



- (51) **International Patent Classification:**
A61F 2/08 (2006.01) *A61F 2/00* (2006.01)
- (21) **International Application Number:**
PCT/US2010/037522
- (22) **International Filing Date:**
4 June 2010 (04.06.2010)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/184,198 4 June 2009 (04.06.2009) US
61/313,116 11 March 2010 (11.03.2010) US
- (71) **Applicant (for all designated States except US):** **ROTATION MEDICAL, INC.** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** **EUTENEUER, Charles, L.** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **MCCARVILLE, Rebecca** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **FRION, Duane** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US).

ZENZ-OLSEN, Nathaniel [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **FEEHAN, Diane, M.** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **QUACKENBUSH, John** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US).

- (74) **Agents:** **LIMBACH, Douglas, C.** et al.; Shay Glenn LLP, 2755 Campus Drive, Suite 210, San Mateo, CA 94403 (US).

- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,

[Continued on next page]

- (54) **Title:** METHODS AND APPARATUS FOR DEPLOYING SHEET-LIKE MATERIALS

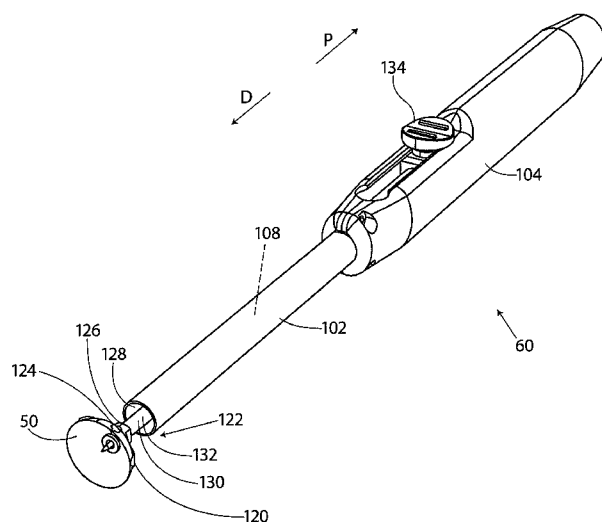


FIG. 9

(57) **Abstract:** Implant delivery systems for delivering sheet-like implants include a delivery shaft, an implant expander (120), a sheath (102), and a sheet-like implant (50). In some embodiments, the delivery shaft has a proximal end and a distal end. The implant expander is mounted to the distal end of the delivery shaft. The implant expander includes a central portion and a plurality of leg portions radiating from the central portion. The implant expander is evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface, and a first compact configuration in which the distal surface of the implant expander defines a convex surface. The implant expander has a first lateral extent when the implant expander is free to assume the unstressed configuration. The sheath defines a lumen having a lumen diameter. At least a portion of the delivery shaft is slidably disposed in the lumen. The lumen diameter is smaller than the first lateral extent of the implant expander so that the sheath holds the implant expander in the first compact configuration when slidably disposed therein. The sheet-like implant overlays at least a portion of the distal surface of the implant expander with portions of the sheet-like implant extending between the leg portions of the implant expander and the sheath. Methods of treating a rotator cuff of a shoulder are also disclosed.



ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

METHODS AND APPARATUS FOR DEPLOYING SHEET-LIKE MATERIALS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application
5 Serial No. 61/184,198 filed on June 4, 2009 and U.S. Provisional Patent Application No.
61/313,116 filed on March 11, 2010, the disclosures of each incorporated herein by reference.

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

[0003] The glenohumeral joint of the shoulder is found where the head of the humerus mates
15 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. U.S. 2008/0188936 A1 and as illustrated
in Figure 1 the rotator cuff muscles are a complex of four muscles. These four muscles are the
20 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.

[0004] The four muscles of the rotator cuff arise from the scapula 12. The distal tendons of
25 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
30 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.

[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
35 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.

5 [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
10 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
15 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
20 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
25 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
30 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
35 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.

SUMMARY OF THE INVENTION

[00010] According to aspects of the invention, implant delivery systems for delivering sheet-like implants are disclosed. In some embodiments, the implant delivery system includes a delivery shaft, an implant expander, a sheath, and a sheet-like implant. In these embodiments, the delivery shaft has a proximal end and a distal end. The implant expander is mounted to the distal end of the delivery shaft. The implant expander includes a central portion and a plurality of leg portions radiating from the central portion. The implant expander is evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface, and a first compact configuration in which the distal surface of the implant expander defines a convex surface. The implant expander has a first lateral extent when the implant expander is free to assume the unstressed configuration. The sheath defines a lumen having a lumen diameter. At least a portion of the delivery shaft is slidably disposed in the lumen. The lumen diameter is smaller than the first lateral extent of the implant expander so that the sheath holds the implant expander in the first compact configuration when slidably disposed therein. The sheet-like implant overlays at least a portion of the distal surface of the implant expander with portions of the sheet-like implant extending between the leg portions of the implant expander and the sheath.

[00011] In some embodiments, a free end of each leg portion of the implant expander is disposed distally of the central portion when the implant expander is assuming the unstressed configuration. The free end of each leg portion is disposed proximally of the central portion when the implant expander is assuming the first compact configuration. The delivery shaft distal end may be fixed to the central portion of the implant expander to urge relative movement between the implant expander and the sheath such that the implant expander and the sheet-like implant can be advanced through a distal opening defined by the sheath so the implant expander is free to assume a deployed configuration.

[00012] In some embodiments, a projection extends distally from the distal surface of the central portion of the implant expander to hold the position of delivery system when the projection is held against a target tissue. The implant expander may generally conform to the surface of a target tissue when the implant expander assumes the deployed configuration. In some embodiments, the distal surface of the implant expander defines a concave surface when the implant expander is assuming the deployed configuration and the target tissue has a generally convex shape. A free end of each leg portion may be disposed distally of the central portion when the implant expander is assuming the deployed configuration and the target tissue has a generally convex shape. In some embodiments, the implant expander causes the sheet-like

implant to conform to the surface of a target tissue when the implant expander assumes the deployed configuration.

[00013] In some embodiments, the implant expander assumes a second compact configuration when the implant expander is retracted proximally into the lumen of the sheath after having
5 assumed the deployed configuration. The distal surface of the implant expander may define a concave surface when the implant expander is assuming the second compact configuration. In some embodiments, the free end of each leg portion is disposed distally of the central portion when the implant expander is assuming the second compact configuration.

[00014] In some embodiments, the implant expander is integrally formed of a single material.

10 The sheet-like implant may define a plurality of pockets. Each pocket may be dimensioned to receive a distal portion of a leg portion of the implant expander. In some of these embodiments, the sheet-like implant can be selectively separated from the implant expander by withdrawing the distal portions of the legs from the pockets. In some embodiments, the implant expander further includes a plurality of retainers to engage the sheet-like implant such that the sheet-like implant
15 moves when the implant expander is moved. In some of these embodiments, the sheet-like implant can be selectively separated from the implant expander by withdrawing the retainers from the sheet-like implant.

[00015] According to aspects of the present invention, methods of treating a rotator cuff of a shoulder are disclosed. In some embodiments, the method includes the steps of providing an
20 implant delivery system, inflating the shoulder to create a cavity therein, placing the sheet-like implant and the implant expander inside the cavity, allowing the implant expander to assume a deployed configuration, attaching the sheet-like implant to the tendon, urging the implant expander to assume a second compact configuration, and removing the implant expander from the cavity. In these embodiments, the implant delivery system that is provided includes an
25 implant expander. The implant expander has a central portion and a plurality of leg portions radiating from the central portion. The implant expander is evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface, and a first compact configuration in which the distal surface of the implant expander defines a convex surface. A sheet-like implant overlays at least a portion of the distal surface of the implant
30 expander. A sheath is disposed about the sheet-like implant and the implant expander. The sheath holds the implant expander in the first compact configuration. When the sheet-like implant and the implant expander are placed inside the cavity, a tendon is contacted with at least a portion of the implant while the implant expander is assuming the first compact configuration. When allowing the implant expander to assume a deployed configuration, the implant expander
35 urges the sheet-like implant against a surface of the tendon. When urging the implant expander

to assume a second compact configuration, the distal surface of the implant expander defines a concave surface.

[00016] In some embodiments, the implant expander includes a projection extending distally from its central portion. The projection holds the position of the delivery system relative to the tendon when the sheet-like implant and implant expander are placed in the cavity against the tendon.

[00017] In some embodiments, the step of allowing the implant expander to assume the deployed configuration includes urging relative movement between the implant expander and the sheath such that the implant expander and the sheet-like implant are advanced through a distal opening defined by the sheath. With this arrangement, the implant expander is free to assume the deployed configuration. In some embodiments, urging relative movement between the implant expander and the sheath includes withdrawing the sheath in a proximal direction relative to the implant expander. In some embodiments, urging relative movement between the implant expander and the sheath includes advancing the implant expander in a distal direction along the lumen of the sheath. In some embodiments, urging the implant expander to assume the second compact configuration includes advancing the sheath over the implant expander so that the implant expander is disposed inside the lumen defined by the sheath. In some embodiments, urging the implant expander to assume the second compact configuration includes drawing the implant expander proximally into the lumen defined by the sheath. In some embodiments, urging the implant expander to assume the second compact configuration includes drawing the implant expander and the projection that extends distally from the central portion of the implant expander proximally into the lumen defined by the sheath.

[00018] According to aspects of the invention, methods of preparing a delivery system are disclosed. In some embodiments, these methods include the steps of providing a delivery sheath and an implant expander, covering at least a portion of the distal surface with a sheet-like implant, and deflecting the implant expander. The sheath defines a lumen having a lumen diameter. The implant expander includes a central portion and a plurality of leg portions radiating from the central portion. The implant expander is evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface, and a first compact configuration in which the distal surface of the implant expander defines a convex surface. The implant expander has a first lateral extent when the implant expander is free to assume the unstressed configuration. The first lateral extent is greater than the lumen diameter of the sheath. When the implant expander is deflected, the implant expander assumes the first compact configuration and the implant expander and the sheet-like implant are placed in the lumen defined by the sheath. The sheath holds the implant expander in the first compact

configuration with portions of the sheet-like implant being interposed between the leg portions of the implant expander and an inner surface of the sheath.

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

5

BRIEF DESCRIPTION OF THE DRAWINGS

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

10 [00021] Figure 2 is a schematic depiction of a full thickness tear in the supraspinatus tendon of the rotator cuff of Figure 1.

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

15 [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.

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

[00025] Figure 6 is an enlarged perspective view further illustrating the procedure shown in the previous Figure.

20 [00026] Figure 7 is an enlarged perspective view showing the delivery system shown in the previous Figure.

[00027] Figure 8 is a stylized perspective view of a shoulder including a supraspinatus muscle having a distal tendon.

25 [00028] Figure 9 is an additional perspective view further illustrating a delivery system in accordance with this disclosure.

[00029] Figure 10A through Figure 10E are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description.

[00030] Figure 11 is a stylized diagram illustrating four configurations of an exemplary implant expander.

30 [00031] Figure 12 is a perspective view illustrating an exemplary delivery system in accordance with this disclosure.

[00032] Figure 13 is a plan view illustrating an exemplary assembly in accordance with the present detailed description.

35 [00033] Figure 14 is a plan view illustrating an exemplary assembly in accordance with the present detailed description.

[00034] Figure 15A through Figure 15F are a series of stylized plan views illustrating exemplary methods and apparatus in accordance with the present detailed description.

[00035] Figure 16 is a stylized depiction of a kit that may be used, for example, for delivering a sheet-like implant to a target location within the body of a patient.

5 [00036] Figure 17A is an enlarged plan view illustrating a delivery aid included in the kit of Figure 16. Figure 17B is a partial cross-sectional perspective view further illustrating the delivery aid shown in Figure 17A.

[00037] Figure 18A through Figure 18I are a series of stylized plan views illustrating exemplary methods and apparatus in accordance with the present detailed description.

10 [00038] Figure 19 is a plan view showing a locating guide included in the kit of Figure 16.

[00039] Figure 20 is a plan view showing a locating guide removal tool included in the kit of Figure 16.

DETAILED DESCRIPTION OF THE INVENTION

15 [00040] 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.

[00041] 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 relative to scapula 12 is controlled by a number of muscles including: the deltoid, the
20 supraspinatus, the infraspinatus, the subscapularis, and the teres minor. For purposes of illustration, only the supraspinatus 26 is shown in Figure 3.

[00042] 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 acromium 32. In Figure 3, a subacromial bursa 34 is shown extending between acromium 32 of
30 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 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 inflamed. This condition is sometimes referred to as bursitis.

[00043] 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 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 avoiding more extensive joint damage, pain, and the need for more extensive joint repair surgery.

[00044] 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 28 of supraspinatus 26 meets humerus 14 at an insertion point 30.

[00045] 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.

[00046] 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.

[00047] 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 by a plurality of staples.

5 [00048] 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.

10 [00049] Shoulder 22 of Figure 5 has been inflated to create a cavity therein. In the exemplary embodiment of Figure 5, 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.

[00050] 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
15 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.

[00051] 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 with 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.
25

[00052] 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
30 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.

[00053] The tendon repair implant may be fixed to the tendon while it is held against the
35 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.

[00054] Figure 6 is an enlarged perspective view further illustrating the procedure shown in the previous Figure. Figure 6 also illustrates the interior structure of shoulder 22 shown in the previous Figure. With reference to Figure 6, it will be appreciated that shoulder 22 includes a humerus 14 and a scapula 12. In Figure 6, 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 6. A distal tendon 28 of supraspinatus 26 can be seen meeting a tuberosity of humerus 14 in Figure 6.

[00055] Delivery system 60 is also shown in Figure 6. In the embodiment of Figure 6, a distal end of delivery system 60 has been positioned near distal tendon 28 of supraspinatus 26. Delivery system 60 comprises a sheath 102 that is fixed to a handle 104. Sheath 102 defines a lumen 108 and a distal opening fluidly communicating with the lumen. In the embodiment of Figure 6, a central portion of a sheet-like implant 50 can be seen extending through the distal opening defined by sheath 102. In the embodiment of Figure 6, sheet-like implant 50 is overlaying an implant expander. The implant expander and sheet-like implant 50 are both assuming a compact configuration. The majority of sheet-like implant 50 is disposed inside sheath 102. A central portion of sheet-like implant 50 is extending out of sheath 102. This central portion of sheet-like implant 50 is contacting an outer surface of distal tendon 28 in the embodiment of Figure 6.

