(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2012 (27.12.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/177759 A1

(51) International Patent Classification:
A61F 2/08 (2006.01)

(21) International Application Number:
PCT/US2012/043346

(22) International Filing Date:
20 June 2012 (20.06.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/498,687	20 June 2011 (20.06.2011)	US
61/515,009	4 August 2011 (04.08.2011)	US
61/591,304	27 January 2012 (27.01.2012)	US

(71) Applicant *(for all designated States except US)*: **RDC HOLDINGS, LLC** [US/US]; 17 South Long Lake Trail, North Oaks, MN 55127 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SCHWAPPACH, Karl** [US/US]; C/o RDC Holdings, LLC, 17 South Long Lake Trail, North Oaks, MN 55127 (US).

(74) Agents: **PEDERSEN, Brad, D.** et al.; Patterson Thuente Christensen Pedersen, P.A., 4800 IDS Center, 80 South Eighth Street, Minneapolis, MN 55402-2100 (US).

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

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR REPAIRING JOINTS

(57) Abstract: A fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient. The fixation system includes a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone, and a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone. A neck portion extends through the bone tunnels between the first and second fasteners and spans the joint. An adjustment mechanism is supplied to apply a tension force across the joint between the first and second fasteners. A ligament replacement is located in the bone tunnels with the neck portion in intimate contact with surfaces of the bone tunnels in the first and second bones.

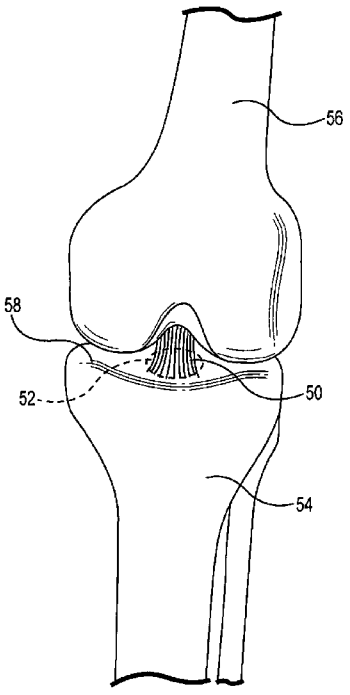


Fig. 1

WO 2012/177759 A1

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SYSTEM AND METHOD FOR REPAIRING JOINTS

Related Applications

The present application claims the benefit of U.S. Provisional Application No. 61/498,687, entitled Orthopedic Fixation System and Method of Use, filed June 20, 2011; U.S. Provisional Application No. 61/515,009, entitled Orthopedic Fixation System and Method of Use, filed August 4, 2011; and U.S. Provisional Application No. 61/591,304, entitled Fixation System and Method for Repairing Joints, filed January 27, 2012, the disclosures of which are hereby incorporated by reference.

Field of the Invention

[0001] The present disclosure is directed to a fixation system for repairing joints including a support structure that can be used alone or in combination with a ligament replacement. The ligament replacement and any support structure can be tensioned independently. A biasing structure promotes in-growth between the ligament replacement and the bones of the joint.

Background of the Invention

[0002] Ligaments are tough bands of tissue which serve to connect the articular extremities of bones, or to support or retain organs in place within the body. Ligaments are typically composed of coarse bundles of dense white fibrous tissue which are disposed in a parallel or closely interlaced manner, with the fibrous tissue being pliant and flexible, but not significantly extensible.

[0003] In many cases, ligaments and tendons are torn or ruptured as a result of accidents. As a result, various procedures have been developed to repair or replace such damaged ligaments. In some circumstances a ligament replacement is implanted. The graft may be a ligament or tendon harvested from elsewhere in the patient or a synthetic device. Common examples include the Anterior Cruciate Ligament (ACL) and collateral ligament reconstructions of the knee, medial and lateral elbow collateral ligament reconstructions, ankle collateral ligament reconstruction, finger and hand collateral ligament reconstructions and the like.

[0004] By way of example, various surgical procedures have been developed for reconstructing the ACL so as to restore normal function to the knee joint. Traditional techniques that are used to fix tendon to bone suffer from a number of limitations as a result of the methodology used, including the use of a "keyhole" tenodesis, pull-out sutures, bone tunnels, and

interference screw fixation. The "keyhole" tenodesis requires the creation of a bone tunnel in the shape of a keyhole, which allows a knotted tendon to be inserted into the upper portion, and subsequently wedged into the lower narrower portion of the tunnel where inherent traction on the tendon holds it in place. This technique is challenging as it is often difficult to sculpt the keyhole site and insert the tendon into the tunnel. In addition, if the tendon knot unravels in the postoperative period, the tendon will slide out of the keyhole, losing fixation.

[0005] Another traditional form of tendon fixation is the use of the "pull-out stitch." With this technique, sutures attached to the tendon end are passed through bone tunnels and tied over a post or button on the opposite side of the joint. This technique has lost favor in recent years due to a host of associated complications, which include wound problems, weak fixation strength, and potential injury to adjacent structures.

[0006] The most common method of fixation of tendon to bone is the use of bone tunnels with either suture fixation, or interference screw fixation. The creation of bone tunnels is relatively complicated, often requiring an extensive exposure to identify the margins of the tunnels. Drill holes placed at right angles are connected using small curettes. This tedious process is time-consuming and fraught with complications, which include poor tunnel placement and fracture of the overlying bone bridge. Graft isometry, which is easy to determine with single point fixation, is difficult to achieve because the tendon exits the bone from two points. After creation of tunnels, sutures must be passed through the tunnels to facilitate the passage of the tendon graft. Tunnels should be small enough to allow good tendon-bone contact, yet large enough to allow for graft passage without compromising the tendon. This portion of the procedure is often time-consuming and frustrating to a surgeon. Finally, the procedure can be compromised if the bone bridge above the tunnel breaks, resulting in loss of fixation. The technique restricts fixation to the strength of the sutures, and does not provide any direct tendon to bone compression.

[0007] More recent advances in the field of tendon fixation involve the use of an internally deployed toggle button, for example, the ENDOBUTTON, and the use of interference screws to provide fixation. The ENDOBUTTON allows the fixation of tendon into a bone tunnel by creating an internally deployed post against a bony wall. While this technique eliminates the need for secondary incisions to place the post, the fixation strength is limited to suture strength alone. This technique does not provide direct tendon to bone compression. As such this technique may slow healing and lead to graft tunnel widening due to the "bungee effect" and "windshield wiper effect". As a result, this technique has limited clinical applications and is used primarily for salvage when bone tunnels break or backup fixation is important.

[0008] U.S. Pat. No. 8,048,158 (Hays et al.) discloses an expandable anchor that fixes a ligament replacement within a bone tunnel. The anchor urges the graft into contact with the side walls of the bone tunnel. As with the ENDOBUTTON the anchor has limited pull-out strength, and both solutions require the graft to carry the entire load of the joint.

[0009] The use of the interference screw is the most notable advance in the fixation of tendon to bone. The screw is inserted adjacent to a tendon in a bone tunnel, providing axial compression between the screw threads and the bony wall. Advantages include acceptable pull-out strength and relative ease of use. Aperture fixation, the ability to fix the tendon to bone at its entrance site, is a valuable adjunct to this technique as it minimizes graft motion and subsequent tunnel widening. Some disadvantages related to soft tissue interference screws are that they can be difficult to use, and can also cut or compromise the tendon during implantation.

[0010] The newest generation interference screw allows the ability to provide tendon to bone fixation with limited exposure. For example, the BIO-TENODESIS SCREW (Arthrex, Inc.) allows the tensioning and insertion of tendon into bone, followed by insertion of an adjacent soft tissue interference screw. While this screw system provides advantages in the insertion of tendon into bone in cases when a pull through stitch is not available, it is still limited by the potential for tendon rotation or disruption as the screw compresses the tendon. The surgical technique is also complicated, typically requiring two or more hands for insertion, making it difficult to use the system without assistance during arthroscopic or open procedures. Finally, the use of the screw requires preparation of the tendon end, which can be difficult, time consuming, and can also require conversion of an arthroscopic procedure to open.

[0011] Focusing particularly on the ACL, current ACL repairs utilizing soft tissue for the replacement graft are either difficult to perform or they result in less than favorable outcomes due to their relatively low tendon-to-bone fixation. Existing ACL reconstruction techniques that have acceptable outcomes (high tendon-to-bone fixation) involve extra operating room time and surgeon effort due to the requirement of multiple drill holes, external guides and fixtures for the drill holes, and multiple assistants. Moreover, these approaches do not closely replicate the native ACL in its anatomy or physiology.

[0012] Two important factors in replicating the native ACL are aperture compression and tendon length. Compressing the tendons at the aperture of the femoral tunnel will improve the healing process by increasing the intimate contact between the tendon and the bone. A study shows that without intimate contact between the tendon and the bone, the result is a graft having less well organized fibrous tissue and lower pull-out strength. The stiffness of the repair is also important to replicate the native ACL.

Brief Summary of the Invention

[0013] The present disclosure is directed to a fixation system and method for repairing joints. The present fixation system includes a flexible structure that spans the joint that can be used alone or in combination with a ligament replacement and/or synthetic tension members. The support structure can be tensioned independently from the ligament replacement. A biasing system biases the ligament replacement against the bones in the joint to promote in-growth. The biasing system preferably surrounds the ligament replacement with bone growth agent at the interface with the bones.

[0014] One embodiment is directed to a fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient. The fixation system includes a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone and a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone. A support structure extends through the bone tunnels to span the joint. The support structure is retained at a support tension by the first and second fasteners. At least one segment of ligament replacement is attached to the support structure at one or more locations and spans the joint such that the ligament replacement is indirectly attached to the first and second bones by the support structure. The ligament replacement is retained generally at the support tension by the support structure.

[0015] In one embodiment, the support structure includes a porous structure substantially surrounding the graft tension such that the ligament replacement is maintained in intimate contact with surface inside the first and second bone tunnels through openings in the porous structure. The support structure preferably biases the ligament replacement in intimate contact with surfaces inside the first and second bone tunnels.

[0016] In one embodiment, the support structure includes at least one porous expandable member that is expanded in situ within one of the bone tunnels by a flowable biomaterial to compressively engage the ligament replacement. A flowable biomaterial is preferably a resorbable, bone-growth stimulating composition. The biomaterial interacts with the surfaces inside of the bone tunnel and the ligament replacement through the porous structure. The expandable member biases the ligament replacement against the surfaces inside the bone tunnels.

[0017] A tension member optionally extends through the bone tunnels to span the joint with the support structure and the ligament replacement. The tension member is retained at a supplemental tension by the first and second fasteners, wherein the support tension and the

supplemental tension are independently adjustable. The tension member is preferably located within a sheath adapted to reduce adhesion between the tension member and the patient.

[0018] In one embodiment, the support tension is initially less than the supplemental tension. The supplemental tension is subsequently reduced to an overload tension that is less than the support tension. As used herein, "overload tension" refers to a tension generally corresponding to a maximum tension sustainable by a joint. The present fixation system provides an upper limit of tension the joint can withstand in order to protect the ligament replacement.

[0019] The present disclosure is also directed to a fixation system with at least one segment of ligament replacement adapted to extend through the bone tunnels to span the joint. The ligament replacement is retained at a graft tension by the first and second fasteners. A support structure extends through the bone tunnels to span the joint with the ligament replacement. The support structure is retained at a support tension by the first and second fasteners. The graft tension and the support tension are independently adjustable.

[0020] The present disclosure is also directed to a fixation system with at least one segment of ligament replacement adapted to extend through the bone tunnels to span the joint. The ligament replacement is retained at a graft tension by the first and second fasteners. At least one porous expandable member is expanded within one of the bone tunnels to compressively engage the ligament replacement. A flowable biomaterial including a resorbable, bone-growth stimulating composition is used to expand the porous structure. The biomaterial interacts with the ligament replacement and the surfaces inside of the first and second bone tunnel through the porous structure. The biomaterial accelerates attachment of the ligament replacement to the surface inside the first and second bone tunnels. This embodiment can be used with or without a support structure.

[0021] One embodiment of the fixation system includes a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone, and a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone. A neck portion extends through the bone tunnels between the first and second fasteners and spans the joint. An adjustment mechanism is supplied to apply a tension force across the joint between the first and second fasteners. A ligament replacement is preferably located in the bone tunnels with the neck portion in intimate contact with surfaces of the bone tunnels in the first and second bones.

[0022] In one embodiment, at least one of the first and second fasteners includes an expandable member adapted to be positioned in cancellous bone in one of the first and second bones. A delivery tube is inserted through the bone tunnels to deliver a flowable biomaterial to the expandable member. The combination of the flowable biomaterial and the expandable

member provide an expanded configuration with at least one dimension greater than a diameter of the bone tunnel to secure the expandable member in the bone.

[0023] At least one check-valve assembly is preferably located on the expandable member to receive the delivery tube and to retain the flowable biomaterial in the expandable member after the delivery tube is removed. In one embodiment, the expandable member is preferably a porous structure and the biomaterial is a resorbable, bone-growth stimulating composition that interacts with the bones through openings in the porous structure. The biomaterial preferably fuses with the bone to secure the expandable member.

[0024] In one embodiment, the biomaterial delivery system is delivered at sufficient pressure to prepare the cancellous bone. An inflatable device is optionally inserted through the bone tunnels and expanded in the first or second bones to prepare the cancellous bone to receive the expandable member. At least one screw or pin is optionally implanted through cortical bone of one of the first or second bones and into the expandable member. The expandable member can be integrally formed with the neck portion, or attached to the neck portion by a releasable coupling.

[0025] In one embodiment, the neck portion biases the ligament replacement into contact with the surfaces of the bone tunnels. The neck portion is preferably a porous structure and the ligament replacement can be located inside the neck portion and/or attached to the outside of the neck portion. In one embodiment, an elastomeric member is located inside the neck portion to bias the ligament replacement into contact with the surfaces of the bone tunnels through openings in the porous structure.

[0026] In another embodiment, the neck portion includes at least one expandable chamber adapted to be selectively expanded by a biomaterial to bias the ligament replacement into contact the surfaces of the bone tunnels. For example, a pair of check valves are located in the neck portion to create an expandable chamber adjacent at least one of the bone tunnels in the first or second bones without substantially extending into the joint. A delivery tube is inserted through the neck portion to deliver a flowable biomaterial to the expandable chamber. The flowable biomaterial expands the expandable chamber to bias the ligament replacement into contact the surfaces of the bone tunnels. At least a portion of the ligament replacement is preferably sandwiched between the biomaterial and the surface of the bone tunnel. Over time the biomaterial fuses with the bone through and around the ligament replacement.

[0027] In one embodiment, the neck portion is attached to the first and second fasteners and carries at least a portion of the tension force across the joint between the first and second fasteners. In another embodiment, a tension member extends through the neck portion between

the first and second fasteners. The tension member carries at least a portion of the tension force across the joint between the first and second fasteners. The tension member is preferably located in a sheath to prevent adhesion with the first and second bones.

[0028] In one embodiment, the tension on the tension member only acts on the joint at or near the range of motion. Consequently, the ligament replacement and the neck portion support and stabilize the joint most of the time, while the tension member only acts on the joint at the extreme ranges of motion.

[0029] In another embodiment, the tension member is elastic or otherwise designed to stretch. In this embodiment, the tension member acts as a shock absorber on the joint. The tension member preferably reaches maximum elongation before the joint exceeds the desired range of motion, thereby acting as a stop on the joint.

[0030] The present disclosure is also directed to a kit for stabilizing a joint between first and second adjacent bones in a patient. The kit includes a first fastener adapted to be secured in a first bone tunnel formed in the first adjacent bone. A second fastener is provided with an expandable member adapted to be positioned in a second bone tunnel extending into cancellous bone in the second adjacent bone. A delivery tube is provided to be inserted through the bone tunnels to deliver a flowable biomaterial to the expandable member. The combination of the flowable biomaterial and the expandable member include an expanded configuration with at least one dimension greater than a diameter of the second bone tunnel to secure the expandable member in the second bone. A neck portion is attached to the expandable member and extends through the second bone tunnel, across the joint, and to the first fastener. An adjustment mechanism is provided to adjust a tension force across the joint between the first and second fasteners. A ligament replacement is located in the bone tunnels with the neck portion in intimate contact with surfaces of the bone tunnels in the first and second bones.

[0031] The present disclosure is also directed to a method for stabilizing a joint between first and second adjacent bones in a patient. A first fastener is secured in a first bone tunnel located in the first adjacent bone. A second fastener is secured in a second bone tunnel located in the second adjacent bone. A neck portion is positioned in the bone tunnels between the first and second fasteners so the neck portion spans the joint. A tension force is applied across the joint between the first and second fasteners. A ligament replacement is located in the bone tunnels with the neck portion in intimate contact with surfaces of the bone tunnels in the first and second bones.

[0032] The present method is preferably performed using minimally invasive techniques.

[0033] The present disclosure is also located to a method of stabilizing joints. Bone tunnels are formed in a first bone and a second bone at a location of the joint. A first expandable member is located in the bone tunnel in the first bone. A neck portion attached to the first expandable member is positioned to span the joint and to extend into the bone tunnel in the second bone. A flowable biomaterial is delivered through a delivery tube into the first expandable member located in a cancellous portion of the first bone. The first expandable member is expanded so that at least one dimension is greater than a diameter of the bone tunnel to secure the first expandable member to the first bone. The neck portion is secured in the bone tunnel of the second bone such that the neck portion controls the motion of the first bone relative to the second portion.

[0034] The bone tunnels are preferably formed to extend through ligament connection sites in the joint so that the neck portion mimics the operation of the ligament. The biomaterial is preferably isolated in the first expandable member.

[0035] In all of the embodiments, the tension force can be adjusted post surgery.

[0036] The expandable members optionally have a pre-determined volume and shape. In another embodiment, the expandable member assumes a shape of a cavity in the bones.

[0037] The method preferably includes permitting intimate contact of the biomaterial with the bones through porous openings in the expandable member. The biomaterial is preferably permitted to interact with the bones through openings in the first expandable member such that the biomaterial is substantially absorbed by the bone. In one embodiment, the biomaterial is cured in-situ. The biomaterial preferably fuses with the surfaces of the bone tunnels to secure the ligament replacement to the bone.

[0038] The present method includes coupling a biomaterial injection system with a proximal end of the delivery tube to delivery the biomaterial under pressure to the expandable chamber in the expandable member.

[0039] In another embodiment the expandable member includes from a plurality of expandable members. The method optionally includes positioning at least one check-valve between at least two of the fluidly coupled expandable members.

[0040] In another embodiment, the expandable member and the neck portion include a plurality of discrete expandable members and neck portions fluidly coupled in a modular manner. The plurality of discrete expandable members are optionally a plurality of different sizes and shapes.

Brief Description of the Several Views of the Drawing

[0041] Figure 1 illustrates a frontal view of the bones of the knee and the anterior cruciate ligament.

[0042] Figure 2 is a side view of a knee joint being prepared to receive a fixation system in accordance with the present disclosure.

[0043] Figure 3 is a side view of a knee joint with an inflatable device used to create a cavity to receive a fixation system in accordance with an embodiment of the present disclosure.

[0044] Figure 4 is a side view of a knee joint with a fixation device being positioned in bone tunnels in accordance with an embodiment of the present disclosure.

[0045] Figure 5 is a side view of the knee joint of Figure 4 with the fixation device secured to the bones of the knee joint in accordance with an embodiment of the present disclosure.

[0046] Figure 6A is a side view of a knee joint with an alternate fixation device secured to the bones of the knee joint in accordance with an embodiment of the present disclosure.

[0047] Figure 6B is a sectional view of the neck portion of the fixation device in accordance with an embodiment of the present disclosure.

[0048] Figure 7 illustrates a kit for reconstructing a joint in accordance with an embodiment of the present disclosure.

[0049] Figures 8A and 8B are schematic illustrations of a fixation device and method in accordance with an embodiment of the present disclosure.

