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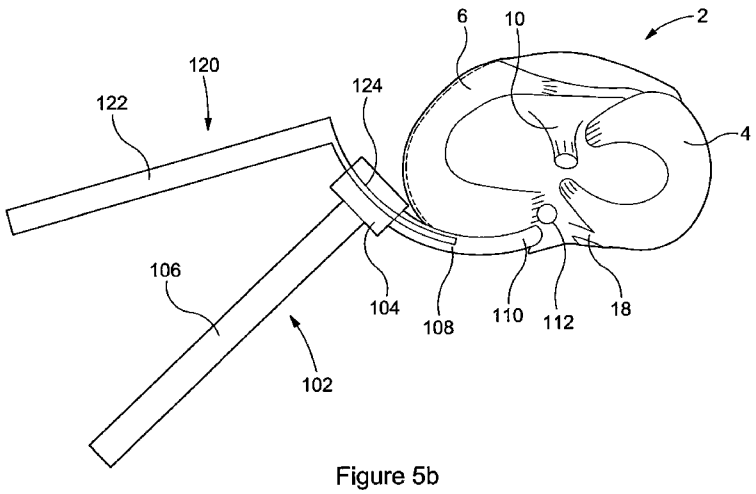

Figure 5b

(57) Abstract: A method for treating a damaged or displaced meniscus of the knee of a subject, the method comprising providing an elongate retaining member having a first end and a second end; extending the retaining member along at least a portion of the outer periphery of the meniscus; anchoring each of the first and second ends of the retaining member; whereby tension is applied to the retaining member, thereby applying a radially confining force on the outer periphery of the meniscus. An apparatus for applying an elongate member at the periphery of a meniscus of the knee joint of a subject comprises a needle (124) for insertion into the knee joint for introducing the elongate member into the knee joint; a support member (104) comprising a guide means for supporting and orienting the needle for insertion into the knee joint; and a guide member (108) for insertion into the knee joint adjacent the peripheral edge of the meniscus.

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METHOD FOR CONDUCTING A MENISCAL REPAIR AND AN APPARATUS FOR CONDUCTING THE SAME

The present invention relates to a method for conducting a repair procedure on a damaged or displaced meniscus of a subject, in particular a meniscus of the knee. In a further aspect, the present invention concerns an apparatus for carrying out the aforementioned method, in particular an apparatus for use on the knee meniscus of a subject.

Osteoarthritis is a degenerative disease of the joints, in which cartilage covering the end portions of bones of a joint deteriorates. This deterioration results in adjacent bones of the joint coming into contact and rubbing together, in turn leading to a loss of movement of the joint and considerable pain to the sufferer. Osteoarthritis is one of the most common joint disorders and is a leading cause of disability and immobility in the elderly. Osteoarthritis may affect any joint in the body. However, the disease is most prevalent in cervical and lumbar spine, and is particularly aggressive in degeneration of some joints in the hands and in weight-bearing joints in the legs. One particular joint attacked by the disease is the knee joint.

Current non-invasive methods of treating osteoarthritis include diet and weight loss, walking aids, medication to relieve the pain, the application of warmth and cold. Injections of steroid or hyaluronic acid are sometimes administered to patients..

In cases of severe pain and/or restrictions on mobility, surgical treatments may be applied. For example, the subject may be provided with a replacement knee. Other surgical procedures include a high tibial osteotomy and arthroscopic lavage. Further surgical procedures currently undergoing development are the provision of offloading devices and spacer insert devices.

It has been shown that healthy knee menisci are responsible for carrying at least 50% of the weight transmitted through the knee joint. Reference in this respect

is made to Fairbank, T.J., 'Knee Joint Changes after Meniscectomy', J. Bone Joint Surg. Am., November 1948, 30B(4), pages 664 to 670, and to Shrive, N.G., et al., 'Load-bearing in the Knee Joint', Clin. Orthop. Relat. Res., March 1978, (131), pages 279 to 287.

Displacement of the meniscus is known to occur in knee joints and results in exposure of the articular cartilage of the knee. This development is seen on MRI scans as meniscal subluxation, reported for example by Breitenseher, M.J., 'MR imaging of meniscal subluxation in the knee', Acta. Radiol., September 1997, 38(5), pages 876 to 879, who concluded that meniscal subluxation was associated with osteoarthritis. More recent studies have shown an association between the presence of meniscal subluxation and the progression of osteoarthritis, in particular Madan-Sharma R et al., 'Do MRI features at baseline predict radiographic joint space narrowing in the medial compartment of the osteoarthritic knee 2 years later?', Skeletal Radiol., September 2008, 37(9), pages 805-11. Furthermore, osteoarthritis has been noted in subjects having undergone a meniscectomy by Fairbank, T.J., noted above, and by Roos, H., et al., 'Knee osteoarthritis after meniscectomy: prevalence of radiographic changes are twenty one years, compared with matched controls', Arthritis Rheum. April 1998, 41 (4), pages 687 to 693.

