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(71) Applicant: **ROTATION MEDICAL, INC.** [US/US]; 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US).

(72) Inventors: **EUTENEUER, Charles, L.;** 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **ZENZ-OLSON, Nathaniel, Z.;** 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **QUACKENBUSH, John;** 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **SIMS, Jeff;** 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US). **VAN KAMPEN, Craig;** 15350 25th Avenue N., Suite 100, Plymouth, MN 55447 (US).

(74) Agents: **BUCKINGHAM, David, K.** et al; Shay Glenn LLP, 2755 Campus Drive, Suite 210, San Mateo, CA 94403 (US).

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(54) Title: GUIDEWIRE HAVING A DISTAL FIXATION MEMBER FOR DELIVERING AND POSITIONING SHEET-LIKE MATERIALS IN SURGERY

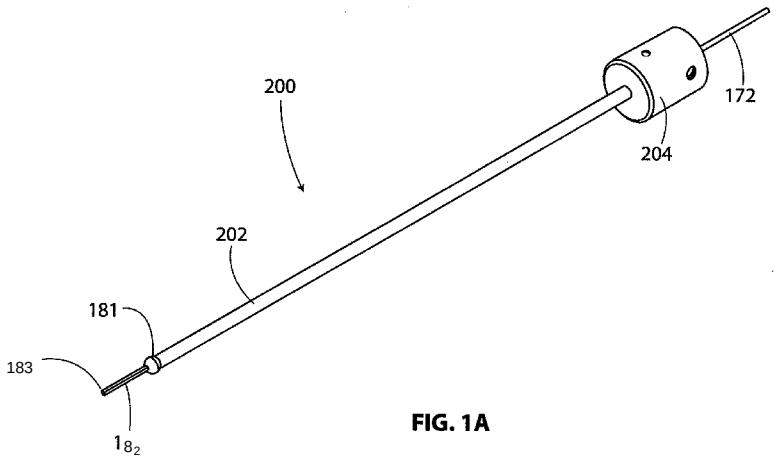

FIG. 1A

(57) Abstract: A guidewire for use with an implant delivery system in delivering a sheet-like implant is disclosed. The guidewire can include a distal tissue fixation member for releasable connection to a first location proximate a treatment site. An implant delivery system can include a distal guidewire port for receiving the proximal end of the guidewire. The implant delivery system is tracked over the guidewire to a selected position defined by the guidewire attachment. The tissue fixation member includes means for temporarily or reversibly fixing the distal end of the guidewire to tissue, such as bone. The means for affixing can include a K-wire, a screw, a pin or other fixation member.

GUIDEWIRE HAVING A DISTAL FIXATION MEMBER FOR DELIVERING AND POSITIONING SHEET-LIKE MATERIALS IN SURGERY

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/581,629 filed on December 29, 201 1, the disclosure of which is incorporated by reference herein. The present disclosure is related to the following commonly assigned co-pending applications, the disclosures of which are incorporated herein by reference: U.S. Application No. 61/443,169 Filed on February 15, 201 1; U.S. Provisional Application No. 61/581,628, Attorney Docket No. 10322-715.100, entitled, "METHODS AND APPARATUS FOR DELIVERING AND POSITIONING SHEET-LIKE MATERIALS IN SURGERY," filed on December 29, 201 1 and U.S. Provisional Application No. 61/581,631, Attorney Docket No. 10322-717.100 entitled, "ANATOMICAL LOCATION MARKERS AND METHODS OF USE IN POSITIONING SHEET-LIKE MATERIALS DURING SURGERY" filed on December 29, 201 1.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The present invention relates generally to orthopedic medicine and surgery. More particularly, the present invention relates a guidewire having a distal fixation member for use in positioning and delivering a sheet-like material to a desired treatment site for treating tendons or like tissue, such as tendons in the rotator cuff of the shoulder.

BACKGROUND

[0004] The glenohumeral joint of the shoulder is found where the head of the humerus mates with a shallow depression in the scapula. This shallow depression is known as the 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. The rotator cuff muscles are a complex of muscles. The muscles of the rotator cuff include the supraspinatus, the infraspinatus, the subscapularis, and the teres minor. The centering and stabilizing roles played by the rotator cuff muscles are critical to the proper function of the

shoulder. The rotator cuff muscles provide a wide variety of moments to rotate the humerus and to oppose unwanted components of the deltoid and pectoral muscle forces.

[0005] The muscles of the rotator cuff arise from the scapula. The distal tendons of the rotator cuff muscles splay out and interdigitate to form a common continuous insertion on the humerus. The supraspinatus muscle 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. The mechanics of the rotator cuff muscles are complex. The rotator cuff muscles rotate the humerus with respect to the scapula, compress the humeral head into the glenoid fossa providing a critical stabilizing mechanism to the shoulder (known as concavity compression), and provide muscular balance. The supraspinatus and deltoid muscles are equally responsible for producing torque about the shoulder joint in the functional planes of motion.

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

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

thickness tear which is further classified based on how much of the thickness is torn, whether it is greater or less than about 50% of the thickness.

[0008] The accepted treatment for a full thickness tear or a partial thickness tear greater than 50% includes reconnecting the torn tendon via sutures. For the partial thickness tears greater than 50%, the tear is completed to a full thickness tear by cutting the tendon prior to reconnection. In some procedures, the surgeon will position a sheet-like patch over the sutured area to strengthen the repair and try to prevent the sutures from tearing through the tendon. The placement of the patch can be accomplished readily in an open surgical procedure, however, placement and attachment of the patch in an arthroscopic procedure has been shown to be very difficult.

[0009] In contrast to the treatment of a full thickness tear or a partial thickness tear of greater than 50%, the current standard 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, and 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 removed or ablated. Again, the tendon partial thickness 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 causes further 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 the 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.

[00010] As described above, adequate devices and methods for positioning sheet-like patches or implants during an arthroscopic procedure do not currently exist. It has been shown to be very difficult to properly position and attach a sheet-like implant unless the treatment site is accessed in an open procedure. Further, adequate procedures do not 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. Therefore, it would be beneficial to be able to position, deliver and attach a sheet-like implant to a treatment site in an arthroscopic procedure. It would also be beneficial to treat partial thickness tears greater than 50% without cutting the untorn portion of the tendon to complete the tear before suturing back together. There is a large need for surgical techniques and systems to position, deploy and attach implants during an arthroscopic procedure and to treat partial thickness tears and prevent future tendon damage by strengthening or repairing the native tendon having the partial thickness tear.

SUMMARY OF THE DISCLOSURE

[00011] The disclosure is directed to a guidewire that is used in conjunction with an implant delivery system for accurately positioning and deploying or delivering a sheet-like implant. The guidewire can include a distal portion having a tissue fixation member for releasably coupling the guidewire to the humeral head and a proximal portion including a length of wire extending proximally from the tissue fixation member.

[00012] In some embodiments, the tissue fixation member provides a temporary connection of the distal end of the guidewire to the bone or other tissue. The tissue fixation member typically includes means for temporarily or reversibly fixing the distal end of the guidewire to tissue, such as bone. The means for affixing can include a K-wire (Kirshner wire) which can be a smooth stainless steel pin with a drill tip that cuts into bone when rotated. Alternatively, the means for fixing can include a screw that is threaded or a fine pin that is hammered into bone or other tissue. The fine pin can include barbs or other projections and/or surface texture that aid in temporarily fixing the distal end of the guidewire to the bone or other tissue. The proximally extending wire can be coupled to the tissue fixation member via a strain relief that allows the wire to bend proximate the tissue fixation member. The strain relief can include a spring or a

coil. The tissue fixation member and proximally extending wire can be a single piece of wire extending the length of the guidewire. Alternatively, the tissue fixation member and proximal portion can be separate pieces joined together. The proximally extending wire can include a single stainless steel or nitinol wire or alternatively a multi-strand braid of wire can be used depending on desired flexibility characteristics. In some embodiments a proximal guidewire portion can be made from a polymer or multi-strand braid of polymer fibers.

[00013] A weld ball can be included in some embodiments. With a single piece of wire making up the tissue fixation member and the proximal wire portion, the wire can pass through a lumen through the weld ball and be affixed thereto by compression, welding or any other means. In alternative embodiments, the tissue fixation member can be affixed to one side of the weld ball while the proximal wire portion can be affixed to a different portion of the weld ball, such as the opposite side relative to the tissue fixation member. In other embodiments, a strain relief can be affixed to the weld ball generally opposite the tissue fixation member and the proximal wire portion can then be affixed to the strain relief. In this embodiment, the strain relief can be a spring having a distal end affixed to the weld ball and the proximal wire portion extend partially into the proximal end of the spring and affixed therein. The proximal end of the spring or coil can also act as a stop for an implant delivery system delivered over the guidewire, as explained below.

[00014] One embodiment provides an implant delivery system including an implant retainer assembly and an implant spreader assembly. The implant retainer assembly and the implant spreader assembly are provided proximate the distal end of a delivery shaft. The implant retainer assembly is configured to releasably couple a sheet-like implant thereto for positioning the sheet-like implant at a treatment site. The implant spreader assembly is configured to expand the sheet-like implant so that the sheet-like implant covers the treatment site.

[00015] The implant delivery system can include a distal guidewire port located proximate the distal end of the delivery system a fixed and known distance both laterally and longitudinally relative to an implant when it is loaded onto the implant retainer assembly. With this embodiment, the implant delivery system can be included in a kit that includes a guidewire or be used in conjunction with a guidewire that is provided separately from the implant delivery system. The positional relationship (lateral and longitudinal) of a loaded implant relative to the distal guidewire port is advantageously used to position the implant delivery system relative to a first fixed point on the anatomy of the patient and assures the deployed implant will properly cover the treatment site. The first fixed point on the anatomy can be used as the location of the distal end of the guidewire as fixed to the bone or other tissue. The proximal end of the

guidewire is fed through the distal guidewire port and the delivery system is guided by the wire to abut the anatomy or the tissue fixation member proximate the fixed point.

[00016] In one method of using the present system, a first fixed point is determined through observation and/or measurement of a treatment site or tissue to be covered by the implant relative to other anatomy. For example, in treating a rotator cuff injury, the surgeon can measure the supraspinatus tendon lateral width and observe the location of the line generally defining the point of insertion of the tendon into the humeral head. With these measurements known, along with the known size of implant to be used and the longitudinal/lateral location of the loaded implant relative to the guidewire port, a best location for the first fixed point can be selected and the guidewire fixed thereto.

[00017] Determining a first fixed point for the implant location however may not adequately position the implant as it can be rotated, at least to some degree, about that first fixed point. Therefore, in some embodiments, at least a second anatomical point or position is identified and/or marked to assure the implant is rotated to proper position on the first fixed point. In some embodiments a third anatomical point or position may also be identified and/or marked, in which embodiment the second and third point can define a line which is generally parallel to an edge of the implant when properly rotated about the first point. In treating the supraspinatus tendon, a marker can be placed through the skin and tendon while viewing the articular side of the supraspinatus tendon where the biceps tendon is also visible. The marker can be inserted adjacent the biceps tendon to delineate its location and assure the implant is rotated to generally parallel the biceps tendon and avoid any staples attaching to such tendon which may interfere with its function.

[00018] In some exemplary embodiments, the implant spreader assembly includes a first arm and a second arm each having a proximal and a distal end. The proximal end of each arm is pivotably connected proximate the distal end of the delivery shaft. The first and second arms are moveable between a closed position and an open position. When the first and second arms are in the closed position, the arms extend generally in the longitudinal direction. When pivoting to the open position the distal end of each arm travels in a generally transverse direction to spread an implant that has been positioned on the implant retainer assembly. When pivoting from the open position to the closed position, the first arm and the second arm may travel in different planes.

[00019] In some exemplary embodiments, a sheath is disposed about the implant spreader assembly. The sheath is slidable in a direction generally parallel to a longitudinal axis of the delivery shaft such that the sheath can be retracted proximally from around the implant spreader assembly. The sheath can include a bullet nose distal end to ease insertion into the shoulder space.

[00020] A sheet-like implant may be releasably coupled to the implant retainer assembly. When this is the case, the sheet-like implant may fit within the sheath when the implant spreader is in the closed position. The sheet-like implant may then be expanded to cover a treatment site when the sheath is retracted and the implant spreader is opened. In some useful embodiments, the sheet-like implant extends tautly between the arms of the implant spreader when the arms are in the open position. The sheet-like implant may assume a rolled configuration when the implant expander is in the closed position.

[00021] In some exemplary embodiments, the first arm and the second arm pivot transversely in different planes such that in the open position the sheet-like implant extending between the arms forms a generally curved surface to conform to a generally curved treatment site when placed thereon. In some instances, the first arm and the second arm pivot transversely in the same plane such that in the open position the sheet-like implant extending between the arms forms a generally flat surface.

[00022] In some embodiments, the implant retainer assembly comprises a center post disposed proximate the distal end of the delivery shaft. A mating surface having a longitudinally extending groove generally parallel and spaced from the center post cooperates with the center post to retain the implant when it is slidably disposed therebetween. The center post and mating surface define a slot that is dimensioned to receive the sheet-like implant.

[00023] Another embodiment provides an implant delivery system including a delivery shaft having a proximal end and a distal end defining a generally longitudinal direction. An implant spreader assembly is provided proximate the distal end of the delivery shaft. A sheet¬ like implant is coupled to the implant spreader such that the implant is folded when the arms of the implant spreader are in a closed position and unfolded when the arms of the implant spreader are in an open position. The implant spreader assembly may be used to unfold the sheet-like implant, for example, to spread the implant over a treatment site within the body. A hood that extends distally from the distal end of the shaft, generally parallel to the implant spreader assembly can be included. The hood is spaced radially from the implant retention assembly and retains the implant in folded configuration when unsheathed until deployment of the implant spreader.

[00024] A method of treating a site such as a rotator cuff of a shoulder may include the step of providing an implant delivery system as described above. The treatment site or shoulder of the patient may be inflated to create a cavity therein. The treatment site can be observed and/or measured using a probe or other instrument to identify the proper implant size and a first anatomical location for affixing the distal end of a guidewire such that abutment of the guidewire port proximate this location will place the implant at a desired location when deployed. A guide

wire is affixed to the anatomical location selected, as for example, a point near the insertion of the supraspinatus tendon on the humeral head. Further, a second and/or third anatomical point can be identified that will give proper rotational position to the implant delivery system. These points can be identified and markers placed to provide a visual reference. The implant delivery system can be tracked over the guidewire to abut the first reference point. The implant and the implant spreader assembly may be unsheathed inside the cavity. The implant may be spread over a target tissue at the treatment site and rotated to align with the second and/or third reference points as marked. The implant may be affixed to the target tissue. The implant may be released from the implant delivery system. The implant spreader assembly may be removed from the cavity. In some cases, the implant spreader assembly is assuming the closed configuration while the implant spreader assembly is withdrawn from the cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] Figure 1A is a perspective view of a guidewire as disposed in a delivery assembly for attachment to bone or other tissue;

[00026] Figure IB is a perspective view of the guidewire and sheath of Figure 1A depicting the sheath partially retracted as it would be removed proximally after attachment of the guidewire to bone or other tissue;

[00027] Figure 1C is partial perspective view of the distal portion of the guidewire of Figure IB illustrating a drill point tip or a K-wire tip for penetrating bone and a strain relief connection to a proximal wire portion;

[00028] Figure 1D is a perspective view of an alternative guidewire disposed in a delivery assembly having a distal screw that can be rotated by the sheath to attach to bone or other tissue;

[00029] Figure IE is a partial perspective view of another alternative guidewire disposed in a sheath having a distal pin that can be hammered into bone or other tissue;

[00030] Figure 2A is a perspective view illustrating an exemplary implant delivery system including an actuating handle assembly and a barrel;

[00031] Figure 2B is a an alternative perspective view of the implant delivery system of Figure 2A illustrating an implant retainer assembly and implant spreader assembly on a distal portion of the delivery system extending beyond the sheath;

[00032] Figure 2C is a partial cross sectional view of the implant delivery assembly of Figure 2A depicting the actuating mechanism in the handle assembly;

[00033] Figure 2D is a perspective view of the delivery shaft including the implant spreader and implant retainer assemblies of Figure 2B as removed from the sheath and handle;

[00034] Figure 2E is an alternative perspective view of the implant delivery system of Figure 2A illustrating details of the implant retainer assembly and the location of a distal guidewire port;

[00035] Figure 2F is a perspective view of an implant delivery system having a guidewire extending from a distal guidewire port;

[00036] Figure 2G is a partial perspective view illustrating the distal portion of the implant delivery system of Figure 2F, including an implant folded and mounted on the implant retainer assembly and a guidewire extending from the guidewire port;

[00037] Figure 2H is partial perspective view illustrating the distal portion of the implant delivery system of Figure 2F after activation of the implant spreader assembly to unfurl the implant;

[00038] Figure 3A is perspective view of a marker disposed in a needle-like sheath for insertion into tissue to define a reference point;

[00039] Figure 3B is a perspective view of the marker of Figure 3A as removed from the needle-like sheath;

[00040] Figure 3C is a partial perspective view of the distal portion of the marker of Figure 3B illustrating a plurality of distal arms extending longitudinally as they would be when constrained within the sheath;

[00041] Figure 3D is a partial perspective view of the arms of Figure 3C as deployed upon removal of the sheath to extend laterally and retain the marker in tissue;

[00042] Figure 4A is a perspective view of an exemplary probe used to observe and measure tissue in a treatment site;

[00043] Figure 4B is a partial perspective view of the distal portion of the probe of Figure 4A;

[00044] Figure 5 is a stylized anterior view of a patient with the shoulder being shown in cross-section for purposes of illustration;

[00045] Figure 6 is a stylized view of a shoulder depicting the head of the humerus shown mating with the glenoid fossa of the scapula at a glenohumeral joint and a sheet-like material is affixed to the tendon;

[00046] Figure **7A** is a stylized perspective view showing a portion of the body of a human patient divided into quadrants by planes for descriptive purposes;

[00047] Figure **7B** is a stylized perspective view illustrating an exemplary procedure for arthroscopic treatment of a shoulder of a patient in accordance with one embodiment of the disclosure;

[00048] Figure 8A is a perspective view of a portion of the shoulder with parts removed to illustrate the supraspinatus tendon in relation to other anatomical features;

[00049] Figure 8B is a partial perspective view of the articular side of the supraspinatus tendon illustrating the position relative to the biceps tendon and a marker inserted from the bursal side to identify the location of the biceps tendon which is not visible from the bursal side;

[00050] Figure 8C is another partial perspective view of the articular side of the supraspinatus tendon as shown in Figure 8B with a second marker inserted to delineate the biceps tendon over its length which is not visible from the bursal side;

[00051] Figure 8D is a partial perspective view of the shoulder showing the two markers of Figure 8C as they extend proximally from a point of insertion in the skin;

[00052] Figure 8E is a partial perspective view of the shoulder of Figure 8D with the inclusion of two portal incisions made relative to the markers;

[00053] Figure 8F is a partial perspective view of the shoulder of Figure 8A depicting the two markers from the bursal side of the tendon as they extend therethrough and would be seen during arthroscopic placement of an implant;

[00054] Figure 8G is a partial perspective view of the shoulder of Figure 8F illustrating the placement of a guidewire relative to the markers;

[00055] Figure 8H is a partial perspective view illustrating a guidewire as affixed to bone relative to the markers;

[00056] Figure 81 is a partial perspective view of the shoulder of Figure 8H with an implant delivery system distal sheath illustrated as guided over the wire;

[00057] Figure 8J is a partial perspective view of the shoulder of Figure 81 illustrating the extension of an implant retention assembly from the sheath;

[00058] Figure 8K is a partial perspective view of the shoulder of Figure 8J illustrating the deployment of an implant spreader assembly and positioning of the implant relative to the markers;

[00059] Figure 8L is a partial perspective view of the shoulder of Figure 8K depicting partial retraction of the implant delivery system as the implant is affixed by staples to the tendon;

[00060] Figure 8M is a partial perspective view of the shoulder of Figure 8L depicting the closing of the implant spreader assembly in conjunction with removal from the shoulder; and,

[00061] Figure 8N is a partial perspective view of the shoulder of Figure 8M depicting removal of the guidewire attachment from the shoulder prior to affixing the proximal portion of the implant to the humeral head.

DETAILED DESCRIPTION

[00062] 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.

[00063] The present disclosure is directed to a guidewire that is particularly useful with an implant delivery system that can be used for accurately positioning and deploying or delivering a sheet-like implant to a treatment site. The guidewire and delivery device are discussed in detail with respect to treatment of tendons in articulating joints, specifically the supraspinatus tendon of the rotator cuff in the shoulder. However, it is recognized that the guidewire and/or delivery system and other components of a kit disclosed herein can be utilized in any areas of the body wherein it is desired to accurately position a sheet-like implant, especially during an arthroscopic procedure where access and visibility are limited.