[0050] Figure 8C is a schematic illustration of the fixation device of Figure 8A with an internal tensioning mechanism in accordance with an embodiment of the present disclosure.

[0051] Figure 8D is a schematic illustration of a fixation device that directly tensions a ligament replacement in accordance with an embodiment of the present disclosure.

[0052] Figures 9A and 9B are schematic illustrations of an alternate fixation device and method in accordance with an embodiment of the present disclosure.

[0053] Figure 9C is a schematic illustration of the fixation device of Figure 9A with an internal tensioning mechanism in accordance with an embodiment of the present disclosure.

[0054] Figure 9D is a schematic illustration of a fixation device that directly tensions a ligament replacement in accordance with an embodiment of the present disclosure.

[0055] Figure 10A and 10B illustrate a modular fixation system with a plurality of expandable members joined by a living hinge extension in accordance with an embodiment of the present disclosure.

[0056] Figure 11 illustrates a kit for a modular fixation system in accordance with an embodiment of the present disclosure.

[0057] Figure 12 is a side view of a knee with the fixation device having an internal tension member in accordance with an embodiment of the present disclosure.

[0058] Figure 13 is a schematic illustration of adjacent hand bone stabilized using a fixation system in accordance with an embodiment of the present disclosure.

[0059] Figure 14 illustrates a fastener for the fixation device of Figure 13.

[0060] Figure 15 is a schematic illustration of adjacent hand bone stabilized using an alternate fixation system in accordance with an embodiment of the present disclosure.

[0061] Figures 16A-16D illustrate a method of deploying a fixation device with a plurality of expandable members in accordance with an embodiment of the present disclosure.

[0062] Figure 17 illustrates an alternate fixation device for the knee in accordance with an embodiment of the present disclosure.

[0063] Figures 18A and 18B illustrate an alternate fastener for a fixation system in accordance with an embodiment of the present disclosure.

[0064] Figure 18C illustrates an alternate fastener for a fixation system in accordance with an embodiment of the present disclosure.

Detailed Description of the Invention

[0065] Figure 1 illustrates a partially torn ligament of the knee, e.g., the anterior cruciate ligament (ACL) 50. The ACL 50 is attached to attachment location 52 on the tibial plateau 58 of the tibia 54. The tibial attachment lies in front of the anterior intercondylar tubercle and is blended with the anterior extremity of the lateral meniscus (not shown). The tendon 50 passes upward, backward, and laterally to be fixed into the posterior part of the medial surface of the lateral condyle (not shown) of the femur 56.

[0066] Figure 2 illustrates a method of repairing an anterior or a posterior cruciate ligament using arthroscopic or minimally invasive surgical procedure in accordance with an embodiment of the present disclosure. The patient's skin 60 is opened to permit entry of the cannula 62 to the distal femur 56. A drill is used by the surgeon to drill bone tunnels 64A, 64B ("64") beginning at the anterior surface of the femur 56 and ending within the cancellous bone 66 of the tibia 54. The present method is preferably performed through a single access portal, such as through cannula 62. The bone tunnel 64 preferably extends through the ligament 50 connection sites or points of origin in the knee joint 70 (see Figure 1). Various methods of creating such bone tunnels utilizing arthroscopic procedures are disclosed in U.S. Pat. No. 5,702,397 (Goble et al.); 4,772,286 (Goble et al.); and U.S. Pat. Publ. 2011/0153018 (Walters et al.), which are hereby incorporated by reference.

[0067] Catheter 72 is optionally inserted into the tunnels 64 to facilitate the procedure. In one embodiment, probe 74 is optionally inserted through lumen 76 of the catheter 72 to prepare the cancellous bone 66. The probe 74 is rotated and otherwise manipulated so that tip 78 prepares cavity 80 in cancellous bone 66. As used herein, "prepare" refers to compressing, fracturing, displacing, and/or puncturing cancellous bone to at least partially form a cavity to receive a fixation device.

[0068] Figure 3 illustrates the optional use of inflatable device 82 to form cavity 80 in accordance with an embodiment of the present disclosure. The inflatable device 82, such as for example a balloon catheter, is delivered through the lumen 76 and positioned in the cancellous bone 66. Delivery tube 84 is used to inflate the inflatable device 82 and to form the cavity 80, such as disclosed in U.S. Pat. No. 6,235,043 (Reiley et al.), which is hereby incorporated by reference. The inflatable device 82 is preferably inflated with a liquid, and the volume of liquid is used as an estimate of the amount of biomaterial 104 required to fill the cavity 80. The liquid and the inflatable device 82 are then sequentually removed from the lumen 76 and the fixation device 75 is implanted using any of the methods disclosed herein.

[0069] Figure 4 illustrates an alternate embodiment in which the cavity 80 is formed during delivery of biomaterial to inflation of the fixation device 75 in accordance with an embodiment of the present disclosure. The fixation device 75 preferably includes neck portion 94 that spans the knee joint 70 with porous expandable member 92 located at the distal end. The neck portion 94 is preferably hollow or tubular in structure to receive delivery tube 96. In an alternate embodiment, the neck portion 94 is a solid structure and the delivery tube 96 is positioned parallel with the neck portion 94.

[0070] One or more ligament replacements 102 optionally spans the knee joint 70 with the neck portion 94. In one embodiment, the ligament replacement 102 is attached to the neck portion 94 (see e.g., Figure 7). In another embodiment, the ligament replacement 102 can be tensioned independently from the neck portion 94 (see e.g., Figures 8D and 9D).

[0071] The ligament replacement 102 are preferably one or more segments of material. The ligament replacement may be fashioned out of various soft ligament replacement materials, such as for example, allografts, autografts, xenografts, bioengineered ligament replacements, synthetic grafts, and the like. In another embodiment, the neck portion 94 is seeded with fibroblasts, fibrocytes, tenocytes, or synovioctye cells, to promote integration with the ligament replacement 102 or existing tissue in the knee joint 70. The ligament replacement 102 is preferably configured to contact inner surface of the tunnels 64A, 64B.

[0072] The catheter 72 extends to the end of the bone tunnel 64 to position the expandable member 92 in the cancellous bone 66 of the tibia 54. The catheter 72 is then withdrawn so that neck portion 94 of the ligament replacement 102 extends through the bone tunnels 64 and spans the knee joint 70.

[0073] Biomaterial 104 is delivered through delivery tube 96 to fill in situ the chamber 98 of the expandable member 92. The delivery tube 96 may be constructed from a variety of metal or polymeric materials and can be flexible or rigid depending on the application. In one embodiment, the delivery tube 96 has sufficient column stiffness to displace and compress the cancellous bone 66, eliminating the need for the probe 74 or the inflatable device 82. Valve assembly 100A, such as a check-valve, is preferably provided to retain the biomaterial in the expandable member 92.

[0074] As used herein, "biomaterial" refers to any filler material that is suitable with in situ applications. In its broadest application, the biomaterial 104 only needs to expand the expandable member 92 a sufficient amount to form an interference fit with the cavity 80. The biomaterial 104 can be any flowable biocompatible material that can be delivered through delivery tube 96.

[0075] In the preferred embodiment, the biomaterial 104 is a curable, resorbable, bone-growth stimulating composition that interacts with the cancellous bone 66 through the porous expandable member 92. Bone in-growth preferably extends substantially through the chamber 98 of the expandable member 92 so that the biomaterial 104 is all eventually incorporated into the cancellous bone 66. In the preferred embodiment, the biomaterial fuses with the bone while surrounding and penetrating the ligament replacement, creating a secure fixation.

[0076] In one embodiment, the biomaterial 104 cures or hardens in-situ to provide immediate fixation. As used herein, the term "cure" and inflections thereof, will generally refer to any chemical transformation (e.g., reacting or cross-linking), physical transformation (e.g., hardening or setting), and/or mechanical transformation (e.g., drying or evaporating) that allows the biomaterial to change or progress from a first physical state or form (generally liquid or flowable) that allows it to be delivered to the site, into a more permanent second physical state or form (generally solid) for final use in vivo. When used with regard to the method of the present disclosure, for instance, "curable" can refer to uncured biomaterial, having the potential to be cured in vivo (as by catalysis or the application of a suitable energy source), as well as to the biomaterial in the process of curing.

[0077] It is not necessary for the biomaterial 104 to harden or cure for the fixation device 75 to be secured in the cavity 80. The biomaterial 104 is preferably a substantially incompressible

material located within a fixed space (i.e., cavity 80). In embodiments where the biomaterial 104 does not cure or harden in-situ, the patient may require an external structure, such as a brace or cast, to secure the joint 70 until sufficient bone in-growth occurs.

[0078] In one embodiment, the biomaterial 104 is small fragments of an osteogenic sponge composition having enhanced osteoinductive properties for use in bone repair, such as disclosed in U.S. Pat. Publication Nos. 2002/0082694 (McKay) and 2010/0255042 (Jennissen et al.), which are incorporated by reference. The fragments of sponge composition are sufficient small and compressible to fit into the lumen of the delivery tube 96. The composition enables increased osteoinductive activity while maintaining a reliable scaffold for the formation of new bone within the chamber 98 of the expandable member 92.

[0079] The osteogenic factor can be one that stimulates production or activity of osteoblasts and osteoclasts. The factor is preferably a bone morphogenetic protein (BMP) or a LIM mineralization protein (LMP), or comprises a nucleotide sequence encoding a BMP or LMP. Recombinant human BMPs may be commercially obtained or prepared as described and known in the art, e.g. in U.S. Pat. No. 5,187,076 to Wozney et al.; U.S. Pat. No. 5,366,875 to Wozney et al.; U.S. Pat. No. 4,877,864 to Wang et al.; U.S. Pat. No. 5,108,932 to Wang et al.; U.S. Pat. No. 5,116,738 to Wang et al.; U.S. Pat. No. 5,013,649 to Wang et al.; U.S. Pat. No. 5,106,748 to Wozney et al; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/2693 to Celeste et al.; and WO94/26892 to Celeste et al., which are incorporated by reference. Such osteogenic factors are preferably delivered in conjunction with cells, for example autologous cells from the recipient of the implant. Most preferably the vector is delivered in conjunction with autologous white blood cells derived from bone marrow or peripheral blood of the recipient. These cells may be applied to the sponge composition along with the osteogenic factor prior to implantation.

[0080] The biomaterial 104 may be in the form of a flowable putty or paste, such as the bone-growth stimulating composition, such as disclosed in U.S. Pat. Publication No. 2006/0204586 (Alexander et al.) and U.S. Pat. No. 7,172,629 (McKay), which are hereby incorporated by reference. U.S. Pat. No. 6,770,695 (Ricci et al.) discloses a bone growth stimulating material with a controlled resorption rate that includes a calcium sulfate compound and a polymer containing particles with a setting agent that is flowable through the delivery tube 96. The biomaterial 104 optionally includes radiopaque properties to facilitate imaging.

[0081] In another embodiment, the biomaterial 104 is a flowable carrier matrix including collagen sponge, ranging from about 0.1 mm to about 1.0 mm in size, wetted with a fluid, such as morphogen, such as disclosed in U.S. Pat. No. 7,671,014 (Beals et al.), which is hereby incorporated by reference. A bulking material may be added to the carrier matrix, such as for

example collagen-ceramic composite materials, allograft and bio-compatible ceramics or minerals that provide bone in-growth scaffolding.

[0082] By way of example and not limitation, the biomaterial 104 may also include bone cement or in situ curable polymeric materials including, for example, elongated polymeric materials, polymeric beads, hydrogel materials, fusion promoting materials, autograft bone, allograft bone, xenograft bone, or any combination thereof. The biomaterial 104 is preferably bioresorbable, such as for example, poly(lactic acid), poly(glycolic acid), p-dioxanon fibers, polyarylethyl, polymethyl methacrylate, polyurethane, amino-acid-derived polycarbonate, polycaprolactone, aliphatic polyesters, calcium phosphate, unsaturated linear polyesters, vinyl pyrrolidone, polypropylene fumarate diacrylate, or mixtures thereof, or other biocompatible compounds. A flowable, biodegradable polymer that cures in-situ suitable for use as the biomaterial 104 is disclosed in U.S. Pat. No. 5,990,194 (Dunn et al.), which is hereby incorporated by reference.

[0083] The expandable member 92 and the neck portion 94 can be constructed from elastic or inelastic materials that provide an optimal combination of such properties as flexibility under static and dynamic conditions, tensile strength, elongation, tensile modulus, ductility, stability and durability, and compliance. In one embodiment, the expandable member 92 has a pre-determined volume and shape corresponding to the implantation site, such as disclosed in U.S. Patent No. 5,972,015 (Scribner et al.), which is hereby incorporated by reference.

[0084] The expandable member 92 and the neck portion 94 are preferably constructed from a porous material with pore sizes sufficient to generally retain the biomaterial 104, but also permit intimate contact between the biomaterial 104 and the cancellous bone 66, such as for example, the biocompatible mesh disclosed in U.S. Pat. Publication Nos. 2008/0300683 (Altman et al.); 2009/0024147 (Ralph et al.) and U.S. Pat. No. 7,850,711 (Stone et al.), which are hereby incorporated by reference. "Porous" refers to a material with a maximum void diameter corresponding to a viscosity of a biomaterial to generally retain the biomaterial within an expandable member and a void fraction that permits substantial in-growth with adjacent bone. Examples of suitable porous structures include, for example, woven meshes, scrims, screens, semi-permeable membranes or films, woven or non-woven structures, knitted or fabric structures such as gauze, braided structures, or combinations thereof. Nonwoven structures broadly include sheet or web structures bonded together by entangling fibers or filaments (and by perforating films) mechanically, thermally or chemically. Suitable materials for constructing the expandable member 92 and/or neck portion 94 are disclosed in U.S. Patent Nos. 6,592,622 (Ferguson); 7,828,855 (Ellis et al.); 7,740,657 (Brown et al.); and U.S. Pat. Publication Nos. 2009/0138082

(Reah et al.); 2009/0216326 (Hirpara et al.); 2010/0161054 (Park et al.); and 2010/0298937 (Laurencin et al.), all of which are hereby incorporated by reference.

[0085] Void fraction can be about 30% to about 80% and void diameter is about 1 mm to about 0.1 mm. The porous structures may incorporate various reinforcing structures, such as for example, metal or carbon fibers. In one embodiment, the expandable member 92 and the neck portion 94 includes pores in the range of about 0.25 millimeters to about 5.0 millimeters. The size of the pores are determined based on a number of factors, such as the viscosity of the biomaterial 104, the maximum delivery pressure of the biomaterial 104, and the like.

[0086] The expandable member 92 and neck portion 94 may be a woven or non-woven structure made from metal or polymeric fibers. Suitable metals include titanium or one of its alloys, or stainless steel. Suitable polymeric materials include polymethyl methacrylate (PMMA), castable thermoplastic polyurethanes, for instance those available under the tradenames CARBOTHANE (Thermedics) ESTANE (Goodrich), PELLETHANE (Dow), TEXIN (Bayer), Roylar (Uniroyal), and ELASTOTHANE (Thiocol), as well as castable linear polyurethane ureas, such as those available under the tradenames CHRONOFLEX AR (Cardiotech), BIONATE (Polymer Technology Group), and BIOMER (Thoratec).

[0087] In one embodiment, the expandable material 92 is coated with an osteo-conductive tissue scaffold, such as disclosed in U.S. Pat. Publication Nos. 2011/0082564 (Liu et al.) and 2010/0268227 (Tong et al.), which are hereby incorporated by reference. The expandable member 92, neck portion 94, and/or the biomaterial 104 optionally include radiopaque properties. Various configurations of a porous expandable structure are disclosed in U.S. Pat. No. 5,549,679 (Kuslich), which is incorporated by reference.

[0088] In one embodiment, the expandable member 92 and neck portion 94 are constructed from a bio-degradable material, such as disclosed in U.S. Pat. Publication No. 2010/0298937, which is incorporated herein by reference. The bio-degradable material preferably degrades within a period between about six month to about twelve month, to allow for the ligament replacement 102 to attached to the adjacent bones 54, 56 before the structural and mechanical support provided by the expandable member 92 and neck portion 94 are lost.

[0089] The neck portion 94 can also be a coiled structure. In one embodiment the coiled structure is formed around a flexible core. The flexible core can be a compressible material, such as an elastomeric material, or substantially incompressible. The core acts to control the amount of narrowing or necking-down that occurs when the coiled structure is placed in tension. In one embodiment the coiled structure includes a plurality of filaments.

[0090] In one embodiment, the neck portion 94 is engineered to have a percent elongation comparable to that of the ligament replacement 102. The neck portion 94 preferably has a percent elongate within a range of about 5% of the percent elongation of the ligament replacement 102, or about 10% of the percent elongation of the ligament replacement 102.

[0091] The neck portion 94 can have a variety of shapes, such as a hollow or solid tube, a ribbon shape, and the like. The shape may be dictated by the modes of articulation in the joint so as to provide preferential bending in one plane. The neck portion 94 can have a variety of cross sectional shapes, such as for example, circular, rectangular, triangular, irregular, and the like.

[0092] Figure 5 illustrates the expandable member 92 in an expanded configuration 106. The expanded member 92 and the biomaterial 104 preferably substantially fill, and conform to, the shape of the cavity 80 in the bone 54. In the preferred embodiment, the delivery pressure of the biomaterial 104 is sufficient for the expandable member 92 to compress the adjacent cancellous bone 66 to form cavity 80. Once delivery of the biomaterial 104 is completed, the delivery tube 96 is withdrawn from the lumen 76. The valve assembly 100A retains the biomaterial 104 in the expandable member 92. In the illustrated embodiment, the biomaterial 104 preferably does not enter the neck portion 94.

[0093] Expanded configuration 106 of the expanded member 92 preferably has at least one dimension greater than nominal diameter of the bone tunnel 64B at the opening 108 in the cortical bone 110 of the tibia 54. The enlarged upper surface of the expandable member 92 resists the tension forces 112. The neck portion 94 transfers the tension forces 112 between the expandable member 92 and the fastener 124.

[0094] The ligament replacement 102 is preferably attached to the neck portion 94 (see e.g., Figure 7). As a result the ligament replacement 102 is indirectly attached to the bones 54, 56 by the fixation device 75. The ligament replacement 102 is retained generally at the same tension 112 applied by neck portion 94.

[0095] One or more fasteners 130 optionally extend through cortical bone 110 and into the expandable member 92 and/or neck portion 94 to augment the fixation. The fasteners 130 can be screws, pins, and the like. The present fixation device 75 has the advantage that the fasteners 130 do not need to be aligned with a preformed receiving hole. Rather, the fasteners 130 can simply be screwed or inserted through the porous expandable member 92 and/or neck portion 94 and into the biomaterial 104. Holes formed in the expandable member 92 and/or neck portion 94 by the fasteners 130 are self-healing, such that the biomaterial 104 does not substantially leak.

[0096] In one embodiment, the neck portion 94 and the ligament replacement 102 are retained in a compressed configuration within the catheter 72. With the catheter 72 removed the neck portion 94 expands to bias the ligament replacement 102 against the bone tunnels 64.

[0097] In another embodiment, the neck portion 94 is filled with a growth agent 105 that promotes ingrowth between the ligament replacement 102 and the bones 54, 56. The growth agent 105 preferably remains compliant so as to not interfere with operation of the knee joint 70. Valve 100B is provided to retain the growth agent 105 in the neck portion 94. The valves 100A, 100B permit the growth agent 105 to be maintained under pressure to bias the ligament replacement 102 against inside surface of the bone tunnels 64.

[0098] In another embodiment, the valve 100B is omitted and the growth agent 105 is permitted to fill bone tunnel 64A substantially to the fastener 124.

[0099] In another embodiment, a second biomaterial is delivered through the neck portion 94 to fill the bone tunnel 64A between the valve 100B and the fastener 124. The second biomaterial is preferably a bone cement or other curable material. When a bone cement is used, the neck portion 94 is preferably a bioabsorbable material that slowly transfers the load 112 to the ligament replacement 102 over time.