It is postulated that the precursor to the development of idiopathic osteoarthritis of the knee is the loss of circumferential strength of the meniscus, that is a loss of hoop strength. As the fibres of the meniscus become increasingly relaxed, through a process associated with collagen aging, the meniscus in turn becomes less able to resist axial forces transmitted through the knee. As the fibres of the meniscus becomes increasing relaxed they are able to bear less weight. The meniscus begins to sublux radially, thereby exposing more articular cartilage on both the femoral and tibial sides of the joint.

It would be an advantage if a procedure could be provided to strengthen the meniscus of the knee, with a view to slowing or halting the progression of osteoarthritis in the knee joint. It would be further advantageous if the procedure could carry less risk than a total knee replacement (TKR) operation, as is the

commonly applied treatment, in particular while still allowing a TKR to be performed at a later date, if required.

Artificial menisci have been proposed. For example, US 4,344,193 discloses a prosthetic device for insertion between the tibial articulating cartilage and one of the condyles in the adjacent end of the femur.

US 5,092,894 discloses a stabilised prosthetic meniscus for replacing natural components of a condylar joint, in particular the meniscus of a knee joint. The prosthetic device comprises a body of biocompatible, deformable, flexible and resilient material, examples of which are synthetic materials, such as silicone rubber, or natural materials, such as collagen, tendon or fibrocartilage. The body has an arcuate construction of less than 360° and greater than 150° and a shape generally the same as a naturally occurring knee meniscus. The body bears the compressive loads of the femoral condyle against the tibia and translates these loads to a tail as tensile stresses, stabilses the femoral condyle on the tibia, lubricates and aids in the metabolism of the articular surfaces of the joint and expands and bears against the soft tissue surrounding the joint. The body may also serve to attach the prosthesis to the surrounding soft tissue. The tail may comprise a continuous loop formed integrally with the body or attached thereto. The tail provides a continuous loop for the propagation of tensile or hoop stresses in the meniscus.

WO 2009/052208 describes and shows a prosthetic useful for addressing osteoarthritis of the knee joint. The prosthetic uses hyaluronate compositions to increase the duration of effectiveness in lubrication and pain reduction.

Devices for repairing a damaged meniscus are known in the art. For example, EP 0913123, US 2010/0016966, US 4,873,976, USs 5,320,633, US 5,059,206, US 2011/0112556, US 6,190,401, US 2010/0010497, US 2010/0042114, WO 2012/072244, and WO 2011/106369 disclose methods and devices for repairing tears in a meniscus. Methods and devices for replacing part or all of a meniscus are disclosed in US 6,042,610, WO 2011/935017, US 2005/0232967, US 2012/0064043, US 2011/0004305, US 5,116,374,

US 2009/0259312, US 2008/0086210, US 2012/0004725, US 2004/0195727, WO 2011/138045, WO 2008/127942, WO 2003/103543 and US 2011/0093073.

WO 2011/057245 discloses devices, systems and method for repairing a meniscus. In particular, there are disclosed meniscus suture passers for repair of the meniscus of the knee.

It has now been found that a damaged or displaced meniscus of the knee may be strengthened and corrected by providing the meniscus with an augmentation device disposed around the periphery of the meniscus to provide artificial support to the meniscus.

Accordingly, in a first aspect, the present invention provides a method for treating a damaged or displaced meniscus of the knee of a subject, the method comprising:

providing an elongate retaining member having a first end and a second end;

extending the retaining member along at least a portion of the outer periphery of the meniscus;

anchoring each of the first and second ends of the retaining member;

whereby tension is applied to the retaining member, thereby applying a radially confining force on the outer periphery of the meniscus.

The human knee includes two menisci, the arrangement of which is illustrated in Figure 1, which shows the general arrangement of the menisci in a healthy human knee joint. Referring to Figure 1, the knee, generally indicated as 2, is a right knee of a subject as viewed from above and comprises a lateral meniscus 4 and a medial meniscus 6 overlying the articular surface of a tibia 8. The anterior cruciate ligament 10 and posterior cruciate ligament 12 are indicated in Figure 1 for clarity.

The position of the medial meniscus 4 in relation to the tibia 8 is shown in Figure 1 by indicating the outer edge of the tibia underlying the medial meniscus 6 by way of a dotted line 14. As can be seen, the outer edge of the medial meniscus 6 is generally aligned with the periphery of the tibia 8, indicated by the dotted line 14. A

similar arrangement exists for the lateral meniscus 4 in a healthy knee, with the outer edge of the meniscus being generally aligned with the periphery of the tibia.

The ligaments attaching the menisci are indicated in Figure 1, in particular the transverse ligament 16 at the front of the knee and the ligaments of Wrisburg and Humphery 18.