[00064] The guidewire is configured with a distal end that attaches to bone or other tissue at a first fixed point that is determined through observation and measurement of the treatment site. The first fixed point is determined based on knowledge of the size of the implant to be used, the known location of a distal guidewire port on the delivery system relative to an implant when it is loaded on the delivery system and the measured/observed anatomy of the treatment site. Once the guidewire is attached at the first fixed point, the delivery system can track over the wire to the proper position for delivering the implant. Details of the guidewire design are disclosed with respect to the discussion of Figure 1A-1E, while the implant delivery system is discussed with respect to Figures 2A-2H. The above method, as applied to treatment of the supraspinatus tendon of the rotator cuff is described in detail with respect to Figures 8A-8N.

[00065] The delivery system and guidewire of this disclosure can also be used in conjunction with other tissue position markers or included in a kit with tissue position markers. Identifying a first fixed point for attachment of the guidewire may not be sufficient in some applications to accurately position the implant as the delivery system can be rotated to some degree about the first point. By using visual observation and/or other measurement techniques a second, and if necessary a third, fixed point can be identified and marked with the markers to be used as a reference point or line for proper rotation or orientation of the implant as positioned over the wire. The markers are described in detail with respect to Figures 3A-3D and the method of marking a second and third fixed point are described for the rotator cuff with respect to Figures 8A-8N.

[00066] Referring now to Figure 1A, a representative guidewire 172 and delivery system 200 is illustrated. The delivery system can include a shaft 202 having a lumen 203 extending therethrough. The proximal end of the shaft includes mean for holding and positioning the shaft 204 and a proximal end of the shaft can be attached to a rotating tool (not shown). The guidewire 172 extends through the shaft lumen 203. The shaft further includes mean for

rotational engagement between the delivery system and the guidewire. When inserted in the lumen, the guidewire rotates as the shaft rotates. Means for rotational engagement between the shaft and guidewire are generally known, as for example, a keyed portion near the distal end of the guidewire may engage a mating surface extending from the shaft.

[00067] As depicted in Figure IB, the distal end of the guidewire includes a tissue fixation member 182, 183 extending from a weld ball 181. In the embodiment shown, the tissue fixation member is a K-wire or Kirshner wire which includes a shaft or pin portion having a sharpened distal end 183, much like a drill bit. Positioning the distal end 183 at a selected site on bone and rotating with some pressure applied causes the guidewire to auger into the bone and become affixed at that point. Figure IB shows the guidewire with the delivery system being retracted proximally over the guidewire as would be done after the distal tip of the guidewire is embedded in tissue. A strain relief 190 is also visible.

[00068] Referring to Figure 1C, a closer view of the distal portion of the guidewire 172 is illustrated. The K-wire distal tip includes sharpened edges 185 for cutting into bone or other tissue. Further, the strain relief 190 is shown attached to the weld ball in the form of a spring having the guidewire 172 proximal portion extending from and attached to the spring. This configuration allows significant bending of the wire at the spring to allow the delivery system to be tracked to near the ball 181 when in use.

[00069] An alternative embodiment of a guidewire and guidewire delivery system is depicted in Figure ID. The embodiment is similar to the above described system, however, the tissue fixation member 180 is a screw. A strain relief 190 is affixed to the proximal end of the screw and the proximal portion of the guidewire 172 is attached to and extends from the strain relief 190. As illustrated, the guidewire delivery system is essentially a screwdriver with a hollow shaft 202 for receiving the guidewire therein. A distal portion of the hollow shaft 202 engages the head of the screw and a hand can be used to rotate the screw as it augers into bone or other tissue.

[00070] Figure IE depicts another alternative guidewire and guidewire delivery system. In this embodiment, the distal end of the guidewire 172 includes a pin 210 that has a distal point 212. The pin has a proximal end attached to a strain relief 190 to which the proximal guidewire portion is attached extending proximally therefrom. The delivery shaft 202 is designed to abut the proximal end of the pin 210 and the system can then be hammered or otherwise forced into bone or other tissue to affix the pin thereto.

[00071] Referring now to Figure 2A, a perspective view of an exemplary implant delivery system 60 is shown. Implant delivery system 60 includes a handle assembly 100 and barrel assembly 102. As depicted in Figure 2A, the outer barrel assembly 102 is a sheath 103 attached

to and extending distally from the handle assembly 100. The sheath 103 can include a bullet nose or tapered distal tip to aid in inserting the delivery system 60 through an incision to the treatment site. The sheath 103 covers a delivery assembly as discussed with respect to Figure 2B below. The sheath 103 of implant delivery system 60 is coupled to the handle assembly 100 in a fixed position, in the embodiment depicted. In alternative embodiments the sheath 103 may be reciprocally engaged by the handle assembly 100 to allow longitudinal movement in response to movement of the trigger 105. The sheath can include at least a distal portion that is transparent to allow viewing of an implant mounted therein.

[00072] As depicted in Figure 2B, the handle assembly 100 includes a body 107 and reciprocating trigger 105 attached thereto. The handle assembly also includes a first button 111 that releasably engages a delivery shaft 130 (discussed below with respect to Figure 2D). The first button 111 allows movement of the delivery shaft 130 to extend beyond the sheath 103 for loading an implant and reverse movement pulls the delivery shaft 130 back into the sheath 103.

[00073] A second button 109 is connected to longitudinal members that extend within the sheath to move arms of an implant spreader assembly 124 (see Figure 2B). Pushing of the button releases engagement with the longitudinal members and allows the arms to close as the overall system is pulled from the implant site.

[00074] Figure 2B depicts the implant delivery system 60 of Figure 2A with a delivery shaft 130 extended distally beyond the sheath 103 as would be done during delivery of an implant. The extended delivery shaft 130 also allows visualization of the working components on the distal end of the delivery system. These include an implant retainer assembly 148, an implant spreader assembly 124 and a hood 149. To better visualize the extension of the delivery shaft 130 relative to the handle assembly 100. Figure 2C depicts the delivery system of Figure 2B with a portion of the body 107 removed to expose the linkages between the trigger 105, first button 111 and second button 109 with the barrel assembly 102. As illustrated, in this representative embodiment, the sheath 103 is rigidly fixed to a distal portion of the handle 100 with the delivery shaft 130 slidably disposed therein. The delivery shaft is linked to a first member 141 which is also linked to both the trigger 105 and first push button 109. Distal movement of the first push member 141, whether by movement of the trigger 105 or the first push button 109 being moved distally causes distal extension of the delivery shaft 130 relative to the sheath 103.

[00075] With reference to Figure 2D, the delivery shaft 130 is depicted in more detail as removed from the sheath 103 and disconnected from the handle assembly 100. The delivery shaft 130 includes a pair of longitudinally extending members 143 that are operably connected to the tissue spreader assembly 124. Linkage (not shown) within the handle assembly 100 connects

the proximal portion of the longitudinally extending members 143 such that pulling on the trigger after the delivery shaft 130 has been extended causes distal movement of the longitudinally extending members 143 to operate the spreader assembly 124. One of skill in the art will recognize that the mechanisms described are representative of one working embodiment of a handle coupled to the barrel assembly 102 and that other actions and linkages can be used to operate the working portions of the implant delivery system 60, to include both extension of the delivery shaft or retraction of the sheath and also deployment of the spreader assembly.

[00076] As best seen in Figure 2E, a first arm 120 and a second arm 122 can be seen extending distally from the delivery shaft 130. First arm 120 and second arm 122 are both part of an implant spreader assembly 124. Implant spreader assembly 124 may be used to carry a sheet-like implant to a location within the human body. Implant spreader assembly 124 may also be used to unfold the sheet-like implant so that the sheet-like implant covers a treatment site within the body.

[00077] In the exemplary embodiment of Figure 2E, first arm 120 and second arm 122 are disposed in an open position. First arm 120 and second arm 122 are capable of moving between the open position where the arms extend laterally and a closed position wherein the arms generally extend longitudinally parallel to the delivery shaft 130. When pivoting to the open position the arms rotate so that distal end 128A of first arm 120 and distal end 128B of second arm 122 move away from each other in generally transverse or lateral directions. In some embodiments the distal ends of the arms lie in the same plane as the sheath in both the open and closed positions, however, in other embodiments disclosed herein, the arms may move in different planes relative to each other so that the implant will take a curved shape in the open position to better conform to the treatment site as laterally delivered. Further, in some alternative embodiments, one arm may be stationary while the other rotates to spread the implant.

[00078] As also shown in greater detail in Figure 2E, the implant delivery system 60 also includes an implant retainer assembly 148 located near a distal end of delivery shaft 130. In the exemplary embodiment of Figure 2E, implant retainer assembly 148 comprises a center post 150 post disposed proximate the distal end of the delivery shaft 130 that cooperates with a mating surface 152 having a longitudinally extending groove 154 generally parallel and spaced from the center post wherein the mating surface and center post form a slot therebetween to retain the implant when it is slidably disposed thereon.

[00079] As also indicated on Figure 2E, the implant delivery system includes a guidewire port 170 located proximate the distal end of the delivery shaft 130. The guidewire port 170 is sized for receiving a proximal end of a guidewire, discussed above with respect to Figures 1A-1E, therethrough. The guidewire port location is positioned in known relation to an implant on the

implant retainer assembly so that tracking the implant delivery system over the guidewire to a known guidewire location fixes the location to which the implant will be delivered relative thereto.

[00080] Figure 2F depicts the implant delivery system of Figure 2A with a guidewire 172 having been fed from a proximal end thereof through the guidewire port 170 and extending distally from the end of the barrel 102. The interior of the delivery shaft provides a lumen for receiving the proximal portion of the guidewire as it is fed through the guidewire port 170. As depicted, the guidewire 172 includes a tissue fixation member 180 on the distal end thereof. In use, the tissue fixation member 180 is affixed to bone or other tissue at a desired anatomical location. The implant delivery system 60 is then tracked over the guidewire from its proximal end until the distal end of the implant delivery system (after the delivery shaft is extended from the sheath) or delivery shaft abuts the tissue or guidewire proximate the point at which the guidewire is fixed to the bone or other tissue.

[00081] The relationship between the implant delivery system 60, the guidewire 172 and a sheet-like implant 50 mounted thereon for delivery can be better understood, in an exemplary embodiment, by reference to Figure 2G. Figure 2G depicts a distal portion of the delivery system with the delivery shaft extended beyond the sheath. A sheet-like implant 50 is held in place by the implant retention member 148 as previously described. Further, the implant 50 is shown in a folded configuration as it would fit in the sheath and remains in this configuration when the delivery shaft is extended because a hood 149 is included in this embodiment for receiving the edges of the implant 50 thereunder. The guidewire 172 is depicted extending distal of the implant. In use, the delivery shaft would be fed further distal over the guidewire until the ball 181 is in contact or nearly in contact with the guidewire port at the distal end of the delivery shaft, which is generally about 5 mm. distal of the proximal end of the implant or in alternative embodiments may be in longitudinal alignment with the proximal end of the implant. The guidewire port is also generally in lateral alignment with the center of the implant. Thus, the location of the attachment of the guidewire will generally conform to a location about5 mm. distal of the proximal end of the implant and at the lateral center of the implant when delivered in this embodiment. Other spacing could be used if desired, with the longitudinal and lateral relationship of the implant relative to the guidewire port being known.

[00082] Figure 2H depicts the distal portion of the implant delivery system illustrated in Figure 2G after the implant spreader assembly 124 is deployed. As shown, the lateral movement of the arms 120, 122 pull the edge of the implant out from under the hood 149 and cause the implant 50 to lay flat. The implant retention member 148 continues to hold the implant on the assembly in order to allow movement of the implant to a desired position.

[00083] As previously disclosed, embodiments of the implant delivery system disclosed herein can be used in conjunction with tissue markers that visually identify anatomical locations at or near a treatment site to assist in proper placement of the implant with the implant delivery system. Figures 3A-3D detail one embodiment of a tissue marker system 300. Multiple markers can be used in a given procedure.

[00084] Referring first to Figure 3A, a tissue position marker system 300 is depicted. The tissue marker system 300 includes a delivery sleeve 302 having a lumen 304 therethrough. The delivery sleeve can be a needle-like shaft having a tissue penetrating distal end. A tissue marker 308 is slidably disposed within the lumen 304 of the delivery sleeve 302. The tissue marker 308, in this embodiment has an elongate shaft defining a longitudinal direction. A proximal handle, including a first part 306 and second part 310 are coupled to the tissue marker and delivery sleeve. The second part 310 of the proximal handle can be releasably attached to the tissue marker 308 proximal end so that the second part can be removed to allow the delivery sleeve 302 to be removed proximally over the tissue marker after it is affixed to tissue. The second part 310 can then be re-attached to the proximal end of the marker to aid in removing the marker after the procedure is completed.

[00085] Figure 3B depicts the marker 308 as removed from the delivery sleeve 302. The distal portion of the marker 308 includes a plurality of longitudinally extending arms 312 which are formed into the marker 308 or attached to the distal end of the marker. These arms 312 are better depicted in the illustrations of Figures 3C and 3D. When unconstrained, as when the arms 312 are outside of the lumen of the delivery sleeve, the flexible arms project outward from the shaft proximate a distal end thereof, as shown in Figure 3D. However, when the marker 308 is within the delivery sleeve 302, the lumen walls flex and constrain the arms to extend generally longitudinally and fit therein. In the deployed state outside the delivery sleeve 302, the arms retain the marker's position in tissue, yet can be pulled out without any significant effect on the tissue because the arms will flex to extend generally longitudinally as they are pulled through the tissue. In some embodiments, the arms are flexible nitinol members and the marker can include at least three, and typically four or more arms. The proximal handle can also include means for selectively coupling and decoupling the tissue marker and delivery sleeve to allow easier insertion of the combined assemblies into tissue.

[00086] As previously disclosed, the systems and devices disclosed herein are used in procedures that can be performed arthroscopically. To better make use of these systems and devices a surgeon can observe, probe and measure features of a treatment site visually to best identify the right implant and fixed locations for placing both the guidewire and/or markers for accurate delivery of the implant. An exemplary probe and measuring tool 350 is depicted in

Figures 4A and 4B. The probe includes an elongate shaft 352 having a tapered distal portion 354. The tapered distal portion terminates in a hook-shaped distal end 356. Further, the shaft can include ruled markings that can readily be viewed to measure any distance near the treatment site. The probe can be particularly useful in identifying the line of the point of insertion on the supraspinatus tendon to the humeral head by inserting the probe on the articular side of the tendon. The width of the tendon can also be measured in this way for selecting a proper implant size. The probe disclosed is one example of a tool to assist in identifying anatomical points for placement of a guidewire, markers and a delivery system. It is recognized that other tools can be utilized with the delivery system.

[00087] Next referring to Figure 5, an exemplary use or application of the implant delivery system of the present disclosure is described. Figure 5 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 5. Shoulder 22 includes a humerus 14 and a scapula 12. In Figure 5, a head 24 of humerus 14 can be seen mating with a glenoid fossa of scapula 12 at a glenohumeral joint. 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 supraspinatus, the infraspinatus, the subscapularis, and the teres minor. For purposes of illustration, only the supraspinatus 26 is shown in Figure 5.

[00088] With reference to Figure 5, a distal tendon 28 of the supraspinatus 26 meets humerus 14 at an insertion point. Scapula 12 of shoulder 22 includes an acromion 32. A subacromial bursa 34 is shown extending between acromion 32 of scapula 12 and head 24 of humerus 14. Subacromial bursa 34 is shown overlaying supraspinatus 26 as well as supraspinatus tendon 28 and a portion of humerus 14. 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.

[00089] The exemplary implant delivery system described herein may be used to position and deploy sheet-like implants to various target tissues throughout the body. The shoulder depicted in Figure 5 is one example where a tendon repair implant may be affixed to one or more bones associated with an articulating joint, such as the glenohumeral joint. Additionally, the tendon repair implant may be affixed to one or more tendons to be treated. 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.

[00090] Figure 6 is a stylized anterior view of a shoulder 22 including 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. This muscle, along with others, controls the movement of humerus 14 relative to scapula 12. A distal tendon 28 of supraspinatus 26 meets humerus 14 at an insertion point 30.

[00091] As depicted in Figure 6, 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 6. 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 6, 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.

[00092] With reference to Figure 6, distal tendon 28 includes a second damaged portion 38 located near insertion point 30. As illustrated, second damaged portion 38 of distal tendon 28 has become frayed and a number of loose tendon fibers 40 are visible. Second damaged portion 38 of distal tendon 28 includes second tear 44. Second tear 44 begins on the side of distal tendon 28 facing the center of the humeral head 24. Accordingly, second damaged portion 38 may be referred to as an articular side tear.

[00093] Figure 6 illustrates a sheet-like implant 50 has been placed over the bursal side of distal tendon 28. The sheet-like implant 50 is affixed to distal tendon 28 by a plurality of tendon staples 51. Sheet-like implant 50 is affixed to humerus 14 by a plurality of bone staples 100. 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.

[00094] Figure 7A is a stylized perspective view showing a portion of the body 82 of a human patient 20. Body 82 includes a shoulder 22. In the exemplary embodiment of Figure 7A, a plurality of cannulas are positioned to access a treatment site within shoulder 22. In some cases, shoulder 22 may be inflated by pumping a continuous flow of saline through shoulder 22 to

create a cavity proximate the treatment site. The cannulas shown in Figure 7A include a first cannula 80A, a second cannula 80B and a third cannula 80C.

[00095] In Figure 7A, a sagital plane SP and a frontal plane FP are shown intersecting body 82. Sagital plane SP and frontal plane FP intersect one another at a medial axis MA of body 82. With reference to Figure 7A, sagital plane SP bisects body 82 into a right side 84 and a left side 86. Also with reference to Figure 7A, frontal plane FP divides body 82 into an anterior portion 92 and a posterior portion 88. Sagital plane SP and a frontal plane FP are generally perpendicular to one another. These planes and portions are used to describe the procedures used in exemplary embodiments.

[00096] First cannula 80A is accessing a treatment site within shoulder 22 using a lateral approach in which first cannula 80A pierces the outer surface of right side 84 of body 82. The term lateral approach could also be used to describe situations in which an instrument pierces the outer surface of left side 86 of body 82. Second cannula 80B is accessing a treatment site within shoulder 22 using a posterior approach in which second cannula 80B pierces the outer surface of posterior portion 88 of body 82. Third cannula 80C is accessing a treatment site within shoulder 22 using an anterior approach in which third cannula 80C pierces the outer surface of anterior portion 92 of body 82.

[00097] Figure 7B is a stylized perspective view illustrating an exemplary procedure for treating a shoulder 22 of a patient 20. The procedure illustrated in Figure 7B 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.

[00098] Shoulder 22 of Figure 7B has been inflated to create a cavity therein. 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.

[00099] 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 affixed to a bursal surface of the tendon regardless of whether there are visible signs of tendon damage. Applicants believe that the methods and apparatus of the present application and related devices may provide very beneficial therapeutic effect on a patient experiencing joint pain believed to be caused by internal microtears, but having no clear signs of tendon tears. By applying a tendon repair implant early before a full tear or other injury develops, the implant may cause the tendon to thicken and/or at least partially repair itself, thereby avoiding more extensive joint damage, pain, and the need for more extensive joint repair surgery.

[000100] An implant delivery system 60 can be seen extending from shoulder 22 in Figure 7B. Implant delivery system 60 is extending through a first cannula 80A. In certain embodiments, first cannula 80A can access a treatment site within shoulder 22 using a lateral approach in which first cannula 80A pierces the outer surface of a right side of the patient's body. In some cases a physician may choose not to use a cannula in conjunction with implant delivery system 60. When that is the case, the implant delivery system may be advanced through tissue. Implant delivery system 60 comprises a sheath that is affixed to a handle. The sheath defines a lumen and a distal opening fluidly communicating with the lumen. In the embodiment of Figure 7B, the distal opening of the sheath has been placed in fluid communication with the cavity created in shoulder 22.

[000101] A tendon repair implant is at least partially disposed in the lumen defined by the sheath of implant delivery system 60. Implant delivery system 60 can be used to place the tendon repair implant inside shoulder 22. 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, implant delivery system 60 may be used to unfold the tendon repair implant into an expanded shape. Additionally, implant delivery system 60 can be used to hold the tendon repair implant against the tendon.

[000102] The tendon repair implant may be affixed to the tendon while it is held against the tendon by implant 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 7B, 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 and bone with one or more staples while the tendon repair implant may held be against the tendon by implant delivery system 60.