[00100] In another embodiment, an elastomeric matrix impregnated with the growth agent 105 is located in the neck portion 94. The elastomeric matrix 105 serves to bias the ligament replacement 102 into contact with surfaces inside the bone tunnels 64.

[00101] Proximal end 120 of the neck portion 94 is inserted into threaded lumen 122 of fastener 124. Fastener 124 is engaged with bone tunnel 64A in distal femur 56. In one embodiment, the threaded traveler 126 is pre-attached to the proximal end 120 of the neck portion 94. As the fastener 124 is rotated into engagement with the bone tunnel 64A the traveler 126 is engaging with the threaded lumen 122. Tension 112 on the neck member 94 can be adjusted by rotating the threaded traveler 126 in the threaded lumen 122.

[00102] In another embodiment, the threaded traveler 126 is hollow with an opening large enough to receive the proximal end 120 of the neck portion 94. A compression fitting (see e.g., Figure 8B) is inserted into the hollow traveler 126 to attach the neck portion 94. Alternate configurations for attaching the neck portion 94 to the fastener 124 are illustrated in Figures 18A-18C.

[00103] In another embodiment, the threaded traveler 126 is inserted into the lumen 122 in a compressed configuration and allowed to expand into engagement with the proximal end 120 of the neck portion 94 to create a compression fit. The tension 112 can be adjusted by inserting a

tool to compress the threaded traveler 126 so it can be relocated within the lumen 122. Any excess portions of the neck portion 94 are then cut and removed.

[00104] In the illustrated embodiment, the ligament replacement 102 is indirectly attached to the bones 54, 56 by the support structure 94. Consequently, the ligament replacement 102 is retained generally at the tension 112 by the support structure 94. The neck portion 94, however, carries the load 112 in the joint 70 while the ligament replacement 102 is being incorporated into the bones 54, 56.

[00105] Figure 6A illustrates a variation of the fixation device 75 in which ligament replacement 102 is located within the porous neck portion 94 in accordance with an embodiment of the present disclosure. The biomaterial 104 is delivered through the delivery tube 96 to fill the chamber 98 and expand the expandable member 92 as discussed herein. The delivery tube 96 preferably can extend through the neck portion 94, but can also extend outside the neck portion 94. Once delivery of the biomaterial 104 is completed, the delivery tube 96 is withdrawn. The valve assembly 100A retains the biomaterial 104 in the expandable member 92.

[00106] The graft tissue 102 is preferably prepositioned in the neck portion 94 before implantation in the patient. Alternatively, the ligament replacement 102 is inserted into the neck portion 94 and advanced so as to span the knee joint 70.

[00107] The neck portion 94 is a porous structure that permits intimate contact between the ligament replacement 102 and the inside surfaces of the bone tunnels 64A, 64B ("64"). The openings in the neck portion 94 permits in-growth with the bones 54, 56 and the ligament replacement 102, while the high-tensile strength neck portion 94 stabilizes the knee joint 70. In one embodiment, the neck portion 94 has a circular or oval cross-section, although a variety of other cross-sections are possible.

[00108] Again, the ligament replacement 102 is indirectly attached to the bones 54, 56 by the support structure 94. Tension 112 is applied to the neck portion 94 by the fastener 124.

[00109] In one embodiment, biomaterial 102 is retained in space 107 between valves 100A, 100B in order to bias the ligament replacement 102 into engagement with inside surfaces of the bone tunnels 64. The same or a different biomaterial 102 can be located in the neck portion 94 between the valve 102B and the fastener 124. The porous nature of the neck portion 94 permits intimate contact with the bone 56.

[00110] In another embodiment, member 93 (see Figure 6B) is located in the space 107 with the ligament replacement 102 to bias the graft 102 toward the inside surfaces of the bone tunnels 64. In one embodiment, the member 93 is elastomeric and can be compressed in a catheter with

the graft 102 during delivery to the neck portion 94. Once the catheter is removed, the elastomeric member 93 expands to bias the graft 102 against the bone tunnels 64.

[00111] Figure 6B is a cross-sectional view of one embodiment of the member 93 in accordance with an embodiment of the present disclosure. Member 93 includes protrusions 109 that protect the ligament replacement 102 during flexure of the joint 70. In particular, the protrusions 109 protect the ligament replacement 102 from being pinched or compressed at the location where the bone tunnels 64 open to the joint 70. The member 93 optionally extends along the entire length of the ligament replacement 102 or just near entrances of the bone tunnels 64. Opening 111 can be used to receive the delivery tube and/or a tension member, such as illustrated in Figures 8C and 9C.

[00112] Figure 7 illustrates a kit 150 for use in a method in accordance with an embodiment of the present disclosure. The kit 150 includes the fixation device 75, the fastener 124, the probe 74, the inflatable device 82, the delivery tube 96, and biomaterial injection system 152 containing biomaterial 104. In one embodiment, the biomaterial injection system 152 is configured with a quantity of biomaterial 104 corresponding to a volume of the expandable member 92. An alternate fastener 600 is illustrated in Figures 18A and 18B.

[00113] Sliding member 125 of the fastener 124 is preferably attached to neck portion 94, such as with adhesives, spot welding, and the like. Tension member 139, if applicable, is optionally pre-attached to the threaded traveler 126 located in threaded lumen 135.

[00114] In one embodiment, the outer sleeve 127 is implanted in the patient and the entire fixation system 75 can be inserted into the patient through fastener lumen 137. Once the implantation is substantially complete, the surgeon attached nut 131 (see Figure 8C) to the threaded portion 129 of the sliding member 125 to apply tension to the system 75.

[00115] The surgeon has the option to attach ligament replacements 102 to the neck portion 94, such as using suture material 95. In another embodiment, proximal end 103 of the ligament replacement 102 is attached to the sliding member 125, such as with suture material, a compression fitting, adhesives, and the like.

[00116] The ligament replacement 102 may extend entirely around the neck portion 94 or may be a plurality of discrete segments running generally parallel to the neck portion 94. For example, autografts taken from the patient can be attached to the neck portion 94 in the operating room between the harvest procedure and implantation of the present fixation device 75.

[00117] Figure 18A is a side sectional view of an alternate fastener 600 for use with the fixation systems of the present disclosure. Outer sleeve 602 is typically pre-positioned in the bone tunnel (see e.g., Figure 8A). Sliding member 604 is inserted in lumen 606 of the outer

sleeve 602. Proximal end 608 of the neck portion 610 is attached to the sliding member 604 by hollow compression fitting 612. The compression fitting 612 captures proximal end 608 of the neck portion 610 in lumen 614 of the sliding member 604. Nut 616 is then rotated to apply tension 618 on the neck portion 610.

[00118] Figures 18B illustrates tension member 630 extending through the hollow compression fitting 612. Proximal end 620 is threaded through lumen 622 of the threaded traveler 624. The threaded traveler 624 is engaged with threads 626 and positioned in the lumen 614. Tension 628 is applied to the tension member 630. Compression fitting 632 is then attached to the tension member 630 adjacent to the threaded traveler 624 to maintain the tension 628. Further adjustment of the tension 628 is achieved by rotating the threaded traveler 624 along the threads 614. Rotation of the threaded traveler 624 preferably does not transmit torque to the compression fitting 632 or the tension member 630.

[00119] Alternate fasteners that can be adapted for the present disclosure are set forth in U.S. Pat. Nos. 6,780,187 (Supinski); 6,554,862 (Hays et al.); 6,994,715; and U.S. Pat. Publication Nos. 2003/0144735 (Sklar et al.); 2003/0105524 (Paulos et al.); 2004/0153076; 2004/0024456 (Brown et al.); 2005/0203620 (Steiner et al.); 2006/0015107 (Sklar); U.S. Pat. Nos. 2007/0233241 (Graf et al.); and 2008/0183290 (Baird et al.); which are hereby incorporated by reference.

[00120] Figure 18C illustrates an alternate fastener 650 with a threaded tension member 652 in accordance with an embodiment of the present disclosure. Compression fitting 612 secures the neck portion 610 to the sliding member 604. Nut 654 engages with threads 656 on the tension member 652 to adjust the tension 628. Alternatively, the nut 654 forms a friction fit with the tension member 652. Proximal portion 658 of the tension member 652 is preferably left intact so that tension 628 can be adjusted in-situ at a later date.

[00121] Figures 8A and 8B illustrate an alternate fixation device 170 with a plurality of discretely expandable chambers 180A, 180B in the neck portion 180 adapted to bias ligament replacement 102 into engagement with inside surfaces of the bone tunnels 64A, 64B in accordance with an embodiment of the present disclosure. Valve 176 isolates the expandable member 172 and chamber 180A of the neck portion 180. The valves 178A, 178B isolate chamber 180B of the neck portion 180. The expandable member 172 and the chambers 180A and 180B are preferably filled sequentually.

[00122] As illustrated in Figure 8B, the biomaterial 104 is injected into the expandable member 172 and the chamber 180A. The biomaterial 104 expands the chamber 180A, which moves the ligament replacement 102 into engagement with bone tunnel 64B on the bone 54. The

valve 176 retains the biomaterial 104 in the expandable member 172 and the chamber 180A. The delivery tube is then withdrawn far enough so the distal end is located in the chamber 180B. The biomaterial 104 is injected into the chamber 180B to move the ligament replacement 102 into engagement with bone tunnel 64A in the bone 56. The valves 178A, 178B retain the biomaterial 104 in the chamber 180B. The biomaterial 104 is preferably prevented from entering the neck portion 180 spanning the knee joint 70.

[00123] The chambers 180 are preferably sufficient porous to permit the biomaterial 104 to flow into engagement with the ligament replacement 102. The biomaterial 104 preferably flows into the interstitial spaces between the fibers of the ligament replacement 102 and into contact with the bone tunnels 64. In some embodiments, the biomaterial 104 encapsulates or substantially surrounds portions of the ligament replacement 102 against the bones 54, 56. The biomaterial 104 promotes bone growth into and around the ligament replacement 102 within the bone tunnels 64. Over time, the connection between the ligament replacement 102 and the bone tunnels 64 approximates an anatomically natural connection. During the healing process, the neck portion 180 preferably carries most of the load 112 generated in the knee joint 70.

[00124] The neck portion 180 passed through a lumen 122 in threaded traveler 126. Excess portions of the neck portion 180 are removed. Compression fitting 128 is passed through the threaded lumen 122 and into the threaded traveler 126 to secure the neck portion 180 to the traveler 126. Tension 112 on the joint 70 is adjusted by moving the treaded traveler 126 along the threaded lumen 122.

[00125] Figure 8B shows portions of the expanded chambers 180 extending into the joint 70, which is exaggerated for the sake of illustration only. The chambers 180 preferably do not interfere with operation of the joint 70. The expanded chambers 180 are designed to protect the ligament replacement 102 during flexure of the joint 70 by providing rounded support surfaces 181A, 181B ("181") at the entrances 65A, 65B ("65") of the bone tunnels 64. The rounded support surfaces 181 support the ligament replacement 102 and reduce the risk of exposing the ligament replacement 102 to a sharp edge or pinch points at the entrances 65 to the bone tunnels 64.

[00126] In another embodiment, the rounded surfaces 181 are slightly recessed into the bone tunnels 64 (see e.g. Figure 9C). The diameter of the ligament replacement 102 is preferably less than the diameter of the bone tunnels 64 to permit flexure of the joint 70 with impinging at the entrances 65.

[00127] In one embodiment, the position of the threaded traveler 126 engaged with threaded lumen 122 in the fastener 124 is adjusted during the healing process. The amount of tension 112

provided by the neck portion 180 is preferably reduced over time to progressively transfer the load generated by the knee joint 70 onto the ligament replacement 102. Alternatively, the neck portion 180 is bio-absorbable.

[00128] Figure 8C illustrates a variation of the fixation device 170 with an internal tension member 182 that carries a portion of the load of the knee joint 70 in accordance with an embodiment of the present disclosure. In one embodiment, the fastener 127 is implanted in the patient and the implantation procedure is conducted through the lumen 135. The tension member 182 can be constructed from a variety of elongated, flexible materials, such as metal wire, polymeric materials such as a monofilament, or combinations thereof. The tension member 182 can be a single filament or a plurality of filaments, a cable, a braid, woven or non-woven structures, mesh, and the like.

[00129] Distal end 186 of the internal tension member 182 is attached to the expandable member 172 on one side of knee joint 70. Proximal end 184 of the tension member 182 is attached to the threaded traveler 126 located in threaded lumen 135 of the fastener 127. Tension 112 on the tension member 182 is adjusted by moving the threaded traveler 126 within the threaded lumen 135.

[00130] Proximal end 185 of the neck portion 180 is attached to sliding member 125. In one embodiment, the sliding member 125 is attached to the proximal end 185 of the neck portion 180 before the fixation device 170 is implanted in the patient. The neck portion 180 can be attached using spot welding, adhesives, and the like. Nut 131 engages with the threaded portion 129 to adjust tension 113 on the neck portion 180. Consequently, tension 113 on the neck portion 180 can be adjusted independently from tension 112 on the tension member 184.

[00131] The tension member 182 is preferably located in a sheath 188 that prevents adhesion between the tension member 182 and the biomaterial 104. The sheath 188 is preferably made from a flexible biocompatible polymeric material. During delivery of the biomaterial 104, both the sheath 188 and the delivery tube (see Figure 4) extend through the valves 176, 178. After the delivery tube is removed, the valves 176, 178 close around the sheath 188.

[00132] In operation, the surgeon rotates the nut 131 to displace the sliding member 125 in the direction 133 relative to the fastener 127 until the desired level of tension 113 is applied to the neck portion 180. The surgeon then rotates the threaded traveler 126 to adjust the tension 112 on the tension member 182.

[00133] The fastener 127 permits the tension 113 on the tension member 182 and the tension 112 on the neck portion 180 to be readjusted during the healing process. Consequently, whether

the tension 112 provided by the tension member 182 is greater than, less than, or equal to, the tension 113 on the neck portion 180 may vary during the healing process.

[00134] The biomaterial 104 in the chambers 180A, 180B serves to isolate the tension member 182 from the ligament replacement 102 at the entrances to the bone tunnels 64. Consequently, the bone growth into and around the ligament replacement 102 in the bone tunnels 64A, 64B proceeds substantially without disruption from the tension member 182.

[00135] In one embodiment, the tension 112 on the tension member 182 is initially greater than the tension 113 on the neck portion 180. During the healing process the tension member 182 carries most of the load generated at the knee joint 70. The tension member 182 serves to decouple the load generated by the knee joint 70 from the neck portion 180 supporting the ligament replacement 102. Consequently, the neck portion 180 and the ligament replacement 102 are less likely to be damaged or displaced during healing. Again, the position of the threaded traveler 126 within the fastener 124 is preferably adjusted during the healing process so the amount of tension 112 provided by the tension member 182 is reduced over time.

[00136] In one embodiment, the tension member 182 is elastic or otherwise designed to stretch. In this embodiment, the tension member 182 acts as a shock absorber on the joint. The tension member preferably reaches maximum elongation before the joint 70 exceeds the desired range of motion, thereby acting as a stop on the joint 70.

[00137] In another embodiment, the tension 112 on the tension member 182 is less than the tension 113 on the neck portion 180. Consequently, the tension member 182 only acts on the joint 70 at or near the limits of the range of motion. Consequently, the ligament replacement 102 and the neck portion 180 support and stabilize the joint 70 during normal usage, while the tension member 182 provides an overload tension that acts to protect the joint from exceeding the desired ranges of motion.

[00138] Figures 9A and 9B illustrate an alternate fixation device 200 with a plurality of discretely expandable chambers 202A, 202B ("202") adapted to bias ligament replacement 102 into engagement with the bone tunnels 64A, 64B ("64") in accordance with an embodiment of the present disclosure. Valve 204A, 204B ("204") isolate the chamber 202A in neck portion 208. The valves 206A, 206B ("206") isolate portion 202B of the neck portion 208. The chambers 202A, 202B can be filled sequentially from either or both ends of the neck portion 208

[00139] As best illustrated in Figure 9B, the biomaterial 104 is injected into the chambers 202, which moves the ligament replacement 102 into engagement with bone tunnels 64 on the bones 54, 56. The valves 204, 206 retain the biomaterial 104 in the chambers 202.

[00140] Fasteners 124A, 124B ("124") are then attached to the distal ends 210A, 210B of the neck portion 208, such as with compression fittings 128A, 128B, as discussed herein. Both of the fasteners 124 include threaded members 126A, 126B ("126") engaged with threaded lumens 122A, 122B ("122"), respectively, so that tension 112 can be adjusted at either or both fasteners 124.

[00141] Figure 9C illustrates a variation of the fixation device 200 with an internal tension member 222 that carries a portion of the load of the knee joint 70 in accordance with an embodiment of the present disclosure. Ends 224A, 224B of the tension member 222 are attached to the threaded travelers 126A, 126B in the fasteners 127A, 127B.

[00142] Proximal end 207 of the neck portion 208 is attached to sliding member 125A located in the fastener 127A. Threaded portion 129A engages with nut 131A to displace the sliding member 125A in direction 133A. Distal end 209 of the neck portion 208 is attached to sliding member 125B located in fastener 127B. Threaded portion 129B engages with nut 131B to displace the sliding member 125B in direction 133B.

[00143] Tension 113 on the neck portion 208 is adjusted by rotating the nuts 131A, 131B to move the sliding members 125A, 125B in the directions 133A, 133B, respectively. Once the desired level of tension 113 is achieved, the tension 112 on the tension member 222 is adjusted by rotating the threaded travelers 126A, 126B located in the threaded lumens 122A, 122B of the sliding members 125A, 125B.

[00144] The tension member 222 is preferably located in a sheath 228 that prevents adhesion between the tension member 222 and the biomaterial 104. The tension member 222 serves to decouple the load generated by the knee joint 70 from the tension 113 applied to the neck portion 208 supporting the ligament replacement 102. Consequently, the neck portion 208 and the ligament replacement 102 are less likely to damaged during healing. Again, the position of the threaded travelers 126A, 126B within the threaded lumens 122A, 122B of the fasteners 127A, 127B are preferably adjusted during the healing process so the amount of tension 112 provided by the tension member 222 is reduced over time.

[00145] Figure 9C illustrates an embodiment in which the rounded surfaces 181 are slightly recessed into the bone tunnels 64 (see e.g. Figure 9C). Diameter 102D of the ligament replacement 102 is preferably less than diameter 64D of the bone tunnels 64 so permit flexure of the joint 70 with impinging at the entrances 65.

[00146] Figure 8D is a schematic illustration of a fixation device 230 with ligament replacement 102 tensioned directly by fastener 127. Proximal end 232 of the ligament replacement 102 is attached to the sliding member 125, such as by an intermediate mesh

structure, sutures, staples, and the like. Consequently, graft tension 234 can be adjusted by rotating the nut 131 to move the sliding member 125 relative to the fastener 127.

[00147] Porous structures 242 are expanded with biomaterial 104 to compressively engage the ligament replacement 102 with the bone tunnels 64. The flowable biomaterial 104 is preferably a resorbable, bone-growth stimulating composition that accelerates attachment of the ligament replacement 102 to the surface inside the bone tunnels 64. The biomaterial 104 interacts with the surfaces inside of the bone tunnels 64 through openings in the porous structure 242.

[00148] Optional support tension 236 is applied by tension member 238 located in sheath 240 by rotating the threaded traveler 126. Consequently, the graft tension 234 can be adjusted independently from the support tension 236. The porous structures 242 serve to isolate the tension member 238 from the ligament replacement 102 during flexure of the joint 70. In particular, during flexure of the joint 70 the support tension 236 is applied to the ligament replacement 102 over the larger surface area of the porous structures 242, reducing the chance of pinch points.