When a meniscus of the knee is impaired, its ability to separate the opposing surfaces of the tibia and femur of the subject is decreased. This in turn leads to damage to the structure of the knee, as discussed above in relation to the prior art. A meniscus of the knee can become impaired by becoming generally weaker, such that its ability to hold its shape is reduced. Alternatively, the meniscus may become displaced from between the articular surfaces of the tibia and the femur. Such a subluxation of the medial meniscus 6 of the knee is illustrated in Figure 2. As can be seen, the meniscus 6 is deformed and displaced beyond the periphery of the tibia 8 indicated by the dotted line 14 and outwards from between the opposing surfaces of the tibia 8 and the femur.

The method of the present invention may be used to correct a range of different conditions affecting the meniscus. In particular, the method may be used to correct a loss of shape or integrity to the meniscus. Of particular advantage is the use of the method in correcting a displaced or subluxed meniscus. The method may be applied at a wide range of stages of deterioration of the knee joint. In particular, the method may be used to treat the early onset of osteoarthritis of the knee, especially by reinforcing a subluxed meniscus.

In the method of the present invention, an elongate member is provided to extend along at least a portion of the periphery of the meniscus being treated. The elongate member, once in place around the periphery of the meniscus, functions as a form of augmentation device to retain the meniscus in position and retain the form of the meniscus. In this respect, references to the periphery of the meniscus are to the outer peripheral edge portion of the meniscus. Thus, in the case of the medial meniscus, the periphery is the medial edge portion of the meniscus. Similarly, in the

case of the lateral meniscus, the periphery is the lateral edge portion of the meniscus.

The elongate member is provided along at least a portion of the periphery of the meniscus. In a preferred embodiment, the elongate member is provided along a major portion of the periphery, more preferably substantially all of the periphery of the meniscus. More preferably, the elongate member is provided along the entire periphery of the meniscus between the ligaments by which the meniscus is attached.

The elongate member, once provided, acts to retain the meniscus by applying a radially confining force on the periphery of the meniscus. In the case of a meniscus that has lost its shape and form, for example a weakened meniscus, the elongate member acts to restore the healthy form and shape of the meniscus and to retain the meniscus in this form. In particular, the elongate member acts to provide the meniscus with increased dimensional stability and increased integrity. In the case of a meniscal subluxation, the elongate member acts to restore the displaced meniscus towards or to its correct position between the opposing surfaces of the tibia and femur.

The elongate member may be of any suitable form to provide the required dimensional stability and increased integrity to the meniscus and/or relocate the meniscus. The material of the elongate member is flexible, allowing the member to accommodate and conform to the peripheral surface of the meniscus.

The elongate member may be formed from any suitable material or combination of materials. The elongate member may be permanent, that is the material of the elongate member is substantially impermeable to degradation once within the body and retains its strength and form. Such permanent materials may be used for a long-term repair to the knee joint. Alternatively, the material of the elongate member may be absorbable within the body. In this way, the elongate member is considered to be a temporary placement.

Suitable materials for forming the elongate member are known in the art and are commercially available. In one preferred embodiment, the elongate member is

formed from one or more fibrous materials, such as those used to form sutures or artificial ligaments. The material of the elongate member may be synthetic or may be naturally derived. Examples of synthetic materials include polyester, polypropylene, polyethylene, ultra high molecular weight polyethylene, glass fibre, polyamide fibre, polylactic acid, polyglycolic acid or polycaprolactone.

Alternatively, the elongate member may be formed from naturally occurring materials. Again, such materials include those known in the arts of sutures or replacement ligaments. An example of a suitable naturally occurring material for forming the elongate member is silk. In one preferred embodiment, the elongate member is formed from tendon graft tissue, such as hamstring. The graft material may be autologous. Alternatively, the material of the elongate member may be allogenic.

In one preferred embodiment, the elongate member comprises a material, such as polyester, that encourages tissue ingrowth into the elongate member. Materials active in encouraging such tissue ingrowth processes within the human body are known in the art. By encouraging tissue ingrowth into the material of the elongate member, the retention of the elongate member in position along the peripheral edge of the meniscus is improved and the positional stability of the elongate member is increased, in turn reducing the tendency for the elongate member to move relative to the meniscus and become displaced. This effect in turn increases the strength and stability of the knee joint, once the elongate member has been implanted.

The elongate member may be formed in any suitable manner. In a preferred embodiment, the elongate member is formed from fibres of one or more materials, as noted above. In this case, a preferred arrangement for the elongate member is for the fibres to be combined using textile processing techniques, such as braiding, weaving or stitching. In this way, the fibres may be combined to form an elongate member having the requirements of size, shape, strength and flexibility.