[00056] Figure 7 is an enlarged perspective view showing delivery system 60 shown in the previous Figure. In the embodiment of Figure 7, sheath 102 of delivery system 60 has been moved in a proximal direction P relative to handle 104. By comparing Figure 7 to the previous Figure, it will be appreciated that sheet-like implant 50 and implant expander 120 are now disposed outside of lumen 108 defined by sheath 102. Implant expander 120 comprises a central portion 122 and a plurality of leg portions 124 radiating from central portion 122. In Figure 7, leg portions 124 of implant expander 120 are shown overlaying sheet-like implant 50. Hub 126 is shown overlaying central portion 122 of implant expander 120 in Figure 7. Implant expander 120 can be used to expand sheet-like implant 50 and hold sheet-like implant 50 against the surface of a target tissue. Sheet-like implant 50 may be fixed to the target tissue while the implant is held against the target tissue by implant expander 120.

[00057] Figure 8 is a stylized perspective view of a shoulder 22 including a supraspinatus 26 having a distal tendon 28. With reference to Figure 8, 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™. The sheet-like structure may be circular, oval, oblong, square, rectangular, or other shape configured to suit the target anatomy.

[00058] 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 8, a plurality of staples are fixing tendon repair implant 50 to distal tendon 28. In some exemplary methods, a plurality of staples 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 8, 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. In various embodiments, staples may straddle the perimeter edge of the sheet-like implant (as shown in Figure 8), may be applied adjacent to the perimeter, and/or be applied to a central region of the implant. In some embodiments, the staples may be used to attach the implant to soft tissue and/or to bone.

[00059] Figure 9 is an additional perspective view further illustrating delivery system 60. Delivery system 60 comprises a sheath 102 that is fixed to a handle 104. Sheath 102 defines a lumen 108 and a distal opening 128 fluidly communicating with lumen 108. In the embodiment

of Figure 9, a delivery aid 130 can be seen extending through distal opening 128 defined by sheath 102.

[00060] In the embodiment of Figure 9, delivery aid 130 comprises a hub 126 that is disposed at the distal end of a control rod 132. An implant expander 120 is attached to hub 126. Implant expander 120 comprises a central portion 122 and a plurality of leg portions 124 radiating from central portion 122. In Figure 9, a sheet-like implant 50 is shown overlaying a distal surface of implant expander 120. In the exemplary embodiment of Figure 9, implant expander 120 is urging sheet-like implant 50 against a generally spherical surface (not shown in Figure 9).

[00061] Sheath 102 of delivery system 60 is coupled to a button 134. It will be appreciated that various other operative mechanisms may be used in addition to button 134. Relative motion between button 134 and handle 104 will cause similar relative motion between sheath 102 and handle 104. In the exemplary embodiment of Figure 9, sheath 102 will be moved distally (relative to handle 104) when button 134 is moved distally (relative to handle 104).

Additionally, sheath 102 will be moved proximally (relative to handle 104) when button 134 is moved proximally (relative to handle 104).

[00062] In Figure 9, implant expander 120 is shown residing outside of lumen 108 defined by sheath 102. In Figure 9, implant expander 120 is shown assuming a deployed configuration.

Implant expander 120 can be selectively urged to assume a compact configuration, for example, by placing implant expander inside lumen 108 defined by sheath 102. Implant expander can be placed inside lumen 108, for example, by advancing sheath 102 over implant expander 120.

[00063] Figure 10A through Figure 10E are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description. Figure 10A through Figure 10E may be referred to collectively as Figure 10. A proximal direction is illustrated with an arrow P in Figure 10. A distal direction is illustrated with another arrow D in Figure 10. The exemplary method of Figure 10 may be used, for example, to fix a sheet-like implant 50 to a surface 136 of a target tissue 138.

[00064] Figure 10A is a partial cross-sectional view illustrating a distal portion of a delivery system 60 in accordance with this detailed description. In the embodiment of Figure 10, the distal portion of delivery system 60 has been positioned near a target tissue 138. Delivery system 60 comprises a sheath 102 that is fixed to a handle. Sheath 102 defines a lumen 108 and a distal opening fluidly communicating with the lumen. In the embodiment of Figure 10A, a central portion of a sheet-like implant 50 can be seen extending through the distal opening defined by sheath 102. In the embodiment of Figure 10, sheet-like implant 50 is overlaying an implant expander. The implant expander and sheet-like implant 50 are both assuming a compact configuration. With reference to Figure 10, it will be appreciated that the majority of sheet-like

implant 50 is disposed inside sheath 102. A central portion of a sheet-like implant 50 is extending out of sheath 102.

[00065] Implant expander 120 of Figure 10 comprises a central portion 122 and a plurality of leg portions 124 radiating from central portion 122. In the embodiment of Figure 10A, implant expander 120 is assuming a first compact configuration. With reference to Figure 10A, it will be appreciated that the free end of each leg portion 124 is disposed proximally of central portion 122 when implant expander 120 is assuming the first compact configuration. With continuing reference to Figure 10, it will be appreciated that a distal surface 140 of implant expander 120 defines a convex surface when implant expander 120 is assuming the first compact configuration 142. Portions of sheet-like implant 50 can be seen extending between leg portions 124 of implant expander 120 and the wall of sheath 102. In Figure 10, a fold 146 comprising a portion of sheet-like implant 50 can also be seen extending between an adjacent pair of leg portions 124.

[00066] In the embodiment of Figure 10B, a central portion of sheet-like implant 50 is trapped between implant expander 120 and surface 136 of target tissue 138. By comparing Figure 10A and Figure 10B, it will be appreciated that sheet-like implant 50 has been advanced distally so that central portion of sheet-like implant 50 is contacting surface 136 of target tissue 138.

[00067] In the embodiment of Figure 10B, delivery system 60 includes a projection 148 extending distally from distal surface 140 of central portion 122 of implant expander 120. In some applications, projection 148 may be used to temporarily hold the position of delivery system 60 while sheet-like implant 50 is held against surface 136 of target tissue 138. In the exemplary embodiment of Figure 10B, projection 148 comprises a spike 150 having a generally cone-like shape. In the embodiment of Figure 10B, spike 150 has been advanced so that a distal portion of spike 150 has pierced target tissue 138. Spike 150 can be seen extending through sheet-like implant 50 in Figure 10B. Spike 150 may be used to temporarily center implant expander 120 and sheet-like implant 50 on a target location. Once sheet-like implant 50 has been fixed to target tissue 138, spike 150 can be withdrawn from target tissue 138 and sheet-like implant 50.

[00068] In Figure 10C, implant expander 120 of delivery system 60 is shown assuming a deployed configuration. By comparing Figure 10C and Figure 10B, it will be appreciated that sheath 102 has been retracted in proximal direction P. In the embodiment of Figure 10C, leg portions 124 of implant expander 120 are conforming to the shape of surface 136. In the exemplary embodiment of Figure 10, surface 136 has a generally planar shape. Sheet-like implant 50 is resting between implant expander 120 and surface 136 of target tissue 138, with sheet-like implant 50 overlaying surface 136. With reference to Figure 10C, it will be

appreciated that implant expander 120 is causing sheet-like implant 50 to generally conform to the shape of surface 136.

[00069] In Figure 10D, implant expander 120 of delivery system 60 is shown assuming an unstressed configuration. By comparing Figure 10C and Figure 10D, it will be appreciated that implant expander 120 has been lifted in proximal direction P. In the embodiment of Figure 10D, no external forces are acting on leg portions 124 and implant expander 120 is free to assume the unstressed configuration shown in Figure 10D. With reference to Figure 10D, it will be appreciated that the free end of each leg portion 124 is disposed distally of central portion 122 when implant expander 120 is assuming the unstressed configuration. With continuing reference to Figure 10, it will be appreciated that the distal surface 140 of implant expander 120 defines a concave surface when implant expander 120 is assuming the unstressed configuration.

[00070] In Figure 10E, implant expander 120 of delivery system 60 is shown assuming a second compact configuration. By comparing Figure 10E and Figure 10D, it will be appreciated that implant expander 120 and sheath 102 have been moved relative to each other. With reference to Figure 10E, it will be appreciated that implant expander 120 may be urged to assume the second compact configuration moving implant expander 120 and sheath 102 relative to one another so that implant expander 120 is disposed in lumen 108 defined by sheath 102. With reference to Figure 10, it will be appreciated that the free end of each leg portion 124 is disposed distally of central portion 122 when implant expander 120 is assuming the second compact configuration 144. With continuing reference to Figure 10, it will be appreciated that the distal surface 140 of implant expander 120 defines a concave surface when implant expander 120 is assuming the second compact configuration 144.

[00071] Figure 11 is a stylized diagram illustrating four configurations of an exemplary implant expander 120. The step of transitioning between one configuration and another configuration is represented by three arrows in Figure 11. A proximal direction is illustrated with another arrow P in Figure 11. A distal direction is illustrated with an additional arrow D in Figure 11.

[00072] Implant expander 120 of Figure 11 comprises a central portion 122 and a plurality of leg portions 124 radiating from central portion 122. A first arrow 1 represents a transition between a first compact configuration 142 and a deployed configuration 154. With reference to Figure 11, it will be appreciated that the free end of each leg portion 124 is disposed proximally of central portion 122 when implant expander 120 is assuming the first compact configuration 142. With continuing reference to Figure 11, it will be appreciated that a distal surface 140 of implant expander 120 defines a convex surface when implant expander 120 is assuming the first compact configuration 142. In some exemplary methods, implant expander 120 is held in the

first compact configuration 142 while implant expander 120 is disposed in a lumen of a sheath. In these exemplary methods, implant expander 120 may be allowed to assume deployed configuration 154 when the sheath is retracted from around implant expander 120. Implant expander 120 may also be allowed to assume deployed configuration 154 when implant
5 expander 120 is moved in a distal direction so that implant expander 120 exits the lumen via a distal opening of the sheath or when the sheath moves proximally to reveal the implant expander from within the distal opening of the sheath and relieve stress within leg portions 124.

[00073] In the exemplary embodiment of Figure 11, leg portions 124 of implant expander 120 conform to the shape of a target tissue when implant expander 120 is in the deployed
10 configuration. In Figure 11, implant expander 120 is shown conforming to the shape of a generally planar surface (not shown in Figure 11) while implant expander is assuming the deployed configuration. A second arrow 2 represents a transition between the deployed configuration 154 and an unstressed configuration 152. In some exemplary methods, implant expander 120 is free to assume unstressed configuration 152 when implant expander 120 is lifted
15 off of a target surface so that no external forces are acting on leg portions 124 of implant expander 120. With reference to Figure 11, it will be appreciated that the free end of each leg portion 124 is disposed distally of central portion 122 when implant expander 120 is assuming unstressed configuration 152. With continuing reference to Figure 11, it will be appreciated that the distal surface 140 of implant expander 120 defines a concave surface when implant expander
20 120 is assuming the unstressed configuration 152.

[00074] A third arrow 3 represents a transition between the unstressed configuration 152 and a second compact configuration 144. In some exemplary methods, implant expander 120 is urged to assume second compact configuration 144 by drawing implant expander 120 proximally into a lumen of a sheath. With reference to Figure 11, it will be appreciated that the free end of each
25 leg portion 124 is disposed distally of central portion 122 when implant expander 120 is assuming the second compact configuration 144. With continuing reference to Figure 11, it will be appreciated that the distal surface 140 of implant expander 120 defines a concave surface when implant expander 120 is assuming the second compact configuration 144.

[00075] Figure 12 is a perspective view illustrating an exemplary delivery system 360.

30 Delivery system 360 comprises a sheath 302 that is fixed to a handle 304. Sheath 302 defines a lumen 308 and a distal opening 328 fluidly communicating with lumen 308. In the embodiment of Figure 12, a delivery aid 330 can be seen extending through distal opening 328 defined by sheath 302. In the embodiment of Figure 12, delivery aid 330 comprises a hub 326 that is disposed at the distal end of a control rod 332. An implant expander 320 is attached to hub 326.

Implant expander 320 comprises a central portion 322 and a plurality of leg portions 324 radiating from central portion 322.

[00076] Sheath 302 of delivery system 360 is coupled to an actuator 356. Relative motion between actuator 356 and handle 304 will cause similar relative motion between sheath 302 and handle 304. In the exemplary embodiment of Figure 12, sheath 302 will be moved distally (relative to handle 304) when actuator 356 is moved distally (relative to handle 304). Additionally, sheath 302 will be moved proximally (relative to handle 304) when actuator 356 is moved proximally (relative to handle 304).

[00077] In Figure 12, implant expander 320 is shown residing outside of lumen 308 defined by sheath 302. In Figure 12, implant expander 320 is shown assuming an unstressed configuration. Implant expander 320 can be selectively urged to assume a compact configuration, for example, by placing implant expander inside lumen 308 defined by sheath 302. Implant expander can be placed inside lumen 308, for example, by advancing sheath 302 over implant expander 320.

[00078] Figure 13 is a plan view illustrating an exemplary assembly in accordance with the present detailed description. The assembly of Figure 13 includes a sheet-like implant 50 and an implant expander 520. Implant expander 520 of Figure 13 comprises a central portion 522 and a plurality of leg portions 524 radiating from central portion 522. In the embodiment of Figure 13, a sheet-like implant 50 is trapped between implant expander 520 and a target tissue 538. With reference to Figure 13, it will be appreciated that implant expander 520 includes a plurality of retainers 558. In the embodiment of Figure 13, retainers 558 engage sheet-like implant 50 so that sheet-like implant 50 moves when implant expander 520 is moved and may aid in imparting lateral stress of the legs into lateral stress within the implant.

[00079] Figure 14 is a plan view illustrating an exemplary assembly in accordance with the present detailed description. The assembly of Figure 14 includes a sheet-like implant 50 and an implant expander 720. Implant expander 720 of Figure 14 comprises a central portion 722 and a plurality of leg portions 724 radiating from central portion 722. In the embodiment of Figure 14, a sheet-like implant 50 is trapped between implant expander 720 and a target tissue 738. With reference to Figure 14, it will be appreciated that sheet-like implant 50 includes a plurality of pockets 762. In the embodiment of Figure 14, each pocket 762 is dimensioned to receive the end of a leg portion 724 of implant expander 720. When this is the case, implant expander 720 engages pockets 762 so that sheet-like implant 50 moves when implant expander 720 is moved.

[00080] Figure 15A through Figure 15F are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description. Figure 15A through Figure 15F may be referred to collectively as Figure 15. A proximal direction is illustrated with

an arrow P in Figure 15. A distal direction is illustrated with another arrow D in Figure 15. The exemplary method of Figure 15 may be used, for example, to fix a sheet-like implant 50 to a surface of a target tissue 138.

[00081] Figure 15A is a stylized plan view of illustrating a shoulder 22 of a patient.