[00149] Figure 9D is a schematic illustration of fixation device 250 with ligament replacement 102 tension directly by fasteners 127A, 127B. Again, graft tension 234 can be adjusted by rotating nuts 131A, 131B. Porous structures 252 are expanded with biomaterial 104 to compressively engage the ligament replacement 102 with the bone tunnels 64. Optional support tension 236 is adjusted by rotating threaded travelers 126A, 126B located in threaded lumens 135A, 135B, respectively.

[00150] Figure 10A is an exploded view of a modular fixation device 300 for use in a fixation system in accordance with an embodiment of the present disclosure. Expandable members 302A, 302B include tubular couplings 304 with internal threads 306 and optional check-valves 308. The expandable member 302 can be bonded to the couplings 304 using a variety of techniques, such as adhesives, solvent bonding, mechanical deformation, mechanical interlock, spot welding, compression rings, or a variety of other techniques.

[00151] Extension 314 similarly includes tubular couplings 316 with internal threads 318 similar to the internal threads 306. Hollow threaded members 320 are provided with external threads 322 that mate with the internal threads 306, 318, permitting the expandable members 302 to be assembled in a modular fashion to accommodate the individual patient. In the illustrated embodiment, the extension 314 includes a lumen that permits fluid communication between the expandable members 302.

[00152] The couplings 304, 316, 320 are preferably located in the bone tunnels. The rigidity of the couplings 304, 316, 320 protect the ligament replacement from being pinched during flexure of the joint.

[00153] Figure 10B illustrates an alternate modular fixation device 350 connected by an alternate extension 352 for use in a fixation system in accordance with an embodiment of the present disclosure. The extension 352 includes threaded couplings 354 configured to mate with internal threads 356 on couplings 358 attached to the expandable members 360. The extension 352 can be constructed using any of the strategies used for the neck portion 94 discussed above.

[00154] In one embodiment, the extension 352 is a solid material that does not fluidly couple the expandable members 360. Consequently, the biomaterial 104 is delivered through distal couplings 362 having check-valves 364 for each of the expandable member 360. In one embodiment, the extension 352 is a ribbon structure that acts as a living hinge across a natural joint. In another embodiment, the extension 352 is a plurality of filaments. In another embodiment, the extension 352 is a ligament replacement 102. The threaded couplings 354 can be attached to the ligament replacement 102 using a variety of techniques, including compressive coupling, sutures, adhesives and the like.

[00155] Figure 11 illustrates a kit 370 for implanting a fixation system in accordance with an embodiment of the present disclosure. The kit 370 includes a plurality of discrete components 372A-372F ("372") that are assembled in a modular fashion to form a fixation device in accordance with an embodiment of the present disclosure. The kit 370 also includes the probe 374, tension member 376, the delivery tube 378, and fastener 382. The discrete components 372 are provided in a variety of sizes and shapes.

[00156] Each discrete component 372 includes one or more couplings 380 that fluidly couple with mating couplings 380 on an adjacent porous structure 372. The couplings 380 can be a variety of threaded or interlocking fittings that both mechanically interconnect and fluidly couple the components 372. In one embodiment, distal end 384 of the sliding member 386 is preferably configured to mate with the couplings 380.

[00157] The discrete components 372 can be configured to meet the patient's needs. In one embodiment, the couplings 380 include check-valve assemblies, as discussed herein. The modular nature of this alternate embodiment permits the surgeon to reconfigure the porous structure for the particular patient. In particular, the discrete components 372 can be configured in a non-linear arrangement.

[00158] Figure 12 illustrates an alternate fixation device 400 for repair and replacement of an anterior or a posterior cruciate ligament using arthroscopic or minimally invasive surgical

procedure in accordance with an embodiment of the present disclosure. The present method and apparatus permit the fixation device 400 to be implanted through a single access portal, such as through cannula 402.

[00159] The patient's skin 404 is opened to permit entry of the cannula 402 to the distal femur 406. With the knee joint 408 bent, straight or non-straight tunnels 410A, 410B ("410") are formed through the distal femur 406 and proximal tibia 412. The tunnels 410 preferably extend through the ligament connection sites or points of origin in the knee joint 408 with both tunnel ends 410 extending through the bone cortexes.

[00160] Fixation device 400 is inserted through the cannula 402 and positioned in the tunnels 410. Biomaterial 104 is delivered to the expandable members 414, 416, as discussed herein. Valves 418 isolate the biomaterial 104 in the expandable members 414, 416, but prevent biomaterial 104 from entering neck portion 420. The expandable member 416 is preferably filled with biomaterial before the expandable member 414.

[00161] Tension member 422 located in sheath 424 is positioned in the fixation device 400 to adjust the tension 426 applied to the knee joint 408. Proximal end 428 of the tension member 422 attaches to threaded traveler 430. Fastener 432 is engaged with tunnel 410A in distal femur 406. Tension 426 applied to the knee joint 408 is adjusted by rotating the threaded member 430 in the fastener 432.

[00162] Neck portion 420 can be a variety of elongated, flexible materials, such as metal wire or cable, monofilament of a polymeric material, or a variety of other materials. The neck portion 420 is preferably a woven or braided mesh that permits axial elongation. In the illustrated embodiment, ligament replacement 432 is attached to neck portion 420. Any of the methods discussed herein can be used to cause the ligament replacement 434 to contact inside surfaces of bone tunnels 410.

[00163] In one embodiment, the neck portion 420 is a woven hollow mesh tube containing a replacement ligament replacement. The openings in the mesh of the neck portion 420 permits in-growth at the tunnels 410. Various methods of replacing a cruciate ligament utilizing arthroscopic procedures are disclosed in U.S. Pat. Nos. 8,100,969 (Hart); 7,862,612 (Re et al.); 6,679,889 (West et al.); 6,379,384 (McKernan et al.); 5,702,397 (Goble et al.); 4,772,286 (Goble et al.); and U.S. Pat. Publication Nos. 2008/0300683; 2011/0153018; 2004/0194789 (Whelan); 2008/0275453 (Lafosse et al.); 2010/0249930 (Myers); 2010/0292792 (Stone et al.), which are hereby incorporated by reference. In particular, the tunnels 410 can be formed from the proximal tibia 412 side of the knee joint 408.

[00164] In one embodiment, the neck portion 410A is filed with a biomaterial 102, such as for example bone cement, in order to reinforce the bone 406. The sheath 424 serves to isolate the tension member 422 from the biomaterial 102.

[00165] Figure 13 illustrates a fixation device 450 for coupling two or more bones 452A, 452B ("452") in tension to control relative motion between the bones 452 and/or to provide inter-fragmentary stabilization in accordance with an embodiment of the present disclosure. The fixation device 450 gives a physician the ability to manipulate movement between the bones 452 in joints with low relative axial motion. In the preferred embodiment, the fixation device 450 include adjustable fastener 454 to control the position (e.g., alignment), the amount of rotation, and the resistance to shear. The amount of desired rotation and shear is preferably adjustable post-surgery.

[00166] The embodiment of Figure 13 is directed to carpal alignment and restoring normal range of motion between the scaphoid and lunate bones, although the fixation device 450 may be used to position and secure other bones. Examples of other applications include the acromioclavicular joint, scapho lunate joint, coraco clavicular joint, and any other low axial motion joint, as well as joints between the tarsals, metatarsals, other carpal bones and metacarpals.

[00167] The fixation device 450 can be used on a temporary or permanent basis. For example, after healing it is possible to release the tension 476 on the tension member 456 to permit the joint to function substantially normally.

[00168] The fixation device 450 is preferably implanted using minimally invasive techniques. In one embodiment, the physician makes a small incision in the skin 458 and inserts cannula 460 to provide access to bone 452A. The cannula 460 typically has a outside diameter from about 6 millimeters to about 4 millimeters. A hole is drilled through bone 452A, across space 462 of the joint 464 and partway into bone 452B. In one embodiment, the surgeon drills a larger diameter hole in the bone 452A corresponding to diameter of fastener 454.

[00169] Once the joint 464 is prepared, the fixation device 450 is inserted through the cannula 460 and positioned so the expandable member 470 is located in the bone 452B and the expandable member 472 is located in the bone 452A, with neck portion 474 spanning the space 462 of the joint 464. The flowable biomaterial 104 is then delivered under sufficient pressure to expand the expandable members 470, 472, generally as illustrated in Figure 13. The fixation device 450 preferably includes valves 471 to prevent the biomaterial from entering the neck portion 464.

[00170] In one embodiment, the neck portion 474 is filled with a material that prevents bone in-growth with the bones 452. The neck portion 474 can optionally be filled with other materials to promote healing, lubricate the joint 464, and the like. In another embodiment, ligament replacement 102 can be contained in and/or attached to the neck portion 474. The porous structure of the neck portion 474 permits the graft to bond with the bones 452.

[00171] As illustrated in Figure 14, the fixation device 450 includes tension member 456 attached to a threaded member 486 located in threaded lumen 490 of sliding member 491. The neck extension 474 attached to the expandable member 472 is attached to the sliding member 491. Nut 496 serves to displace the sliding member 491 in the direction 494. Consequently, the tension force 476 can be created by tension applied to the neck portion 474, the tension member 456, or a combination thereof.

[00172] The fastener 454 is preferably a bone anchor that is screwed or press fit into the bone 452A. The tension member 456 can be a single strand of material or it can be made from multiple strands that are braided or otherwise formed as a single element. The tension member 456 can be a variety of elongated, flexible materials, such as metal wire or cable, monofilament of a polymeric material, or a variety of other materials. For example, the tension member 456 can be fiber-wire, ultra-braid, dura-braid, and the like. A variety of mechanisms can be used to engage the tension member 756, such as disclosed in U.S. Pat. Publication Nos. 2007/0203498 (Gerber), 2006/0100630 (West, Jr.) and U.S. Pat. Nos. 5,702,397 (Goble et al.); 6,146,406 (Shluzas et al.) and 6,770,076 (Foerster), which are hereby incorporated by reference.

[00173] After the tension 476 is set, the surgeon removes the cannula 460 and closes the incision in the skin 458. In one embodiment the tension member 456 is contained in a flexible polymeric sheath 488 that prevents the biomaterial 104 or the bone 452A from bonding to the tension member 456. Consequently, the surgeon has the option to adjust the tension force at a later date simply by making a small incision in the skin 458 and accessing the fastener 454.

[00174] Figure 15 illustrates using a fixation device 500 spanning joint 502 between adjacent bones 504A, 504B ("504") according to an embodiment of the present disclosure. The expandable member 506 preferably includes check-valve assemblies 508 so that biomaterial 104 does not flow into neck portion 510. Neck portion 510 acts as a living hinge at the joint 502 to maintain alignment of the adjacent bone 504. The neck portion 510 preferably includes a ligament replacement, such as discussed herein.

[00175] Tension member 512 optionally extends from distal end 514 of the expandable member 506, through neck portion 510 to fastener 515. The fastener is located in bore 516 that is oriented at an acute angle with respect to the axis of the joint 502. The bore 516 is preferably

drilled with sufficient depth to fluidly communicate with the bore 519 containing the neck portion 510. The tension member 512 is preferably sufficiently flexible to navigate the angle between the fastener 515 and the axis of the bore 519. In the illustrated embodiment, the load on the tension member 512 at the transition between the fastener 515 and the neck portion 510 is preferably carried by the fastener 515.

[00176] In the preferred embodiment, the tension member 512 is located in a polymeric sheath to prevent bonding with the biomaterial 104 (see e.g., Figure 14). Fastener 515 secured to the tension member 512 maintains the tension force 518 at the joint 502. The tension force 518 can be adjusted by rotating the threaded traveler 517 within the fastener 515. A variety of other mechanisms can be used to tension the tension member 512, such as disclosed in U.S. Pat. Publication Nos. 2007/0203498 (Gerber), 2006/0100630 (West, Jr.) and U.S. Pat. Nos. 6,146,406 (Shluzas et al.); 6,770,076 (Foerster); 5,505,735 (Li); and 5,571,104 (Li), which are hereby incorporated by reference. In embodiments where the biomaterial 104 is prevented from bonding to the tension member 512, the surgeon can adjust the tension force 518 at a later date during an outpatient procedure. A method and device for stabilizing joints with limited axial movement is disclosed in U.S. Pat. Publication No. 2008/0269743 (McNamara et al.), which is hereby incorporated by reference.

[00177] Figures 16A-16D is a schematic illustration of a fixation device 520 with multiple expandable members 522A-522C ("522") connected by neck portions 524A, 524B ("524") in accordance with an embodiment of the present disclosure. The fixation device 520 can be a unitary structure of woven fibers that provides high tensile strength along the length of the fixation device 540 (see Figure 16D). Alternatively, the fixation device 520 can be modular, such as illustrated in Figures 10A, 10B, and 11. The present fixation device 520 can be used alone or in combination with another orthopedic device.

[00178] In one embodiment, the expandable members 522 are a porous structure to permit the biomaterial 104 to fuse with the bone of the patient. The neck portions 524 can be any of a variety of mesh and non-mesh materials.

[00179] In the illustrated embodiment, one or more check-valve assemblies 526A-526E ("526") are located in the fixation device 520 at various transition locations. The check-valve assemblies 526 can be secured to the fixation device 520 by a variety of techniques, such as adhesives, spot welding, compression rings, mechanical fasteners, and the like.

[00180] As illustrated in Figure 16A, check-valve 526A is positioned to isolate expandable member 522A. The check-valve 526A permits the biomaterial 104 to be delivered through

delivery tube 528 under pressure so as to displace any cancellous bone, without entering the other portions of the fixation device 520.

[00181] As illustrated in Figure 16B, the delivery tube 528 is retracted in direction 530 and the check-valve 526A closes. Biomaterial is optionally delivered into neck portion 524A. Alternatively, since the neck portion 524A typically only operates in tension, no biomaterial is required. Distal end 532 of the delivery tube 528 next positioned in the expandable member 522B. Check-valves 526B, 526C isolate the biomaterial 104 in the expandable member 522B.

[00182] As illustrated in Figure 16C, the delivery tube 528 is then moved further in direction 530 so the distal end 532 is located in expandable member 522C. Check-valves 526D and 526E isolate the biomaterial 104 in the expandable member 522C.

[00183] Figure 16D illustrates the fixation system 540 in accordance with an embodiment of the present disclosure. The delivery tube 528 is removed from the fixation device 520 and at least the expandable members 522 are filled with biomaterial 104. All of the check-valve assemblies 526 are closed. It will be appreciated that the number, shape and size of expandable members 522 and the neck portions 524 can vary depending on the application.

[00184] Figure 17 illustrates an alternate fixation system 550 for a knee joint 70 in accordance with an embodiment of the present disclosure. Damaged ligament 552A and healthy ligaments 552B ("552") are threaded through bone tunnel 554 in the femur 56. Proximal ends 556 of the ligaments 552 are attached to sliding member 558 located in fastener 560. In the illustrated embodiment, an intermediate mesh structure 562 is used to attached the proximal ends 556 to the sliding member 558.

[00185] Tension member 564 is attached to threaded traveler 566 as discussed herein. Distal end of the tension member 564 is attached to tibia 54 with fastener 568, along with the damaged ligament 552A.

[00186] In one embodiment, the surgeon rotates the nut 572 to achieve the desire ligament tension 574 in the joint 70. The ligament tension 574 is primarily applied to the health ligament 552B. The threaded traveler 566 is then rotated to increase the support tension 576 on the damaged ligament 552A to match the ligament tension 574. The present embodiment permits the surgeon to independently control the tension on the damaged and the healthy ligament to achieve the desired balance of tensions in the joint 70.

[00187] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range

is encompassed within the embodiments of the disclosure. The upper and lower limits of these smaller ranges which may independently be included in the smaller ranges is also encompassed within the embodiments of the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the embodiments of the present disclosure.

[00188] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the embodiments of the present disclosure belong. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the embodiments of the present disclosure, the preferred methods and materials are now described. All patents and publications mentioned herein, including those cited in the Background of the application, are hereby incorporated by reference to disclose and described the methods and/or materials in connection with which the publications are cited.

[00189] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[00190] Other embodiments of the disclosure are possible. Although the description above contains much specificity, these should not be construed as limiting the scope of the disclosure, but as merely providing illustrations of some of the presently preferred embodiments of this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the present disclosure. It should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed embodiments of the disclosure. Thus, it is intended that the scope of the present disclosure herein disclosed should not be limited by the particular disclosed embodiments described above.

[00191] Thus the scope of this disclosure should be determined by the appended claims and their legal equivalents. Therefore, it will be appreciated that the scope of the present disclosure fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present disclosure is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean “one and only one” unless explicitly so stated, but rather “one or more.” All structural, chemical, and

functional equivalents to the elements of the above-described preferred embodiment(s) that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present disclosure, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims.

What is claimed is:

1. A fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient, the fixation system comprising:

a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone;

a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone;

at least one segment of ligament replacement adapted to extend through the bone tunnels and span the joint, the ligament replacement retained at a graft tension by the first and second fasteners; and

a structure adapted to extend through the bone tunnels and span the joint with the ligament replacement, the structure retained at a support tension by the first and second fasteners, wherein the graft tension and the support tension are independently adjustable.

2. The fixation system of claim 1 wherein the structure comprises:

at least one porous member adapted to expand within one of the bone tunnels to compressively engage the ligament replacement with the adjacent bones; and

a flowable biomaterial comprises a resorbable, bone-growth stimulating composition adapted to expand the porous structure in situ, the biomaterial adapted to interact with the surfaces inside of the bone tunnel through the porous structure.

3. The fixation system of claim 1 wherein the porous member containing the flowable biomaterial comprise support surfaces for the ligament replacement.

4. The fixation system of claim 1 wherein the structure comprises a porous tubular support structure substantially surrounding the graft tension, such that the ligament replacement is maintained in intimate contact with surface inside the first and second bone tunnels through openings in the porous structure.

5. The fixation system of claim 1 wherein the graft tension is less than the support tension.

6. The fixation system of claim 5 wherein the support tension is adapted to be subsequently reduced to less than the graft tension.

7. The fixation system of claim 1 wherein the structure comprises a tension member located within a sheath that is adapted to reduce adhesion between the tension member and the patient.

8. A fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient, the fixation system comprising:

a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone;

a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone;

a support structure adapted to extend through the bone tunnels and span the joint, the support structure is retained at a support tension by the first and second fasteners; and

at least one segment of ligament replacement is attached to the support structure at one or more locations and spanning the joint such that the ligament replacement is indirectly attached to the first and second bones by the support structure and the ligament replacement is retained generally at the support tension by the support structure.

9. The fixation system of claim 8 wherein the support structure comprises a porous structure substantially surrounding the graft tension, such that the ligament replacement is maintained in intimate contact with surface inside the first and second bone tunnels through openings in the porous structure.

10. The fixation system of claim 8 wherein the support structure is adapted to bias the ligament replacement in intimate contact with surfaces inside the first and second bone tunnels.

11. The fixation system of claim 8 wherein the support structure comprises:

at least one porous expandable member adapted to expand within one of the bone tunnels to compressively engage the ligament replacement with the adjacent bones; and

a flowable biomaterial comprises a resorbable, bone-growth stimulating composition adapted to expand the porous structure in situ, the biomaterial adapted to interact with the surfaces inside of the bone tunnel through the porous structure.

12. The fixation system of claim 11 wherein the porous member and the flowable biomaterial comprises support surfaces for the ligament replacement.

13. The fixation system of claim 8 comprising a tension member adapted to extend through the bone tunnels and span the joint with the support structure and the ligament replacement, the tension member is retained at a supplemental tension by the first and second fasteners, wherein the support tension and the supplemental tension are independently adjustable.

14. The fixation system of claim 13 wherein the tension member is located within a sheath adapted to reduce adhesion between the tension member and the patient.

15. The fixation system of claim 13 wherein the support tension is initially less than the supplemental tension and the supplemental tension is adapted to be subsequently reduced to less than the support tension.