[000103] As previously stated, the implant delivery system 60 can be used to deliver any sheet¬ like implant. A 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 embodiments, 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 reconstituted collagen material having a porous structure. Additionally, 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 TM. The sheet-like structure may be circular, oval, oblong, square, rectangular, or other shape configured to suit the target anatomy. 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 embodiment of Figure 6, sheet-like implant 50 is affixed to distal tendon 28 by a plurality of tendon staples 51. Sheet-like implant 50 is affixed to humerus 14 by a plurality of bone staples 52. Details of exemplary tendon staples may be found in commonly assigned co-pending applications: U.S. Application No. 12/684,774 filed January 8, 2010; U.S. Application No. 12/729,029 filed March 22, 2010; U.S. Application No. 12/794,540 filed June 4, 2010; U.S. Application No. 12/794,551 filed on June 4, 2010; U.S. Application No. 12/794,677 filed on June 4, 2010; and U.S. Application No. 61/443,180 filed on February 15, 201 1, the disclosures of which are incorporated herein by reference. Exemplary bone staples are described in commonly assigned co-pending applications: U.S. Application No. 61/577,626 filed December 19, 201 1; U.S. Application No. 61/577,632 filed December 19, 201 1 and U.S. Application No. 61/577,635 filed December 19, 201 1, the disclosures of which are incorporated herein by reference. Exemplary staples in many of the above applications may be used for anchoring in both soft tissue and in bone.

[000104] Referring to Figures 8A-8N, a series of step-wise illustrations are provided of exemplary use of the markers, guidewire and implant delivery system as an overall kit for treatment of the supraspinatus tendon of the shoulder. The supraspinatus tendon is used to illustrate one use of the system which may be adapted for use in other areas of the body, as one of skill in the art will readily recognize. In particular, the system is useful in areas of the body requiring accurate placement of the implant relative to other anatomical structures as the system is guided to a marked first position by the guidewire and rotated to proper orientation relative to at least one, and at times two other markers of anatomical structure.

[000105] Referring now to Figure 8A, a shoulder 22 is schematically illustrated with skin and other obstructing tissue removed so that the humerus 14 and supraspinatus tendon 28 are readily

visible for purposes of better understanding exemplary procedures using the devices and methods of the current disclosure. The humerus 14 and supraspinatus tendon 28 are shown in relation to clavicle 21 and acromion 23. Further, the infraspinatus tendon 25 and teres minor tendon 27 are shown as they attach to the humerus, and as previously stated, interdigitate with the supraspinatus. The point of insertion 30 of the supraspinatus tendon 28 to humeral head 24 is also indicated and generally forms a line. The biceps tendon 29 can be seen as it extends down the arm, however, this tendon is not visible from this bursal side view on the rotator cuff of the shoulder as the biceps tendon 29 passes underneath the supraspinatus tendon and runs on the articular side of the supraspinatus tendon (beneath the tendon).

[000106] Figure 8B illustrates a view of the articular side of the supraspinatus tendon 28 near the point of insertion 30 on the humeral head 24. This view can be seen by a surgeon through the arthroscope when positioned beneath the supraspinatus tendon. As can be seen in the illustration, the biceps tendon 29 is visible as it runs medially to the shoulder attachment. In treating the supraspinatus tendon with an implant over the bursal side of the tendon, it is preferred to not interfere with the biceps tendon by putting a staple or other attachment into this tendon. Therefore, as a first step in one method of the present disclosure, the location of the biceps tendon is marked so it is known when viewing the bursal side of the supraspinatus tendon. As illustrated in Figure 8B, a shaft 302 of a marker assembly 300 has been inserted through the skin of the shoulder and the bursal side of the supraspinatus tendon 28 to project into the space depicted with the location being adjacent the biceps tendon 29 proximate the point of insertion 30. As depicted, the delivery assembly has not been removed nor has the arms of the marker been deployed in the illustration. When deployed the arms will abut the supraspinatus tendon on the articular side and be retained therein until sufficient force is applied to flex the arms longitudinally and be pulled through the tissue.

[000107] In some methods, a second marker system 302 is used to mark a second point medial of first marker. This is illustrated in Figure 8C which shows a shaft 302 penetrating the bursal side of the supraspinatus tendon 28 and adjacent the biceps tendon 29 at a location medial to the first marker. As depicted, the delivery assembly has not been removed nor has the arms of the marker been deployed in the illustration. When deployed the arms will abut the supraspinatus tendon on the articular side and be retained therein until sufficient force is applied to flex the arms longitudinally.

[000108] Figure 8D shows the shoulder as it appears on the skin surface with the two marker systems 300 inserted. The two points of insertion define a line that runs parallel to the biceps tendon under the supraspinatus tendon which indicates an area where the implant should not be located or attached to avoid interfering with the biceps tendon. Figure 8E shows two of three

incision ports that can be made relative to the marker systems 300. A first port can be located on the posterior side of the shoulder for inserting the arthroscope (not shown). A second port, the inferior lateral port 391 is made for insertion of the implant delivery system. A third port, or superior lateral port 392 is made for insertion of devices that are used to attach the implant to the tendon and bone.

[000109] A view of the bursal side of the supraspinatus tendon 28 with markers projecting therethrough is illustrated in Figure 8F. The drawing indicates a clear visible line at the frontal margin of the supraspinatus tendon in line with the markers. Due to other tissue and ligaments in the area this is not visible to the surgeon through the arthroscope. Therefore, the markers, as placed while viewing the biceps tendon from the articular side delineate the front edge of where one would want to place the implant.

[000110] With the front edge location of the implant delineated, the next step in one method of the present disclosure is placement and attachment of the guidewire. As illustrated in Figure 8G, with the width of the implant selected for the tendon known, the first fixed point is located a distance D plus an additional distance X in the posterior direction from the line identified by the two markers 308. In some embodiments the distance D is one-half of the width of the implant plus a distance X of about 2 mm. in the posterior direction from the line defined by the two markers 308. Further, the longitudinal distance between an implant mounted on the delivery system used and the guidewire port on the delivery shaft is known. In the illustrated method, using one representative delivery system, it is known that the longitudinal location of the first fixed point should be at the insertion point. As the implant is delivered, it will then extend proximally down the arm of the patient from the line defined by the insertion point by about 5 mm., which assures the implant extends over the point of insertion and is affixed to the humeral head 24. As illustrated in Figure 8G, a guidewire 172 having a screw 183 for a tissue fixation member is placed at the identified first fixed point.

[000111] Figure 8H illustrates the guidewire 172 after attachment to the humeral head 24 proximate the point of insertion 30 and located posterior to the line defined by the markers 308 by a distance of one-half the width of the implant to be delivered plus about 2 mm. The implant delivery system 60 is then tracked over the guidewire 172 into the vicinity of the implant site as depicted in Figure 81. The delivery shaft is then extended to expose the implant distally of the sheath, which is illustrated in Figure 8J. The entire delivery system is urged distally so that the guidewire port is proximate the first fixed point where the guidewire is attached to the bone. As indicated in Figure 8J, this assures the proximal edge of the implant extends a distance Y beyond the point of insertion 30 and can be affixed to the humeral head 24. In some embodiments the

distance Y is about 5 mm. beyond the point of insertion 30 and assures the implant can be affixed to the humeral head 24.

[000112] Referring now to Figure 8K, the next step in one method includes deploying the implant spreader arms 120, 122 to unfurl the implant and hold it against the tendon 28. Once unfurled, the implant 50 can be rotated about the first fixed point (guidewire attachment to the bone) so that the front edge is generally parallel to the line defined by the two markers 308. As next shown in Figure 8L, the implant 50 can be attached in multiple locations to the supraspinatus tendon 28 using staples 51. Once the medial edge is attached, the implant delivery system can be partially retracted while being used to smooth and pull the implant down and make sure it lays flat against the tendon while more staples are inserted into the tendon. In Figure 8M, it is illustrated that the arms 120, 122 may then be closed while the implant delivery system 60 is removed from the treatment site. Referring to Figure 8M, prior to attaching the rest of the implant, the guidewire 172 is removed in this embodiment as it is located under the edge of the implant. The guidewire delivery shaft 202 is placed over the guidewire and engages the screw head to remove the guidewire. Once removed, additional staples can be inserted in the tendon and in the bone along with removal of the markers 308.

[000113] While exemplary embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims and subsequently filed claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

CLAIMS

What is claimed is:

1. A guidewire for accurately guiding an implant delivery system to a treatment site on the rotator cuff, the guidewire comprising:

a distal portion including a tissue fixation member for releasably coupling the guidewire to the humeral head; and,

a proximal portion including a length of wire extending proximally from the tissue fixation member.

2. The guidewire of claim 1, wherein the tissue fixation member includes a K-wire having a sharpened distal end for cutting into bone or other tissue.

3. The guidewire of claim 1, wherein the tissue fixation member includes a screw for attachment to bone or other tissue.

4. The guidewire of claim 1, wherein the tissue fixation member includes a pin having a sharpened distal end for penetrating bone or other tissue.

5. The guidewire of claim 1, further comprising a weld ball, wherein the wire is a single member extending through the weld ball and extending from opposite sides of the weld ball.

6. The guidewire of claim 1, further comprising a weld ball, wherein a proximal end of the tissue fixation member is affixed to the weld ball and extends distally therefrom.

7. The guidewire of claim 6, wherein the proximal portion is affixed to the weld ball and extends proximally therefrom.

8. The guidewire of claim 5, further comprising a strain relief having a distal end affixed to the weld ball generally opposite the tissue fixation member.

9. A kit for positioning and delivering a sheet-like implant, the kit comprising:

a guidewire having a distal portion including a tissue fixation member for releasably coupling the guidewire to bone or other tissue and a proximal wire portion extending proximally therefrom; and,

an implant delivery system for delivering a sheet-like implant having a delivery shaft with a proximal end and a distal end defining a generally longitudinal direction and including a guidewire port proximate the distal end of the delivery shaft for slidably receiving the guidewire therein to track the proximal wire portion to a delivery site when the guidewire is coupled to bone or other tissue.

10. The guidewire of claim 9, wherein the tissue fixation member includes a K-wire having a sharpened distal end for cutting into bone or other tissue.

11. The guidewire of claim 9, wherein the tissue fixation member includes a screw for attachment to bone or other tissue.

12. The guidewire of claim 9, wherein the tissue fixation member includes a pin having a sharpened distal end for penetrating bone or other tissue.

13. The guidewire of claim 9, further comprising a weld ball, wherein a proximal end of the tissue fixation member is affixed to the weld ball and extends distally therefrom.

14. The guidewire of claim 13, wherein the proximal portion is affixed to the weld ball and extends proximally therefrom.

15. The guidewire of claim 13, further comprising a strain relief having a distal end affixed to the weld ball generally opposite the tissue fixation member.

16. The guidewire of claim 15, wherein the proximal portion has a distal end affixed to the strain relief and extends proximally therefrom.

17. A method of accurately positioning a sheet-like implant over a tendon in the rotator cuff during arthroscopic surgery comprising the steps of:

providing a guidewire having a distal portion including a tissue fixation member and attaching the tissue fixation member to the humeral head;

providing an implant delivery system having a sheet-like implant releasably coupled proximate the distal end thereof and a distal guidewire port a known lateral and longitudinal distance relative to the sheet-like implant;

tracking the implant delivery system over a proximal portion of the guidewire to a position adjacent the tissue fixation member; and,

deploying the positioned implant.

18. The method of claim 17, further comprising the steps of:

observing the treatment site to determine a preferred location for the implant to be delivered;

identifying a guidewire attachment point on the humeral head proximate the treatment site that is the known lateral and longitudinal distance from the preferred location for the implant to be delivered; and,

affixing the guidewire proximate the guidewire attachment point.

19. The method of claim 18, further comprising the step of:

measuring the tendon at the treatment site to determine the lateral position of the guidewire attachment point.

20. The method of claim 17, further comprising the step of providing a marker and inserting the marker through a second location proximate the rotator cuff and rotating the implant delivery system to align the edge of the implant adjacent the marker.