Shoulder 22 of Figure 15A has been inflated to create a cavity 62 therein. In the exemplary embodiment of Figure 15A, a fluid supply 64 is pumping a continuous flow of saline into cavity 62. This flow of saline exits cavity 62 via a fluid drain 66.

[00082] In Figure 15A, a sheath 102 of a delivery system 60 is shown positioned near a shoulder 22. Delivery system 60 also comprises a delivery aid 130 including an implant

expander that is fixed to the distal end of a control rod 132. In the embodiment of Figure 15A, a sheet-like implant 50 is overlaying the implant expander of delivery aid 130. In the embodiment of Figure 15A, delivery aid 130 includes a projection 148 extending distally from the implant expander. In the exemplary embodiment of Figure 15A, projection 148 comprises a spike 150 having a generally cone-like shape. Spike 150 can be seen extending through sheet-like implant 50 in Figure 15A. Spike 150 may be used to temporarily center sheet-like implant 50 on a target location. Once sheet-like implant 50 has been fixed to target tissue 138, spike 150 can be withdrawn from target tissue 138 and sheet-like implant 50.

[00083] Delivery aid 130 can be used to insert sheet-like implant 50 into cavity 62 formed in shoulder 22. Delivery aid 130 can also be used to hold the sheet-like implant against a target tissue 138. In some embodiments, the sheet-like implant is folded into a compact configuration when inside the lumen of the sheath. When this is the case, delivery aid 130 may be used to unfold the sheet-like implant into an expanded shape.

[00084] In Figure 15B, sheath 102 is shown extending into shoulder 22. A distal opening of sheath 102 has been placed in fluid communication with cavity 62 in the embodiment of Figure 15B. By comparing Figure 15A and Figure 15B, it will be appreciated that sheet like implant 50 has been advanced distally so that a central portion of sheet like implant 50 is contacting a surface of target tissue 138. The central portion of sheet like implant 50 is trapped between implant expander 120 and the surface of target tissue 138 in the embodiment of Figure 15B.

[00085] In Figure 15C, implant expander 120 of delivery aid 130 is shown assuming a deployed configuration. By comparing Figure 15C and Figure 15B, it will be appreciated that sheath 102 has been retracted in a proximal direction P. Implant expander 120 of Figure 15 comprises a central portion 122 and a plurality of leg portions 124 radiating from central portion 122. In the embodiment of Figure 15B, implant expander 120 is assuming a deployed configuration. Implant expander 120 is fixed to the distal end of control rod 132 in the embodiment of Figure 15.

[00086] Sheet like implant 50 is shown overlaying an outer surface of target tissue 138 in Figure 15C. In the embodiment of Figure 15C, sheet like implant 50 is generally conforming to the shape of target tissue 138. Implant expander 120 is holding sheet-like implant 50 against target tissue 138 in the embodiment of Figure 15C.

5 [00087] Some exemplary methods in accordance with this detailed description include the steps of inflating a shoulder to create a cavity therein and placing a distal opening of a sheath in fluid communication with the cavity while the sheath is surrounding a delivery device disposed inside a lumen thereof and the sheath is maintaining the delivery device in a first compact configuration. A central portion of the sheet-like material may be placed in contact with a
10 surface of a target tissue. The sheath may be withdrawn from around the delivery device so that the delivery device is free to assume a deployed configuration inside the cavity. The delivery device may be used to hold the sheet-like material against a surface of the target tissue while the delivery device is assuming the deployed configuration. The sheet-like implant 50 may be fixed to the target tissue while sheet-like implant 50 is held against the surface of the target tissue. The
15 delivery device may be urged to assume a second compact configuration as the delivery device is removed from the cavity.

[00088] In Figure 15D, a fixation tool shaft 72 of a fixation tool 70 is shown extending into shoulder 22. In Figure 15D, a distal end of fixation tool shaft 72 is disposed proximate an edge of sheet like implant 50. One or more staples may be disposed inside fixation tool shaft 72.
20 Fixation tool 70 may apply staples to fix sheet like implant 50 to target tissue 138 while sheet like implant 50 is held in place by implant expander 120.

[00089] Various attachment elements may be used to fix sheet like implant 50 to target tissue 138 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,
25 bone anchors, and staples. In the exemplary embodiment of Figure 15E, sheet like implant 50 is fixed to target tissue 138 by a plurality of staples 74. In some exemplary methods, a plurality of staples may be applied using a fixation tool. The fixation tool may then be withdrawn from the body of the patient. In the exemplary embodiment of Figure 15E, delivery aid 130 may be used to hold sheet like implant 50 against target tissue 138 while staples 74 are applied using fixation
30 tool 70.

[00090] With reference to Figure 15F, it will be appreciated that delivery aid 130 has been withdrawn from shoulder 22 and retracted into lumen 108 defined by sheath 102. Implant expander 120 of delivery aid 130 has been urged to assume a second compact configuration in the embodiment of Figure 15F. Implant expander 120 comprises a central portion 122 and a
35 plurality of leg portions 124 radiating from central portion 122. With reference to Figure 15F, it

will be appreciated that the free end of each leg portion is disposed distally of central portion 122 when implant expander 120 is assuming the second compact configuration.

[00091] Figure 16 is a stylized depiction of a kit 123. In the exemplary embodiment of Figure 16, kit 123 comprises a sheet-like implant 50 and a number of tools that may be used in conjunction with sheet-like implant 50. The tools of kit 123 may be used, for example, for delivering sheet-like implant 50 to a target location within the body of a patient. These tools may also be used, for example, for fixing sheet-like implant 50 to a target tissue.

[00092] In the exemplary embodiment of Figure 16, kit 123 comprises a locating guide 125, a locating guide removal tool 127, a fixation tool 70, and a delivery aid 129. In some useful embodiments, locating guide 125 includes a temporary fixation mechanism proximate its distal end. A method in accordance with the present detailed description may include temporarily fixing the distal end of locating guide 125 to a target tissue and advancing sheet-like implant 50 over locating guide 125 for delivering the sheet-like implant to the target location. In some applications, delivery aid 129 may be used for advancing sheet-like implant 50 over locating guide 125 and urging sheet-like implant 50 against a target tissue. Fixation tool 70 of kit 123 may be used, for example, for fixing sheet-like implant 50 to the target tissue. Locating guide removal tool 127 may be used to remove locating guide 125 after sheet-like implant 50 has been fixed to the target tissue. In the embodiment of Figure 16, fixation tool 70 includes a fixation tool shaft 72.

[00093] Figure 17A is an enlarged plan view illustrating delivery aid 129 shown in the previous Figure. Figure 17B is a partial cross-sectional perspective view further illustrating delivery aid 129. Figure 17A and Figure 17B may be collectively referred to as Figure 17. A distal direction is illustrated with an arrow D in Figure 17.

[00094] In the exemplary embodiment of Figure 17, delivery aid 129 includes an implant expander 133 fixed to a distal end of a control rod 135. Implant expander 133 of Figure 17 has a central portion 137 and an outer portion 139 extending radially from central portion 137. In the embodiment of Figure 17, no external forces are acting on implant expander 133 and implant expander 133 is free to assume an unstressed configuration. With reference to Figure 17B, it will be appreciated that a distal surface 143 of implant expander 133 comprises a generally concave surface 145 when the implant expander is assuming an unstressed configuration. With continuing reference to Figure 17, it will be appreciated that an outermost edge 147 of outer portion 139 is disposed distally of central portion 137 when implant expander 133 is assuming the unstressed configuration.

[00095] Figure 18A through Figure 18I are a series of stylized plan views illustrating an exemplary method in accordance with the present detailed description. Figure 18A through

Figure 18I may be referred to collectively as Figure 18. A proximal direction is illustrated with an arrow P in Figure 18. A distal direction is illustrated with another arrow D in Figure 18. The exemplary method of Figure 18 may be used, for example, to fix a sheet-like implant 50 to a surface of a target tissue 138.

5 [00096] In Figure 18A, a cannula 149 is shown extending into a shoulder 22. Cannula 149 defines a lumen 153. A distal end of cannula 149 is located proximate a target tissue 138. The distal end of cannula 149 defines a distal opening that fluidly communicates with lumen 153.

[00097] In Figure 18B, a locating guide 125 is shown extending through lumen 153 defined by cannula 149. Some methods in accordance with the present disclosure may include the step of advancing the distal end of a locating guide through a cannula. In the embodiment of Figure 18B, a distal portion of locating guide 125 is disposed in target tissue 138. In some useful embodiments, the distal portion of locating guide 125 includes a barb. When this is the case, the barb may help maintain the position of the distal end of locating guide 125 in the target tissue.

10 [00098] In Figure 18C, a sheet-like implant 50 is shown disposed about locating guide 125. Some methods in accordance with the present disclosure may include the step of inserting a locating guide through a sheet-like implant. Some of these methods may also include the step of advancing the sheet-like implant over the locating guide toward a target tissue.

[00099] In Figure 18D, a delivery aid 129 is shown disposed about locating guide 125. Some methods in accordance with the present disclosure may include the step of inserting the proximal end of a locating guide 125 into a distal aperture of a delivery aid 129. When this is the case, the delivery aid 129 may be advanced over locating guide 125 for urging a sheet-like implant 50 toward a target tissue (e.g., target tissue 138). In this way, delivery aid 129 may be used to urge sheet-like implant 50 in a longitudinal direction along locating guide 125. In some applications, delivery aid 129 may also be used to hold sheet-like implant 50 against a target tissue.

25 [000100] In the embodiment of Figure 18E, sheet-like implant 50 is disposed in a lumen 153 defined by cannula 149. By comparing Figure 18E and Figure 18D, it will be appreciated that sheet-like implant 50 has been pushed distally into lumen 153. In the embodiment of Figure 18E, sheet-like implant 50 has been folded into a compact configuration. Sheet-like implant 50 is shown overlaying the implant expander of delivery aid 129 in Figure 18E. In the exemplary embodiment of Figure 18E, the implant expander is urged to assume a first compact configuration as the implant expander and sheet-like implant 50 are advanced into lumen 153.

30 [000101] In the exemplary embodiment of Figure 18F, sheet-like implant 50 is shown overlaying target tissue 138. Some methods in accordance with the present detailed description include the step of passing a sheet-like implant through a cannula. In the exemplary embodiment of Figure 18F, for example, sheet-like implant 50 may be pushed through cannula 149 using

delivery aid 129. Delivery aid 129 may also be used to hold sheet-like implant 50 against target tissue 138 while a surgeon attaches sheet-like implant 50 to target tissue 138.

[000102] In Figure 18G, a fixation tool shaft 72 of a fixation tool 70 is shown extending through cannula 149. In Figure 18G, a distal end of fixation tool shaft 72 is disposed proximate sheet-like implant 50. One or more staples may be disposed inside fixation tool shaft 72. Some methods in accordance with the present detailed description include the step of passing a staple through a cannula. In the exemplary embodiment of Figure 18G, for example, a staple may be passed through cannula 149 while the staple resides in fixation tool shaft 72.

[000103] In the exemplary embodiment of Figure 18H, sheet-like implant 50 is fixed to target tissue 138 by a plurality of staples 74. In some exemplary methods, a plurality of staples may be applied to a sheet-like implant and a target tissue using a fixation tool. The fixation tool may then be withdrawn from the body of the patient. With reference to Figure 18H, it will be appreciated that delivery aid 129 has been withdrawn from shoulder 22 and locating guide 125 remains in the position shown in Figure 18H.

[000104] In the exemplary embodiment of Figure 18I, locating guide 125 has been withdrawn from shoulder 22. Some useful methods in accordance with the present detailed description, include the use of a locating guide including a temporary fixation mechanism located proximate its distal end. These exemplary methods may also include the use of a locating guide removal tool to aid in withdrawing the locating guide from the body of the patient. In Figure 18I, a plurality of staples 74 can be seen fixing sheet-like implant 50 to target tissue 138.

[000105] Figure 19 is a plan view showing a locating guide 125. With reference to Figure 19, it will be appreciated that locating guide 125 has a point 155 at its distal end. In the embodiment of Figure 19, locating guide 125 includes a barb 157 near its distal end. In Figure 19, point 155 is shown pointing in a distal direction D and barb 157 is shown pointing in a proximal direction P.

[000106] Figure 20 is a plan view showing a locating guide removal tool 127. Locating guide removal tool 127 may be used, for example, to remove a locating guide 125 from a target tissue. In the embodiment of Figure 20, locating guide removal tool 127 includes a tubular body 159 that is fixed to a grip 163. In operation, tubular body 159 is advanced over the proximal end of a locating guide so that a portion of the locating guide extends into a lumen defined by tubular body 159. Locating guide removal tool 127 may then be used to grasp a proximal portion of the locating guide and produce relative motion between the locating guide and tubular body 159.

[000107] In the embodiment of Figure 20, a lever 165 is pivotably coupled to grip 163. Relative motion between locating guide 125 and tubular body 159 can be produced by rotating lever 165 relative to grip 163 when locating guide removal tool 127 is grasping the proximal

portion of locating guide 125. This relative motion can be used to advance tubular body 159 over the barb 157 of locating guide 125. Locating guide 125 may be withdrawn from the body of the patient while tubular body 159 is covering barb 157.

5 **[000108]** 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. An implant delivery system for delivering a sheet-like implant, the implant delivery system comprising:

5 a delivery shaft having a proximal end and a distal end;

an implant expander, mounted to the distal end of the delivery shaft, including a central portion and a plurality of leg portions radiating from the central portion, the implant expander being evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface and a first compact configuration in which the distal surface of the implant expander defines a convex surface, the implant expander having a first lateral extent when the implant expander is free to assume the unstressed configuration;

10 a sheath defining a lumen having a lumen diameter, at least a portion of the delivery shaft slidably disposed in the lumen, the lumen diameter being smaller than the first lateral extent of the implant expander so that the sheath holds the implant expander in the first compact configuration when slidably disposed therein; and

15 a sheet-like implant overlaying at least a portion of the distal surface of the implant expander with portions of the sheet-like implant extending between the leg portions of the implant expander and the sheath.

20 2. The delivery system of claim 1, wherein:

a free end of each leg portion is disposed distally of the central portion when the implant expander is assuming the unstressed configuration; and

the free end of each leg portion is disposed proximally of the central portion when the implant expander is assuming the first compact configuration.

25 3. The delivery system of claim 2, wherein the delivery shaft distal end is fixed to the central portion of the implant expander to urge relative movement between the implant expander and the sheath such that the implant expander and the sheet-like implant can be advanced through a distal opening defined by the sheath so the implant expander is free to assume a deployed configuration.

30 4. The delivery system of claim 3, further comprising a projection extending distally from the distal surface of the central portion of the implant expander to hold the position of delivery system when the projection is held against a target tissue.