16. A fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient, the fixation system comprising:

a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone;

a second fastener adapted to be secured in a second bone tunnel extending into the second adjacent bone;

a neck portion adapted to extend through the bone tunnels between the first and second fasteners and span the joint;

an adjustment mechanism adapted to apply a tension force across the joint between the first and second fasteners; and

at least one segment of ligament replacement adapted to be located in the bone tunnels with the neck portion, the neck portion retaining the ligament replacement in intimate contact with surfaces of the bone tunnels in the first and second bones.

17. The fixation system of claim 16 wherein at least one of the first and second fasteners comprises:

an expandable member adapted to be positioned in at least one of the first and second bone tunnels;

a delivery tube adapted to be inserted through the bone tunnels to deliver a flowable biomaterial to the expandable member; and

a flowable biomaterial adapted to flow through the delivery tube and into the expandable member located in the bone tunnels, the combination of the flowable biomaterial and the expandable member comprising an expanded configuration with at least one dimension greater than a diameter of the bone tunnel to secure the expandable member in the bone.

18. The fixation system of claim 16 comprising at least one check-valve assembly on the expandable member adapted to receive the delivery tube and to retain the flowable biomaterial in the expandable member after the delivery tube is removed.

19. The fixation system of claim 18 wherein the expandable member comprises a porous structure and the biomaterial comprises a resorbable, bone-growth stimulating composition that interacts with the cancellous bone through openings in the porous structure.

20. The fixation system of claim 16 wherein one of the first or second fasteners comprise an expandable structure.

21. A fixation system for stabilizing a connection between first and second adjacent bones of a joint in a patient, the fixation system comprising:

a first fastener adapted to be secured in a first bone tunnel extending into the first adjacent bone;

a second fastener adapted to be secured to the second adjacent bone;

at least one segment of ligament replacement adapted to extend through the first bone tunnel and span the joint, the ligament replacement retained at a graft tension by the first and second fasteners; and

a structure adapted to extend through the first bone tunnel and span the joint with the ligament replacement, the structure retained at a support tension by the first and second fasteners, wherein the graft tension and the support tension are independently adjustable.