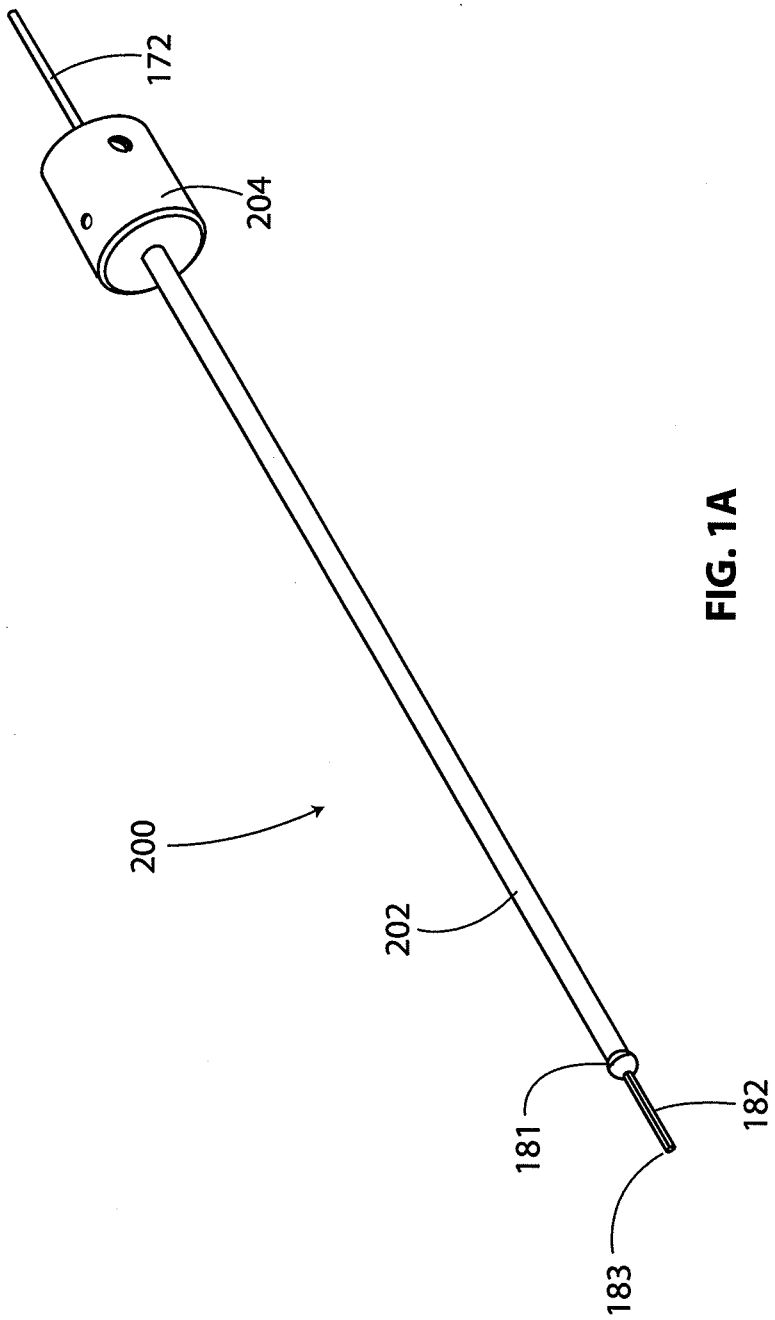

FIG. 1A

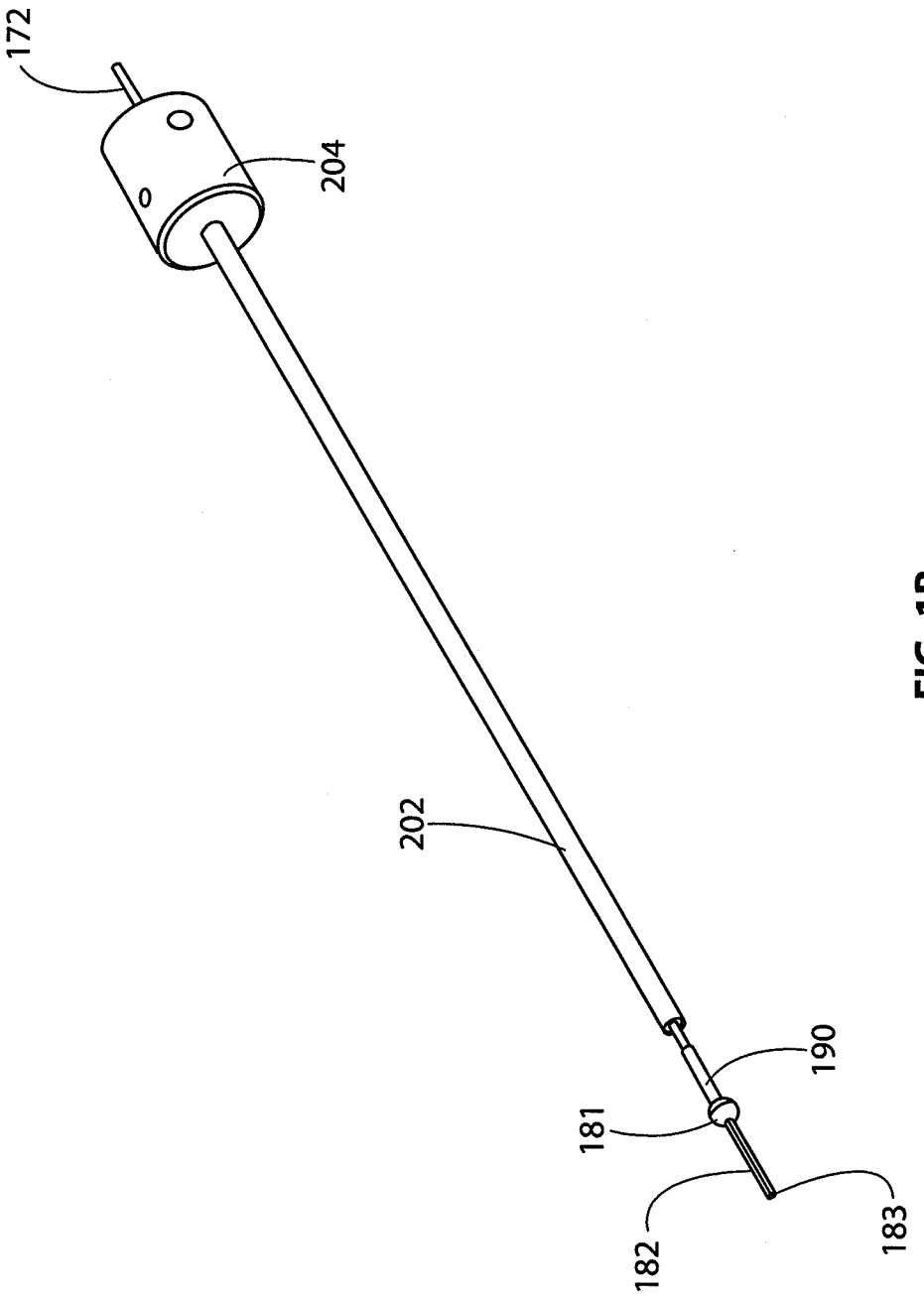

FIG. 1B

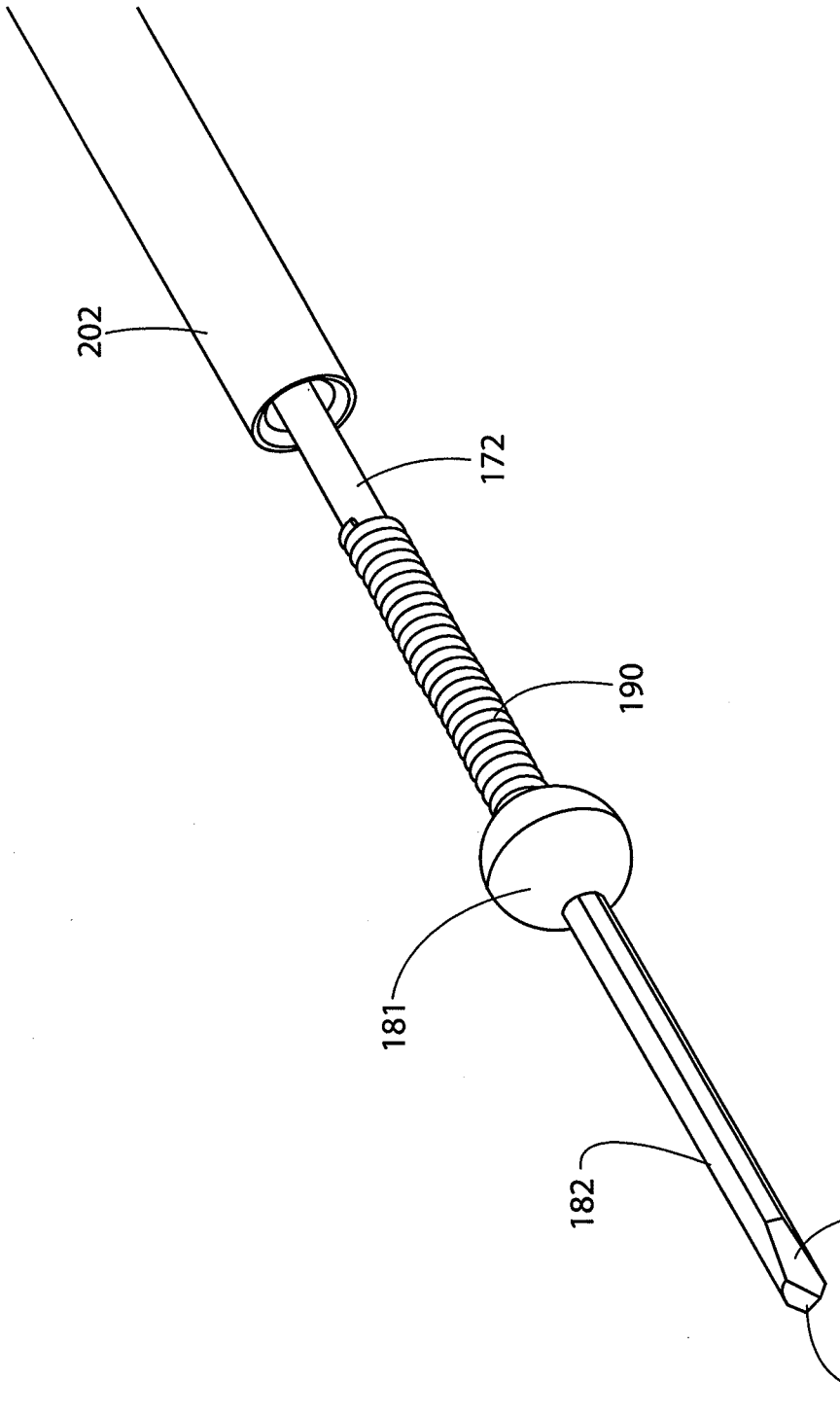

FIG. 1C

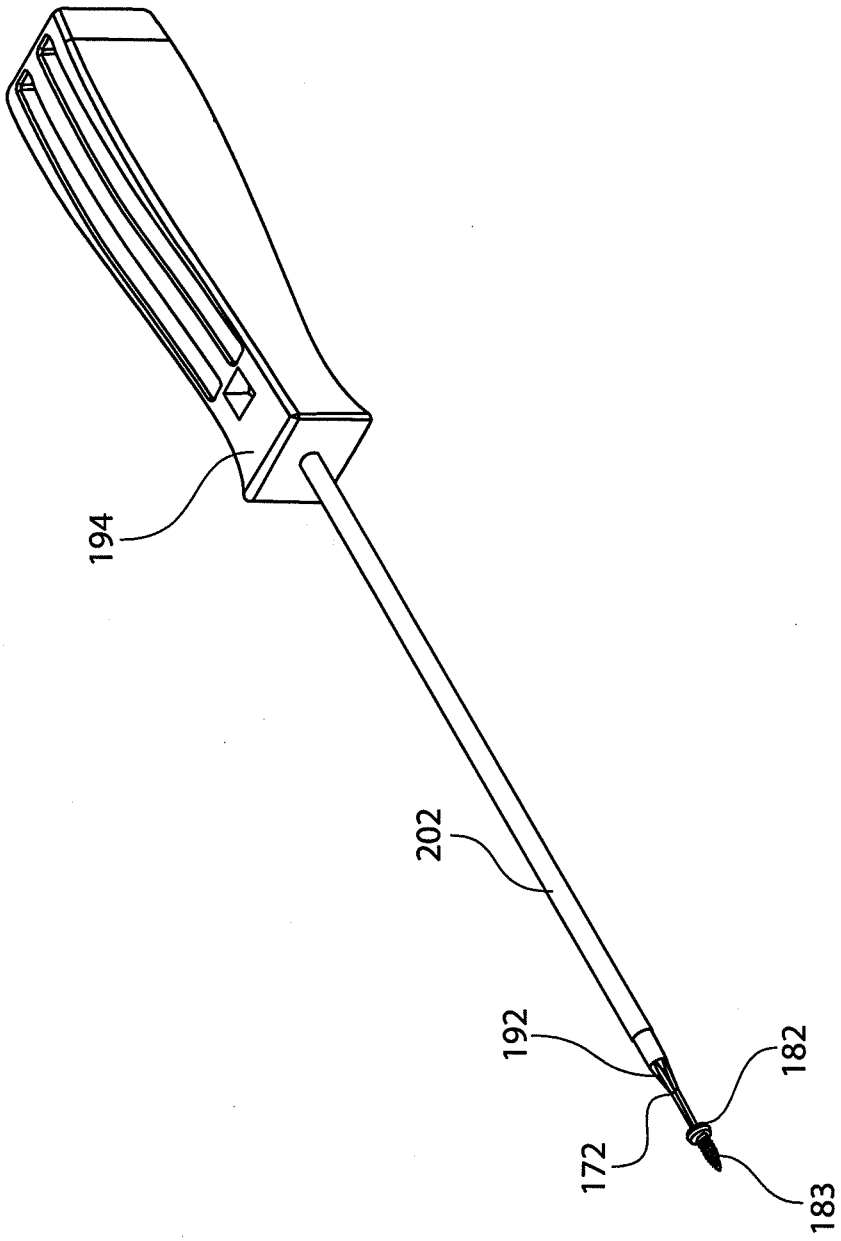

FIG. 1D

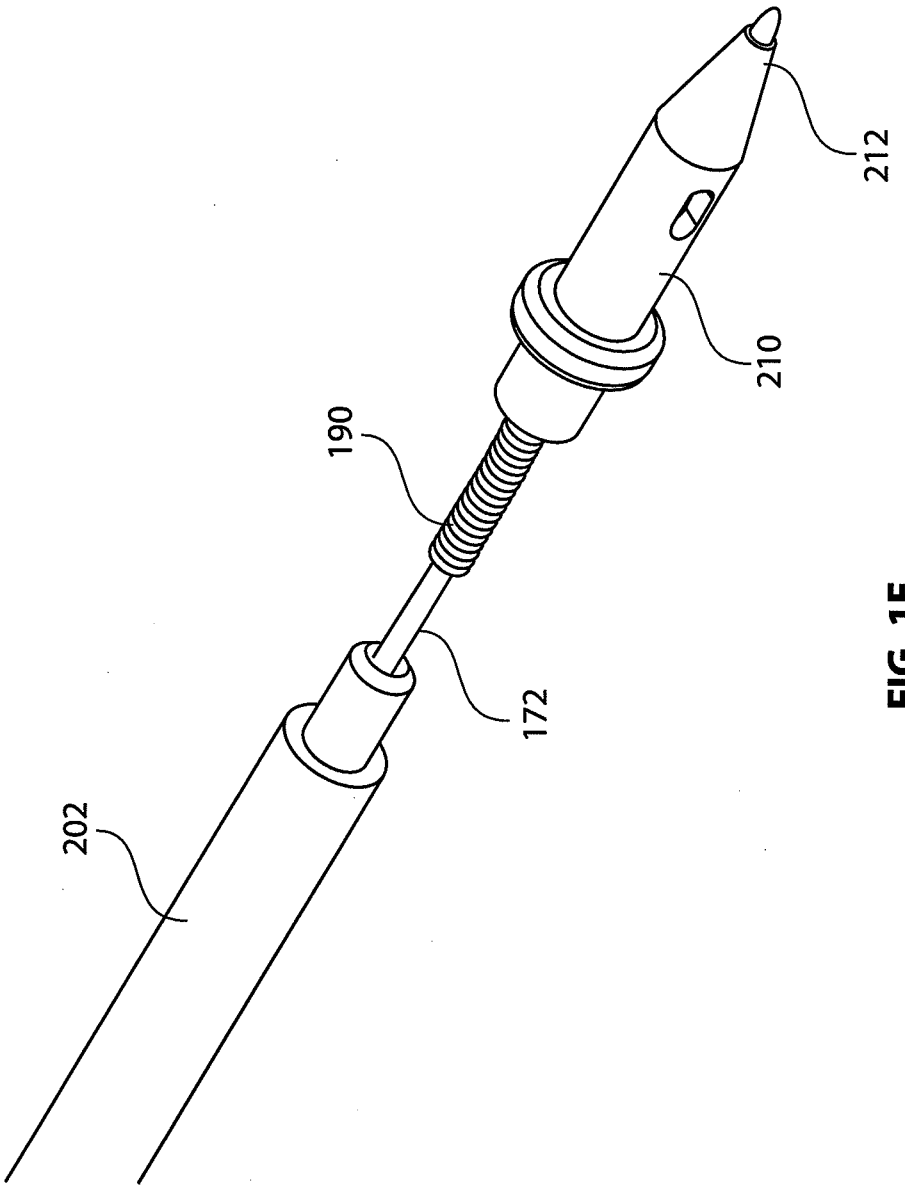

FIG. 1E

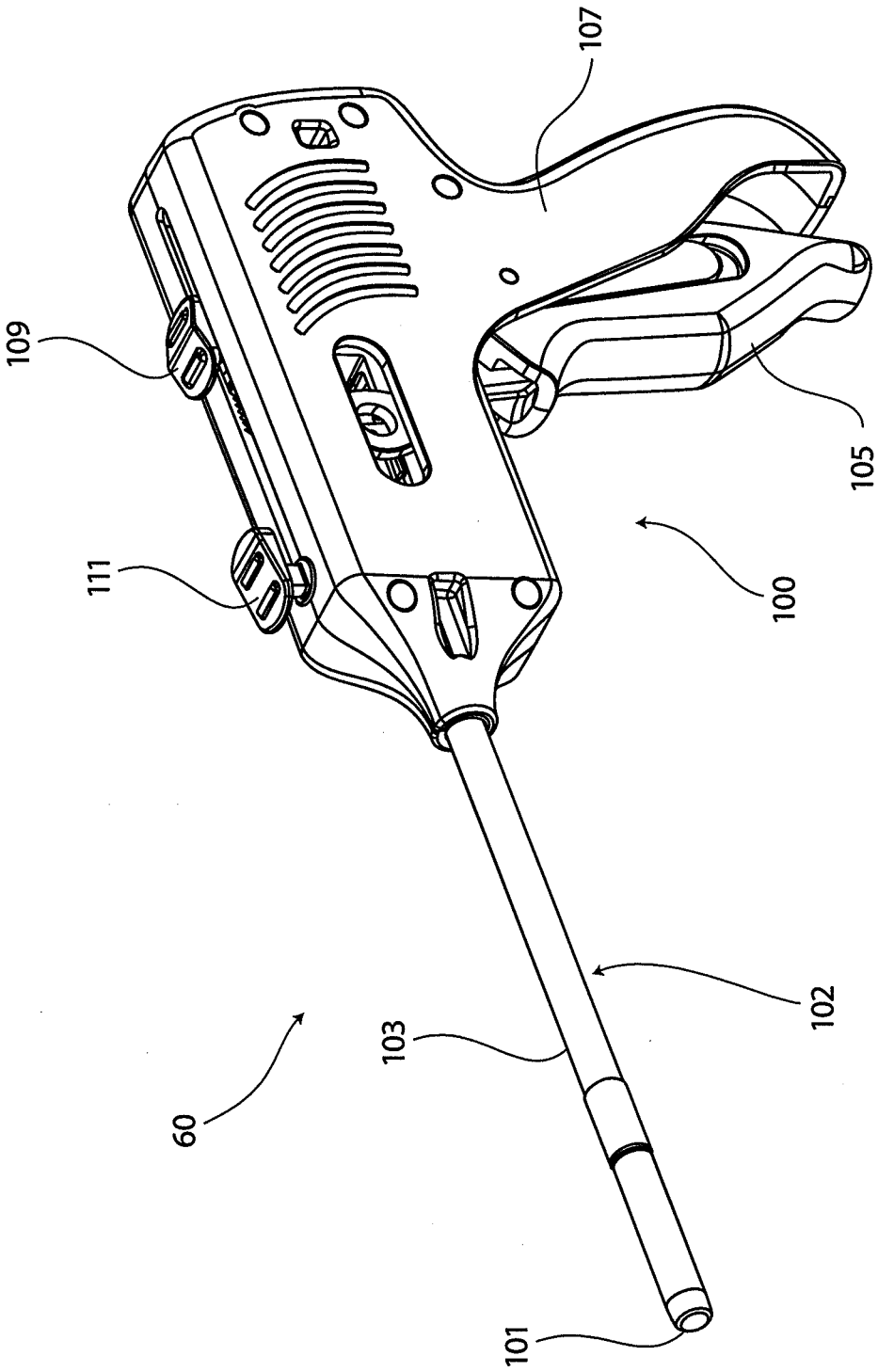

FIG. 2A

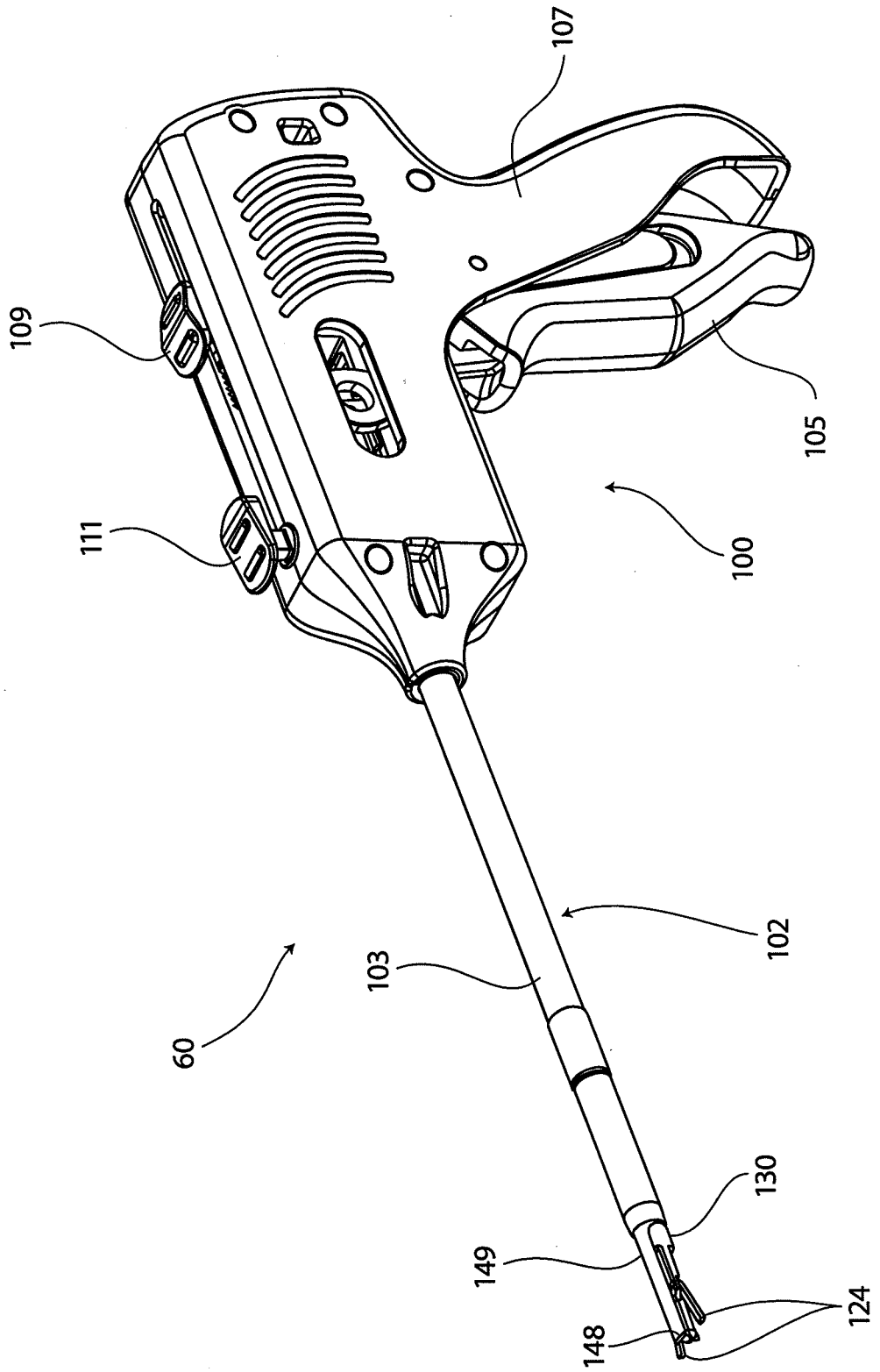

FIG. 2B

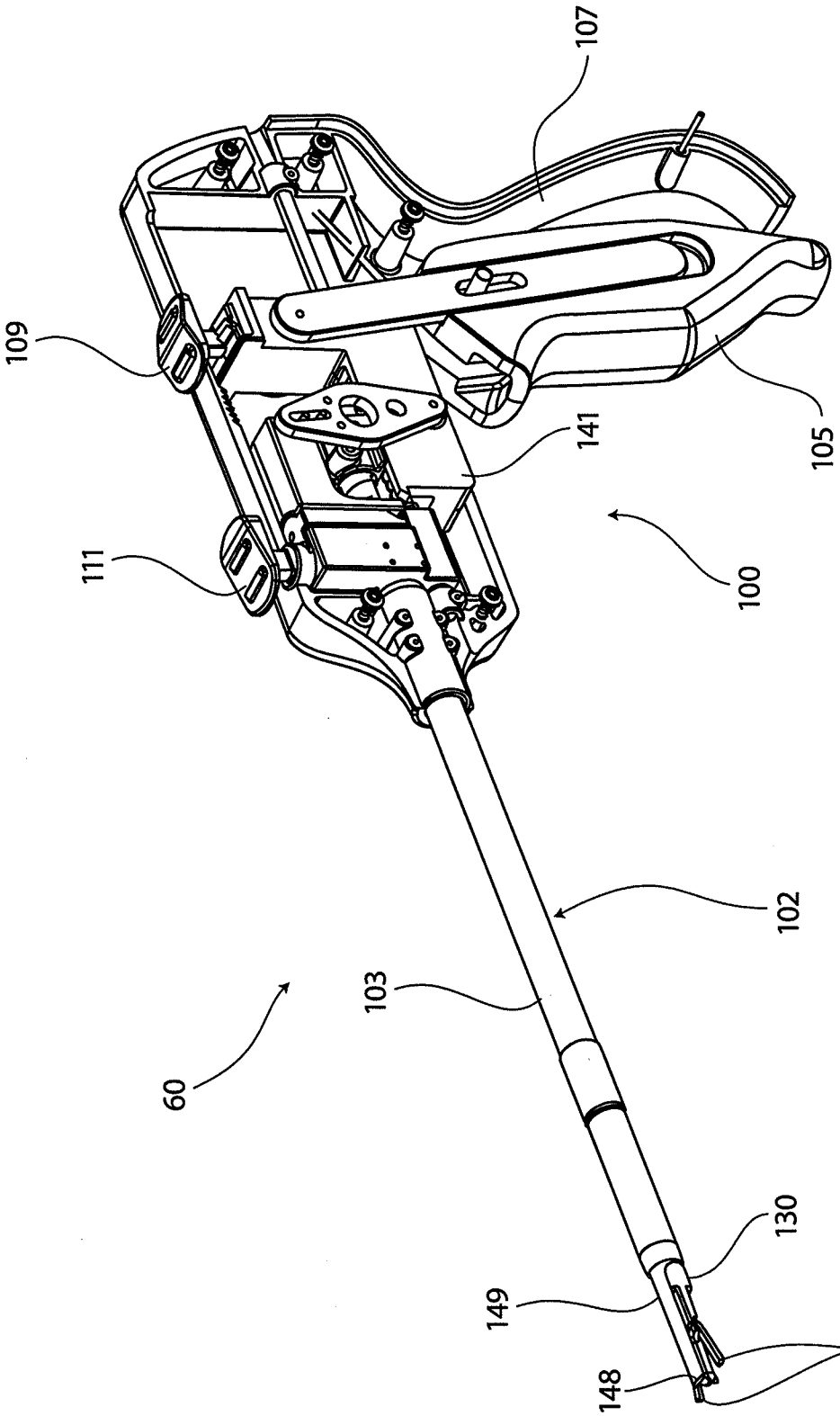

FIG. 2C

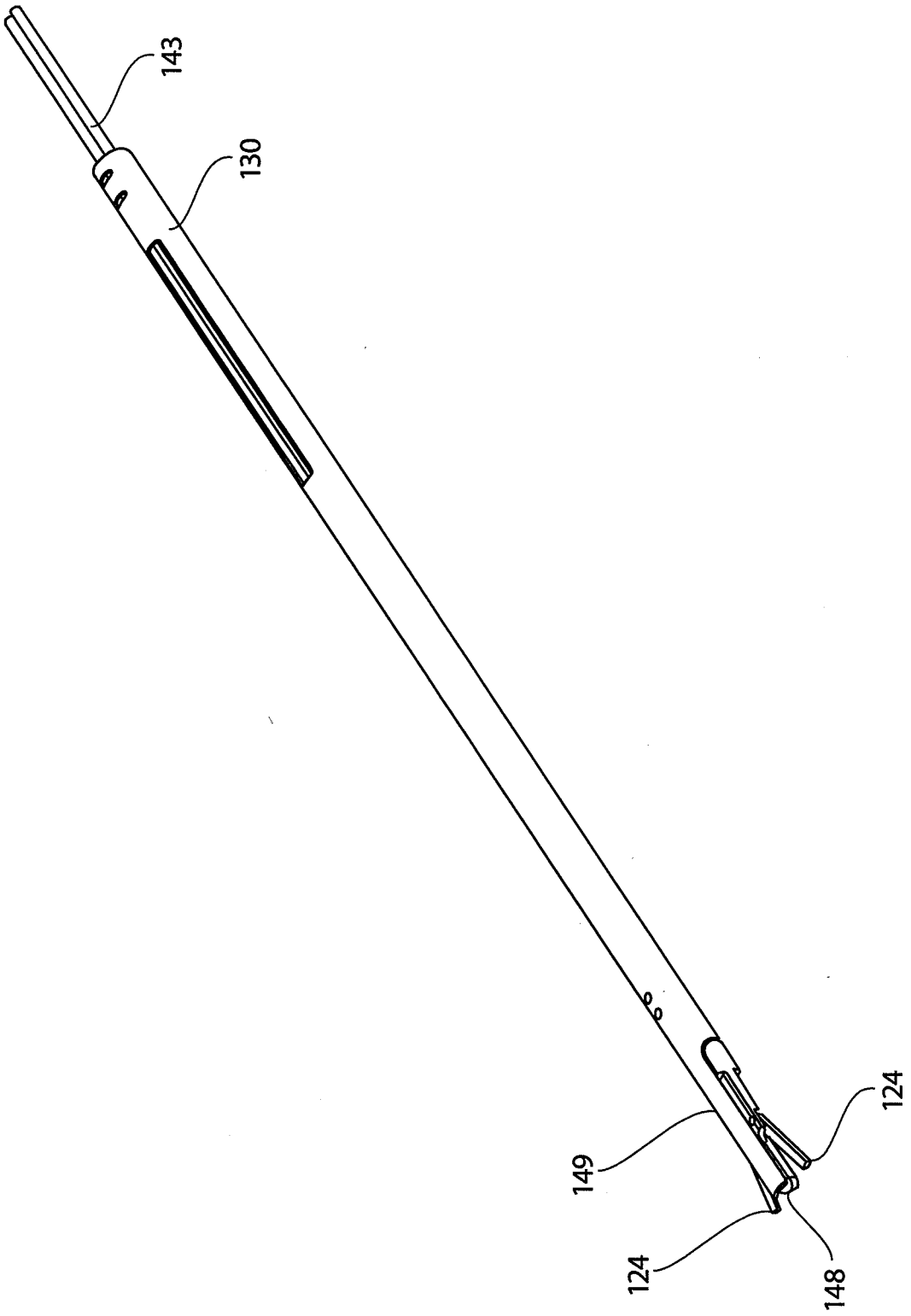

FIG. 2D

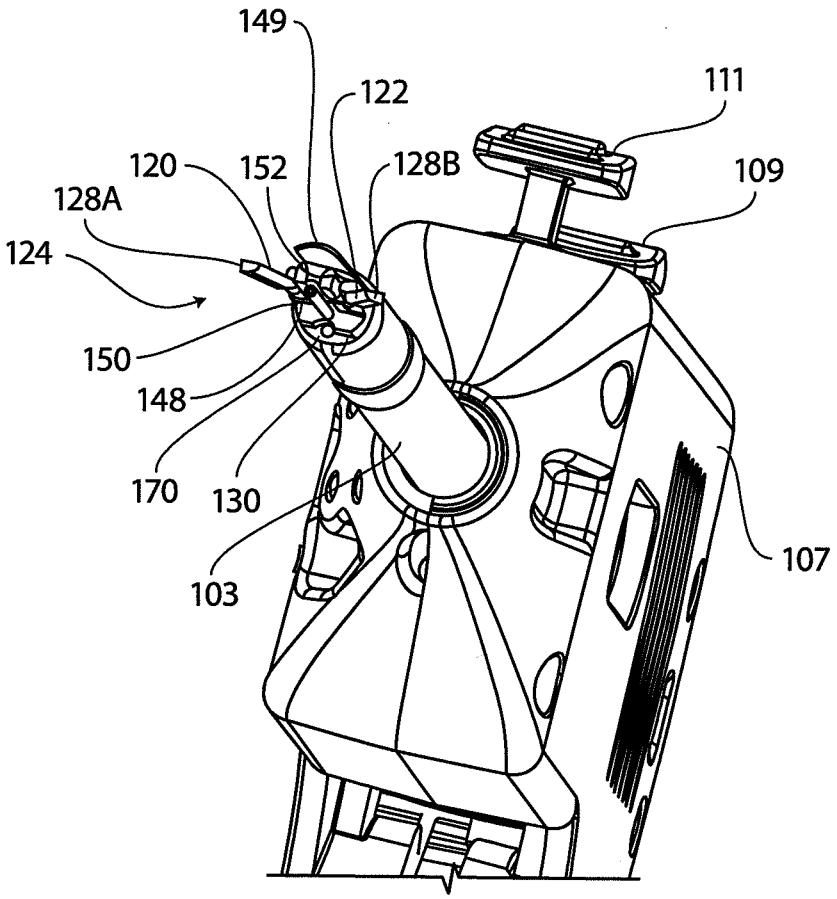

FIG. 2E

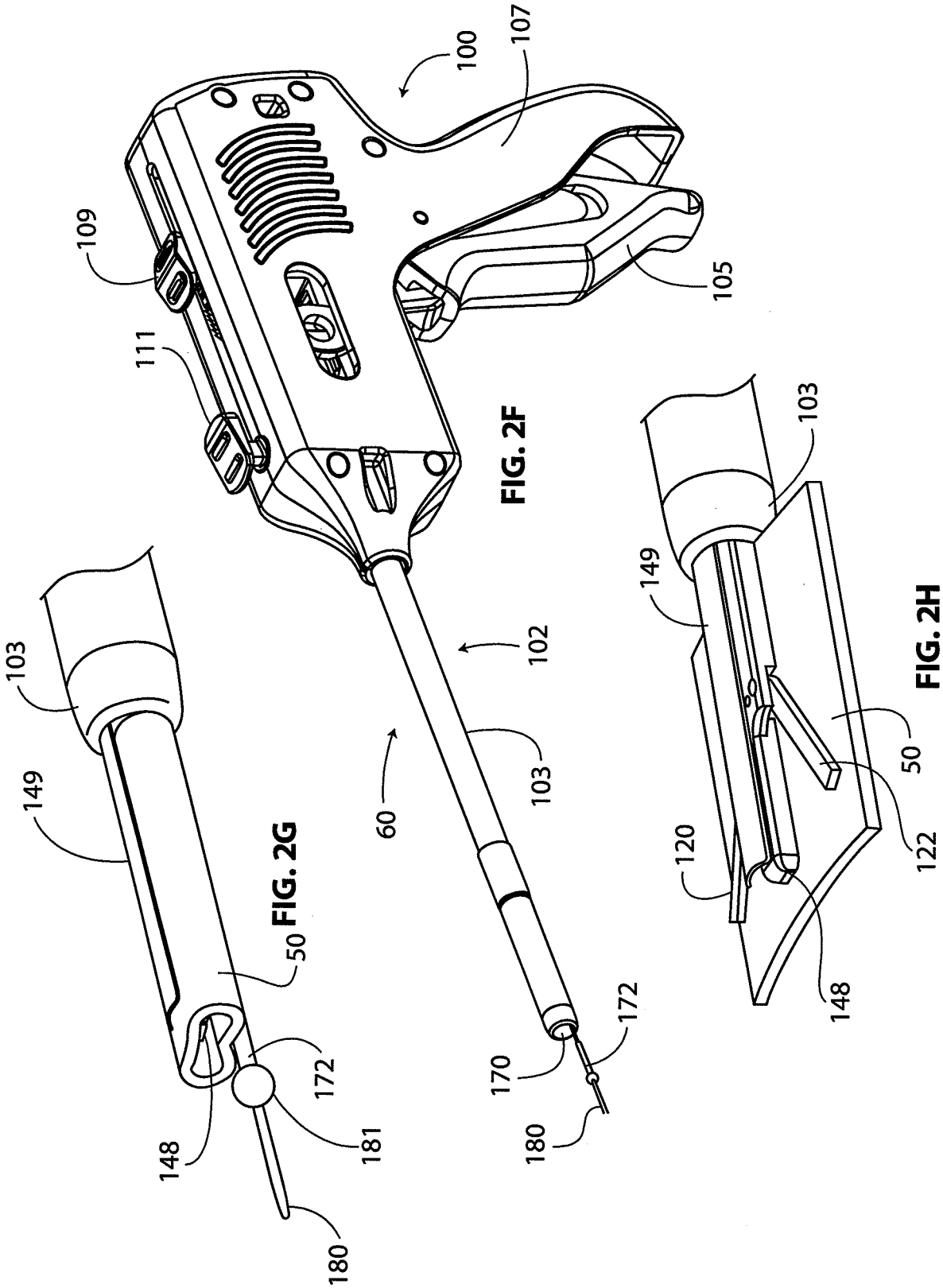

FIG. 2F

FIG. 2G

FIG. 2H

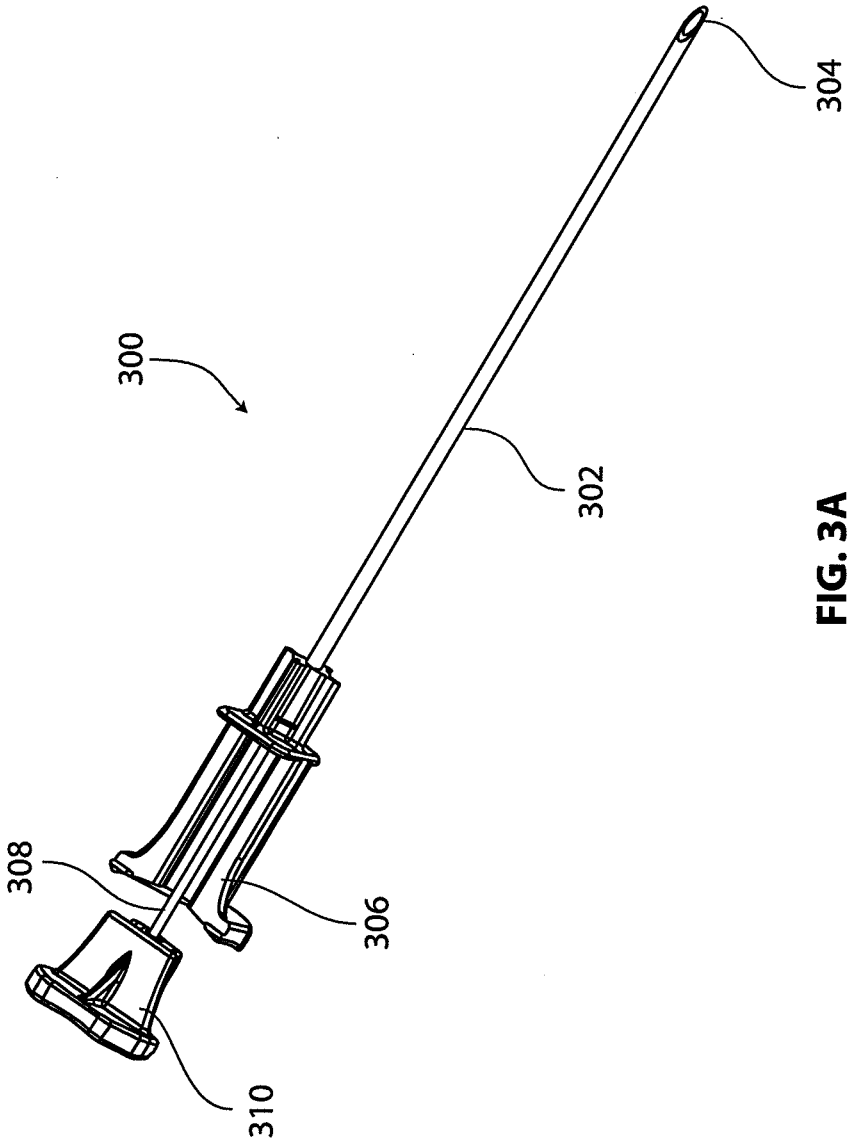

FIG. 3A

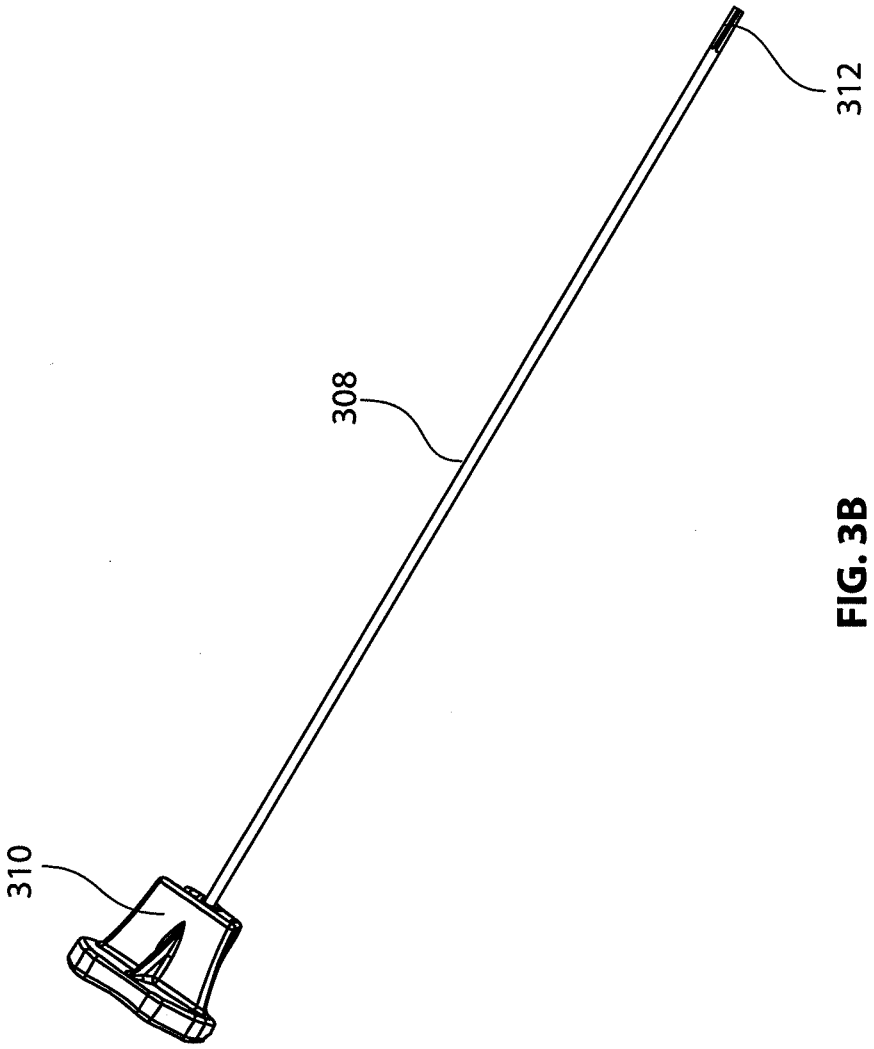

FIG. 3B

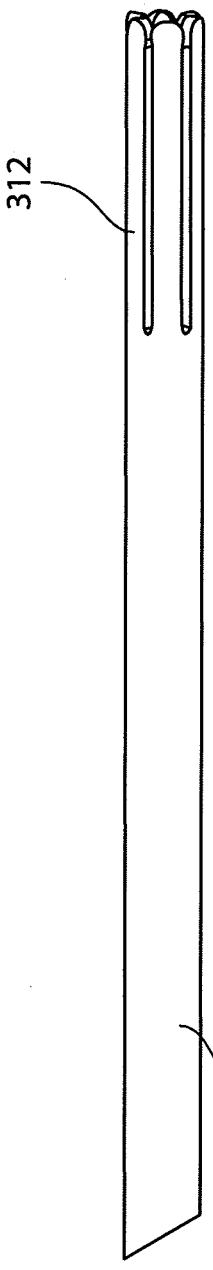

FIG. 3C

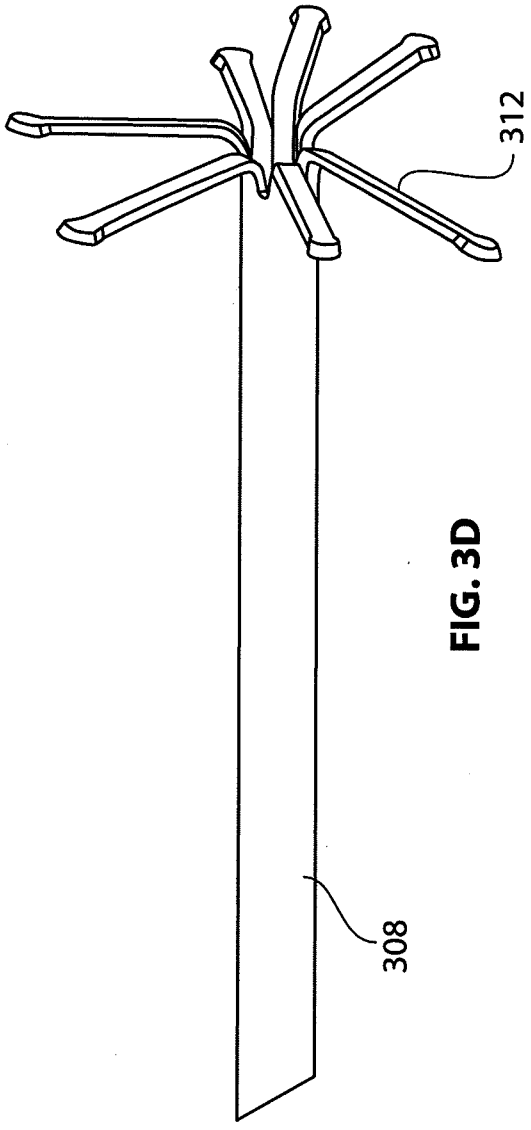

FIG. 3D

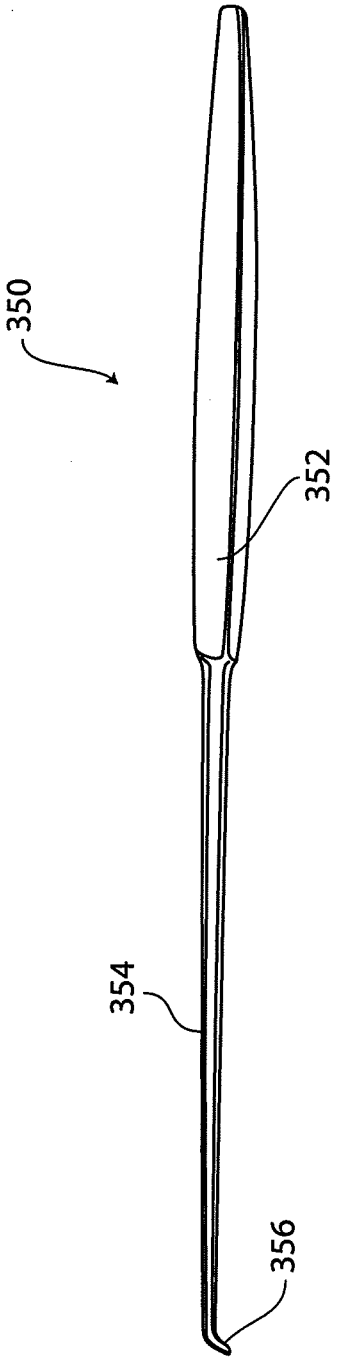