The elongate member may have any suitable form and shape able to provide the confining force on the periphery of the meniscus. The form of the elongate

member should not cause damage to the meniscus. In particular, the form of the elongate member should avoid damage to the meniscus in the region of contact between the elongate member and the meniscus. For example, relative movement between the meniscus and the elongate member can occur in the treated knee joint. The form of the elongate member should minimise and eliminate as far as possible fretting of the meniscus due to such relative movement. Preferably, the elongate member is able to accommodate and conform to the peripheral surface of the meniscus. In one preferred embodiment, the elongate member comprises a major surface for contacting the peripheral surface of the meniscus. The major surface may be formed due to deformation of the elongate member as the member is installed around the meniscus. Alternatively, or in addition thereto, the elongate member may comprise a major surface when at rest. One preferred form for the elongate member is a band having opposing major surfaces, one of which is placed in contact with the peripheral surface of the meniscus.

The elongate member may have a uniform cross-section along its length. More preferably, the elongate member has a non-uniform cross-section along its length. More particularly, the elongate member preferably comprises at least one fixation portion, by which the elongate member is anchored, and a working portion, the working portion being in contact with the periphery of the meniscus. In a preferred embodiment, the elongate member comprises a first fixation portion at a first end of the elongate member and a second fixation portion at the second end of the elongate portion, with the working portion disposed between the first and second fixation portions. The elongate member is anchored at both the first and second fixation portions. As noted, the cross-section of each fixation portion and the working portion may be same or different. In particular, the cross-section of each fixation portion may differ in shape and/or size to the cross-section of the working portion.

The cross-section of the elongate member may be any suitable shape. In particular, the fixation portion of the elongate member may have a cross-section that is suitable to interact with the anchoring means being employed, such as a graft fixation screw or a staple. The techniques for anchoring the elongate member are described in more detail below. Suitable cross-sectional forms for the fixation portion include generally circular or elliptical in shape. Alternatively, the fixation portion may

be generally flat, that is having one or more flat surfaces. In one embodiment, the elongate member is in the form of a band, with a cross-section having opposing major edges and opposing minor edges.

Similar cross-sectional forms may be used for the working portion of the elongate member. Preferably, the working portion of the elongate member is generally flat having at least one major flat surface, arranged to have in use a major surface in contact with the periphery of the meniscus. In one embodiment, the working portion has a generally D-shaped cross-section, having a major flat surface. In use, the major flat surface is in contact with the peripheral region of the meniscus. The elongate member may be formed with a D-shape cross-section, or may be formed with another shape, such as circular or elliptical cross-section, such that the elongate member adopts a generally D-shaped cross-section when implanted and placed under tension.

The elongate member may be provided with a fixation portion at one or both ends that incorporates an anchoring means, such as a button. Alternatively, one or both ends of the elongate member may be provided with a fixation portion in the form of a loop for extending through and/or around an anchoring means, such as a button or screw. In this way, the elongate member may be located in the knee around the periphery of the meniscus and anchored at one or both ends to an anchoring means, such as a screw. Generally, the installation of at least one of the anchoring means is left to the end of the emplacement procedure, allowing the appropriate tension to be applied to the elongate member, prior to finally anchoring the elongate member in place.

The elongate member has a first end and a second end. The elongate member is anchored at each of the first and second ends, thereby allowing the elongate member to be placed under tension, in turn applying an inwardly directed or confining force on the meniscus. Preferably, the elongate member is anchored at one of the first and second ends, more preferably at both the first and second ends to the tibia. The position at which each of the first and second ends of the elongate member are anchored may vary and will depend in part upon the length of the elongate member and its position relative to the meniscus.

Suitable means for anchoring the elongate member are known in the art. As noted above, the elongate member is preferably anchored to the tibia. Suitable means for anchoring the elongate member to the tibia include surgical or graft fixation screws, also known as an interference screw, and one or more staples.

Each end of the elongate member may be attached to a respective anchoring means. In one embodiment, a bore is formed extending through the tibia, the elongate member being passed around the periphery of the meniscus and having one or both end portions passed through the bore. In this way, the two ends of the elongate member may be connected together to form a continuous loop.

The first end of the elongate member is generally anchored to a region of the tibia that is forwards or anterior of the midline of the knee joint. Preferably, the first end of the elongate member is attached to an anterior portion or region of the tibia. In a preferred embodiment, the first end of the elongate member is anchored to the tibia at a location adjacent to, or on, the anterior meniscal root insertion. As access to the anterior region of the knee joint may generally be readily obtained on a subject, the first end of the elongate member may be secured to the tibia in a number of alternative ways. For example, the first end may pass over the anterior edge on the surface of the tibial plateau, may pass through a bore formed through the tibia or be secured in a blind bore, for example by way of a screw.