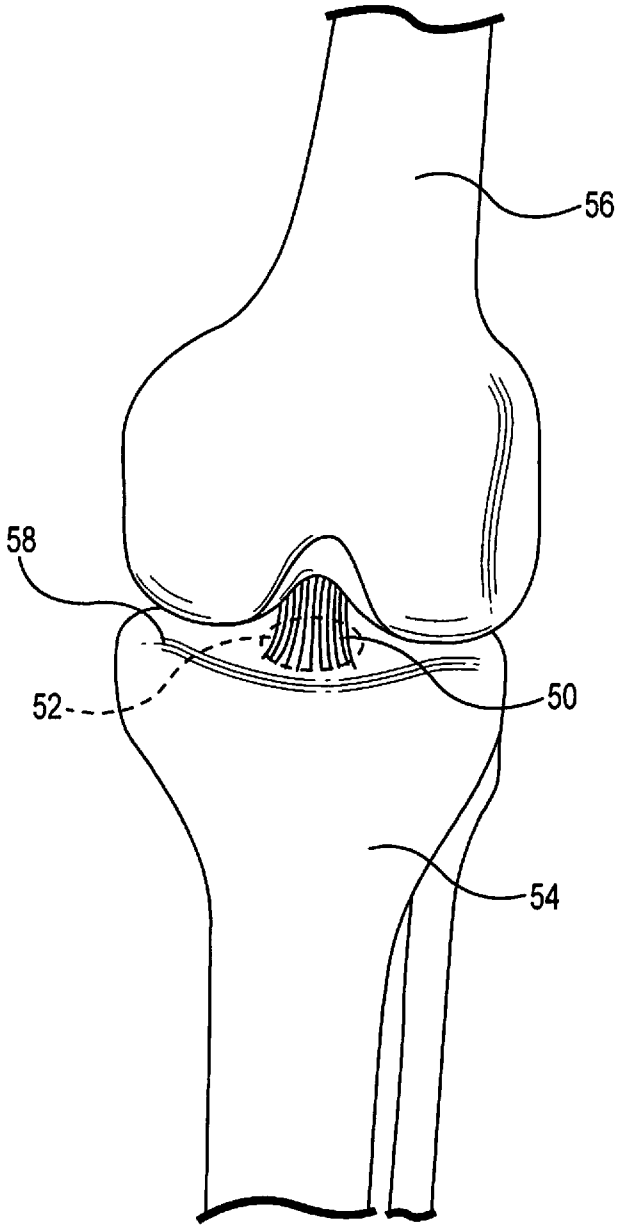


Fig. 1

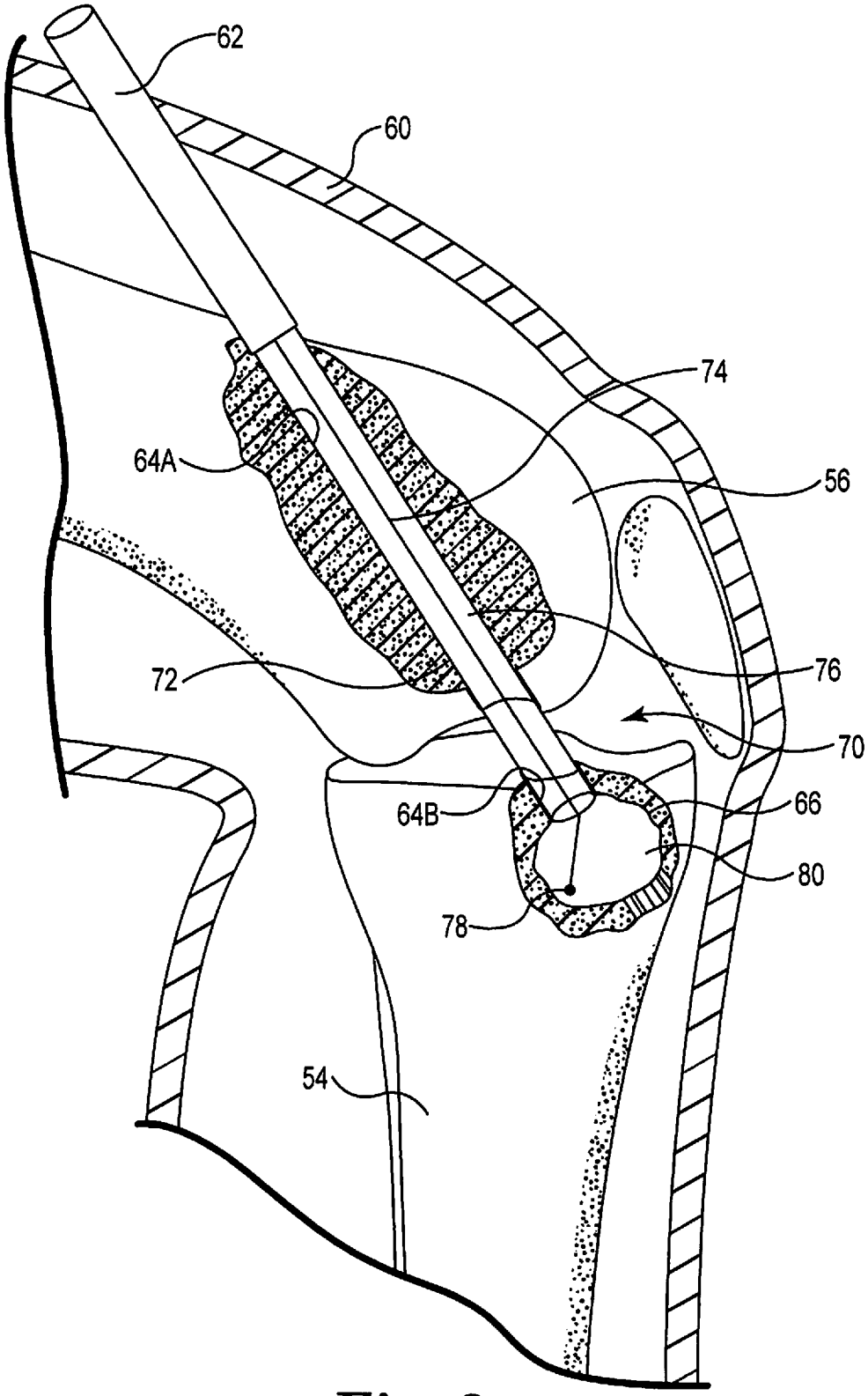


Fig. 2

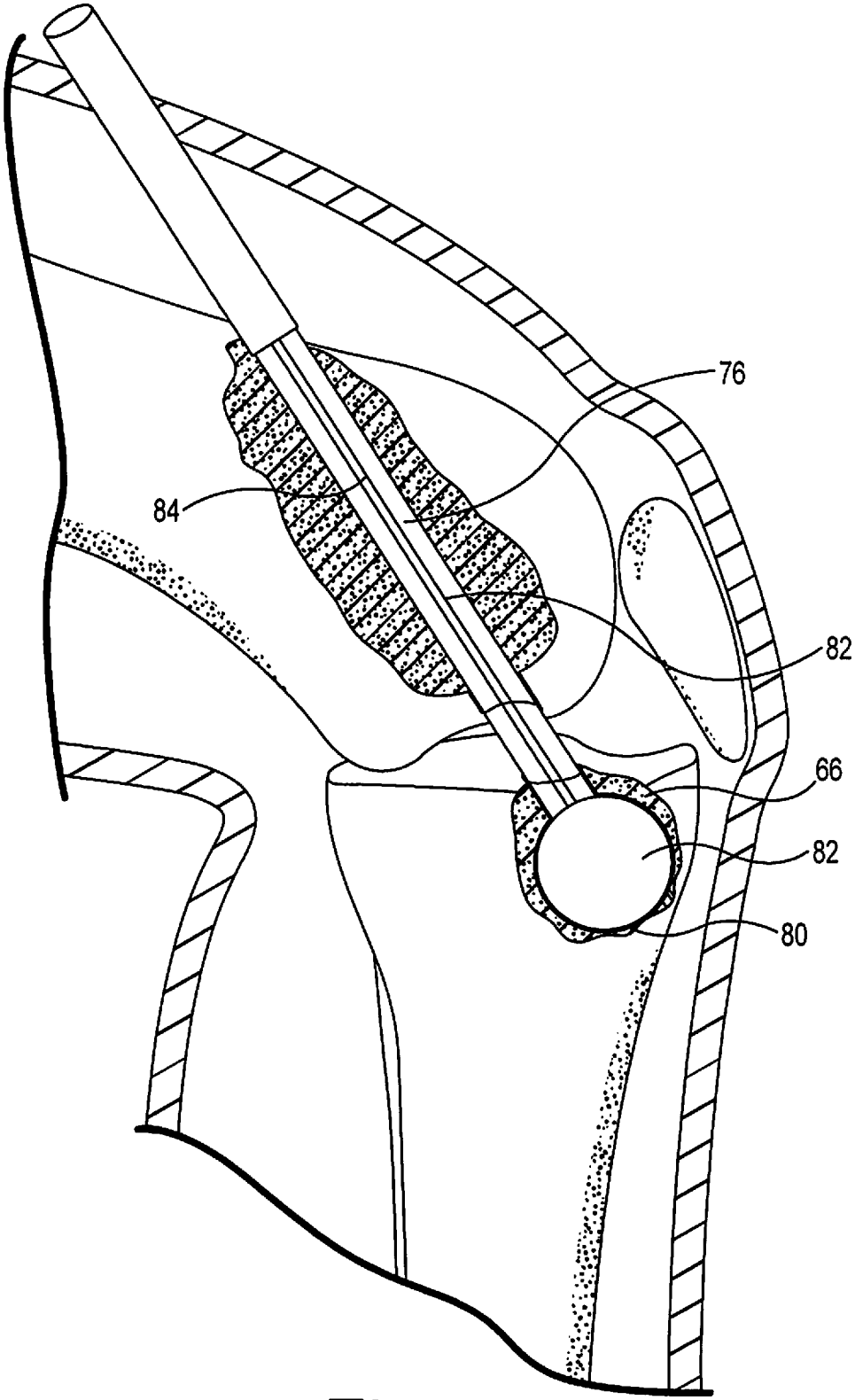


Fig. 3

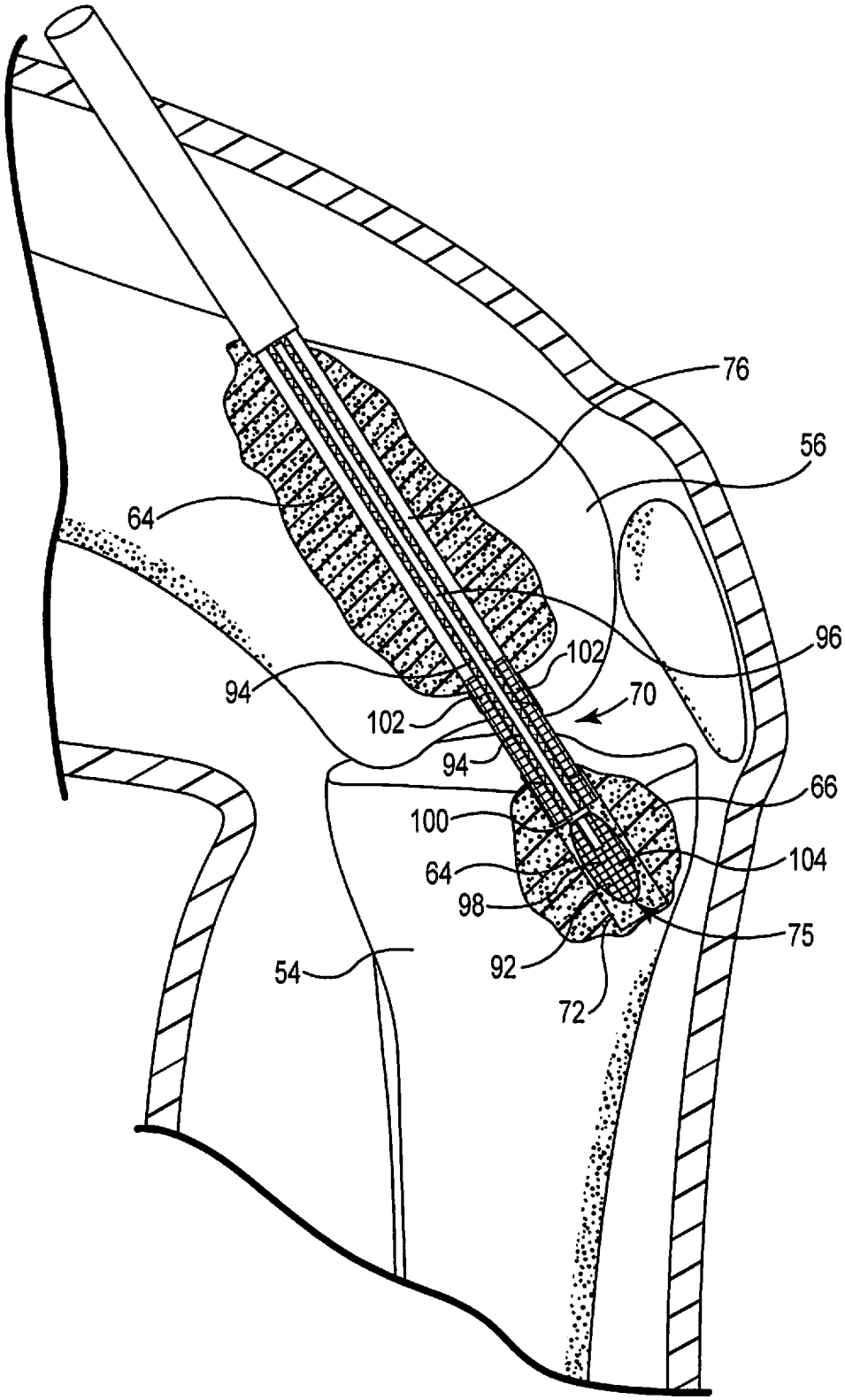


Fig. 4

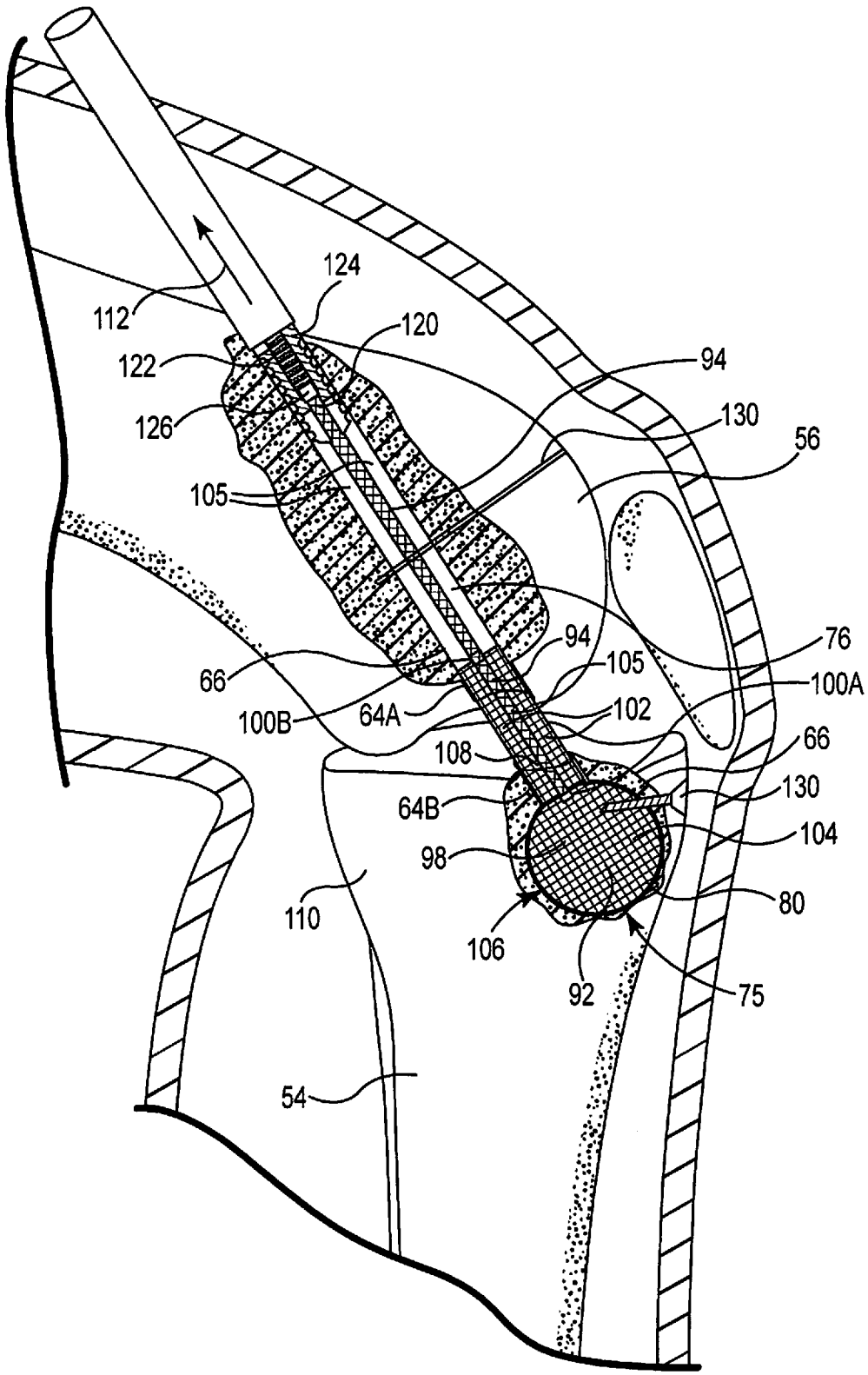

124
112
120
122
94
126
130
56
105
94
76
105
66
100A
64A
102
100B
66
108
130
64B
104
98
80
110
106
92
75
54

Fig. 5

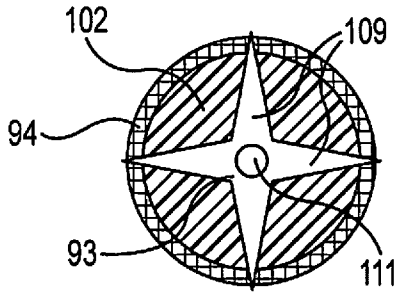
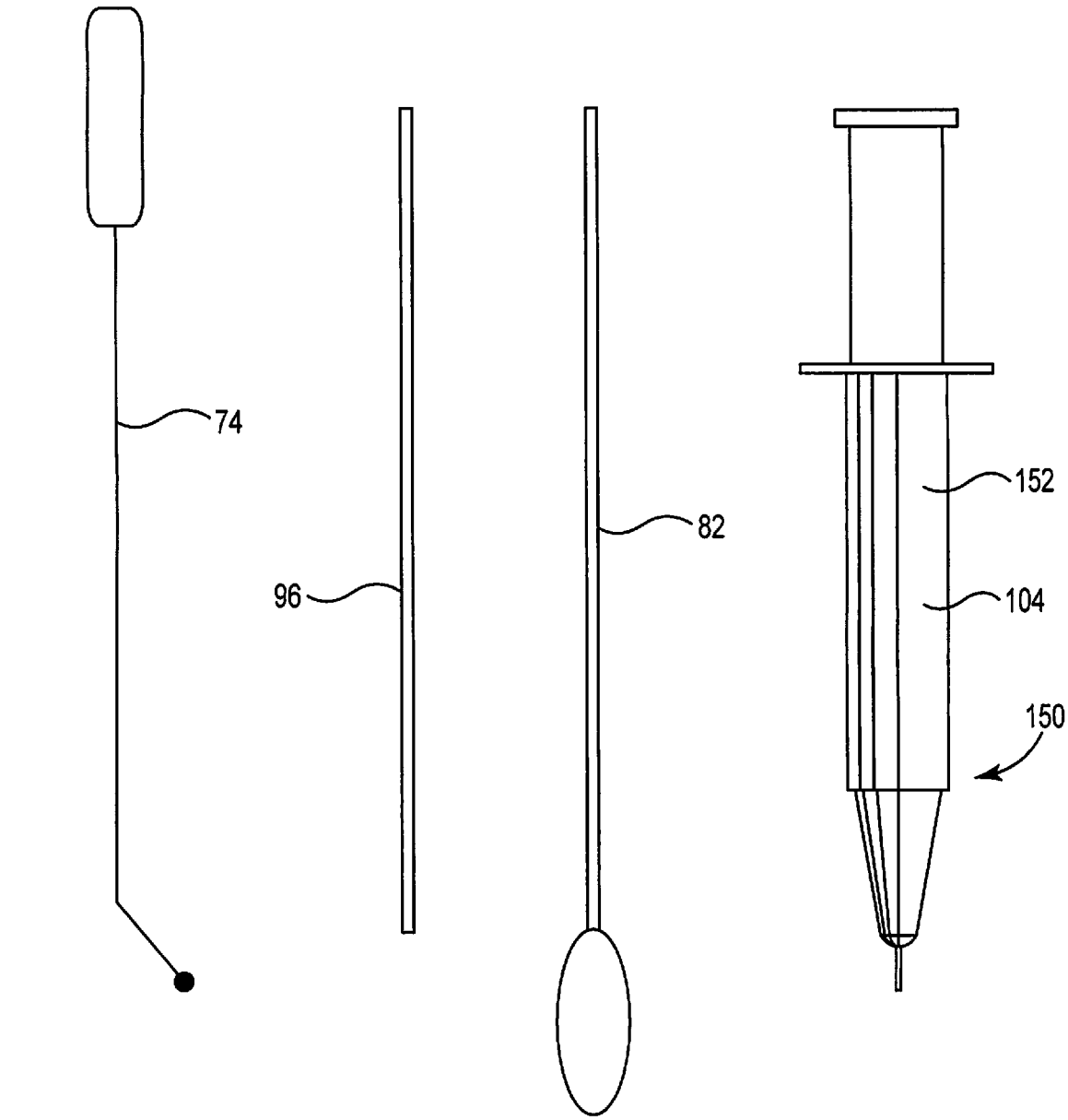

102
109
94
93
111

Fig. 6B

112
56
124
94
100B
64A
107
70
102
64B
100A
130
104
75
98
92
54

Fig. 6A


74
96
82
152
104
150

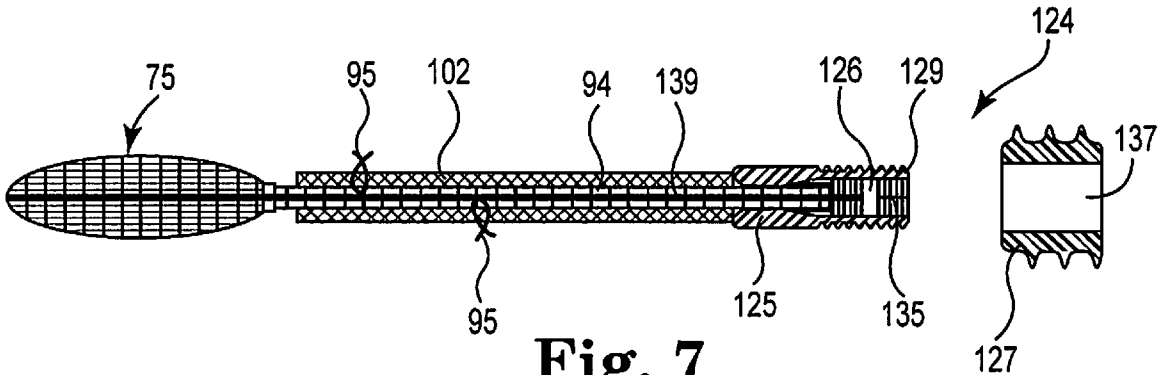

75
95
102
94
139
126
129
124
137
95
125
135
127

Fig. 7

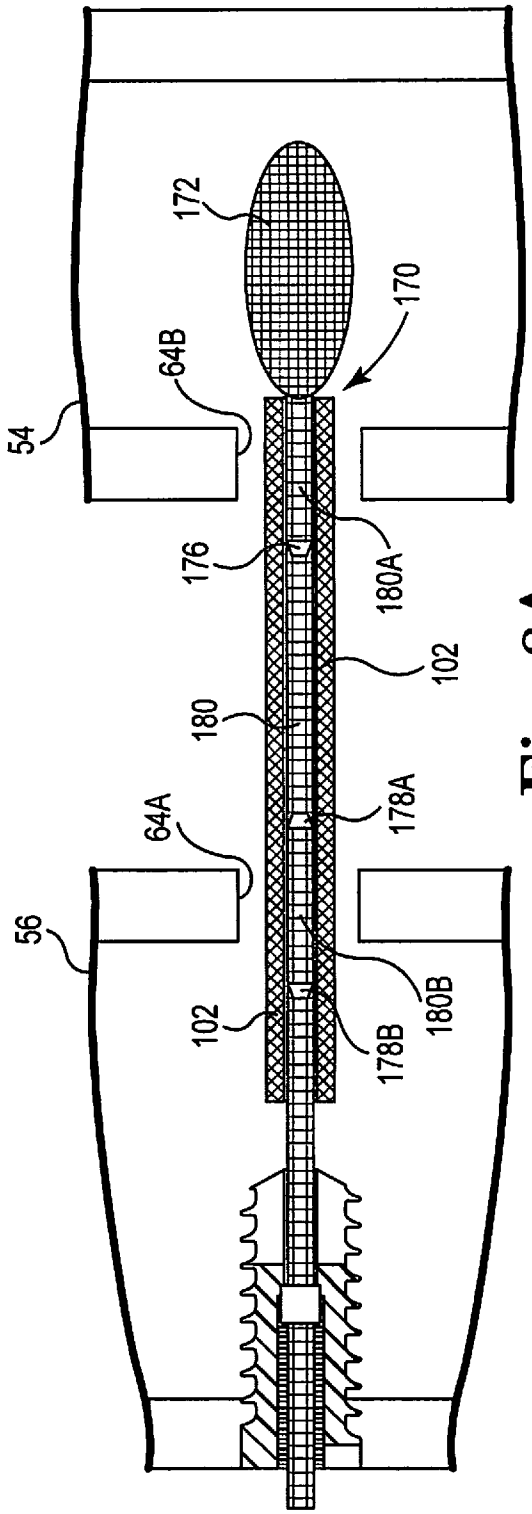

172
170
64B
54
176
180A
102
180
178A
64A
56
102
178B
180B

Fig. 8A

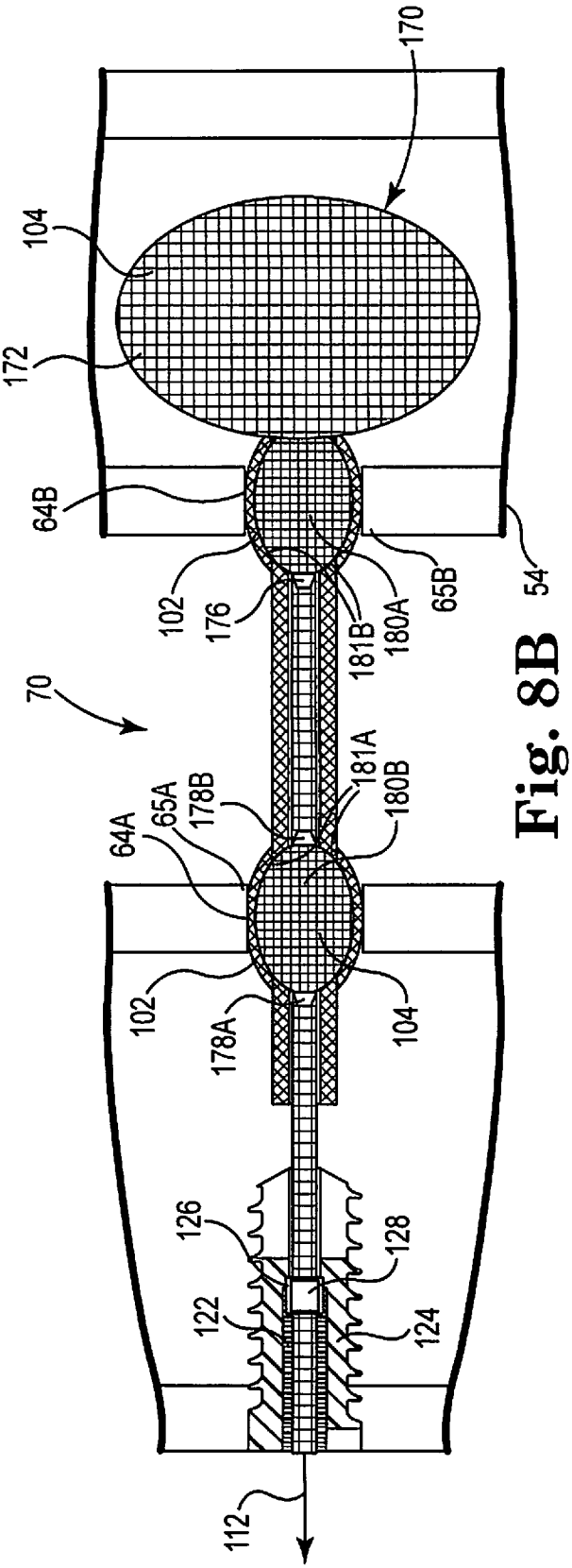

170
104
172
64B
102
176
181B
180A
65B
54
70
181A
180B
64A
65A
178B
102
178A
104
126
128
122
124
112

Fig. 8B

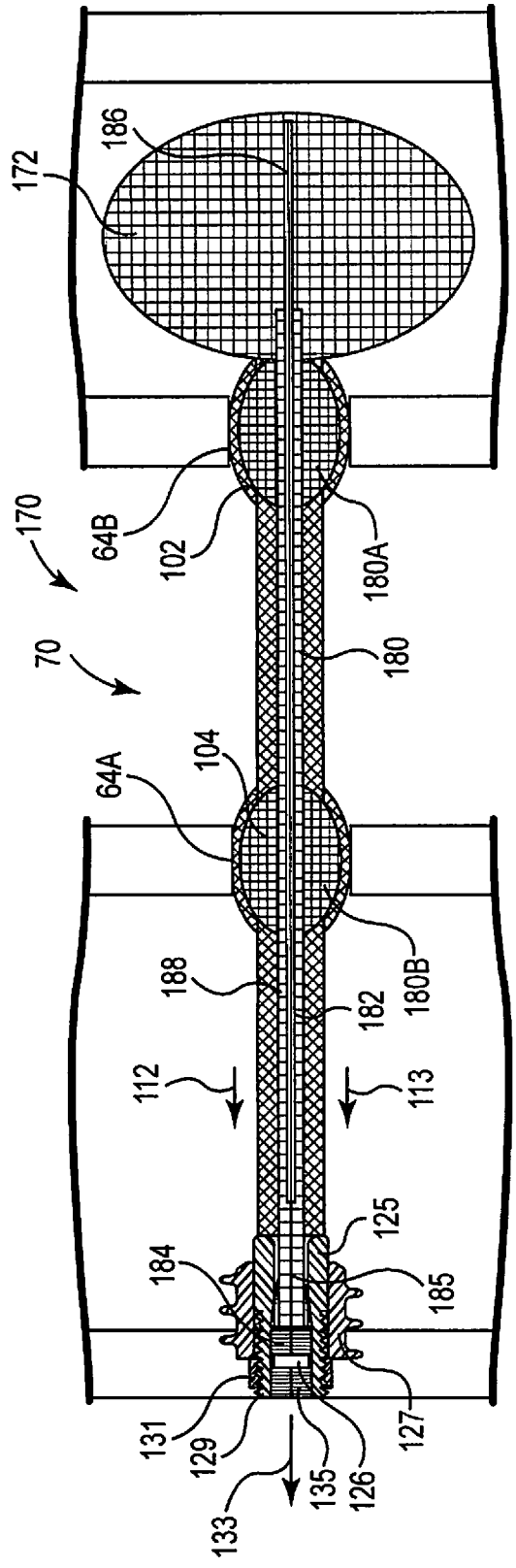

172
186
170
64B
102
180A
70
180
64A
104
188
182
180B
112
113
125
184
185
131
129
135
126
127
133

Fig. 8C

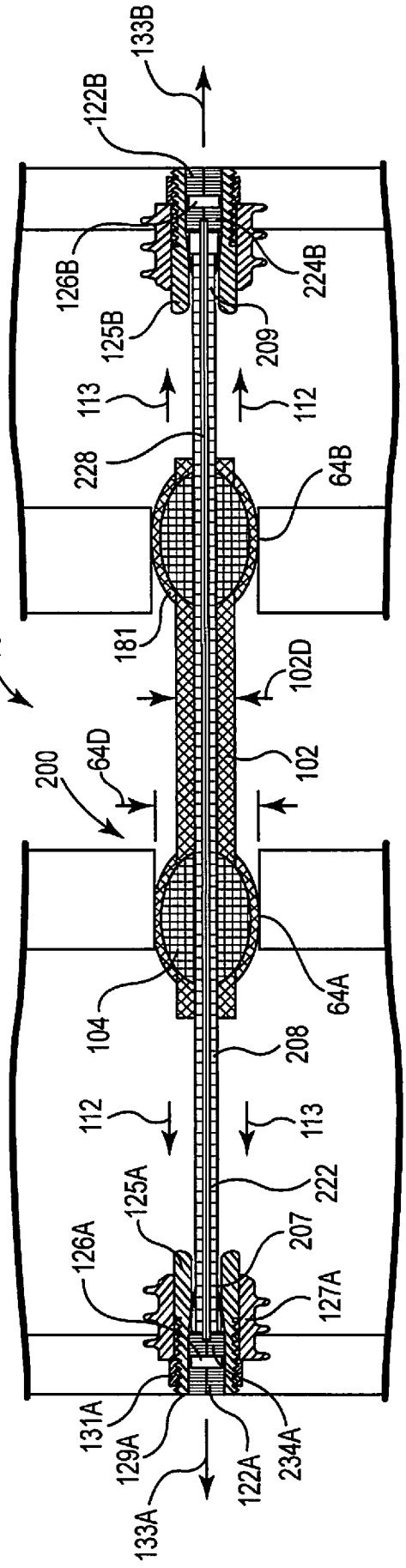

133B
122B
126B
224B
125B
209
113
112
228
64B
181
102D
70
200
64D
102
104
64A
208
112
113
222
125A
126A
207
127A
131A
129A
234A
122A
133A