FIG. 4A

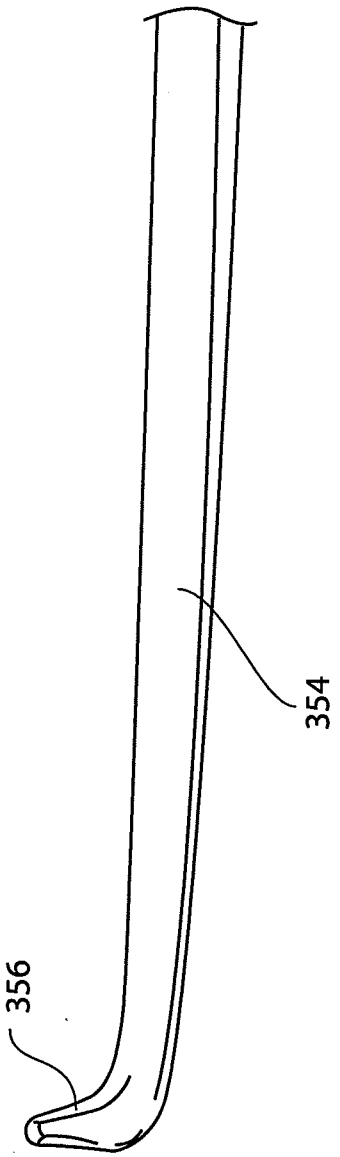

FIG. 4B

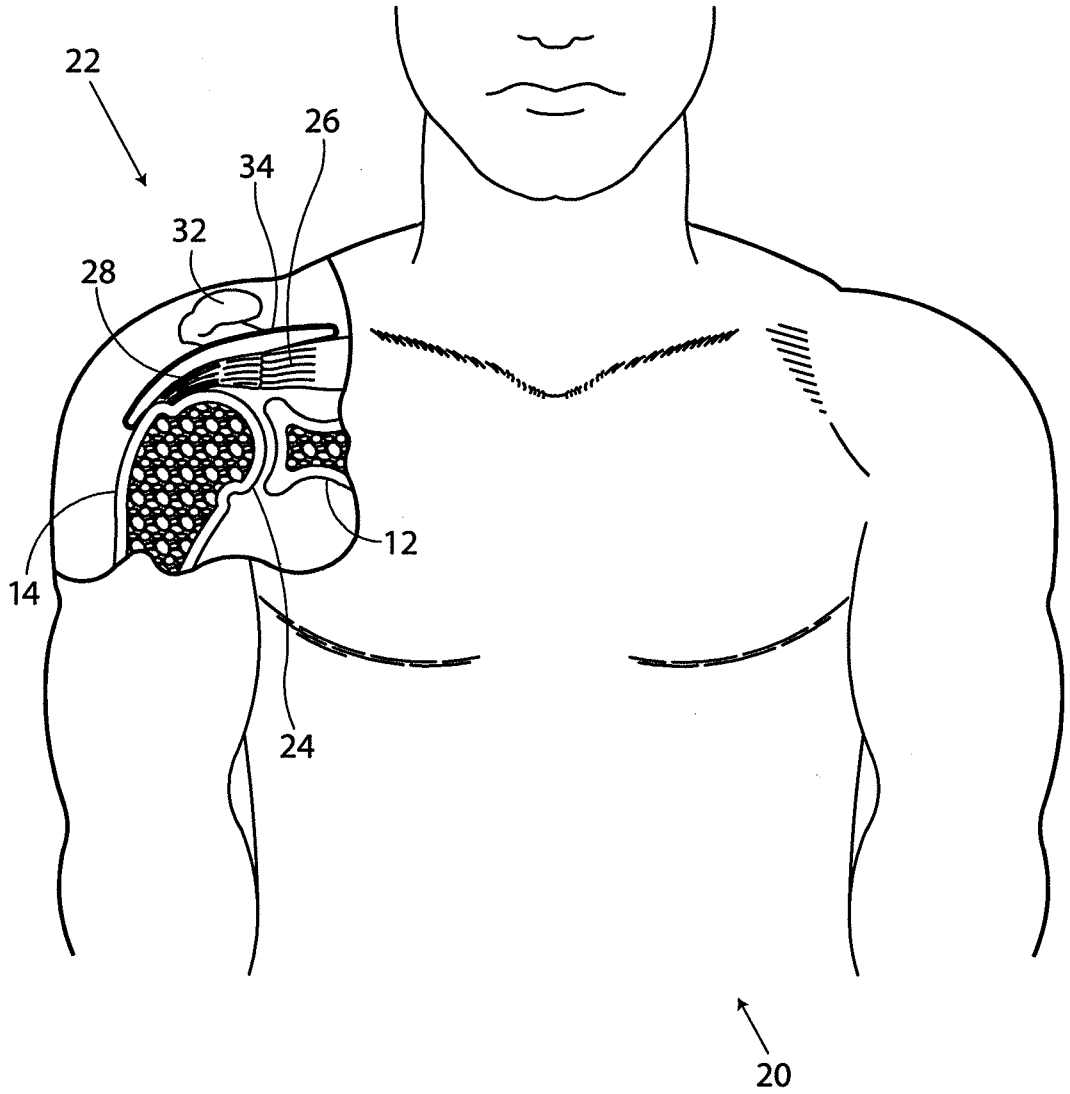

FIG. 5

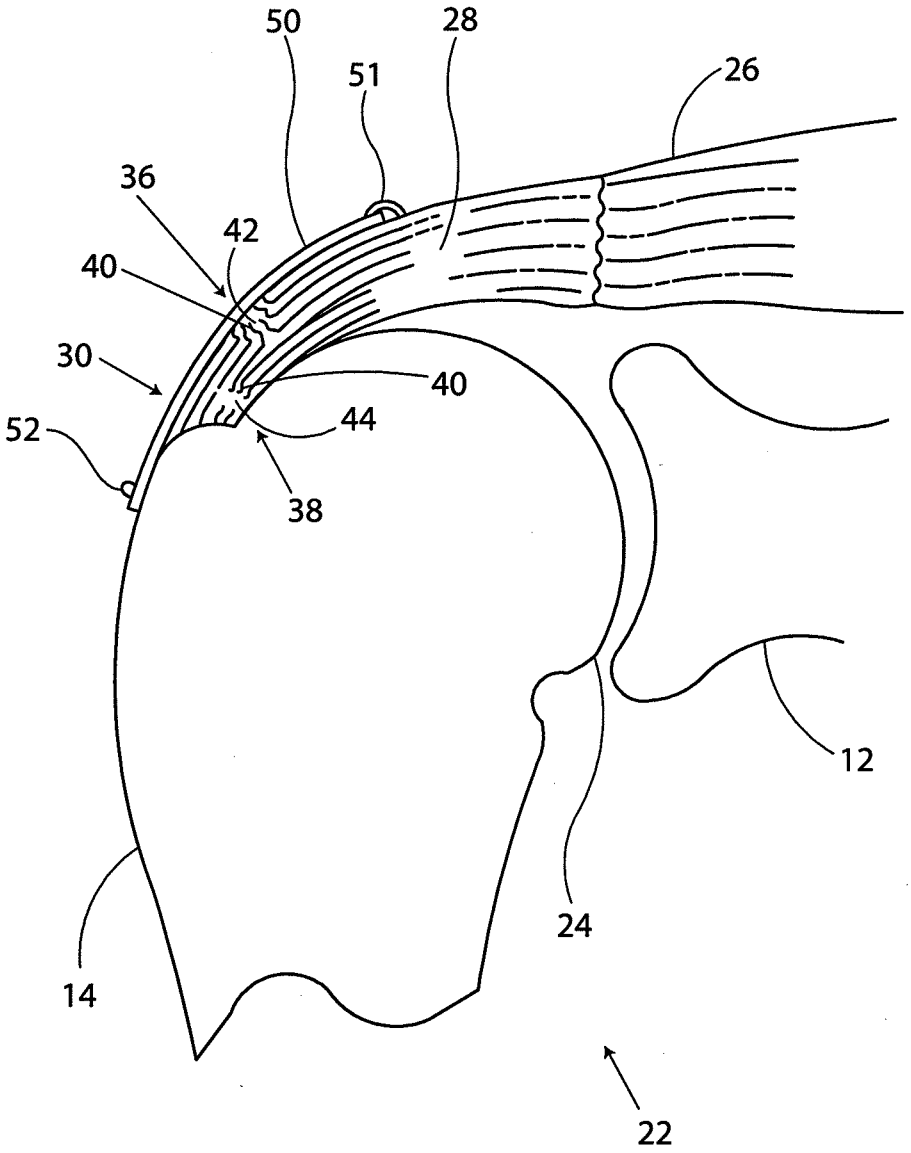

FIG. 6

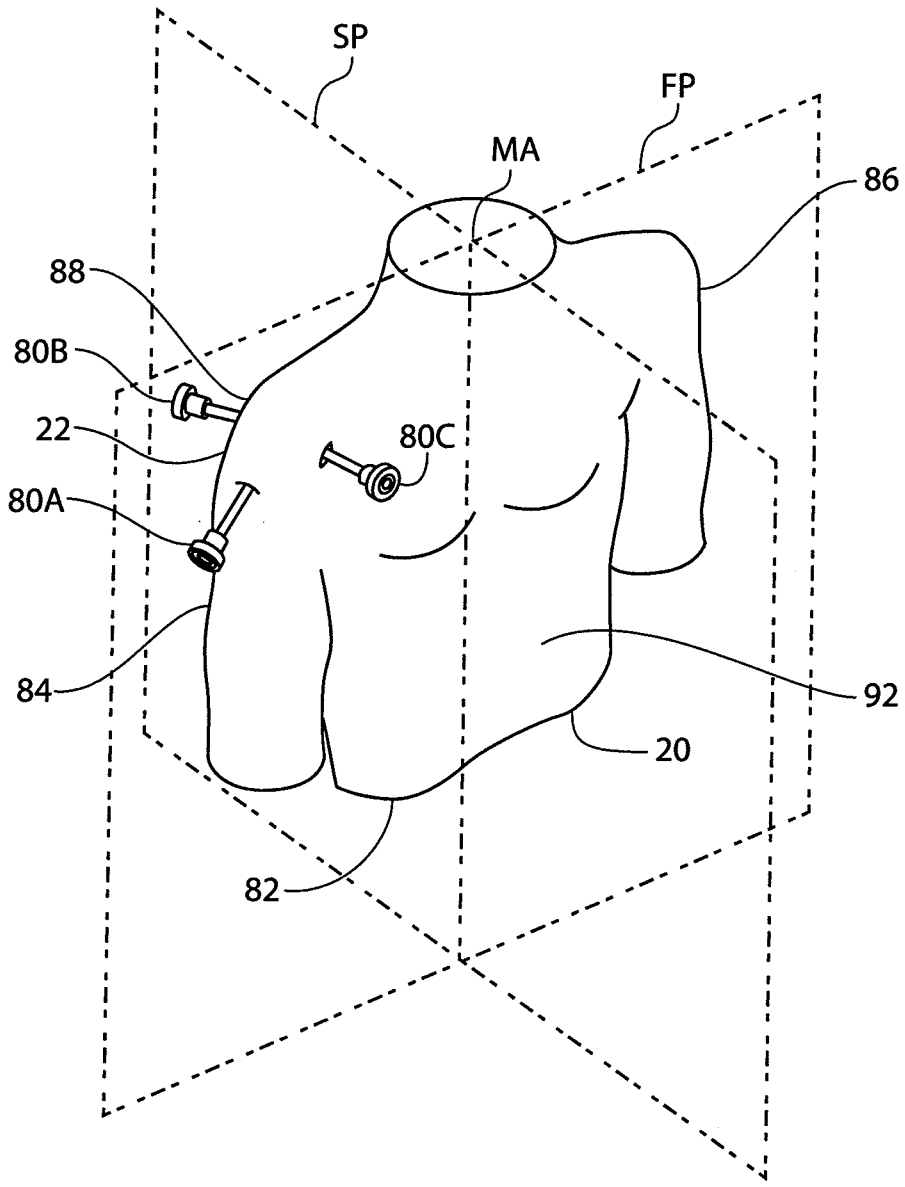

FIG. 7A

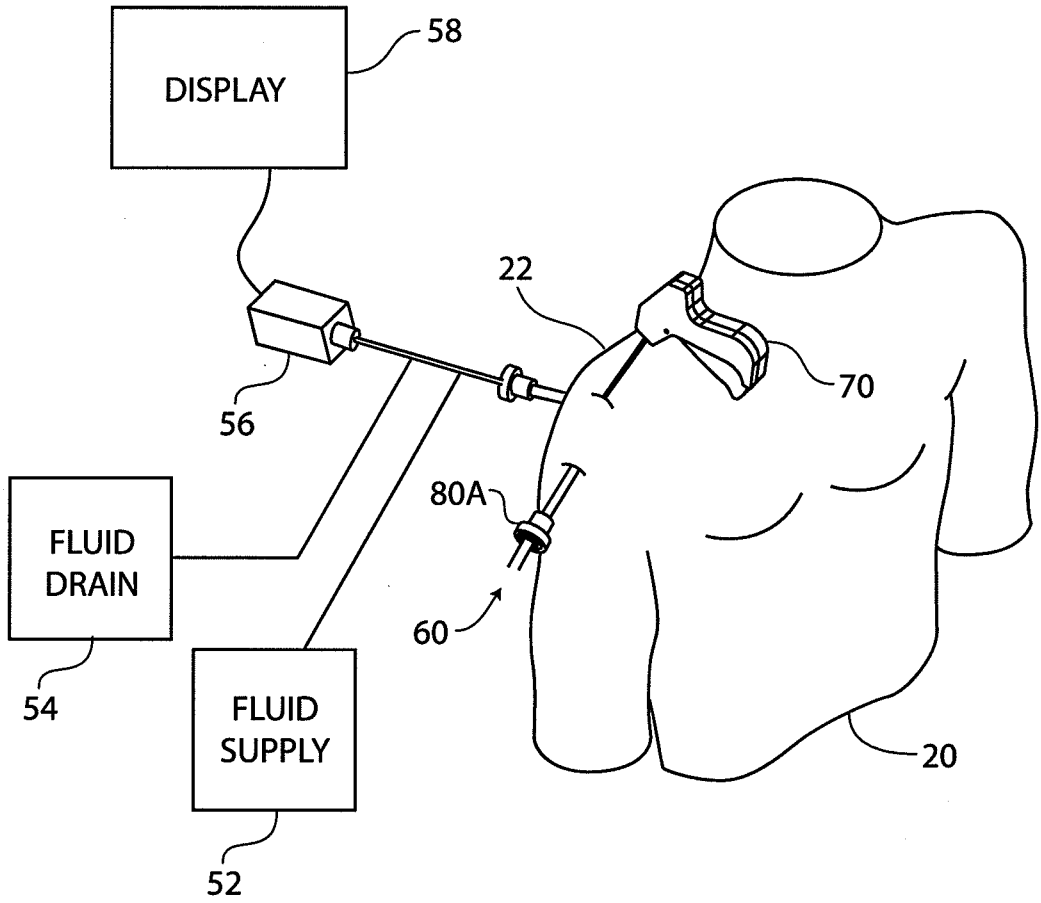

FIG. 7B

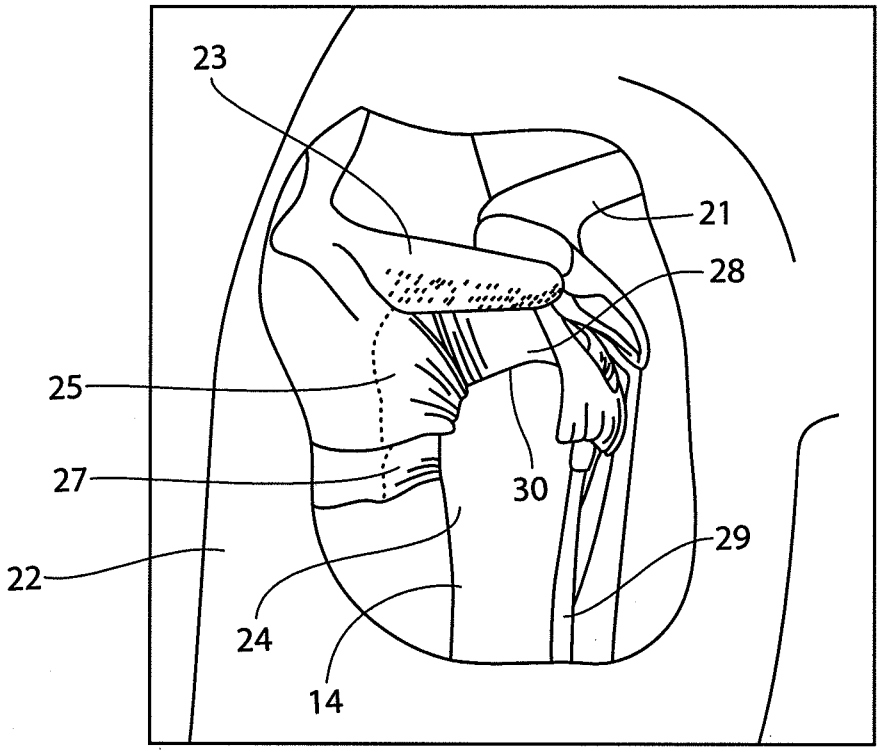

FIG. 8A

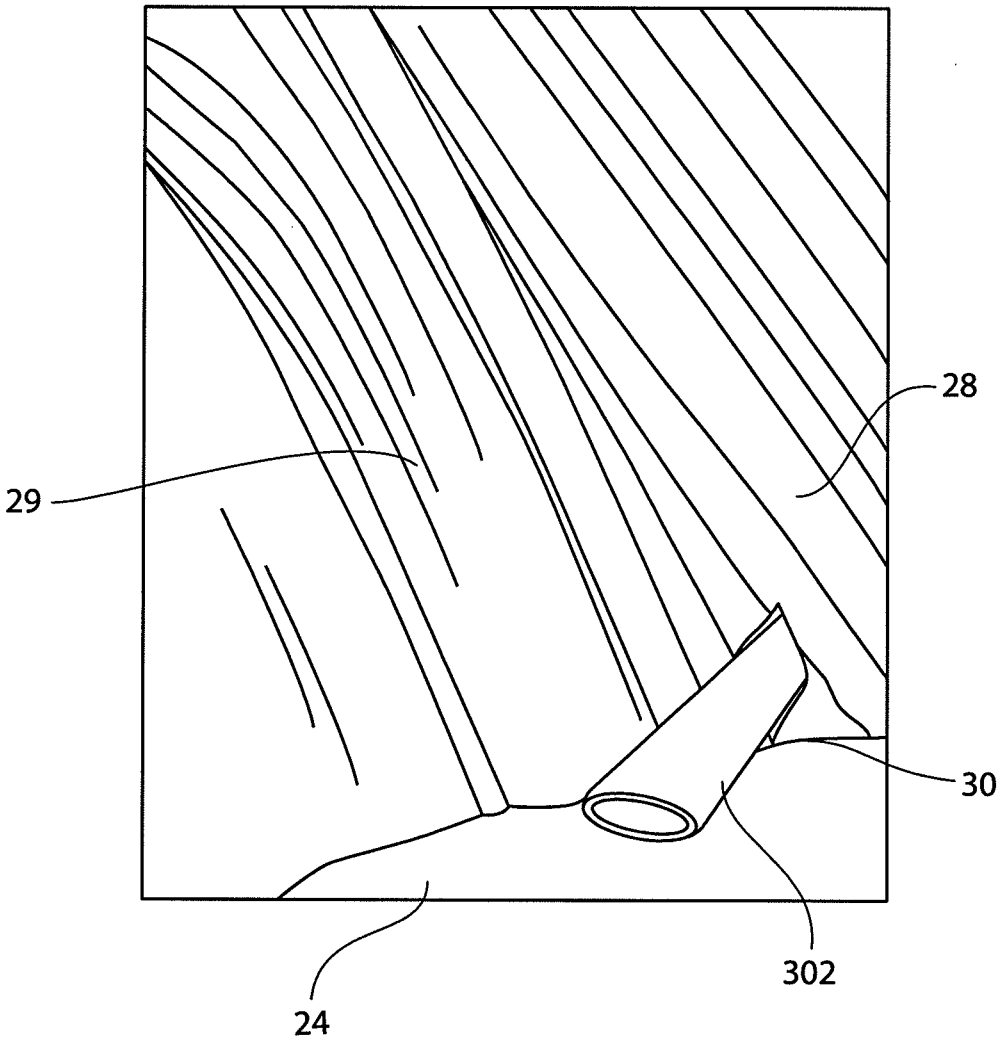

FIG. 8B

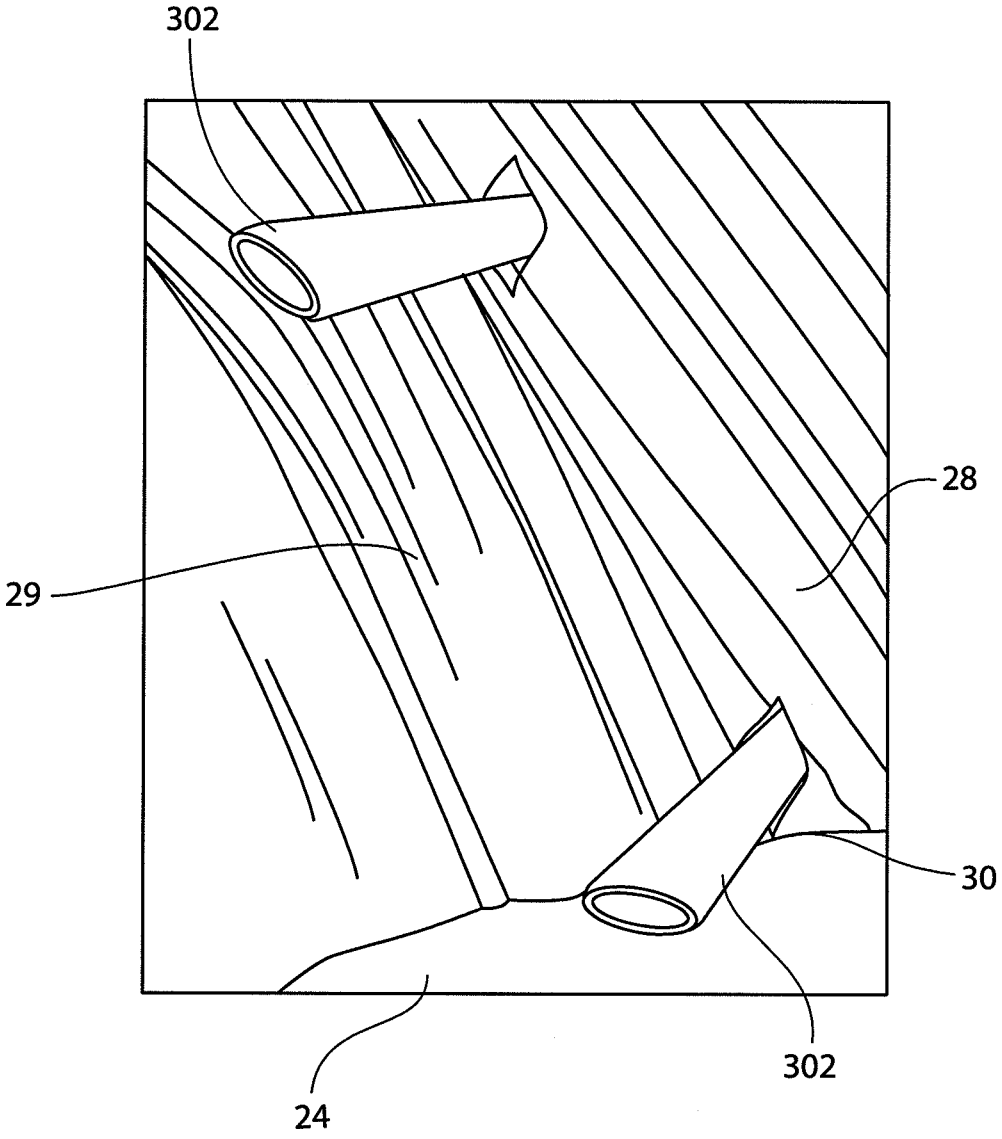

FIG. 8C

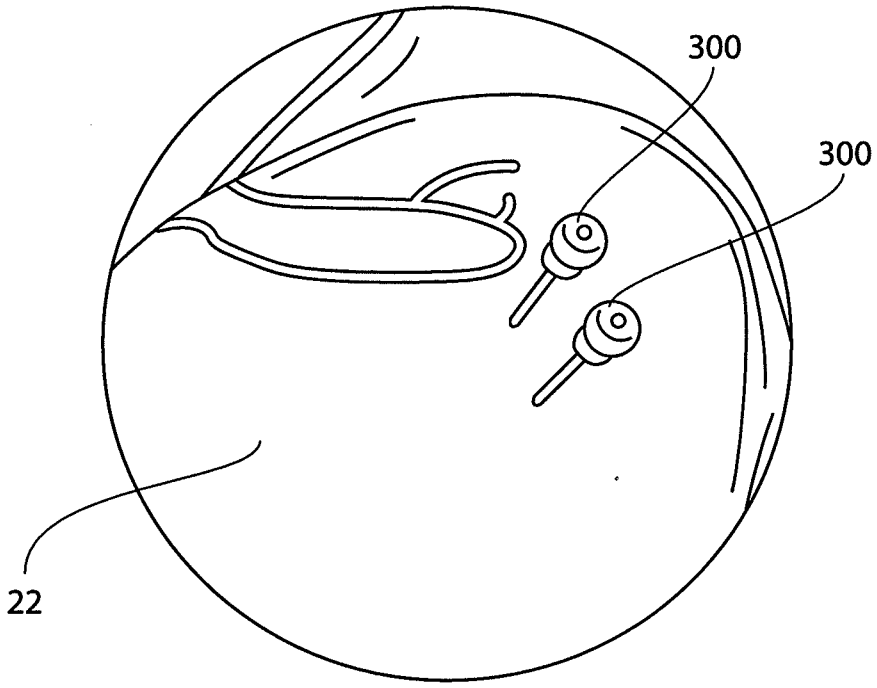

FIG. 8D

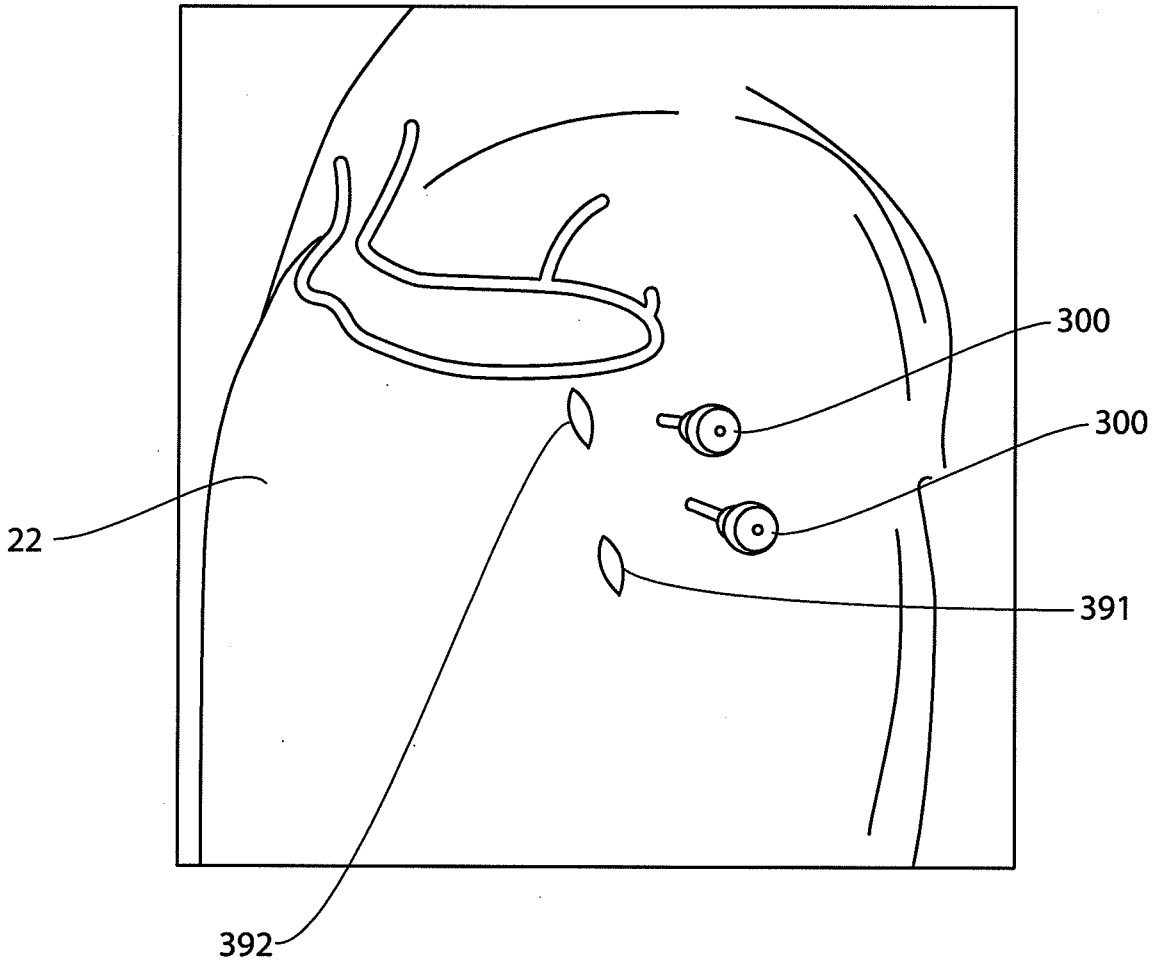

FIG. 8E

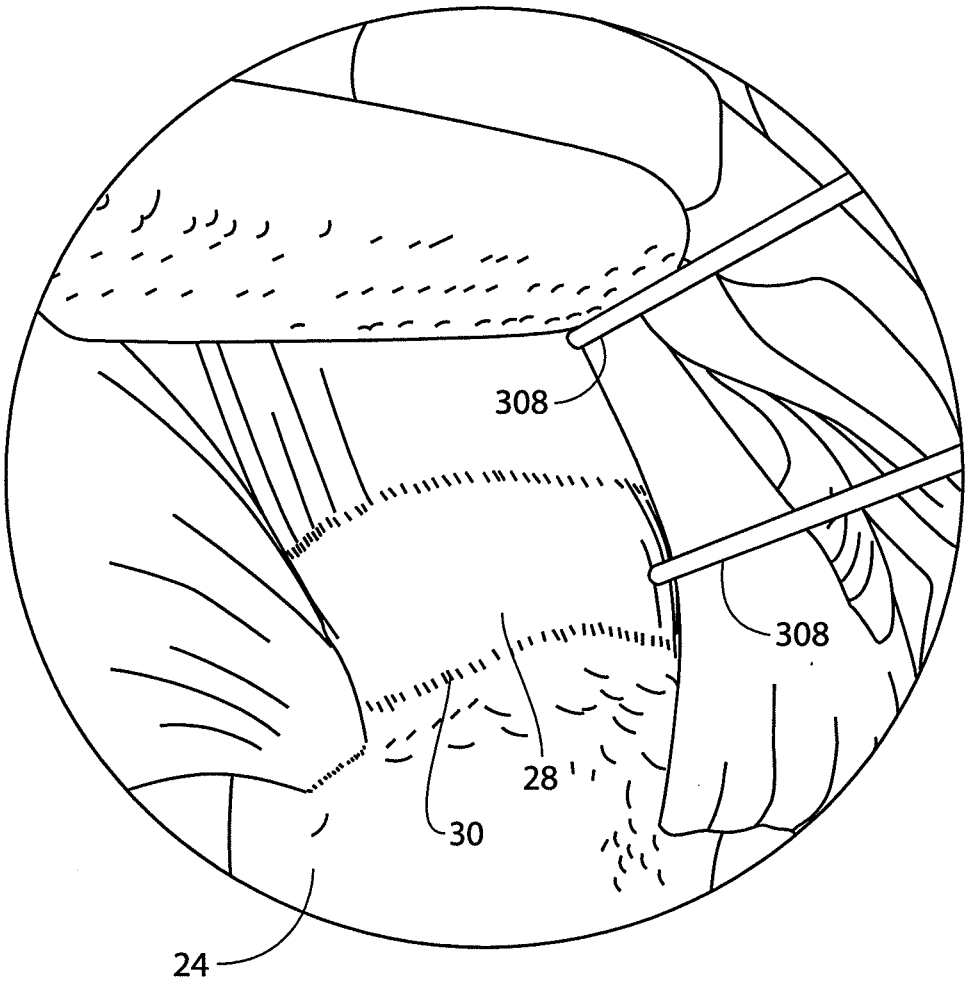

FIG. 8F

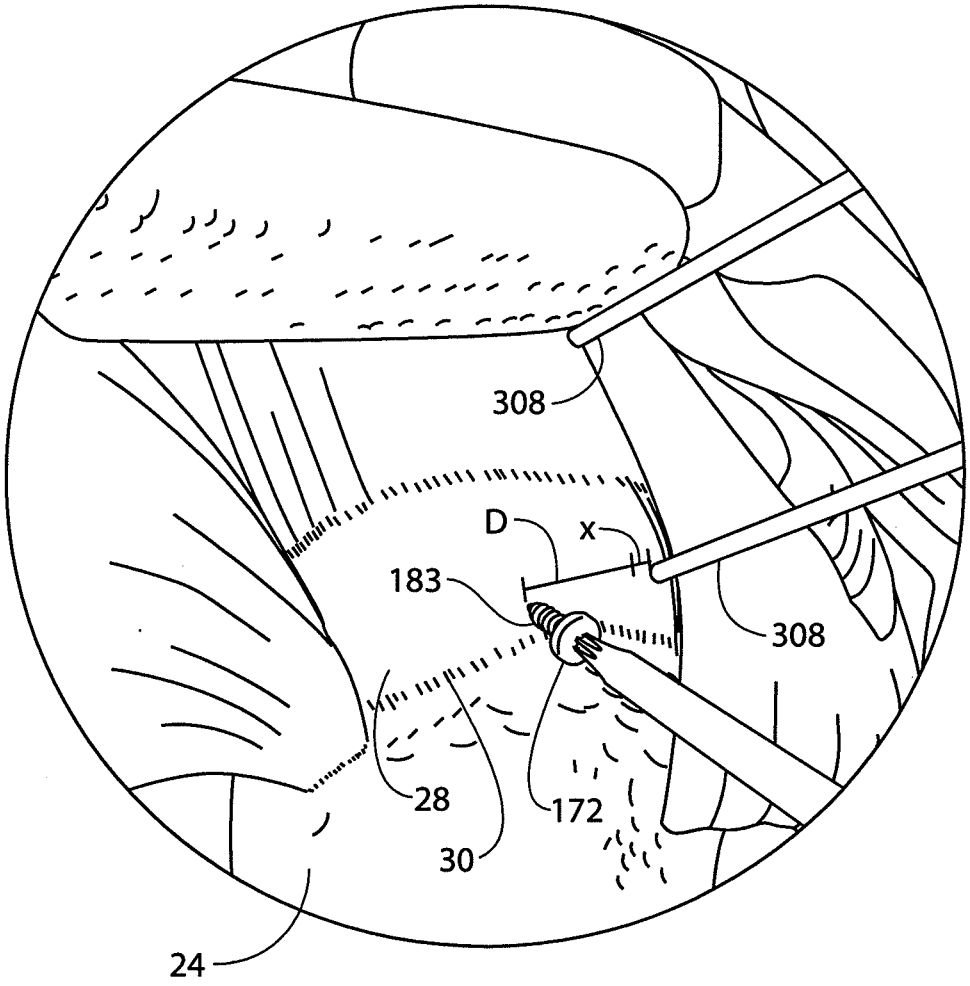

FIG. 8G

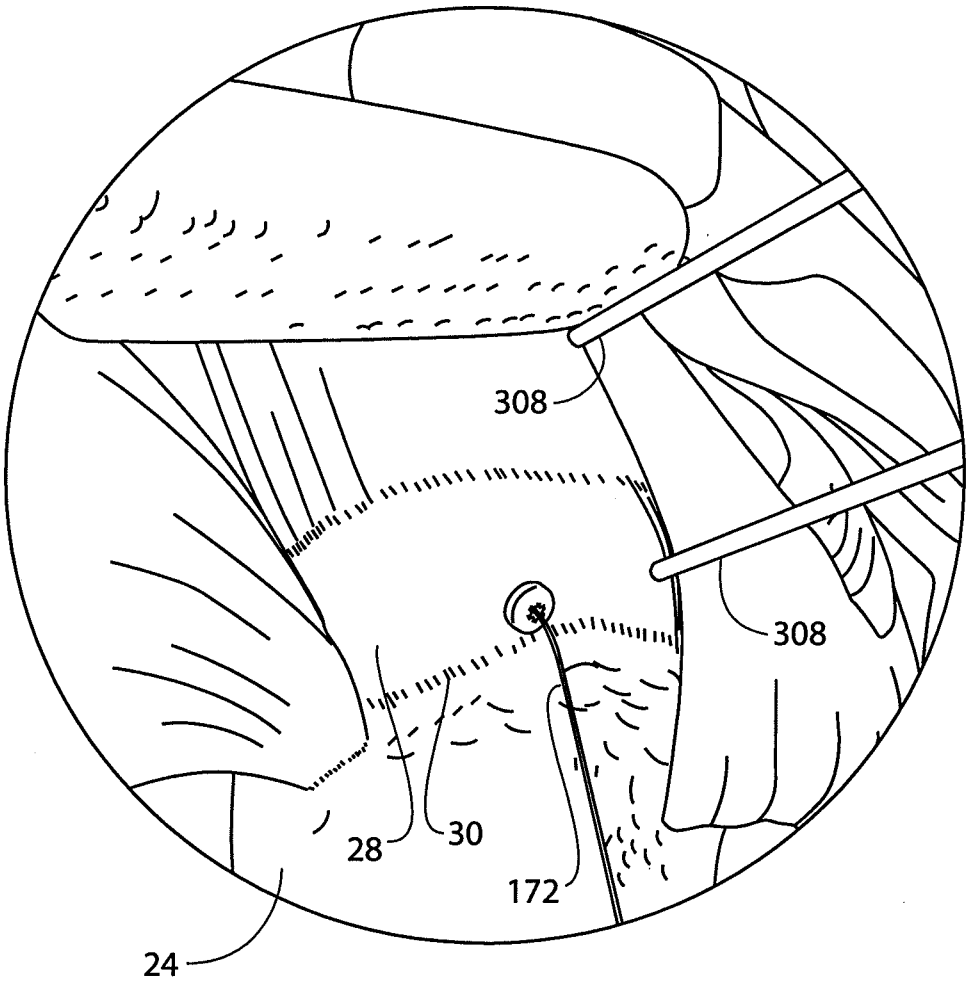

FIG. 8H

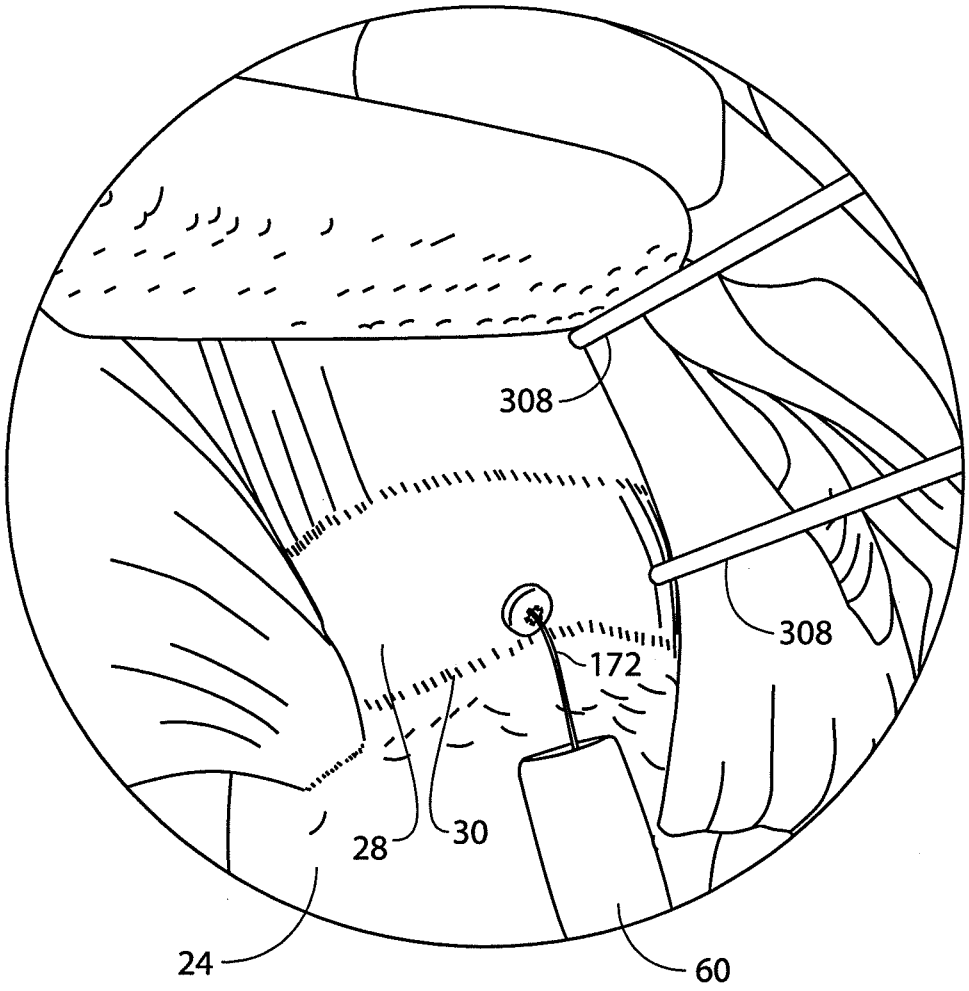

FIG. 8I

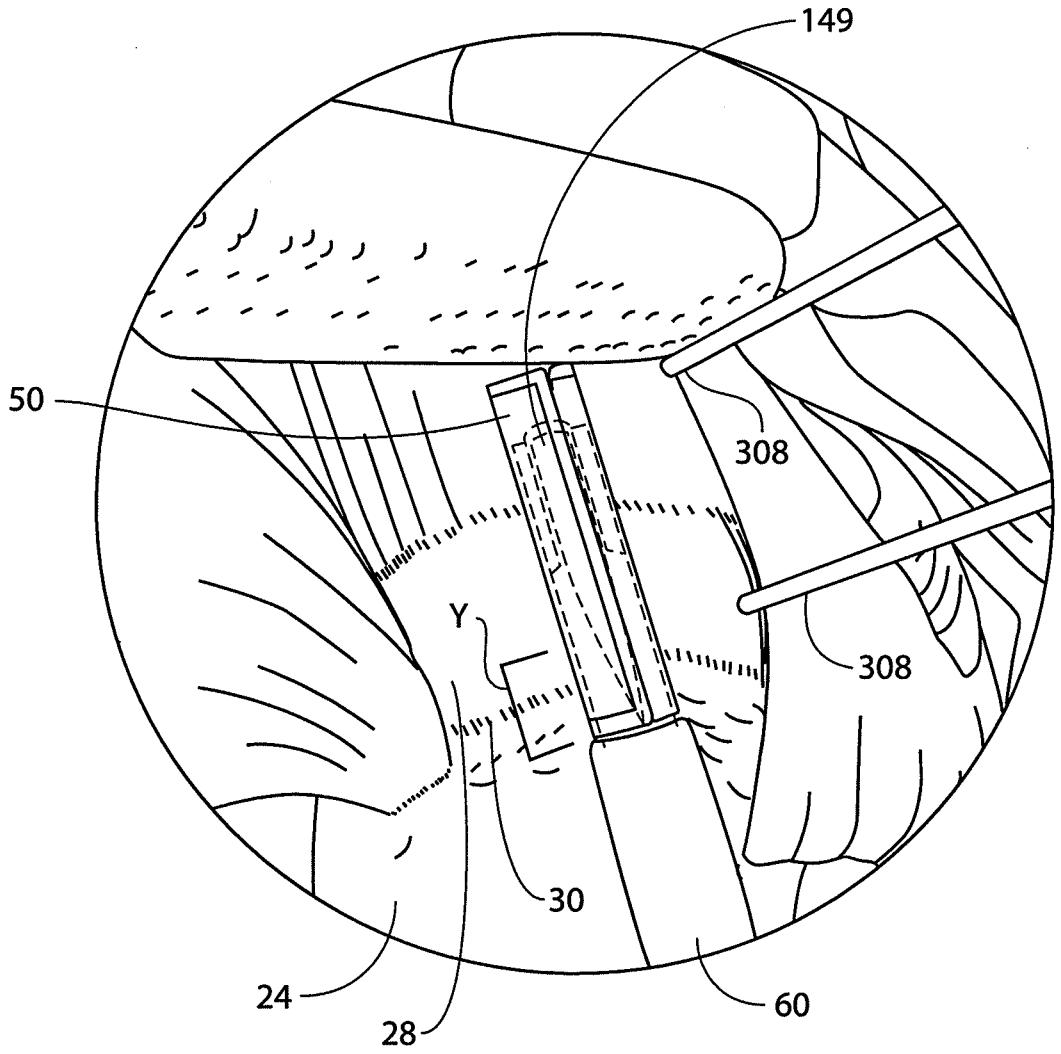

FIG. 8J

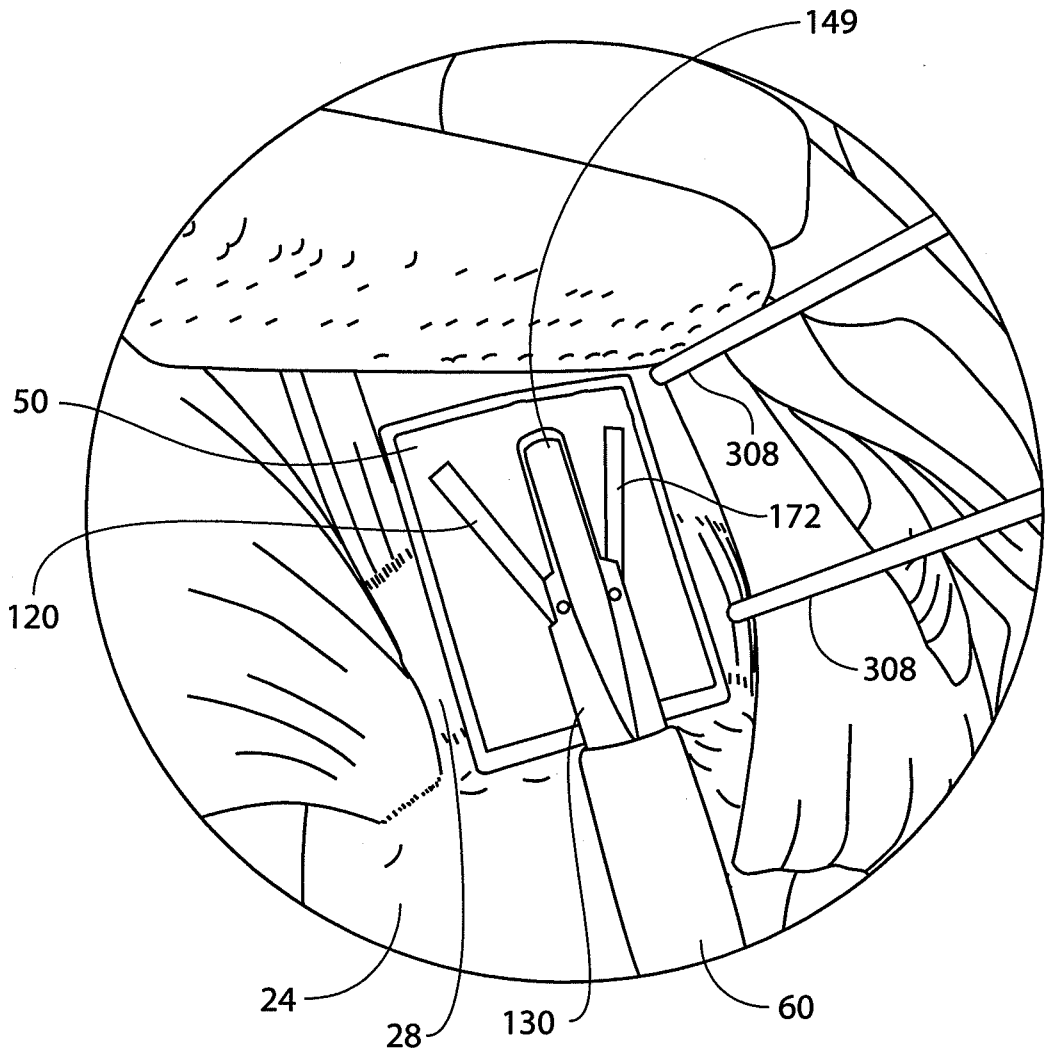