5. The delivery system of claim 3, wherein the implant expander generally conforms to the surface of a target tissue when the implant expander assumes the deployed configuration.

6. The delivery system of claim 4, wherein the distal surface of the implant expander defines a concave surface when the implant expander is assuming the deployed configuration and the target tissue has a generally convex shape.

7. The delivery system of claim 4, wherein a free end of each leg portion is disposed distally of the central portion when the implant expander is assuming the deployed configuration and the target tissue has a generally convex shape.

8. The delivery system of claim 3, wherein the implant expander causes the sheet-like implant to conform to the surface of a target tissue when the implant expander assumes the deployed configuration.

9. The delivery system of claim 3, wherein the implant expander assumes a second compact configuration when the implant expander is retracted proximally into the lumen of the sheath after having assumed the deployed configuration.

10. The delivery system of claim 9, wherein the distal surface of the implant expander defines a concave surface when the implant expander is assuming the second compact configuration.

11. The delivery system of claim 9, wherein the free end of each leg portion is disposed distally of the central portion when the implant expander is assuming the second compact configuration.

12. The delivery system of claim 1, wherein the implant expander is integrally formed of a single material.

13. The delivery system of claim 1, wherein the sheet-like implant defines a plurality of pockets, each pocket being dimensioned to receive a distal portion of a leg portion of the implant expander.

14. The delivery system of claim 13, wherein the sheet-like implant can be selectively separated from the implant expander by withdrawing the distal portions of the legs from the pockets.

5 15. The delivery system of claim 1, wherein the implant expander further comprises a plurality of retainers to engage the sheet-like implant such that the sheet-like implant moves when the implant expander is moved.

10 16. The delivery system of claim 15, wherein the sheet-like implant can be selectively separated from the implant expander by withdrawing the retainers from the sheet-like implant.

17. A method of treating a rotator cuff of a shoulder, comprising:
providing an implant delivery system comprising an implant expander including a central portion and a plurality of leg portions radiating from the central portion, the implant expander
15 being evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface and a first compact configuration in which the distal surface of the implant expander defines a convex surface, a sheet-like implant overlaying at least a portion of the distal surface of the implant expander, and a sheath disposed about the sheet-like implant and the implant expander, the sheath holding the implant expander in the first compact
20 configuration;

inflating the shoulder to create a cavity therein;

placing the sheet-like implant and the implant expander inside the cavity and contacting a tendon with at least a portion of the implant while the implant expander is assuming the first compact configuration;

25 allowing the implant expander to assume a deployed configuration in which the implant expander urges the sheet-like implant against a surface of the tendon;

attaching the sheet-like implant to the tendon;

urging the implant expander to assume a second compact configuration in which the distal surface of the implant expander defines a concave surface; and

30 removing the implant expander from the cavity.

18. The method of claim 17, further comprising a projection extending distally from the central portion of the implant expander, wherein the projection holds the position of the delivery system relative to the tendon when the sheet-like implant and implant expander are
35 placed in the cavity against the tendon..

19. The method of claim 17, wherein the step of allowing the implant expander to assume the deployed configuration comprises urging relative movement between the implant expander and the sheath such that the implant expander and the sheet-like implant are advanced through a distal opening defined by the sheath so the implant expander is free to assume the deployed configuration.

20. The method of claim 19, wherein urging relative movement between the implant expander and the sheath comprises withdrawing the sheath in a proximal direction relative to the implant expander.

21. The method of claim 19, wherein urging relative movement between the implant expander and the sheath comprises advancing the implant expander in a distal direction along the lumen of the sheath.

22. The method of claim 19, wherein urging the implant expander to assume the second compact configuration comprises advancing the sheath over the implant expander so that the implant expander is disposed inside the lumen defined by the sheath.

23. The method of claim 19, wherein urging the implant expander to assume the second compact configuration comprises drawing the implant expander proximally into the lumen defined by the sheath.

24. The method of claim 18, wherein urging the implant expander to assume the second compact configuration comprises drawing the implant expander and the projection extending distally from the central portion of the implant expander proximally into the lumen defined by the sheath.

25. A method of preparing a delivery system, comprising:
providing a sheath defining a lumen having a lumen diameter;
providing an implant expander including a central portion and a plurality of leg portions radiating from the central portion, the implant expander being evertable between an unstressed configuration in which a distal surface of the implant expander defines a concave surface and a first compact configuration in which the distal surface of the implant expander defines a convex surface, the implant expander having a first lateral extent when the implant expander is free to

assume the unstressed configuration, the first lateral extent being greater than the lumen diameter of the sheath;

covering at least a portion of the distal surface with a sheet-like implant;

- 5 deflecting the implant expander such that the implant expander assumes the first compact configuration and placing the implant expander and the sheet-like implant in the lumen defined by the sheath so the sheath holds the implant expander in the first compact configuration with portions of the sheet-like implant being interposed between the leg portions of the implant expander and an inner surface of the sheath.