Fig. 9C

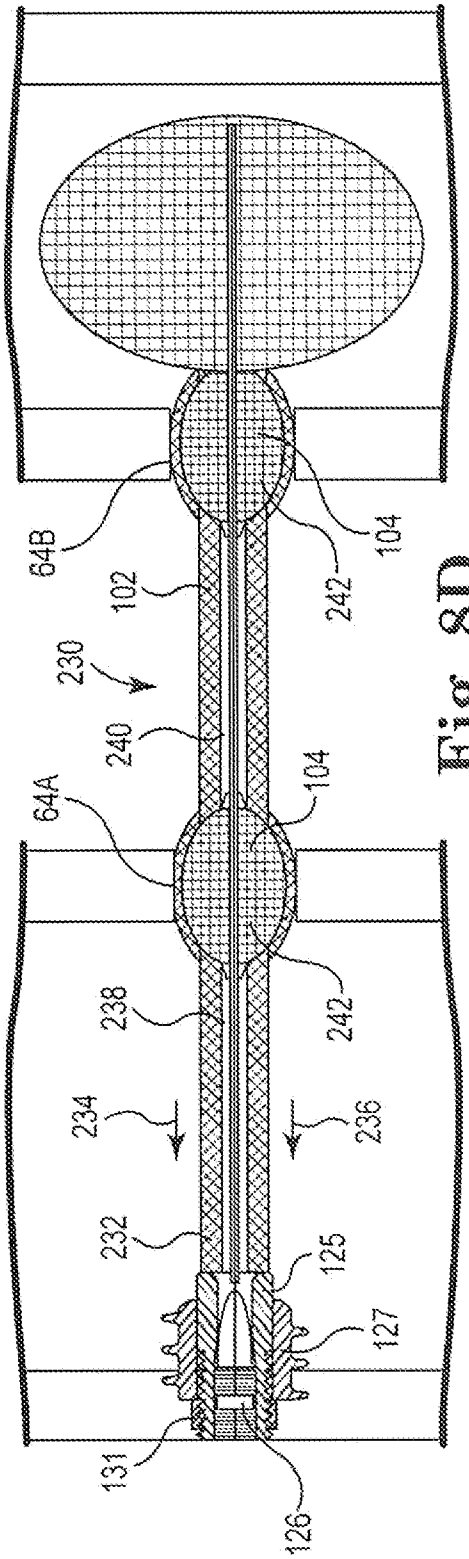

64B
102
230
240
64A
104
242
238
234
236
232
125
127
131
126

Fig. 8D

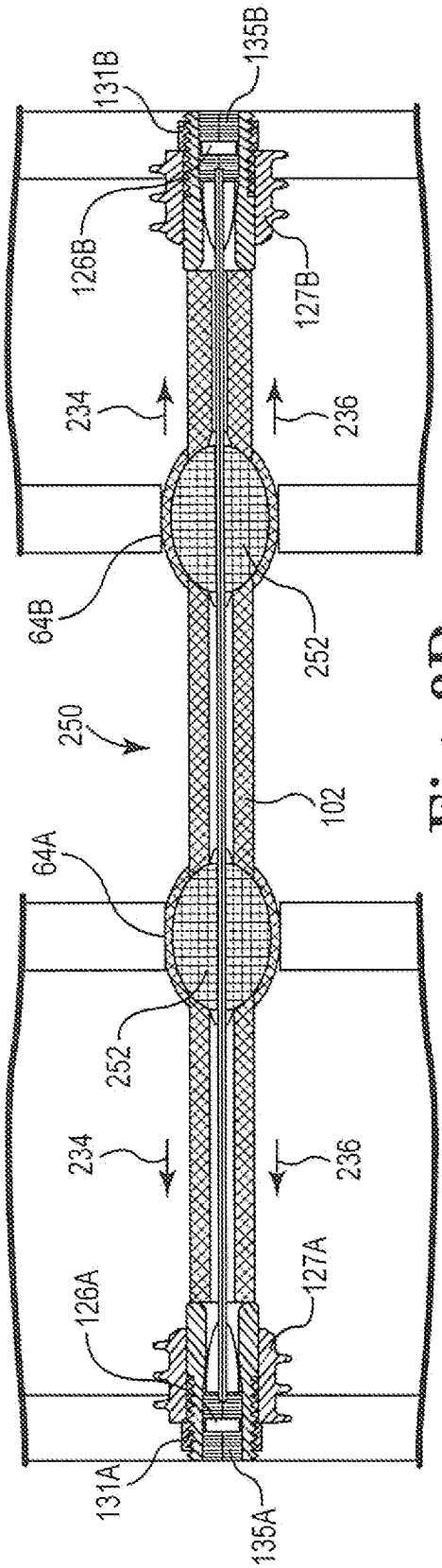

131B
135B
126B
127B
234
236
64B
252
250
102
64A
252
234
236
126A
127A
131A
135A

Fig. 9D

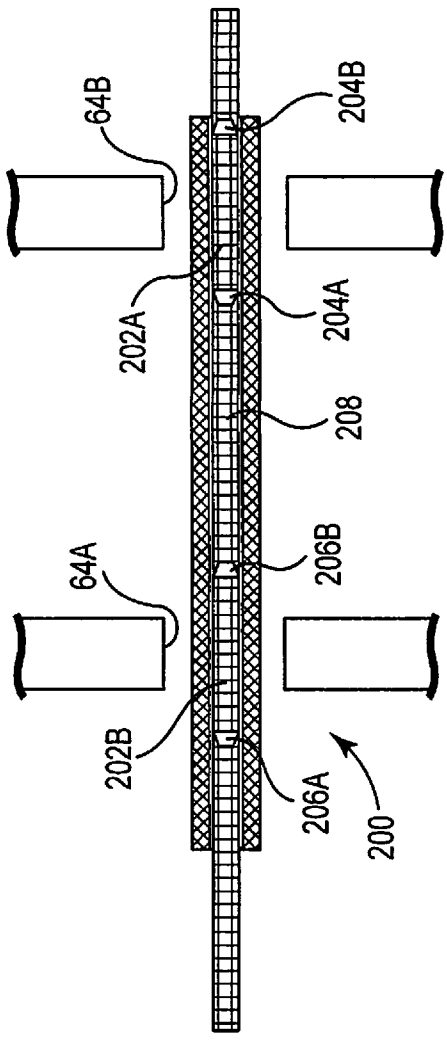

64B
204B
202A
204A
208
206B
64A
202B
206A
200

Fig. 9A

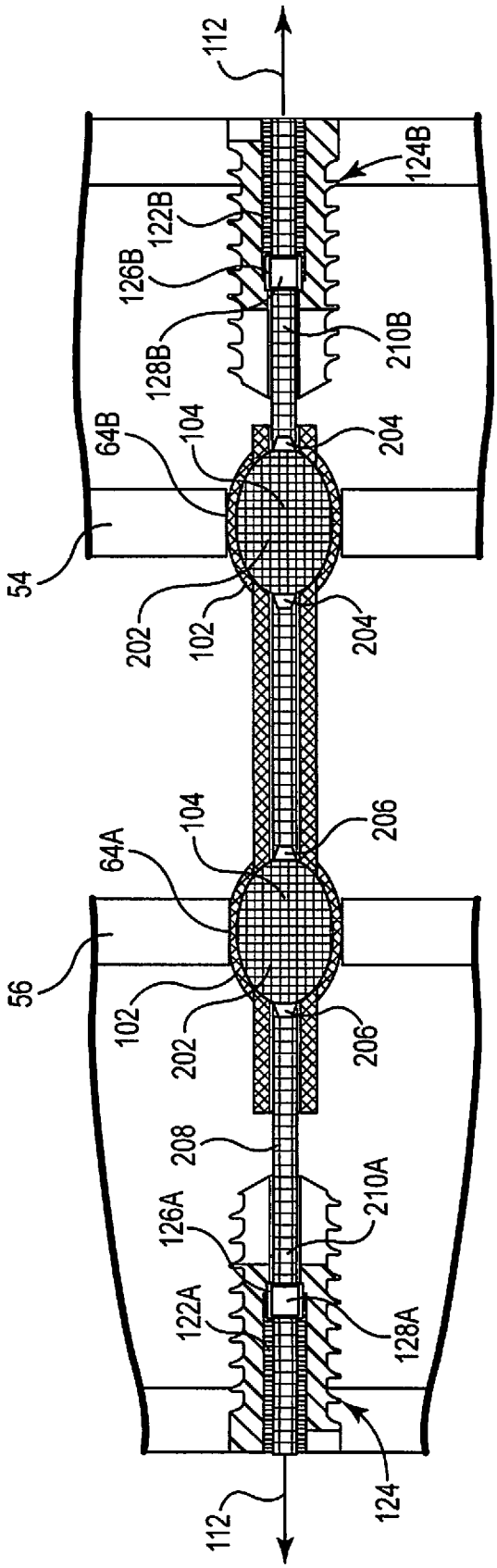

112
124B
122B
126B
128B
210B
64B
104
204
54
202
102
204
206
64A
104
56
102
202
206
208
210A
126A
122A
128A
124
112

Fig. 9B

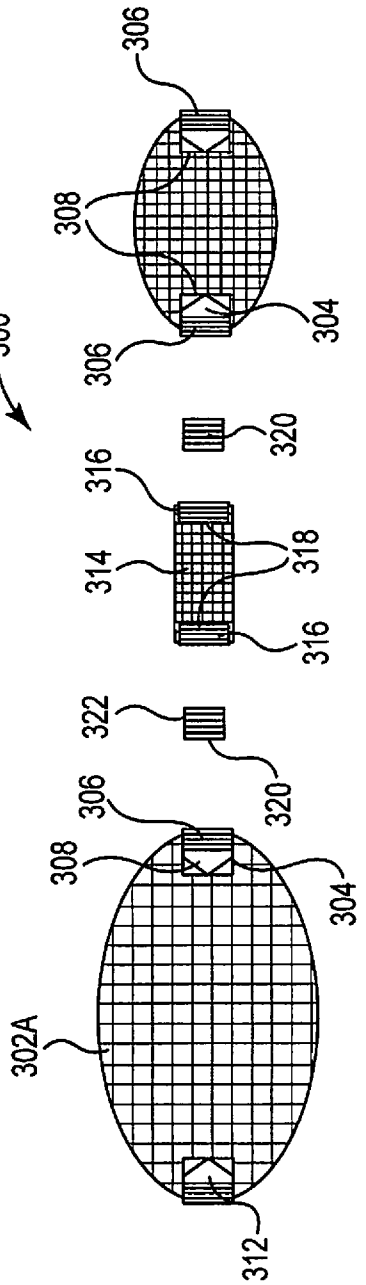


Fig. 10A

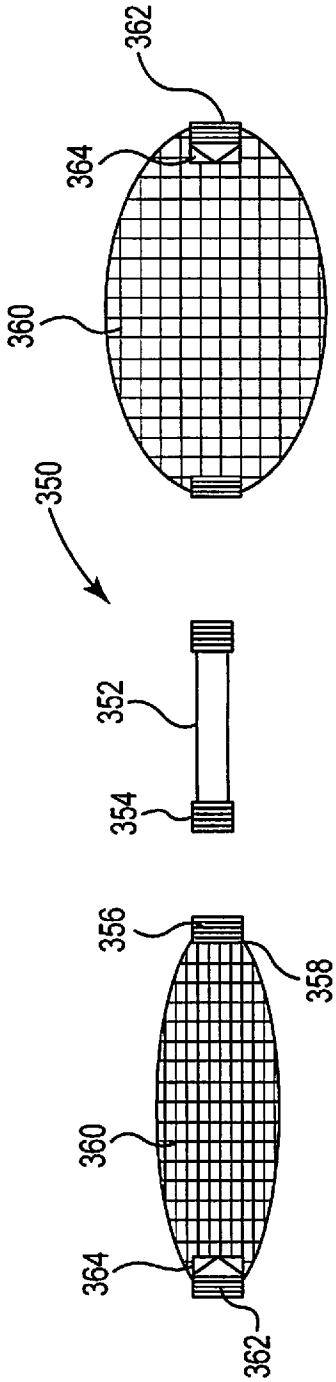


Fig. 10B

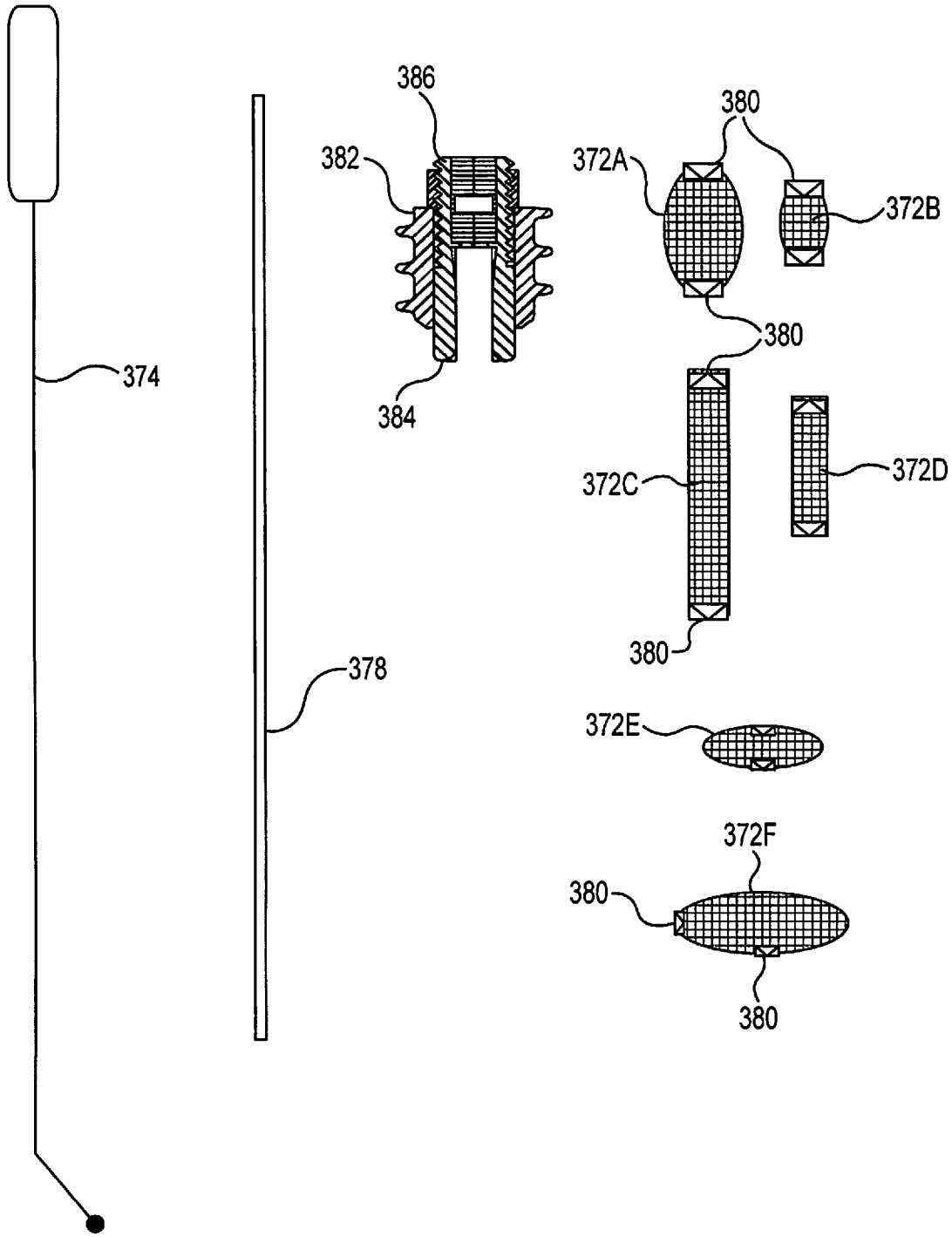

386
382
384
380
372A
372B
380
372C
372D
380
374
378
372E
372F
380
380

Fig. 11

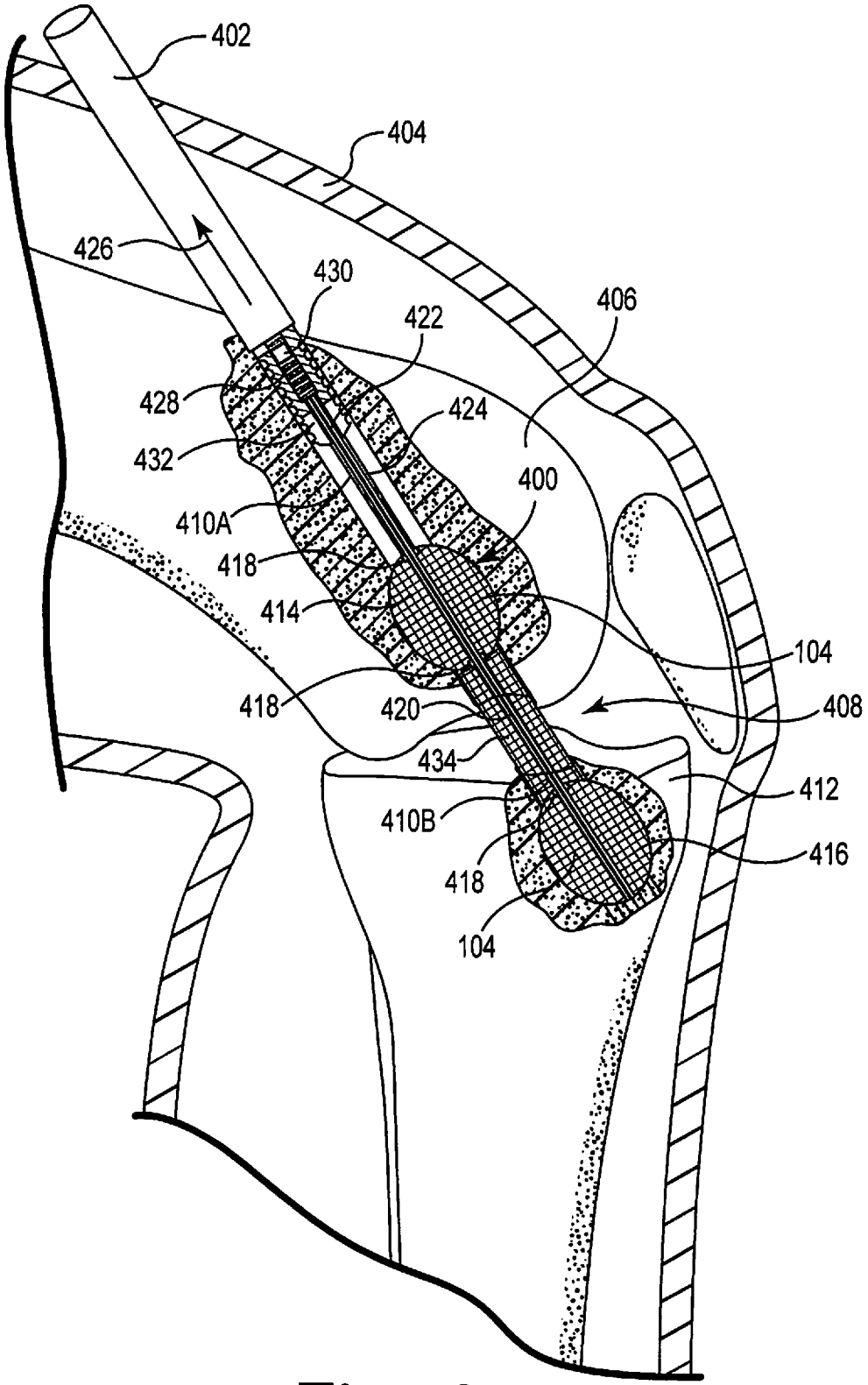

402
404
426
430
422
406
428
424
432
400
410A
418
414
104
418
420
408
434
412
410B
416
418
104

Fig. 12

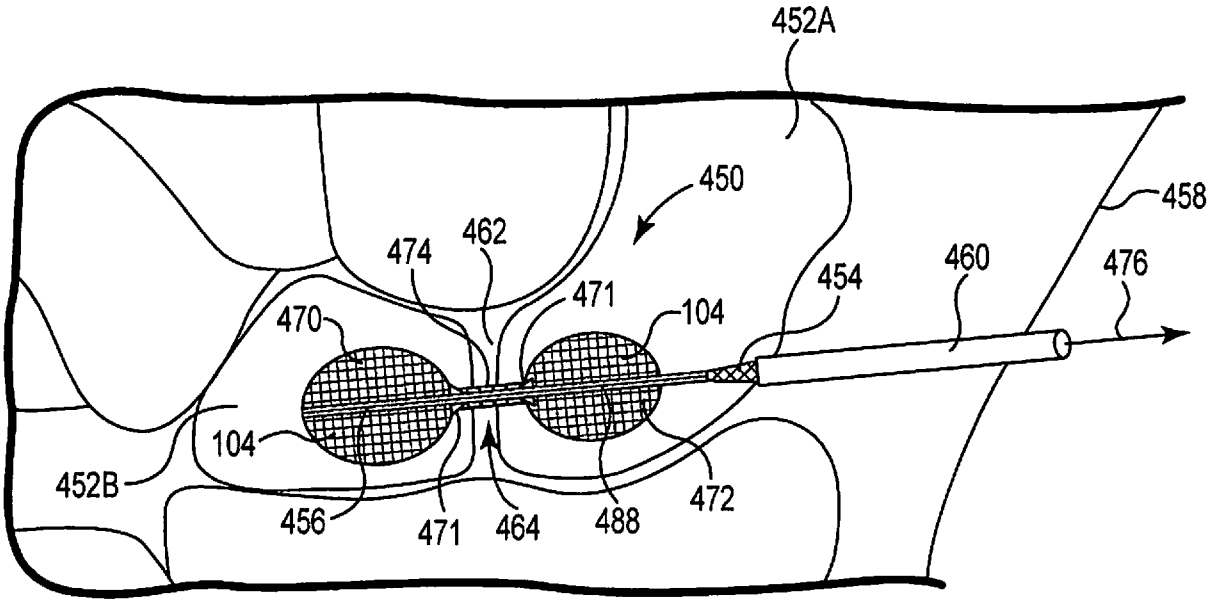

452A
450
458
474
462
460
476
471
454
470
104
104
452B
456
471
464
488
472

Fig. 13

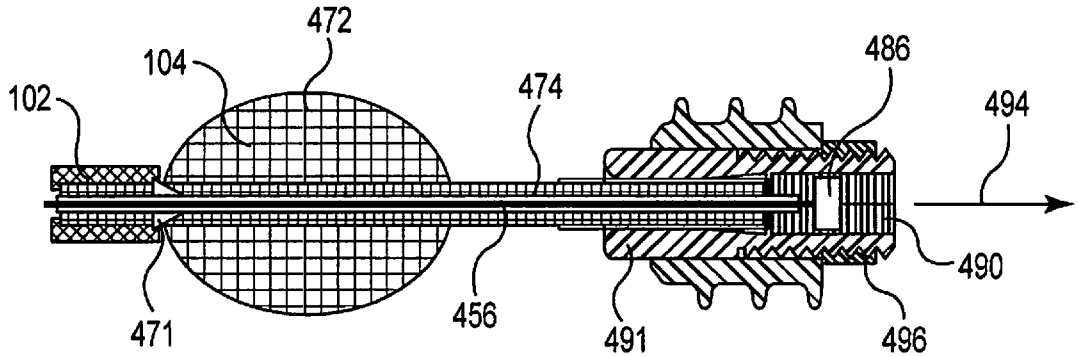

472
104
102
474
486
494
490
471
456
491
496

Fig. 14

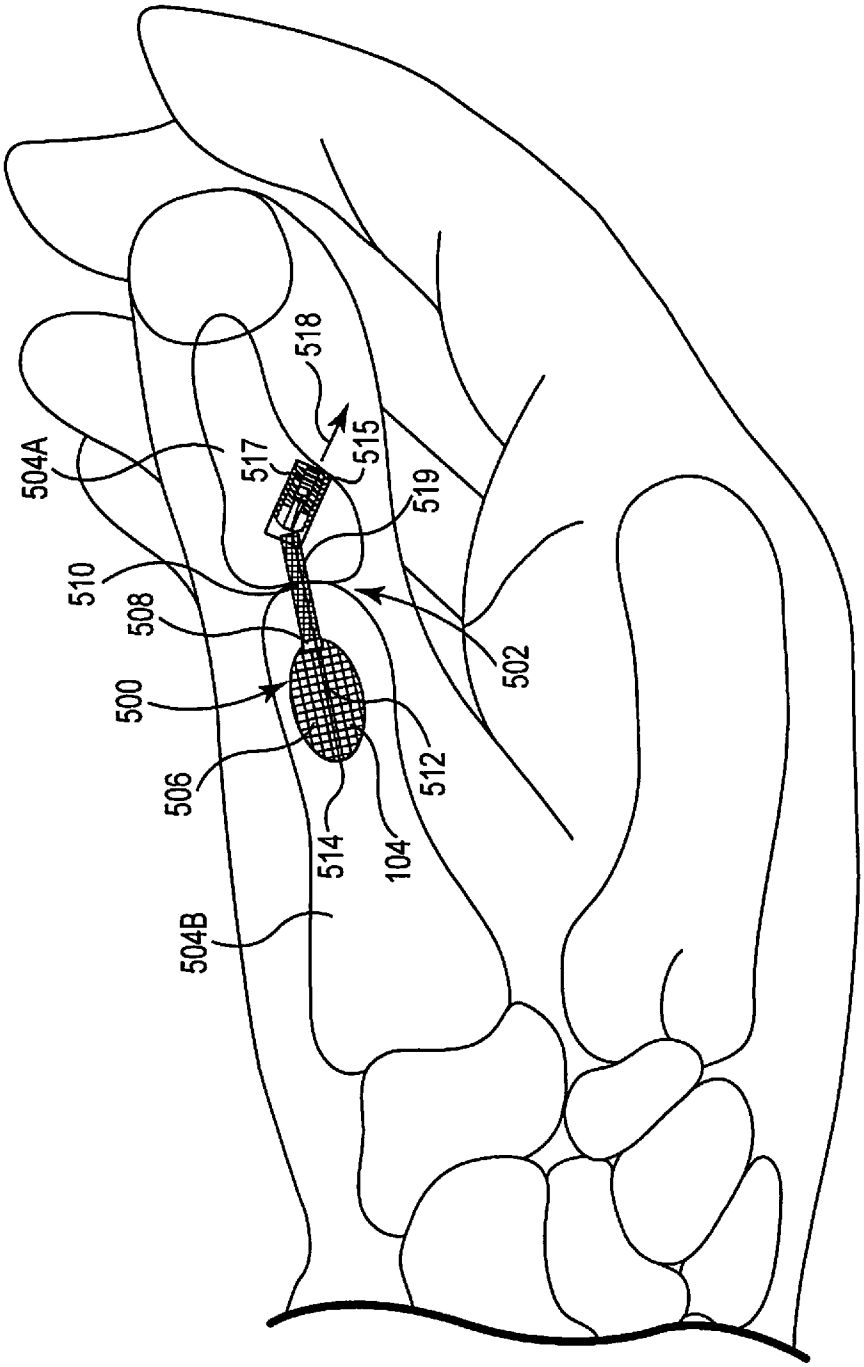


Fig. 15

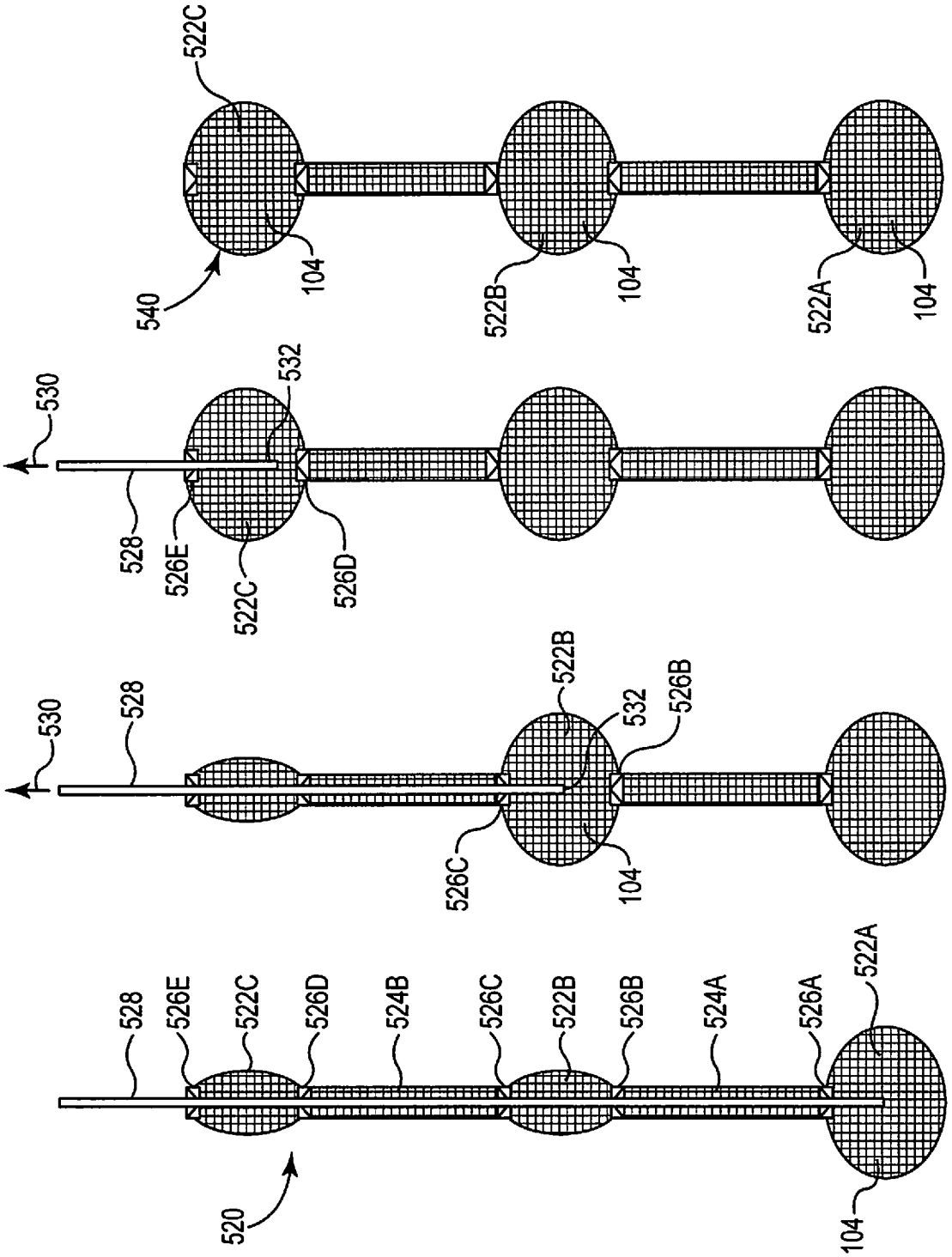


Fig. 16D

Fig. 16C

Fig. 16B

Fig. 16A

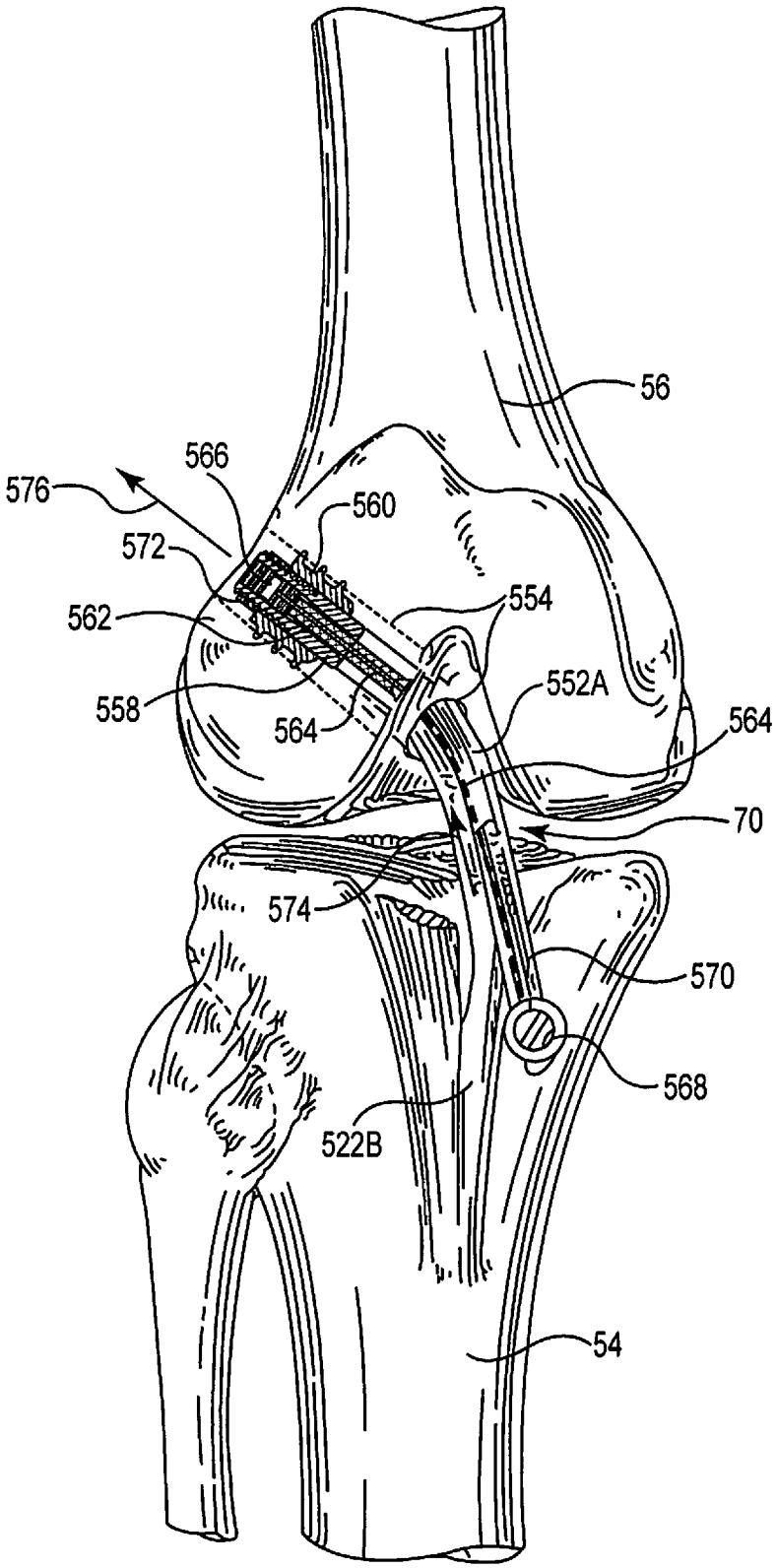

56
566
576
560
572
554
562
552A
558
564
564
70
574
570
568
522B
54

Fig. 17

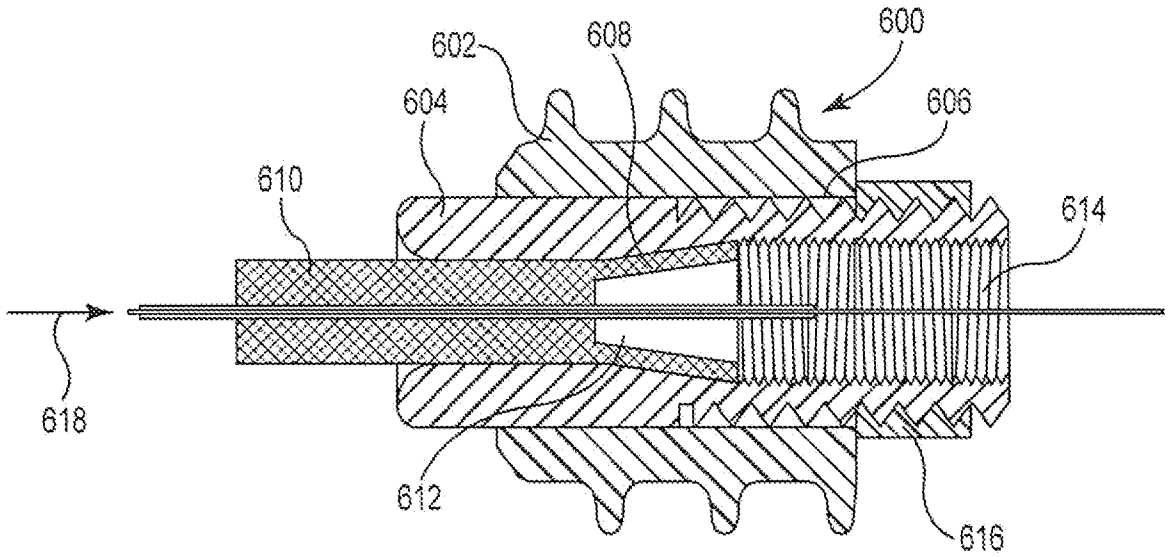


Fig. 18A

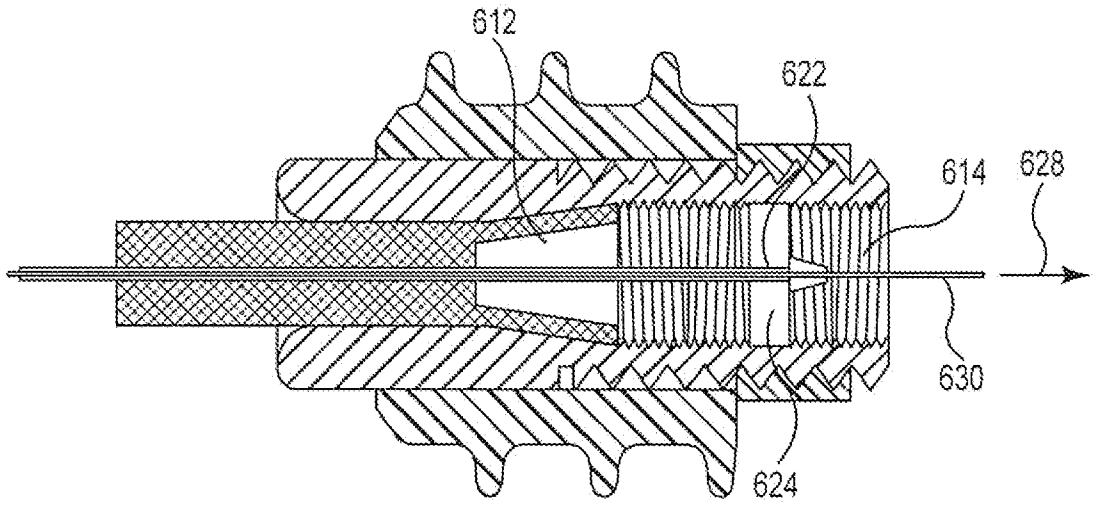


Fig. 18B

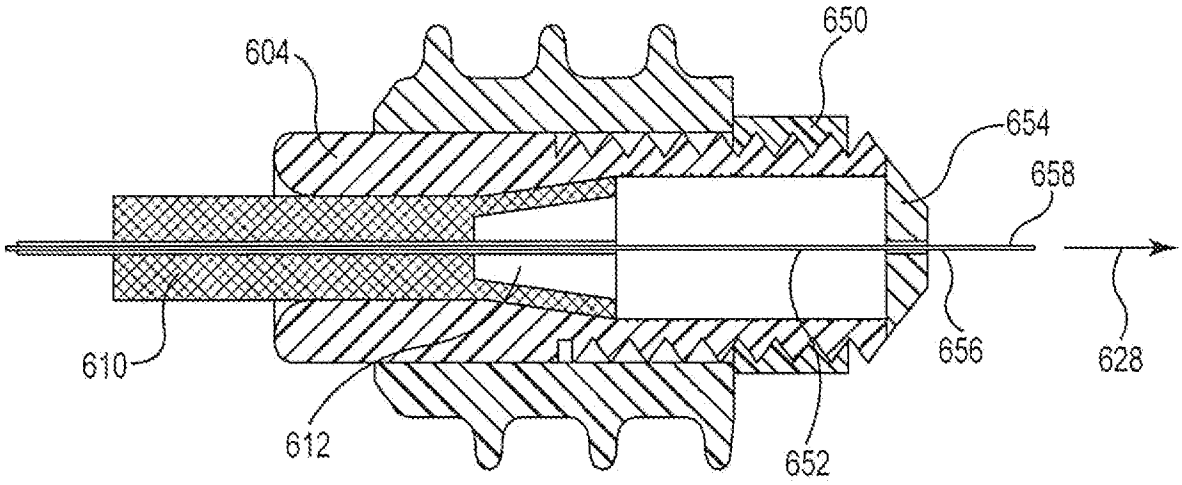


Fig. 18C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/43346

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/08 (2012.01)
USPC - 623/13.14
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)
IPC(8) - A61F 2/08 (2012.01)
USPC - 623/13.14

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
