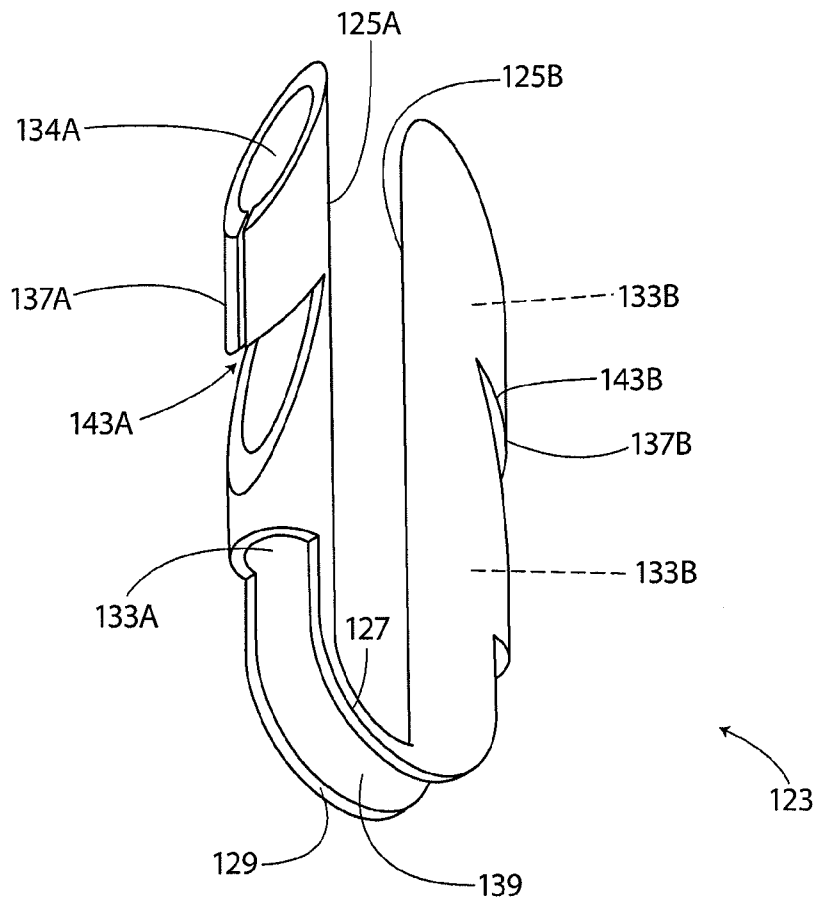
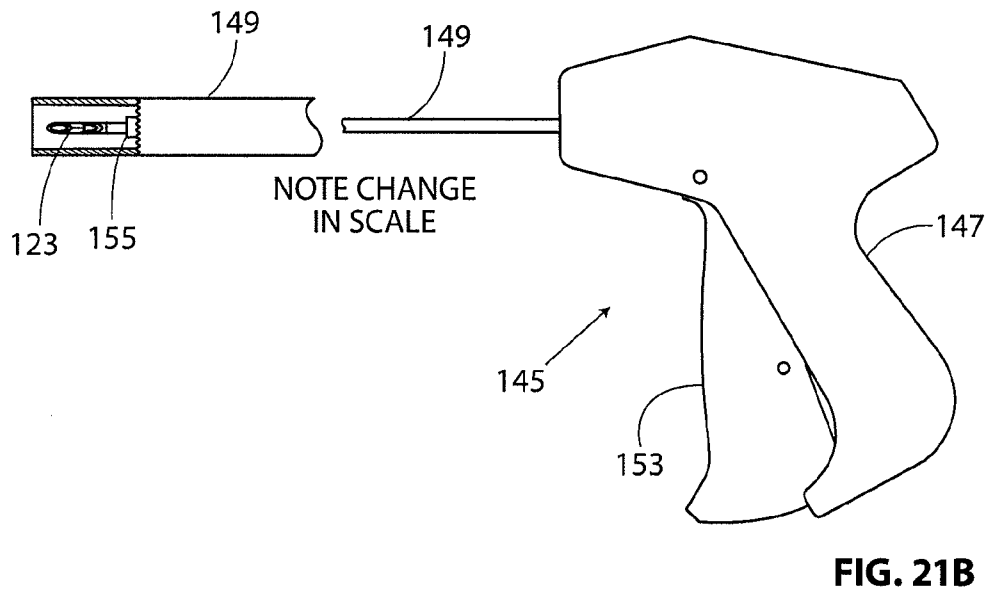
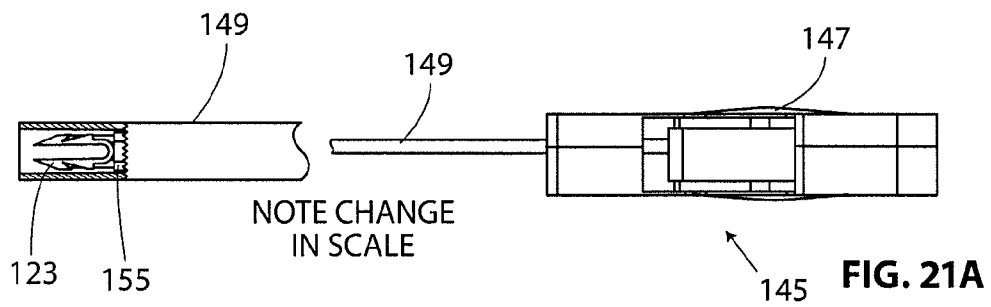