1/24

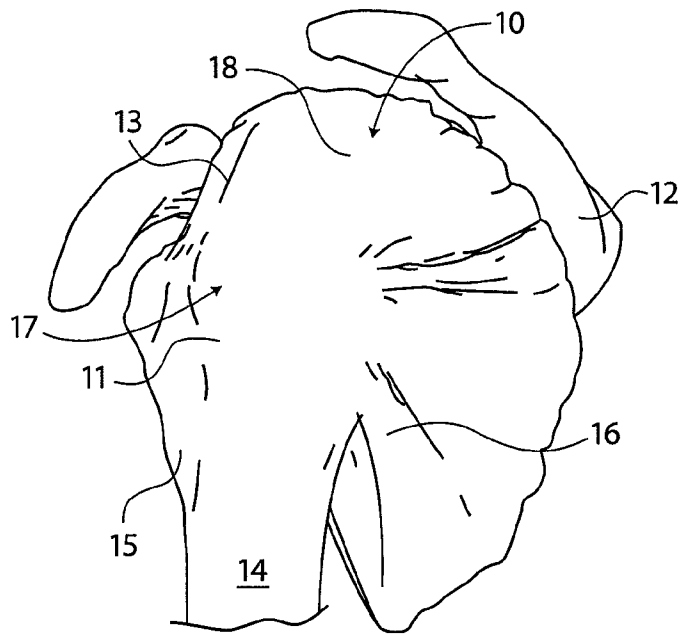


FIG. 1

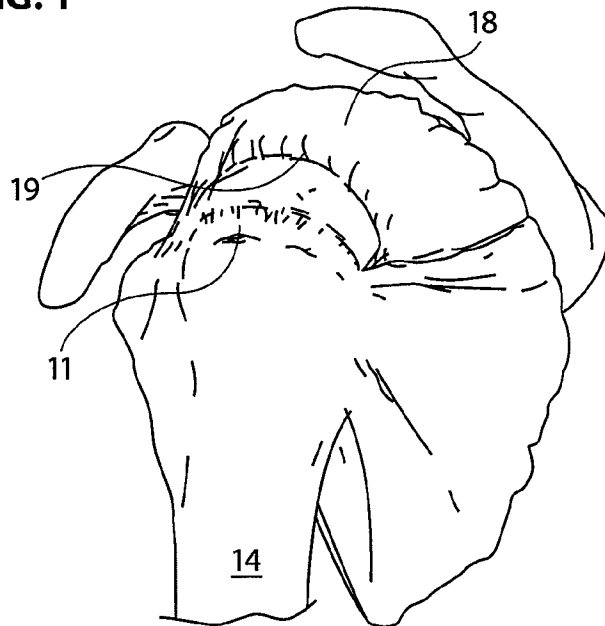


FIG. 2

2/24

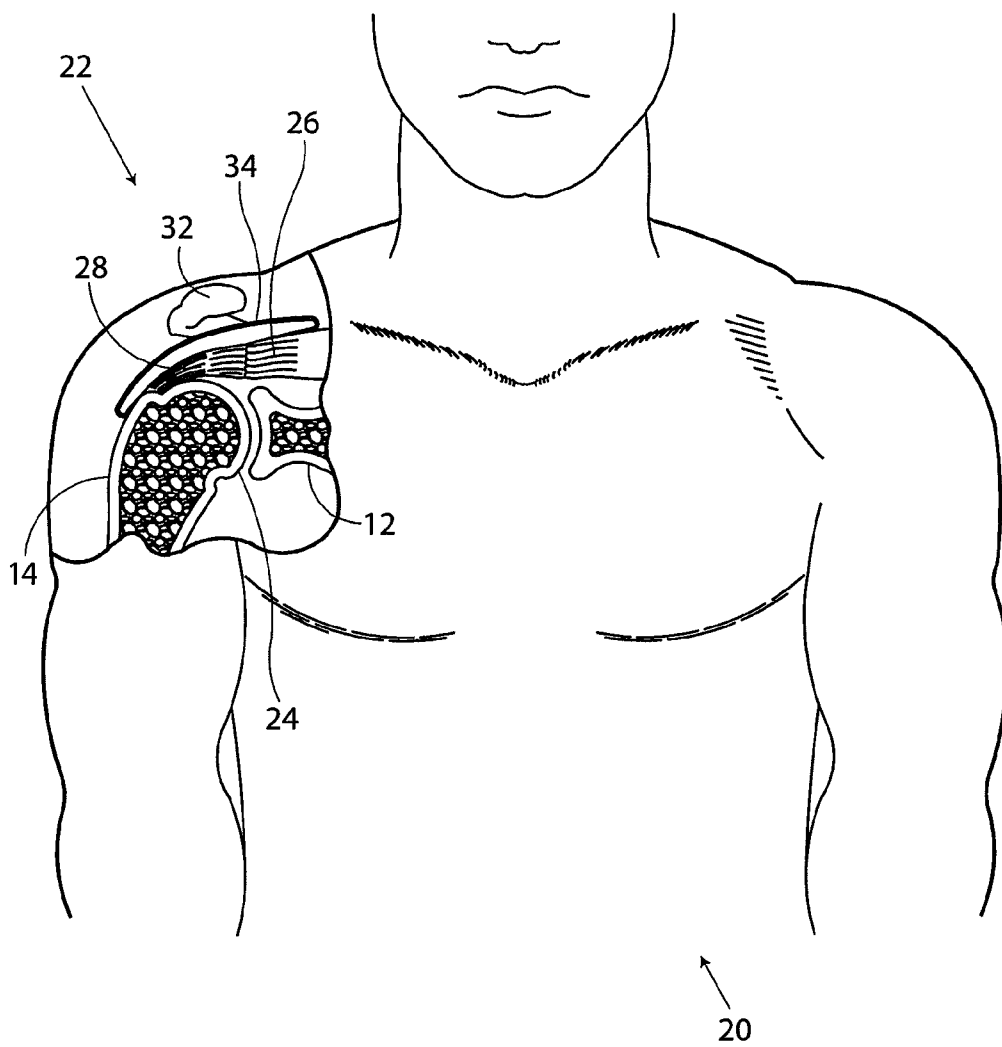


FIG. 3

3/24

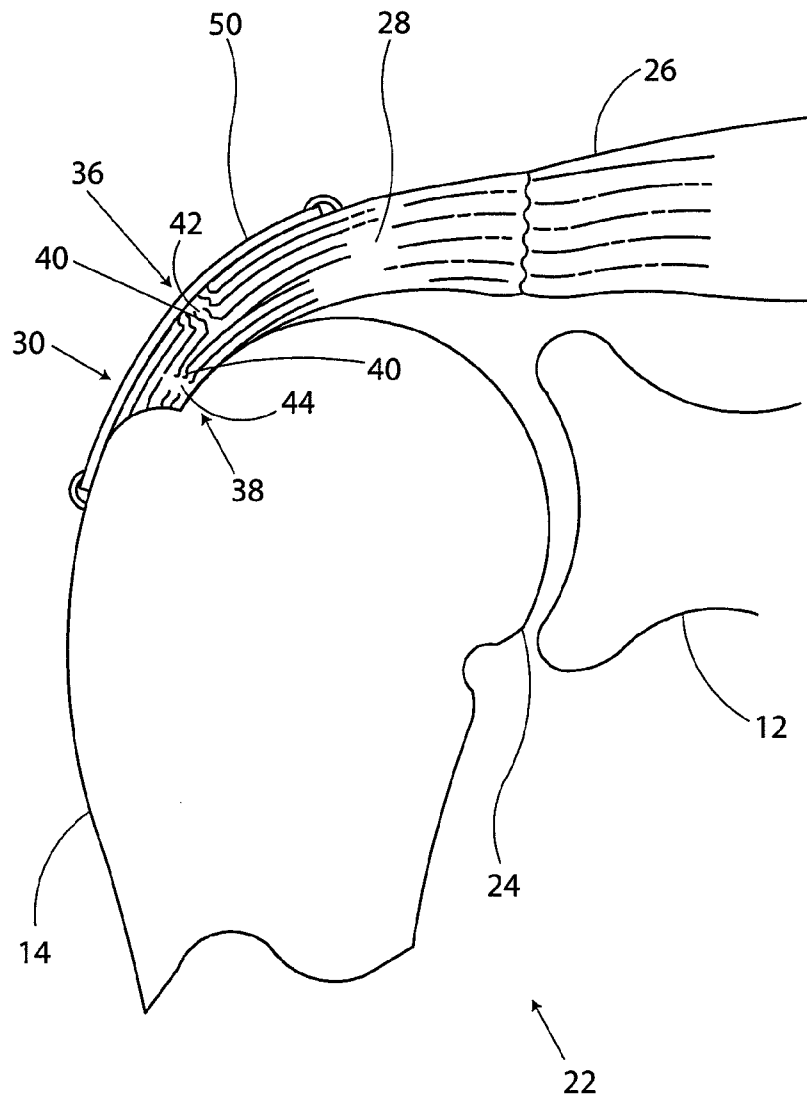


FIG. 4

4/24

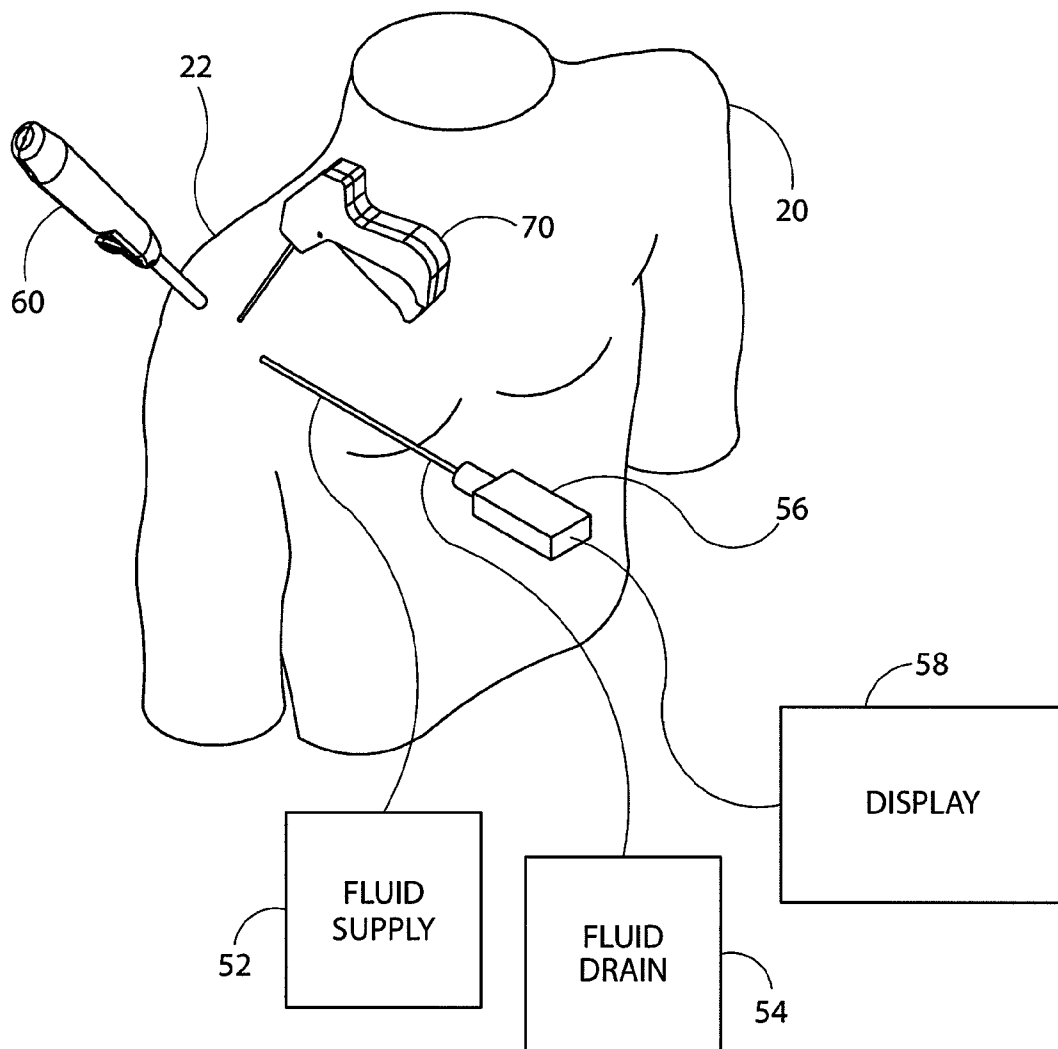


FIG. 5

5/24

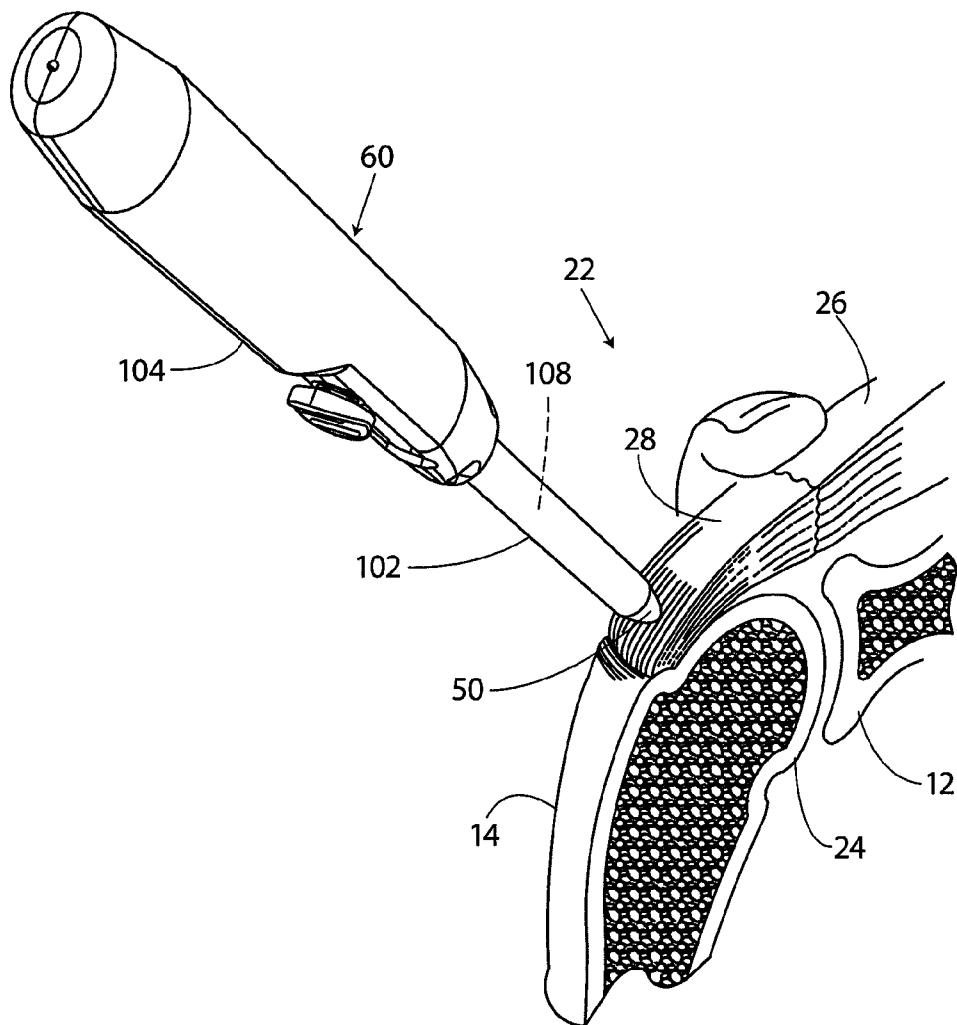


FIG. 6

6/24

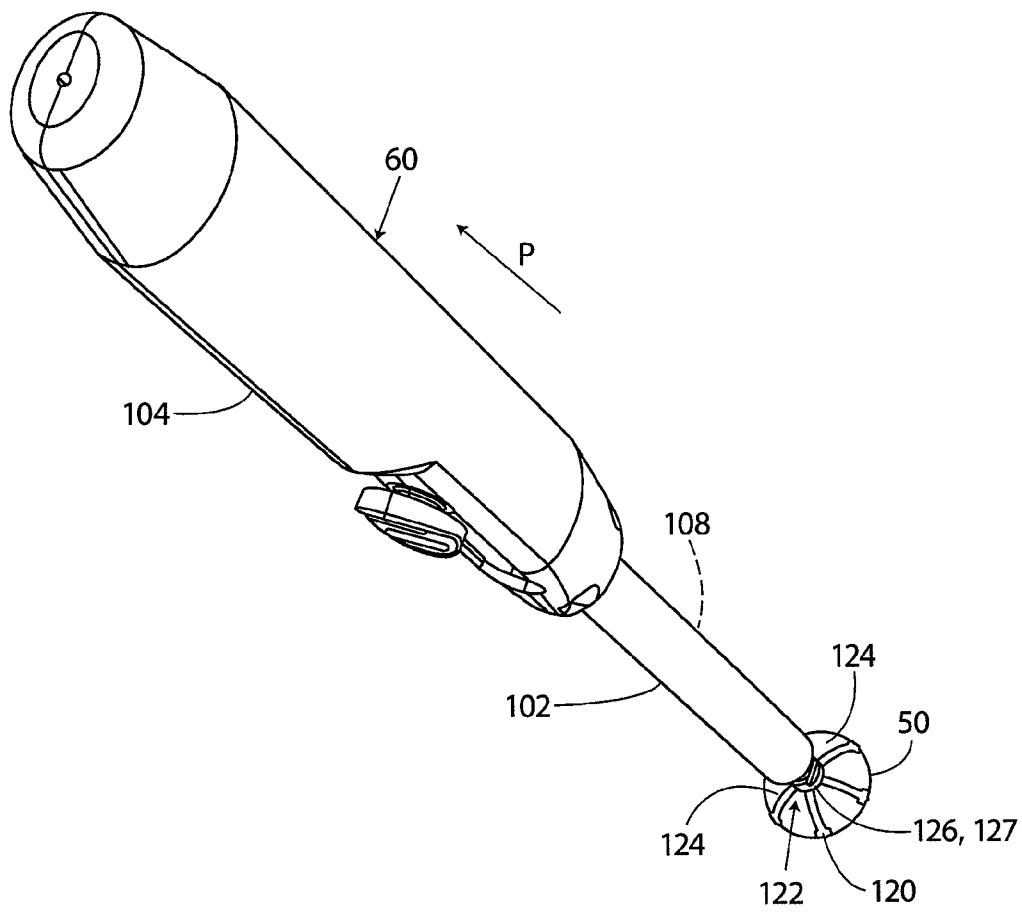