The second end of the elongate member is generally anchored to prevent movement to a region of the tibia that is rearwards or posterior of the midline of the knee joint. The second end of the elongate member is preferably anchored to a posterior portion or region of the tibia. In a preferred embodiment, the second end of the elongate member is anchored to the tibia at or to prevent relative movement a location adjacent or close to the posterior attachment of the meniscus. In one embodiment, the second end of the elongate member extends into a bore formed in the tibia adjacent or close to the posterior attachment of the meniscus. The second end of the elongate member may be secured to the tibia in a similar manner to those mentioned above with respect to anchoring the first end of the elongate member. As access to the posterior region of the knee joint is relatively limited, it is preferred to

form a bore extending through the tibia from the anterior portion to the posterior portion, with the posterior opening of the bore being adjacent the posterior attachment of the meniscus. The second end of the elongate member may be secured within the bore or at the anterior end of the bore, for example by way of a screw.

In one preferred embodiment of the present invention, a bore is formed in the tibia, into which an end of the elongate member is anchored. In a preferred embodiment, a bore is formed in the tibia, the bore extending from a posterior surface of the tibia to an anterior surface, preferably from the posterior aspect of the tibial plateau to the anterior face of the tibia below the edge of the tibial plateau. More preferably, the bore has a first opening in the posterior aspect of the tibial plateau in the region of the natural posterior attachment of the meniscus. The bore has a second opening in the anterior face of the tibia adjacent the tibial tuberosity, such that the bore extends upwards through the tibia from the second opening in the anterior surface or face of the tibia to the first opening in the posterior aspect of the surface of the tibial plateau. The elongate member may extend through the bore, in particular being anchored to the tibia either within the bore or at the second opening of the bore and emerging from the first opening of the bore. Preferably, the elongate member is connected at its second end to an anchoring member, the anchoring member extending through the aforementioned bore and secured either within the bore with an anchoring means, such as an interference screw referred to hereinbefore, or to the anterior surface of the tibia at the second opening of the bore with an anchoring means, such as a button. The anchoring member may be used to apply tension to the elongate member, as described in more detail hereinbelow.

The first end of the elongate member may be anchored in an analogous manner to the second end, as described above. However, this is not preferred. Rather, more preferably, the first end of the elongate member is secured by means of an interference screw into a blind bore formed in the anterior region of the tibial plateau adjacent the natural anterior attachment of the meniscus.

As noted above, the elongate member is placed under tension, in turn applying a radially confining force on the peripheral surface of the meniscus.

Preferably, the elongate member is tensioned by first being anchored at one of the first or second ends, the required tension then being applied to the elongate member, after which the other of the first and second ends is anchored.

In the aforementioned preferred embodiment, the elongate member is first anchored at its first end to the anterior region of the tibia. Thereafter, tension is applied to the elongate member through the bore from the anterior region of the tibia, either directly to the second end of the elongate member or to the anchoring member connected to the second end of the elongate member, if employed. Finally, the second end of the elongate member is anchored, either directly or indirectly by means of the anchor member, at the second opening of the bore in the anterior surface of the tibia. In this way, the installation, tensioning and anchoring of the elongate member may all be achieved from the anterior side of the knee joint, avoiding the need for the posterior structures of the knee to be entered directly.

In one embodiment, the elongate member is installed in the knee joint on the outside of the synovial membrane. In this way, any debris arising from the installation procedure and/or otherwise from the presence of the elongate member is kept outside of the synovial membrane and does not contaminate the synovial fluid of the knee. However, it is preferred to locate the elongate member within the synovial membrane, in particular on the inside of a fold of the synovial membrane. In this way, the elongate member may be secured to the meniscus, as described in more detail hereinbelow, in turn allowing the elongate member to be more securely located relative to and in contact with the peripheral edge of the meniscus.

The elongate member is preferably fastened to or retained adjacent the meniscus at one or more points along its length between the first and second ends. In particular, the elongate member is preferably fastened to or retained adjacent the meniscus along the length of the working portion of the elongate member. In this way, the elongate member, in particular its working portion, that is the portion in contact with the meniscus, is held more securely in the optimum position relative to the meniscus. Preferably, the means for holding the elongate member relative to the meniscus are non-invasive of the meniscus. For example, the elongate member may be secured in place by means of one or more ties. In one preferred embodiment, the

elongate member is retained in position along the peripheral edge of the meniscus by means of one or more loops of a suture material passing around the elongate member. The loops may be formed around the meniscus. Preferably, the loops of the suture material extend into the knee joint through holes in the synovial membrane close to and above the meniscus. Preferably, the suture loops are inserted in position from beneath the meniscus, that is between the meniscus and the underlying tibia. A plurality of loops may be formed from a plurality of lengths of suture material. More preferably, a single length of a suture material is employed to form a plurality of loops. The elongate member may then be passed through each of the loops. Applying tension to the suture material tightens the loops around the elongate member and draws the elongate member against the peripheral edge of the meniscus.