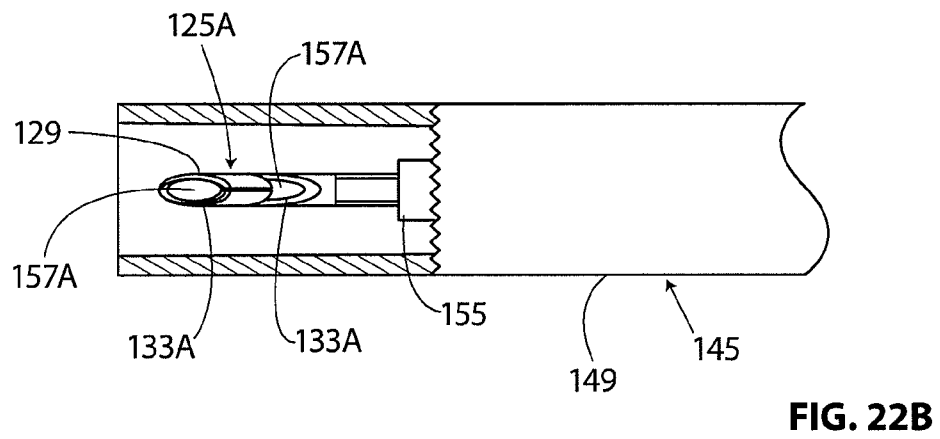
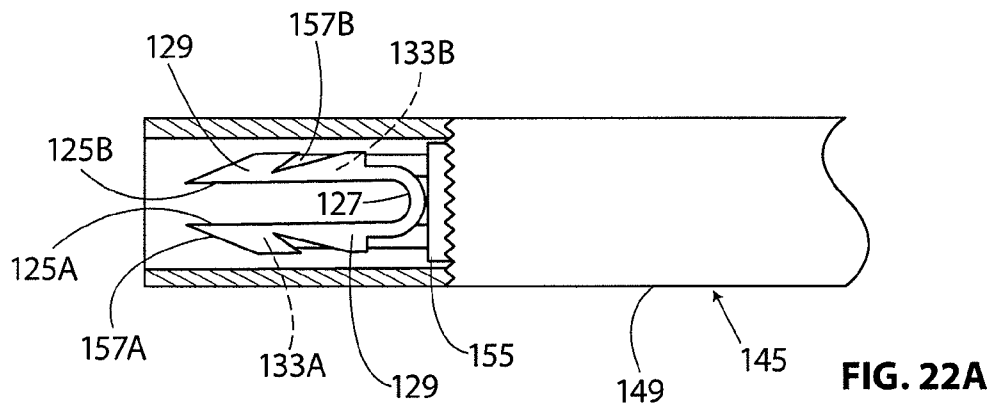