606/151, 606/191, 606/192, 606/198, 606/232, 623/11.11, 623/13.11, 623/13.12, 623/13.13, 623/13.17

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Dialog Classic, USPatFT, USAppFT, PubMED; Keywords: fixation, fixed, stabilizing, stabilized, stabilization, connection, connector, connected, bone, bones, joint, joints, patient, fastener, fastened, fastening, tunnel, tube, hole, passage, passageway, ligament, replacement, replaced, graft, tension, independent, independently, adjust, adjustable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y ----- A	US 6,203,572 A1 (Johnson et al.) 20 March 2001 (20.03.2001) col 2, ln 55-65; col 3, ln 16-32; col 3, ln 55 to col 4, ln 5; Fig. 1, 3-5, 10	1, 4-6, 8-10, 21 ----- 7, 13-16 ----- 2, 3, 11, 12, 17-20
Y	US 2008/0090936 A1 (Fujimura et al.) 17 April 2008 (17.04.2008) para [0023], [0024]	7, 14
Y	US 2006/0271192 A1 (Olsen et al.) 30 November 2006 (30.11.2006) para [0165]; Fig. 28A	13-15
Y ----- A	US 2004/0024456 A1 (Brown et al.) 05 February 2004 (05.02.2004) para [0140]-[0145]	16 ----- 17-20
A	US 2007/0055276 A1 (Edidin) 08 March 2007 (08.03.2007) para [0025], [0026], [0028], [0034]; Fig. 6	2, 3, 11, 12, 17-20
A	US 2008/0015710 A1 (Hays et al.) 17 January 2008 (17.01.2008) para [0078], [0079]; Fig. 27, 28	2, 3, 11, 12, 17-20
A	US 2006/0149280 A1 (Harvie et al.) 06 July 2006 (06.07.2006) para [0086]-[0088]; Fig. 2-2E	2, 3, 11, 12, 17-20
A	US 2008/0097509 A1 (Beyar et al.) 24 April 2008 (24.04.2008) para [0074]; Fig. 1B	1-21
A	US 5,571,184 B1 (Desatnick) 5 November 1996 (05.11.1996) Entire document	1-21

☐ Further documents are listed in the continuation of Box C. ☐

* 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" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 August 2012 (30.08.2012)	12 OCT 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774