In the preferred embodiment mentioned above, that is with the elongate member implanted in the knee on the inside of the synovial membrane, the suture loops are required to pierce and pass through the synovial membrane both above and below the meniscus.

The loops of suture material may be installed in the knee joint in any suitable manner. The loops of suture material may be introduced and formed in the knee joint around the meniscus using a suitable needle. More preferably, the suture material is introduced into the knee by way of an introducer, comprising an insertion cannula having a longitudinal bore therethrough, along which a needle is introduced and guided into place in the knee joint.

Preferably, one or more loops is formed above the meniscus, more preferably a plurality of loops of suture material are formed above the meniscus. The elongate member is passed through the loops, which are then tensioned to draw the elongate member into contact with the peripheral edge of the meniscus. In one preferred embodiment, a plurality of loops are formed from a single length of suture material, the suture material forming a plurality of loops above the meniscus, with adjacent such upper loops in the suture material being separated by a lower loop of the material below the meniscus. Preferably, the suture material forming each upper loop extends from a starting point on the inside of the synovial membrane below the

meniscus through a first hole, outside of the synovial membrane and extends back onto the inside of the synovial membrane through a second hole above the meniscus. In this way, both the upper and lower loops lie on the inside the synovial membrane and are connected by suture material extending outside of the synovial membrane through holes in the membrane.

In one preferred method, the suture material forming the loops is introduced into the knee from an anterior arthroscopic portal formed in the tissue surrounding the knee. The midpoint of a length of suture material is held in the eye of a surgical needle. The ends of the suture material are held outside the tissue, while a cannulated introducer is used to introduce the eye of the needle into position within the knee joint between the meniscus and the surface of the tibial plateau. The needle and introducer are passed from the inside edge of the meniscus, under the meniscus until contact is made with the synovial membrane linking the inferior edge of the outer face of the meniscus to the top edge of the tibia along the periphery of the tibial plateau. The synovial membrane is pierced by the introducer to form a first hole. The eye of the needle is guided by the introducer upwards behind the meniscus until reaching the synovial membrane linking the superior edge of the outer face of the meniscus to the femur. A second hole is formed in the synovial membrane using the needle, allowing the eye of the needle to reenter the joint above the meniscus. The portion of suture material extending through the eye of the needle is then grasped from within the joint. With the needle held in this position, the suture material is pulled into the joint to form a first upper loop. During this loop forming step, one free end of the suture material is held outside the knee tissue, while sufficient suture material is drawn into the knee joint through the two holes in the synovial membrane to form the desired loop.

The upper loop so formed is held in position within the knee joint. The needle is withdrawn, in turn withdrawing the suture material passing through the eye of the needle back through the second hole in the synovial membrane and into the introducer. The introducer and needle are then both withdrawn through the first hole in the synovial membrane and out from beneath the meniscus.

The introducer and needle are moved to a second location around the knee joint corresponding to a second position on the periphery of the meniscus and the aforementioned procedure is repeated.

The result of the method is to install a plurality of lower loops below the meniscus and a plurality of upper loops above the meniscus from a single length of suture material. The elongate member is threaded through the plurality of upper loops, in particular to have the loops extending around the working portion of the elongate member. The ends of the suture material are tensioned, drawing the elongate member into contact with the peripheral edge of the meniscus.

Suitable materials for the suture loops are known in the art and are commercially available. In one preferred embodiment, the suture material is a synthetic material that induces tissue growth. In this way, tissue formed around the suture material acts to adhere the elongate member to the meniscus.

The elongate member and the suture material for retaining the elongate member in position adjacent the peripheral edge of the meniscus, if being used, may be introduced into the knee joint in any suitable manner from any suitable location around the knee joint. As noted above, access to the knee joint from the rear of the knee joint is generally hindered by the presence of blood vessels and nerves. Accordingly, access to the joint may be obtained from the anterior side of the knee, in particular when preparing the means for anchoring the elongate member, for example when drilling one or more bores in the tibia. Preferably, the elongate member and suture material, if being used, are introduced into the knee joint from a medial location, with the posterior and anterior regions of the meniscus being accessed from the medial tissue opening in turn.

The elongate member may be introduced directly into the knee joint, by suitable means, for example when employing the retaining loops described above. Alternatively, one or more introducing sutures may first be installed in the knee joint around the meniscus, the free ends of which are then connected to respective ends of the elongate member. The sutures may then be tensioned, to draw the elongate member into the knee joint around the meniscus.