FIG. 8K

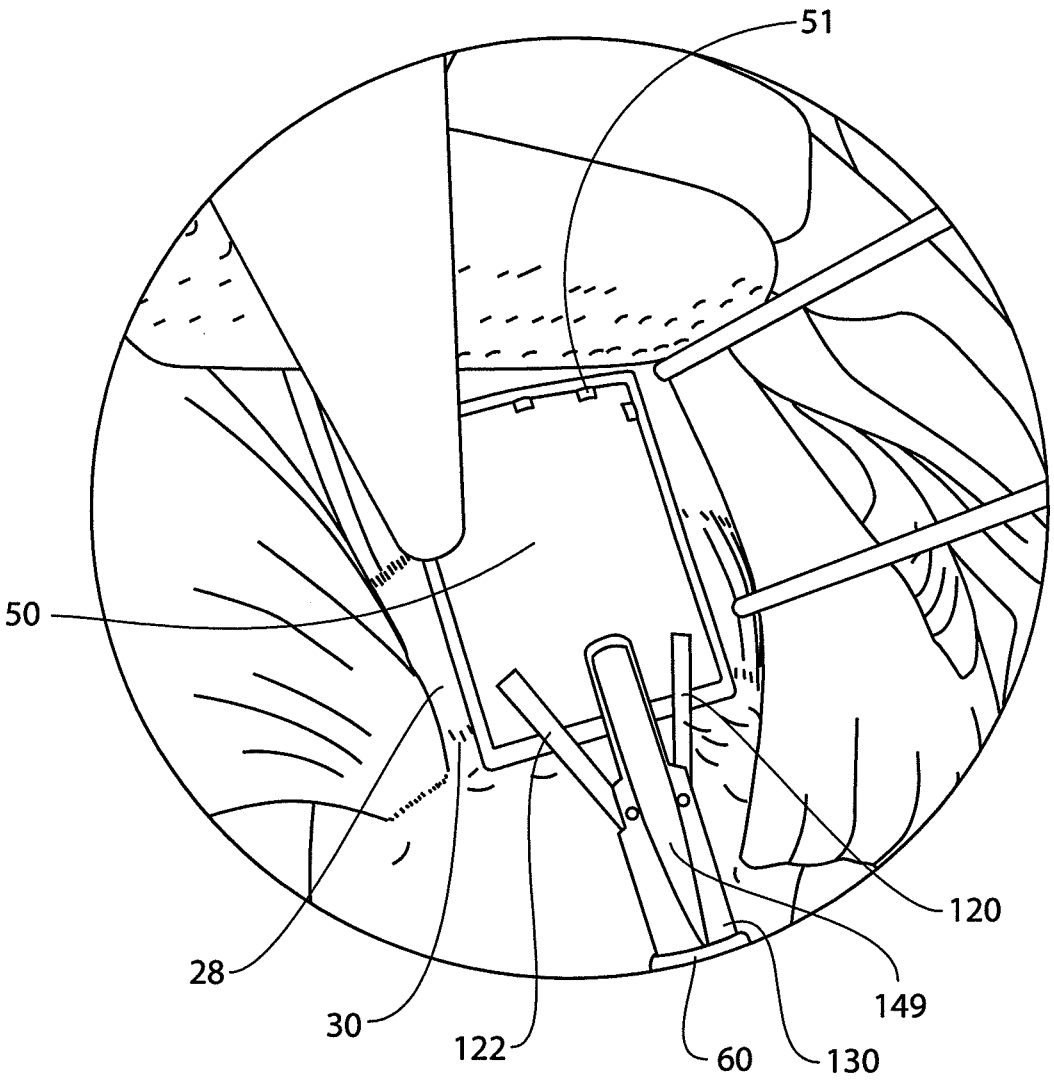

FIG. 8L

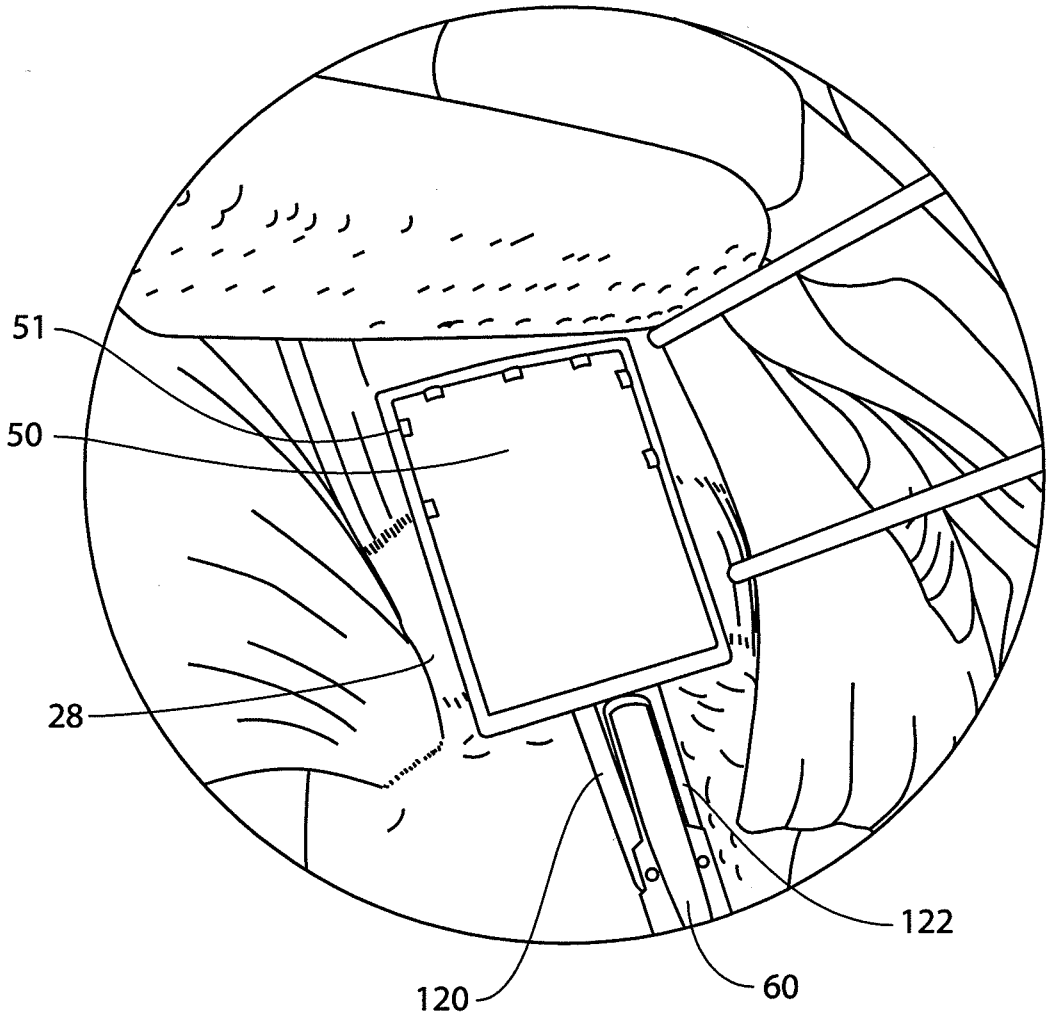

FIG. 8M

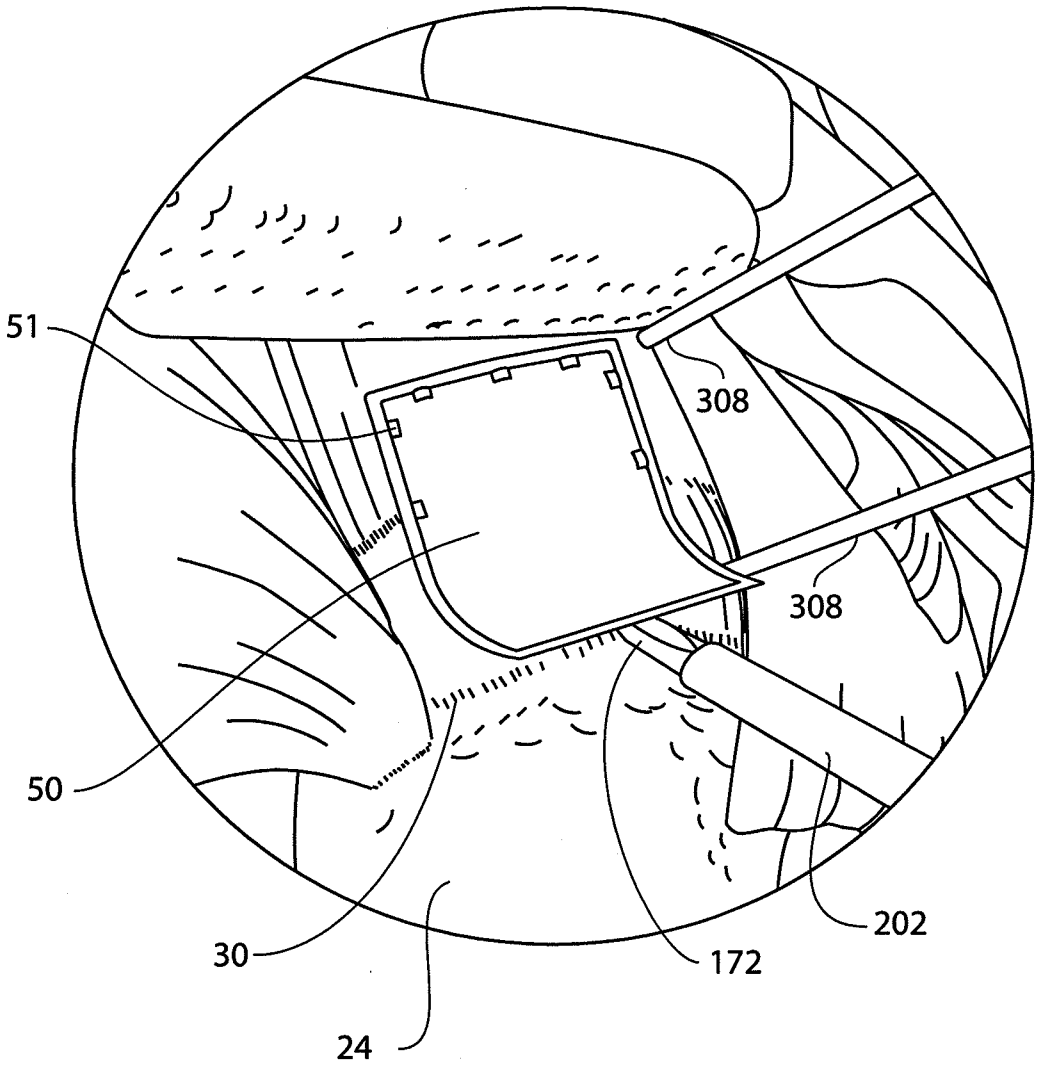

FIG. 8N

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/070845

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/84 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)
A61B 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 practicable, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/241227 Al (EUTENEUER CHARLES L [US] ET AL) 23 September 2010 (2010-09-23) paragraph [0022] - paragraph [0032] ; figures 1, 2	1-16
X	US 2011/264149 Al (PAPPALARD0 DANA [US] ET AL) 27 October 2011 (2011-10-27)	1-8
A	paragraph [0114] - paragraph [0117] ; figures 6a, b	13-16
X	US 2004/167519 Al (WEI NER L0N S [US] ET AL) 26 August 2004 (2004-08-26) abstract; figure 4	1