FIG. 20





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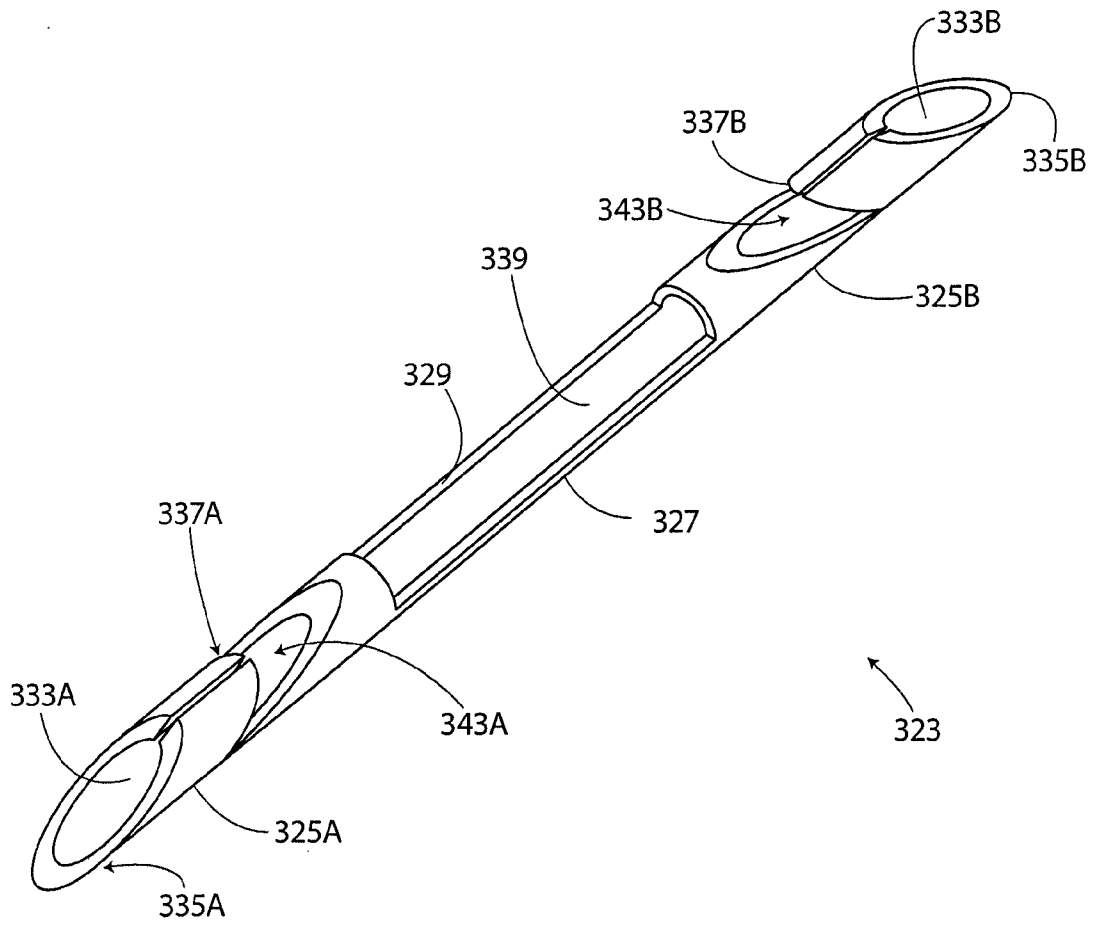


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/037526

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/068
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/049618 A1 (MASUDA HARUHIKO [JP] ET AL) 3 March 2005 (2005-03-03) paragraphs [0051] - [0053]	1, 4, 5
Y	US 2008/188936 A1 (BALL ROBERT J [US] ET AL) 7 August 2008 (2008-08-07) paragraphs [0077] - [0080]	1, 4, 5
Y	US 5 156 609 A (NAKAO NAOMI L [US] ET AL) 20 October 1992 (1992-10-20) columns 7-8; figure 3	1, 4, 5
A	WO 03/105670 A2 (GUIDED DELIVERY SYSTEMS INC [US]) 24 December 2003 (2003-12-24) the whole document	1-11
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

9 September 2010

Date of mailing of the international search report

15/09/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Chopinoud, Marjorie

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/037526

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 142 225 A1 (TECHNALYTICS INC [US]) 22 May 1985 (1985-05-22) the whole document -----	1-11
A	US 5 242 457 A (AKOPOV ERNEST [SU] ET AL) 7 September 1993 (1993-09-07) the whole document -----	1-11

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 12-22

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037526

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 12-22
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2010/037526

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005049618 A1	03-03-2005	WO 03053256 A1 JP 4116567 B2	03-07-2003 09-07-2008
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