FIG. 7

7/24

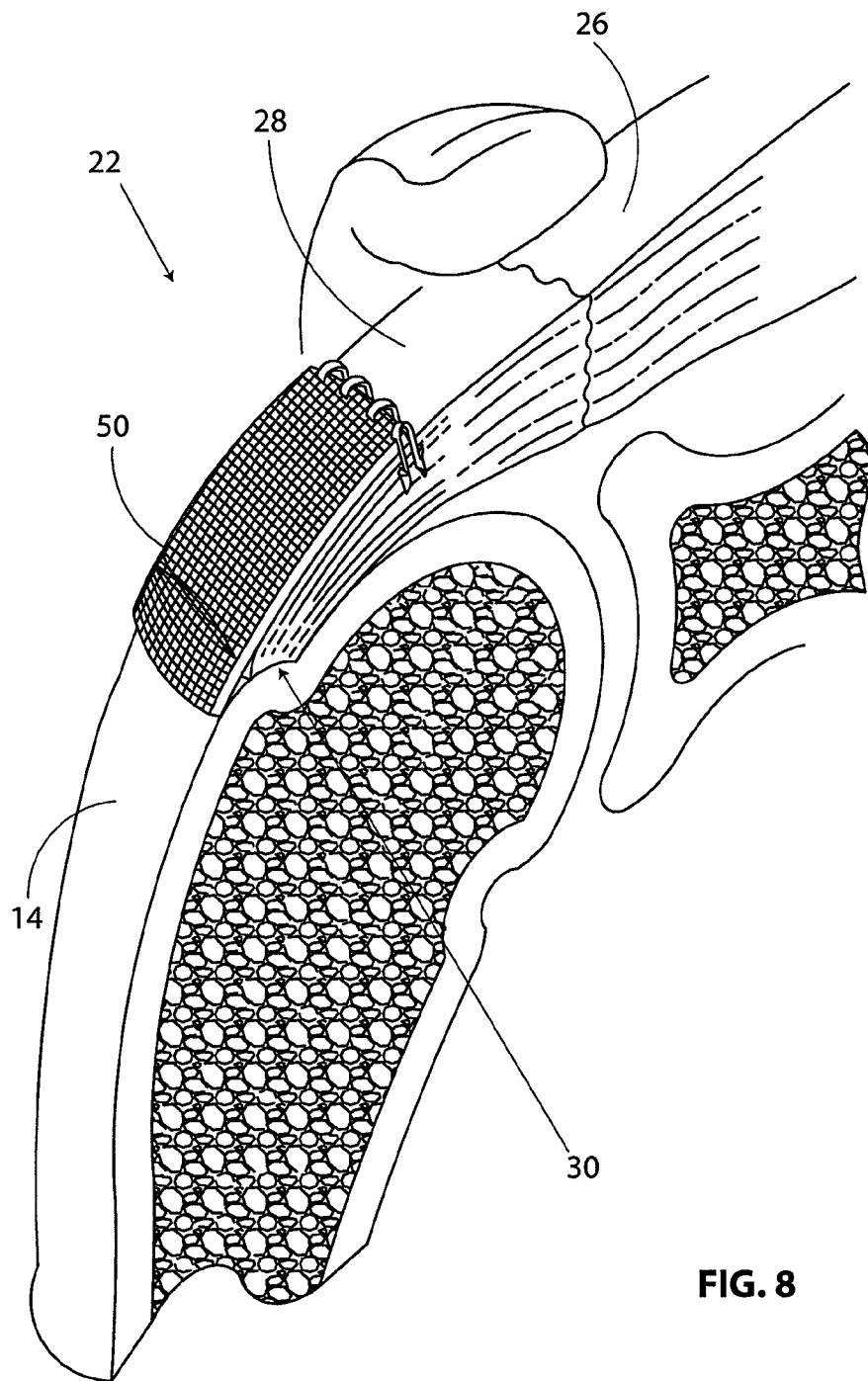


FIG. 8

8/24

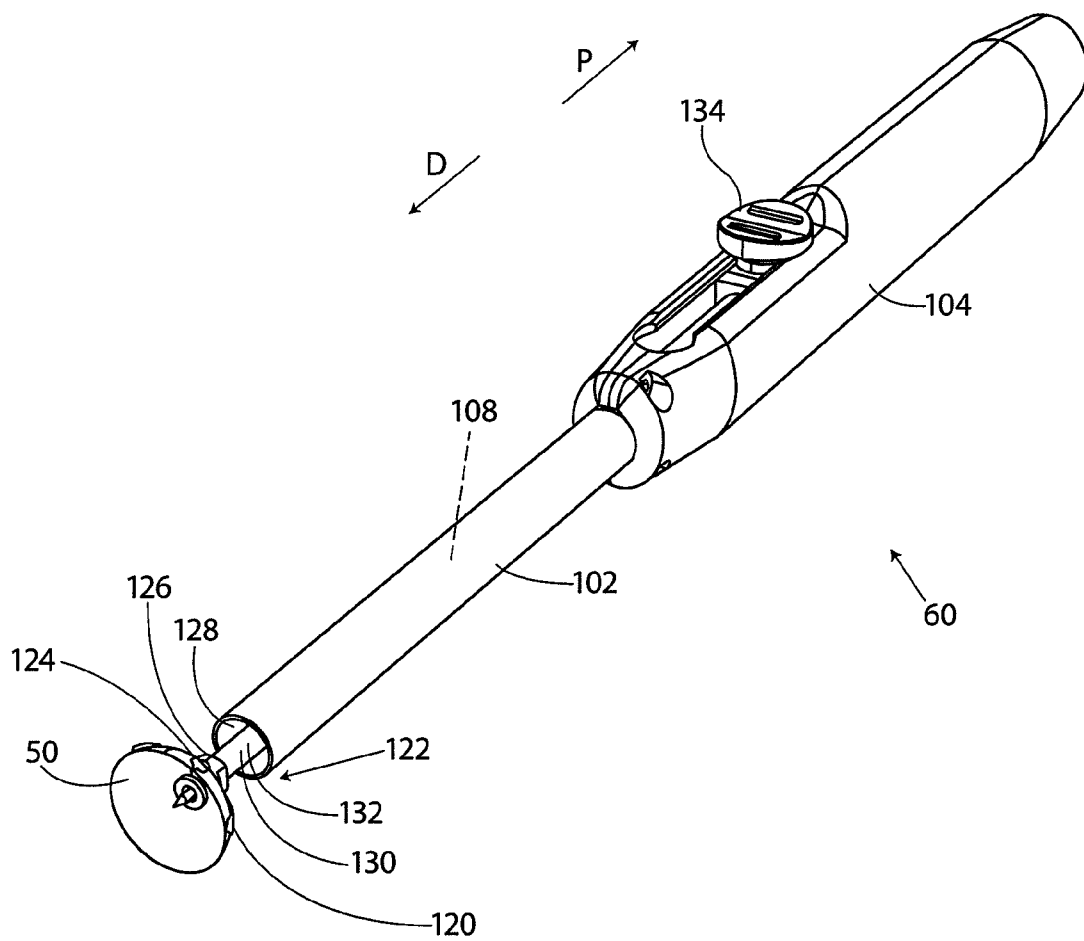


FIG. 9

9/24

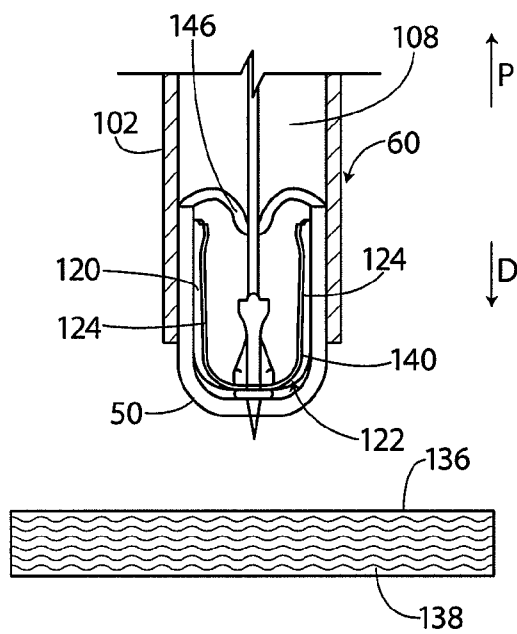


FIG. 10A

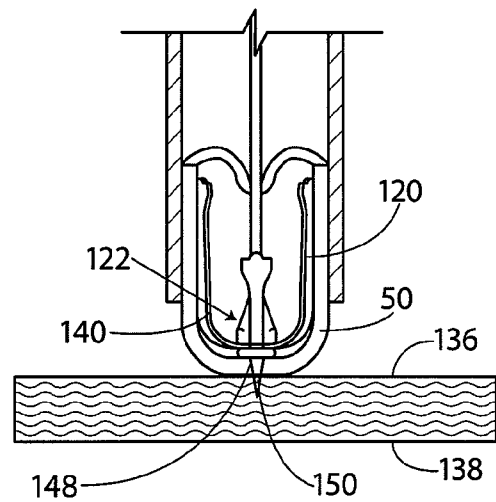


FIG. 10B

10/24

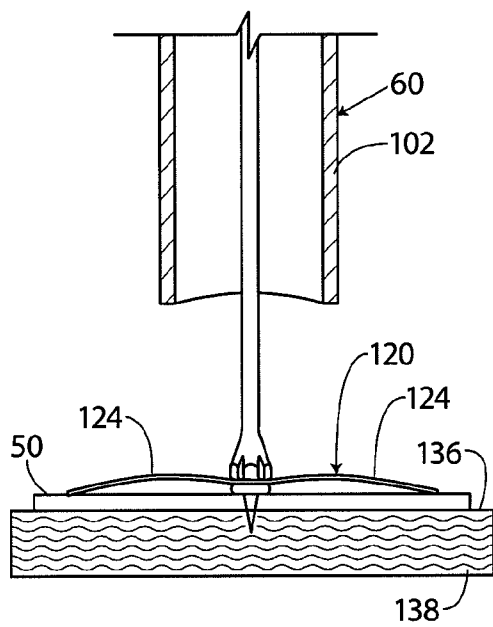


FIG. 10C

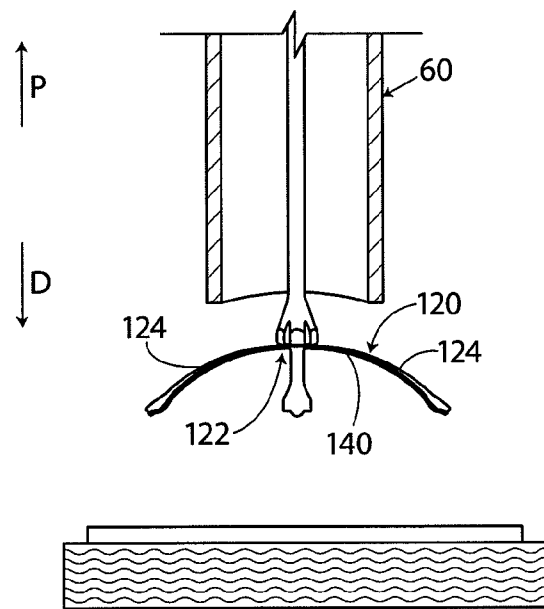


FIG. 10D

11/24

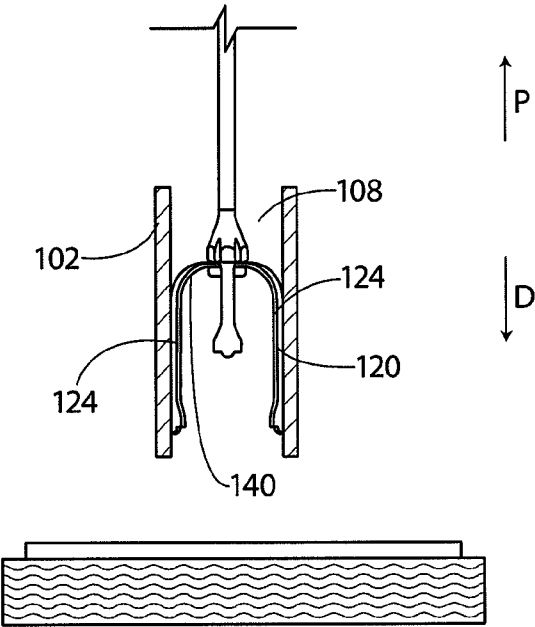