Techniques for introducing the elongate member and/or sutures into the knee are known in the art, as are suitable means for carrying out the same. In one embodiment, a needle is employed to introduce the elongate member and/or the suture material into place within the knee joint. The needle may be hollow, allowing the elongate member or the suture material to be passed through the needle into position in the knee joint. Alternatively, the needle may be provided with an eye at the distal end thereof, in conventional manner, with a portion of the elongate member or the suture material being passed through the eye of the needle. In addition, or alternatively thereto, one or more arthroscopic grasping devices, as known in the art, may also be employed to introduce and position the elongate member or the suture material within the knee joint. In one embodiment, such a grasping device is passed through the bore formed in the tibia, as described hereinbefore, to locate and secure the elongate member in position.

In a further aspect, the present invention provides an apparatus for applying an elongate member at the periphery of a meniscus of the knee joint of a subject, the apparatus comprising:

a needle for insertion into the knee joint for introducing the elongate member into the knee joint;

a support member comprising a guide means for supporting and orienting the needle for insertion into the knee joint; and

a guide member for insertion into the knee joint adjacent the peripheral edge of the meniscus.

The apparatus of the present invention comprises a needle. In use, the needle is inserted into the knee of the subject for introducing and securing the elongate member about the meniscus. To accurately access the knee about the meniscus, the needle is preferably arcuate or curved in the longitudinal direction, at least in the portion of the needle to be inserted into the knee. The length of the arcuate portion and/or its radius of curvature may vary, according to the size of the knee in the subject. The needle may be provided in a range of sizes, for example, to accommodate a range of different subjects.

The arcuate portion of the needle may have any suitable radius of curvature, preferably to match the curvature of the outer edge portion of the meniscus of the knee. The arcuate portion may have a radius of curvature in the range of from 20.0 to 50.0 mm, more preferably from 25.0 to 45.0 mm, still more preferably from 30.0 to 40.0 mm. In one embodiment, the arcuate portion of the needle has a radius of curvature between 35.0 and 40.0 mm, for example about 38.0 mm.

The arcuate portion of the needle may be of any suitable length and extend through any suitable arc. Preferably, the arcuate portion extends through an arc of from 20 to 80°, more preferably from 30 to 75°, still more preferably from 35 to 65°. An arc of about 60° is particularly preferred for many embodiments.

The portion of the needle to be inserted into the knee of the subject may have any suitable cross-sectional form. For example, the portion may have a generally circular cross-section. More preferably, the portion of the needle to be inserted into the knee of the subject has a rectangular cross-section.

The distal end of the portion of the needle for insertion into the knee of the subject is preferably provided with a bevel.

In a preferred embodiment, the needle comprises a first portion for insertion into the knee of the subject and a second portion for holding by the medical practitioner. The first portion is preferably arcuate, as noted above. The second portion is for holding by the practitioner during the procedure and provides support for the arcuate portion of the needle. The first and second portions may be releasably attached to one another. More preferably, the first and second portions are formed as a single component.

The second portion may have any suitable form that allows the needle to be firmly held and the portion of the needle for insertion into the knee to be supported, guided and manipulated by the practitioner. In one embodiment, the second portion comprises a curved portion to be held in the hand of the practitioner. More preferably, the second portion is generally or substantially straight.

The second portion may have the same cross-sectional form as the first portion or may be different in cross-sectional form. Preferably, the second portion is provided with opposing major surfaces, with the opposing major surfaces arranged to be parallel to the plane in which the first portion of the needle extends. In a preferred embodiment, the second portion is generally rectangular in cross-section.

The needle is preferably arranged to hold the elongate member or a suture material. Accordingly, in one embodiment, the needle is provided with an eye at its distal end, through which a portion of the elongate member or a portion of suture material may be passed, in known manner. Alternatively, or in addition thereto, the needle may be formed with a bore extending longitudinally therealong, thereby forming a hollow core to the needle, with an opening at the distal end of the needle. The elongate member or a suture material may be passed through the bore in the needle to emerge from the distal end.

The apparatus of the present invention further comprises a support member comprising a guide means for supporting and orienting the needle for insertion into the knee joint. In particular, the support member comprises a guide means for supporting and orienting the portion of the needle to be inserted into the knee of the subject. Preferably, the guide means restricts the translation and/or the rotation of the needle, more preferably in two perpendicular planes, leaving the needle free to be moved by the practitioner in a third plane. The third plane is preferably a lateral plane extending through the knee from the anterior side to the posterior side, that is a plane extending substantially horizontally through the knee when the subject is in a standing position.

In one preferred embodiment, the guide means comprises a groove or channel formed in the support member. In use, the needle, in particular the portion of the needle to be inserted into the knee of the subject or a portion adjacent thereto, is inserted into and moved within the groove or channel. In this way, the movement of the needle into and within the knee of the subject is guided and the needle remains properly oriented with respect to the meniscus in the knee and the ligament being inserted. The groove or channel preferably comprises a cross-section to match the cross-section of the portion of the needle being inserted into the knee of

the subject. Preferably, the groove or channel is generally rectangular in cross-section. The groove or channel should be long enough to provide adequate guidance and support for the needle during the procedure. In a preferred embodiment, the floor of the groove or channel, that is the innermost wall portion thereof, has a contour in the direction of insertion of the needle into the knee tissue to match that of the portion of the needle being inserted into the knee of the subject. Preferably, the floor of the groove or channel is arcuate in the direction of insertion of the needle into the knee tissue, most preferably having substantially the same radius of curvature as the portion of the needle to be inserted into the knee.