X	EP 0 298 400 Al (WASSERSTEIN ISID0R) 11 January 1989 (1989-01-11) column 3, line 17 - line 48; figures 1, 2	1,5

-/- .

[X] Further documents are listed in the continuation of Box C.

[X] 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 application or patent but published on or after the international filing date

"L" documentwhich may throw doubts on priority claim(s) orwhich is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 March 2013	08/04/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers , Roel of

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/015021 A1 (SHIBER SAMUEL [US]) 20 January 2005 (2005-01-20) paragraph [0023]; figures 3, 6	8,15,16
A	US 2010/274278 A1 (FLEENOR RICHARD P [US] ET AL) 28 October 2010 (2010-10-28) paragraph [0092]; figure 1	8,15,16
A	US 5 174 295 A (CHRISTIAN JEFFREY J [US] ET AL) 29 December 1992 (1992-12-29) column 23, line 63 - column 24, line 2; figure 18	8,15,16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/070845

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. [X] Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:

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

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/US2012/070845

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010241227 A1	23-09-2010	NONE	
US 2011264149 A1	27-10-2011	CA 2795819 A1	03-11-2011
		CN 102858263 A	02-01-2013
		EP 2563250 A1	06-03-2013
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US 2005015021 A1	20-01-2005	NONE	
US 2010274278 A1	28-10-2010	US 2010274278 A1	28-10-2010
		WO 2010124129 A1	28-10-2010
US 5174295 A	29-12-1992	NONE	