FIG. 10E

12/24

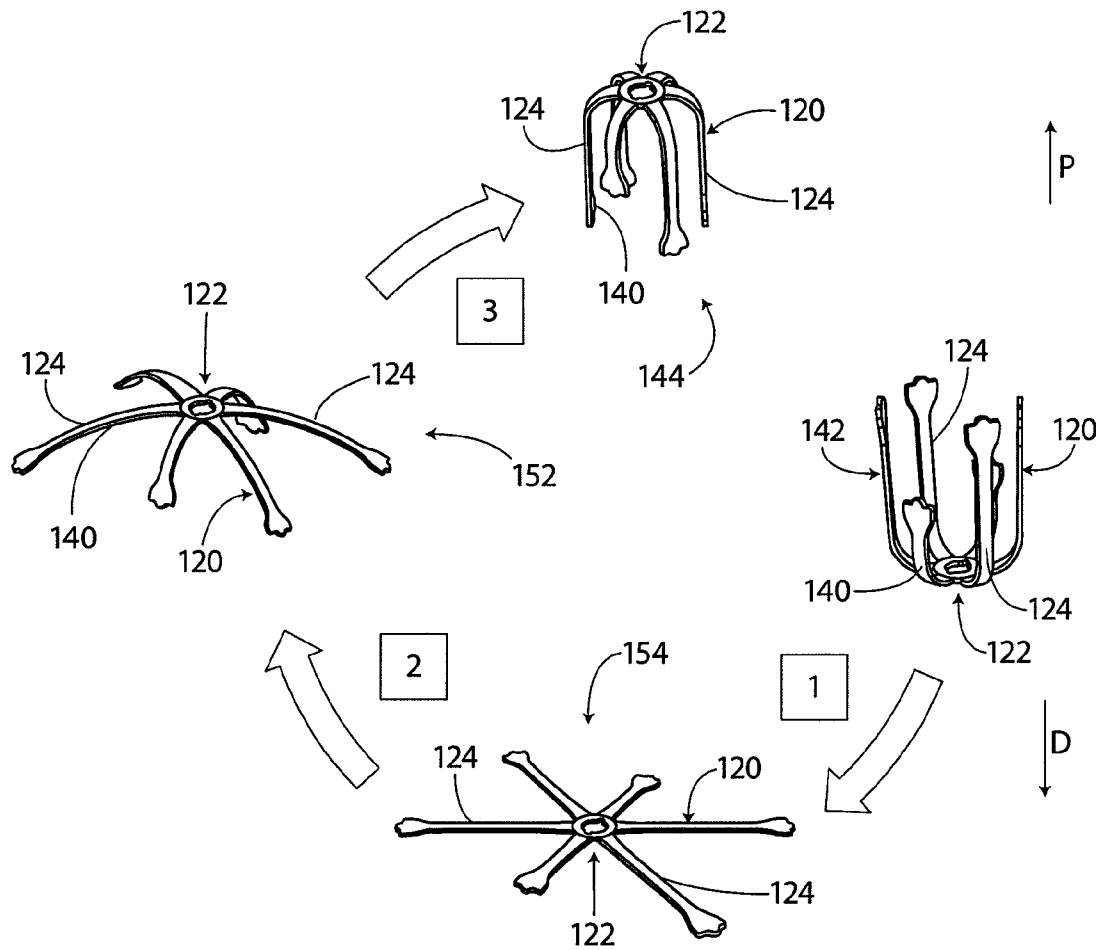


FIG. 11

13/24

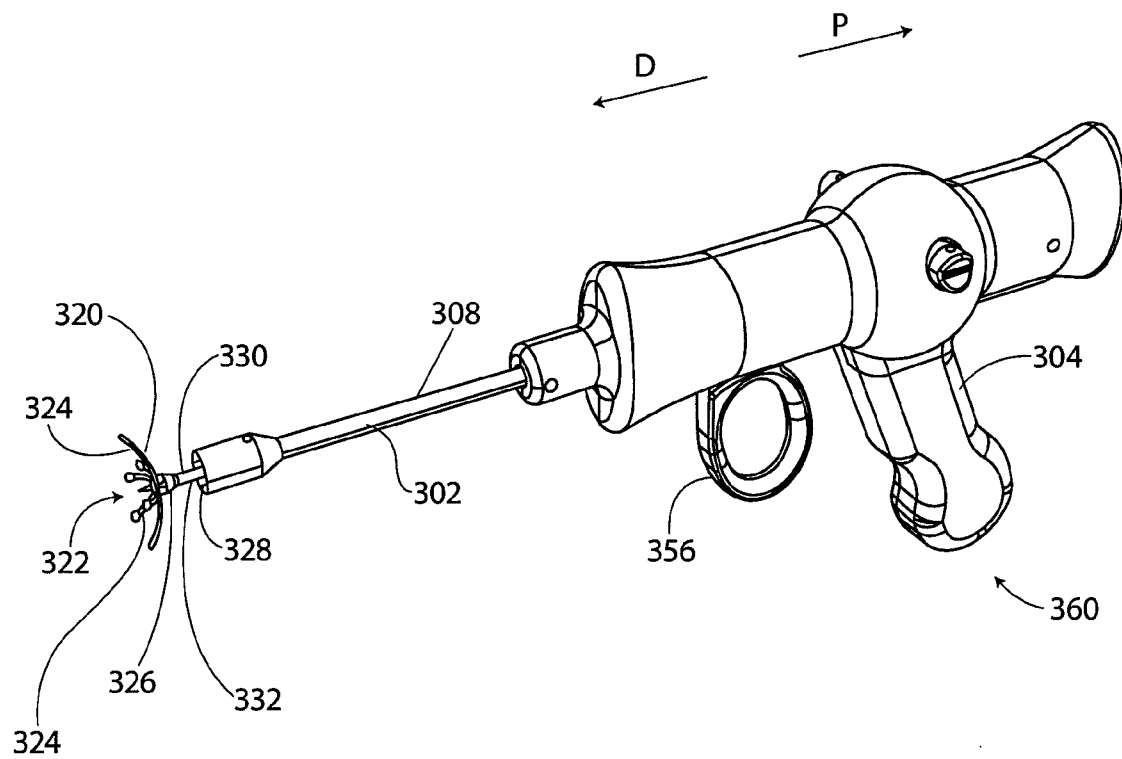


FIG. 12

14/24

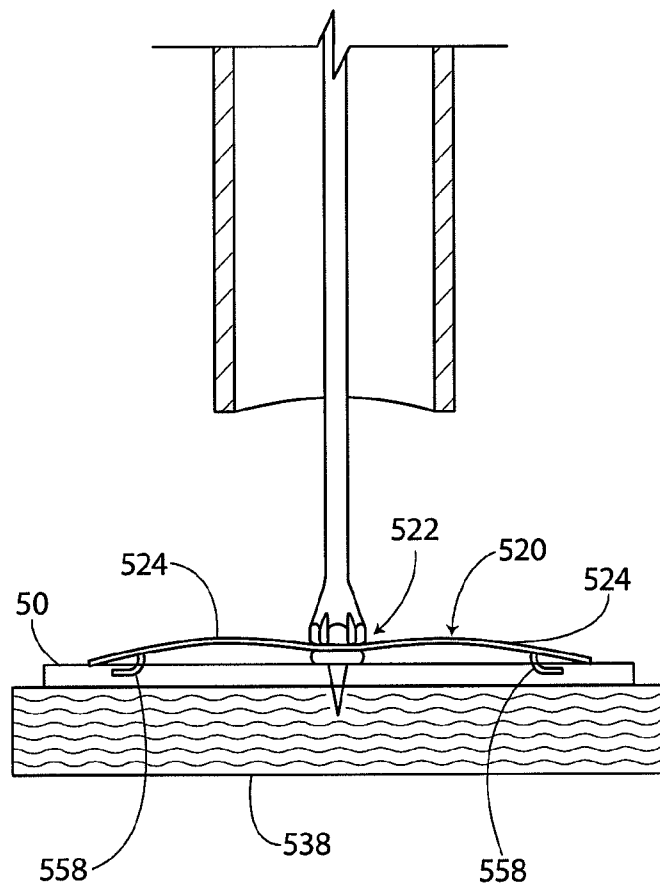


FIG. 13

15/24

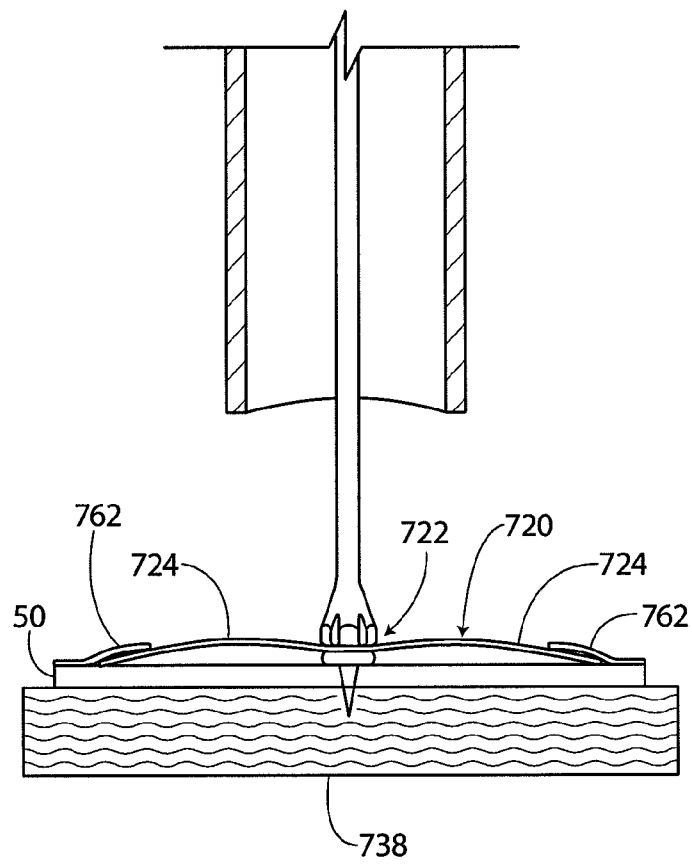
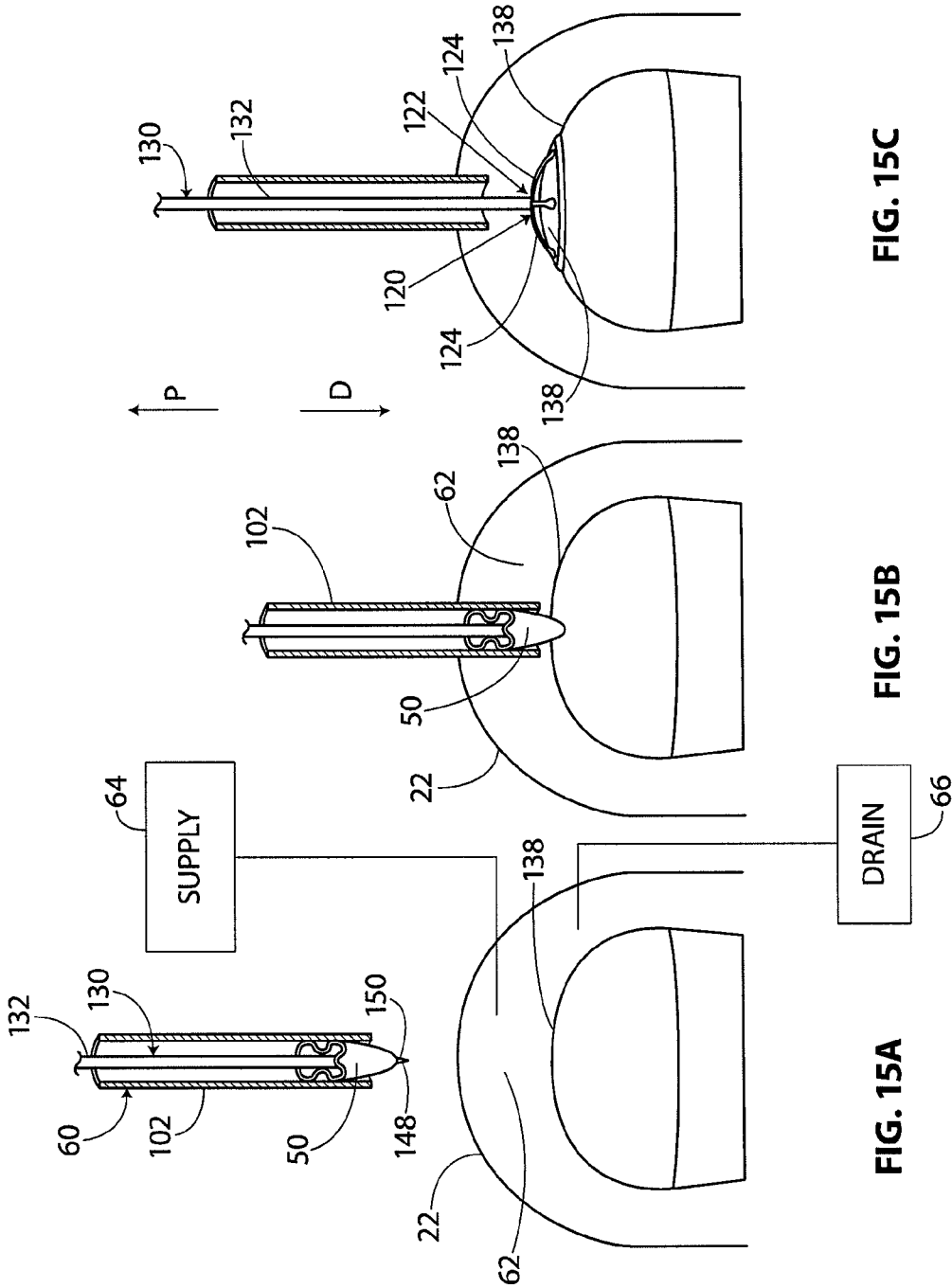


FIG. 14



17/24

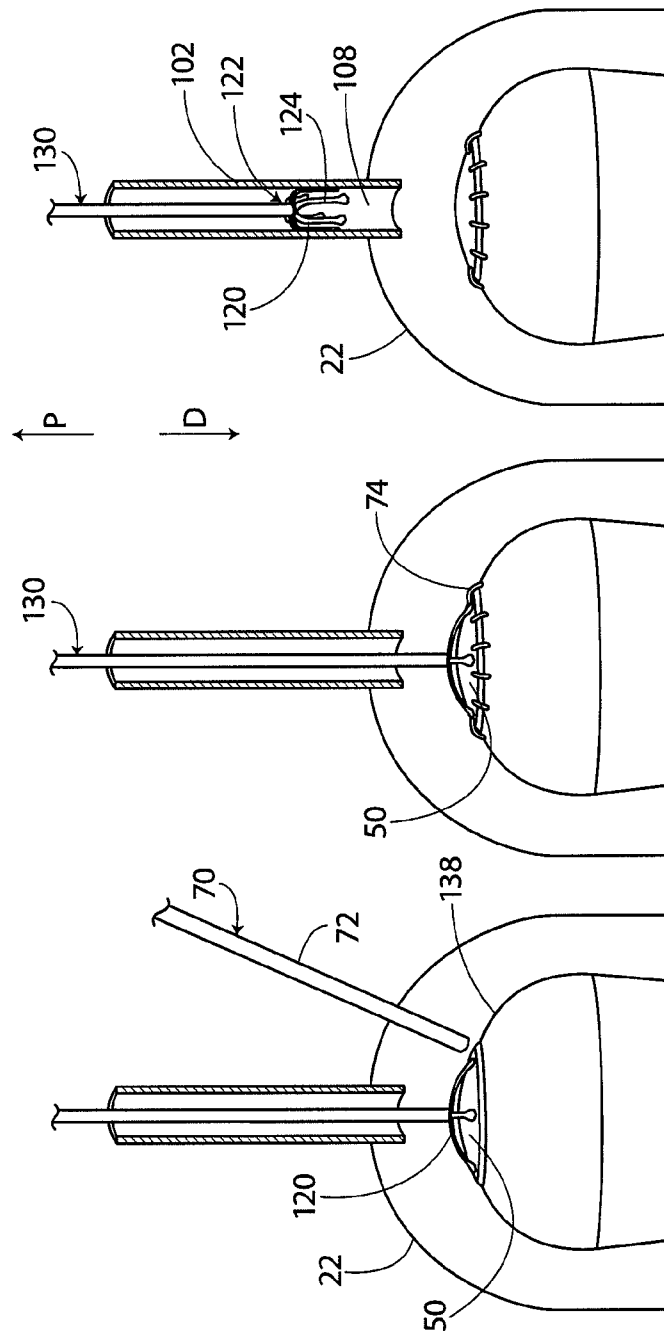
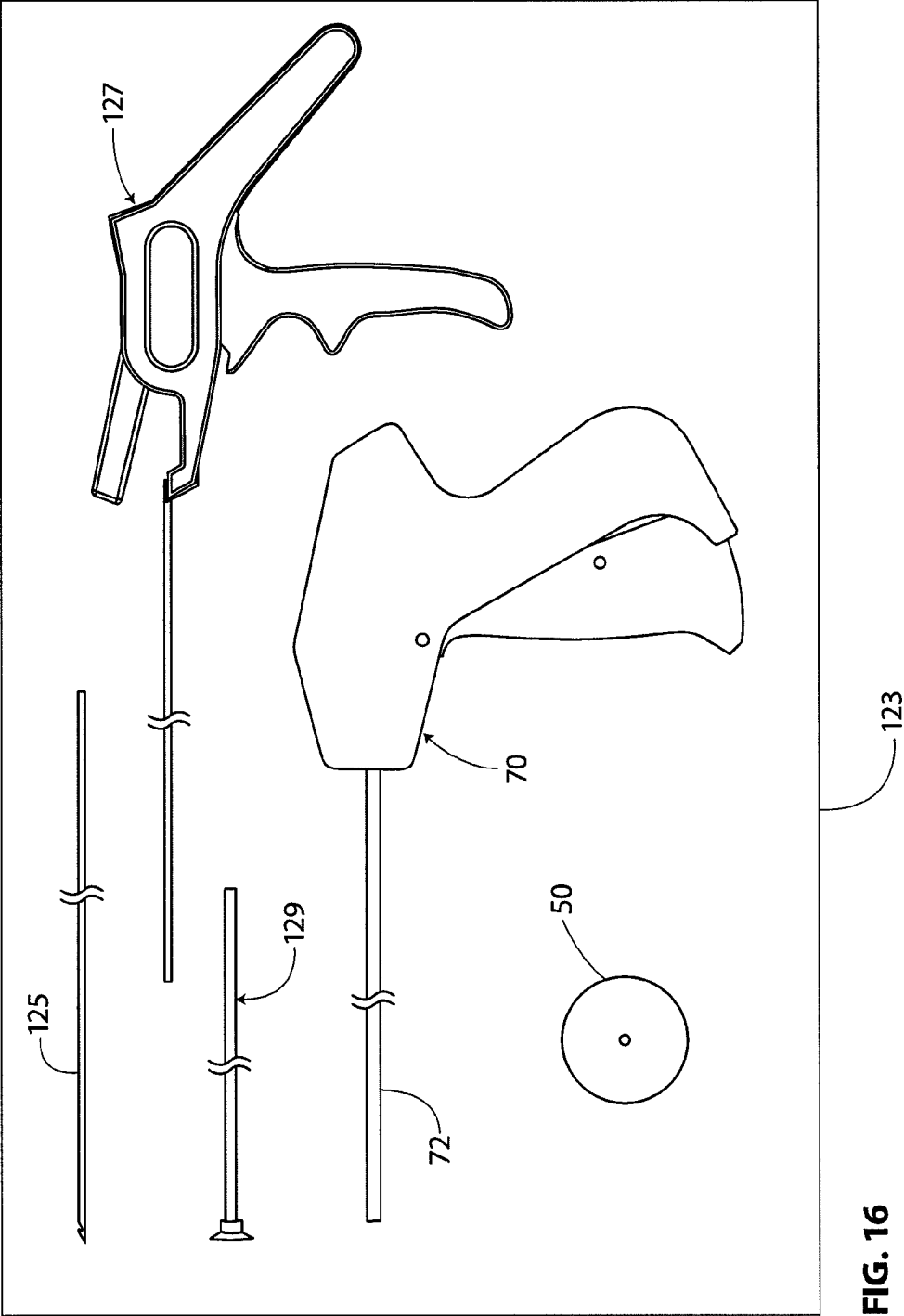


FIG. 15F

FIG. 15E

FIG. 15D



19/24

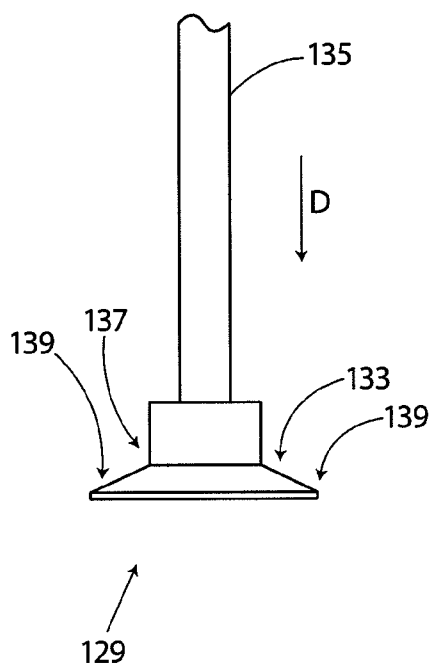


FIG. 17A

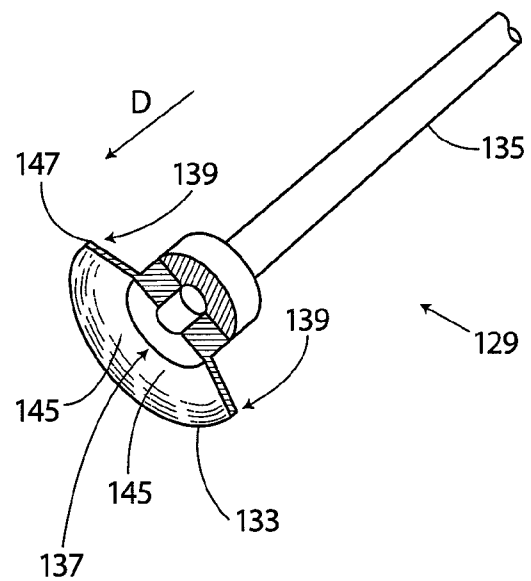


FIG. 17B

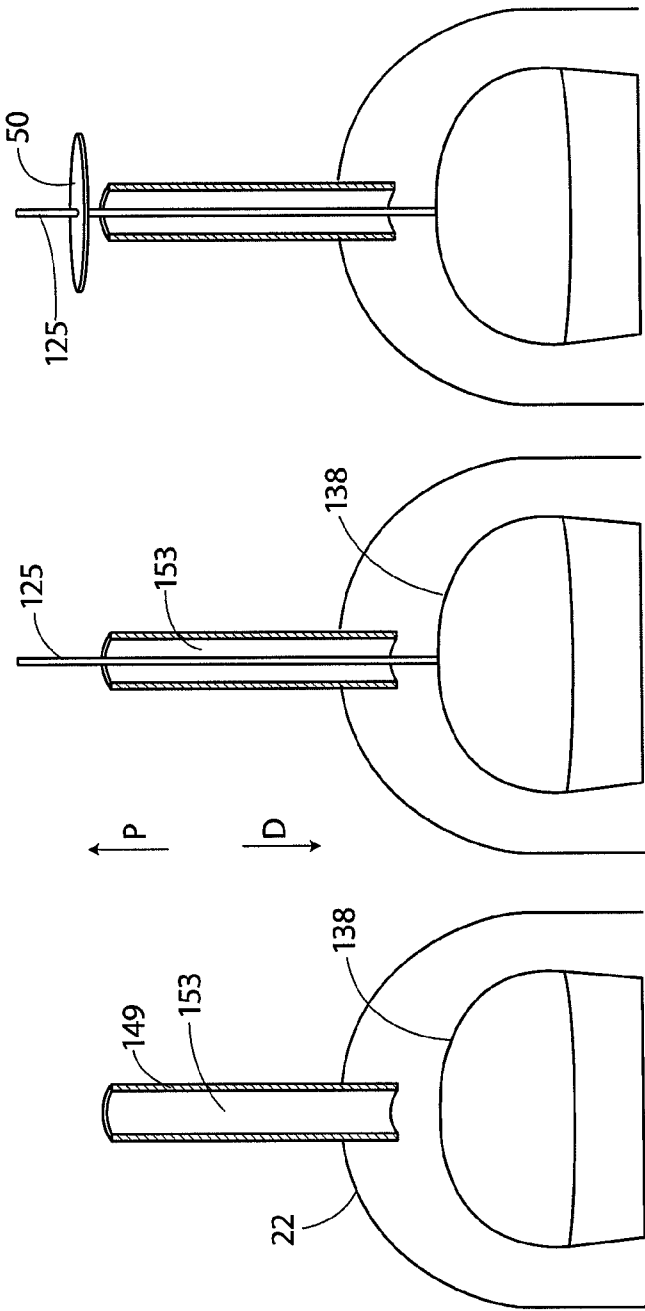


FIG. 18A

FIG. 18B

FIG. 18C

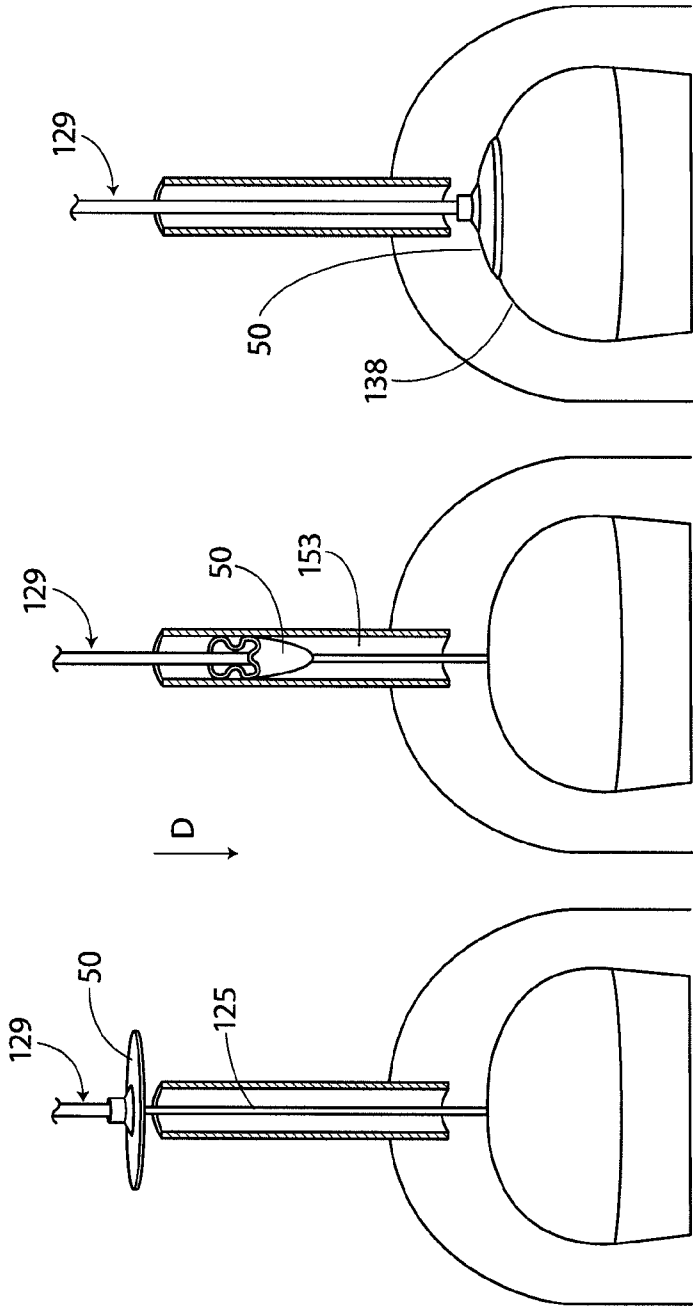


FIG. 18F

FIG. 18E

FIG. 18D

22/24

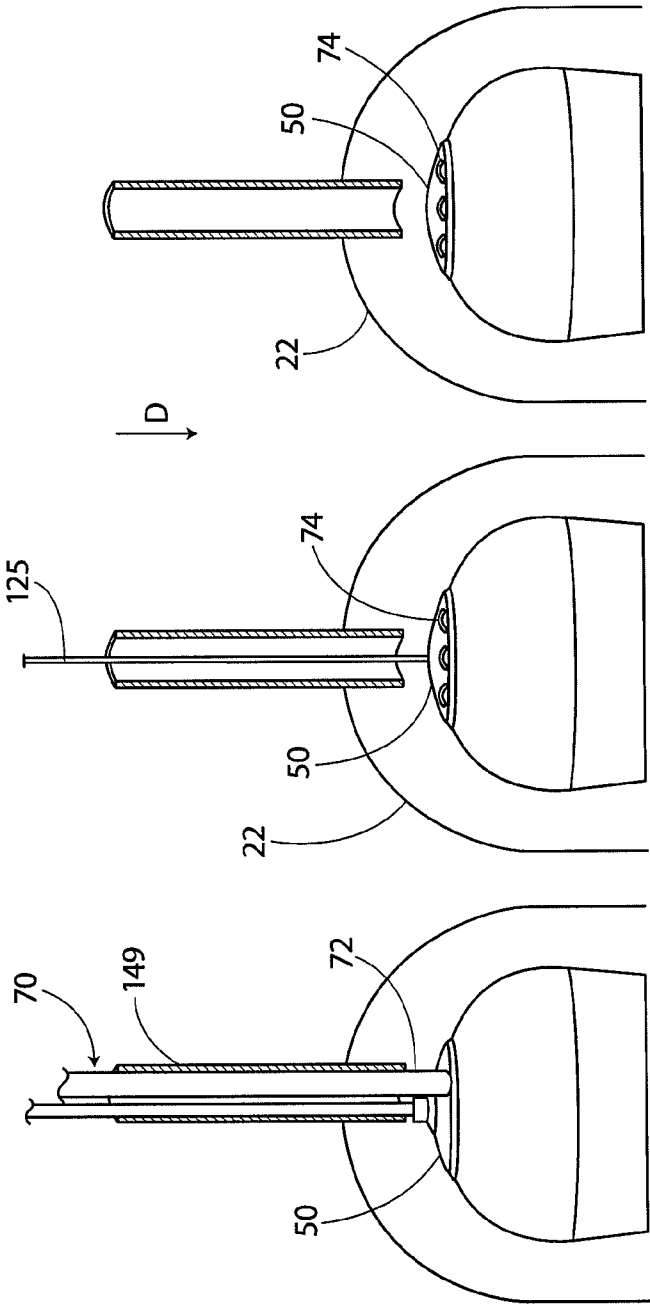


FIG. 18I

FIG. 18H

FIG. 18G

23/24

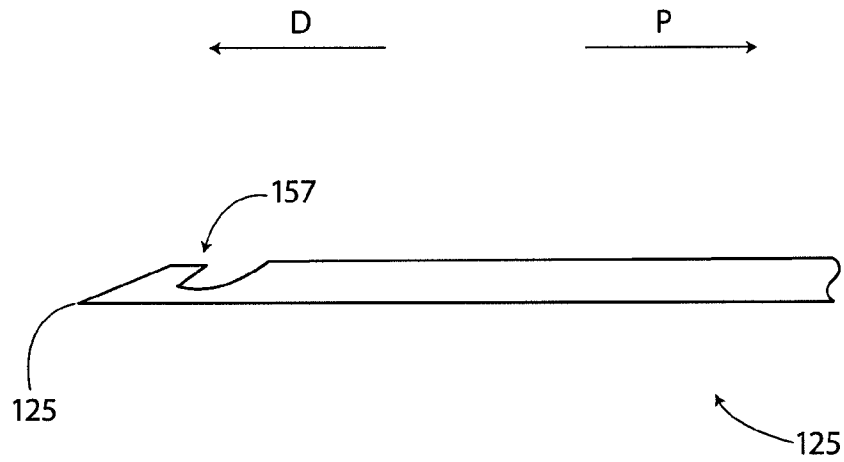


FIG. 19

24/24

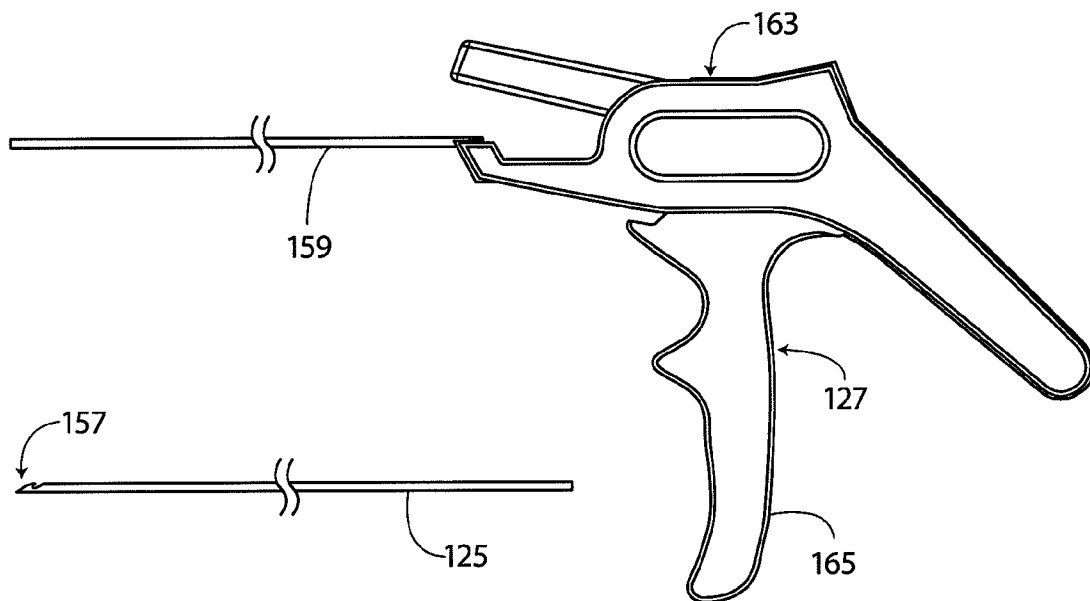


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/037522

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/08 A61F2/00

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)

A61F

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.
X	WO 2004/093690 A1 (LEAHY PATRICK [IE]) 4 November 2004 (2004-11-04)	1,25
Y	page 8 - page 18; figures -----	2-16
X	EP 0 557 963 A1 (UNITED STATES SURGICAL CORP [US]) 1 September 1993 (1993-09-01)	1,25
Y	column 4 - column 9; figures -----	2-16
Y	US 2003/073979 A1 (NAIMARK WENDY [US] ET AL) 17 April 2003 (2003-04-17)	1-16,25
	the whole document -----	
Y	WO 2005/016389 A2 (JACKSON KELLY [US]) 24 February 2005 (2005-02-24)	1-16,25
	the whole document -----	
Y	GB 2 397 240 A (BARKER STEPHEN GEORGE EDWARD [GB]) 21 July 2004 (2004-07-21)	1-16,25
	the whole document -----	



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.

8 document member of the same patent family

Date of the actual completion of the international search

19 July 2010

Date of mailing of the international search report

27/07/2010

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

Serra i Verdaguer, J

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 17-24

The subject-matter of claims 19 to 57, discloses a method of protecting a tendon. The method comprises the step of inserting a device into a bursa of the patient. The International Searching Authority is not required to search methods for treatment of the human body by surgery or therapy (Rule 39.1(iv) PCT).

Continuation of Box II.2

The subject-matter of claims 17 to 24, discloses a method for treating a rotator cuff. The method comprises the step of inflating the shoulder. The International Searching Authority is not required to establish search methods for treatment of the human body by surgery or therapy (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037522

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.: 17-24
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box 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/US2010/037522

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004093690	A1	04-11-2004	EP 1617766 A1	25-01-2006
			US 2007066980 A1	22-03-2007
EP 0557963	A1	01-09-1993	CA 2089999 A1	25-08-1993
			US 5405360 A	11-04-1995
US 2003073979	A1	17-04-2003	AU 2002342074 A1	28-04-2003
			CA 2463574 A1	24-04-2003
			EP 1441784 A2	04-08-2004
			JP 2005506122 T	03-03-2005
			WO 03032815 A2	24-04-2003
			US 2005177106 A1	11-08-2005
			US 2009131882 A1	21-05-2009
WO 2005016389	A2	24-02-2005	US 2007185506 A1	09-08-2007
GB 2397240	A	21-07-2004	AU 2004204397 A1	29-07-2004
			BR PI0406741 A	20-12-2005
			CA 2513237 A1	29-07-2004
			EP 1583483 A2	12-10-2005
			WO 2004062529 A2	29-07-2004
			JP 2006518225 T	10-08-2006
			KR 20050092752 A	22-09-2005
			US 2006189918 A1	24-08-2006