The apparatus of the present invention further comprises a guide member for insertion into the knee joint adjacent the outer edge of the meniscus. The function of the guide member is to provide a reference for the position of the needle within the knee of the subject. In particular, the guide member is inserted into the knee of the subject adjacent the meniscus. The needle is thereafter inserted into the knee adjacent to the guide member. The guide member cooperates with the needle to provide the practitioner with an indication exterior of the knee of the position of the needle relative to the guide member within the knee.

For example, the guide member is arranged to extend into the tissue of the knee of the subject adjacent the upper peripheral edge of the meniscus. The apparatus is arranged to guide the needle into the knee tissue immediately below the guide member.

In a preferred embodiment, the guide member is arranged in use to be fixed in its position relative to the support member and, therefore, the guide means on the support member. More preferably, the guide member is rigidly mounted to the support member, either releasably or permanently, and extends therefrom. In one preferred embodiment, the support member and the guide member are formed as a single component.

In use, the guide member is deployed to extend in a direction parallel to the guide means of the support member. In this way, correct positioning of the needle in the guide means ensure that the needle is directed parallel to the guide member. In

embodiments in which the guide member is mounted to the support member, the guide member preferably extends from the support member adjacent the guide means and in a direction parallel thereto.

As noted, the guide member provides a means to allow the practitioner to position and manipulate the needle within the knee of the subject, while remaining aware of the position of the needle. To achieve this, the guide member is preferably of the same general form as the portion of the needle to be inserted into the knee. In particular, the guide member is preferably arcuate, more preferably having the same radius of curvature as the arcuate portion of the needle for insertion into the knee. Accordingly, the guide member may have a radius of curvature in the range of from 20.0 to 50.0 mm, more preferably from 25.0 to 45.0 mm, still more preferably from 30.0 to 40.0 mm. In one embodiment, the guide member has a radius of curvature between 35.0 and 40.0 mm, for example about 38.0 mm.

The guide member may be of any suitable length and extend through any suitable arc. Preferably, the guide member extends through an arc of from 20 to 70°, more preferably from 30 to 60°, still more preferably from 35 to 50°. An arc of about 45° is particularly preferred for many embodiments.

The guide member may have any suitable cross-section. Preferably, the guide member has a generally circular cross-section.

As noted above, the guide member provides a means to guide and locate the needle inside the knee of the subject, in particular to act as a guide and reference point for the practitioner in inserting and moving the needle within the knee. In addition, the guide member acts as a tissue dilator. That is, the insertion of the guide member into the knee of the subject around the meniscus dilates the tissue as it passes therethrough, in turn easing the passage of the needle into the tissue adjacent the periphery of the meniscus of the knee.

In one embodiment, the guide member is tubular and has a longitudinal bore extending therethrough. In use, the bore may be used to introduce the elongate member or other sutures into the knee. In embodiments in which the guide member

is mounted to the support member, the guide member may be mounted at its proximal end to the support member and the support member provided with a bore therethrough aligning with the longitudinal bore in the guide member.

As noted above, the apparatus of the present invention may be used to implant an artificial ligament in the medial meniscus or the lateral meniscus. In one preferred embodiment, the apparatus is formed to be reversible, that is the support member with the guide means thereon, the guide member and the needle may be rotated through 180° between a first position for accessing the medial meniscus and a second position for accessing the lateral meniscus. Further, this reversible arrangement allows the apparatus to be used from both the anterior and posterior positions, depending upon the treatment required by the knee of the subject.

In one particularly preferred embodiment for achieving this function, the apparatus comprises a support member having a first guide means and a second guide means, as hereinbefore described, with the guide member extending from the support member from between the first and second guide means.

The apparatus may be freely held by the medical practitioner, with the support member and the guide member being positioned and held by hand. Alternatively, the apparatus may be mounted to the subject, in particular in position at the knee joint. For example, the apparatus, in particular the support member, may be mounted to the tibia by means of pins. In this way, additional stability and accuracy during use of the apparatus may be achieved.

The apparatus may further comprise means to assist the user in navigating the guide member and the needle within the knee joint, for example electromagnetic or optical navigation means or shape matching.

As noted above, in one embodiment of the method of the present invention, one or more loops of suture material are formed at the periphery of the meniscus, the loops extending from the inside of the synovial membrane below the meniscus, through a first hole in the synovial membrane, outside of the synovial membrane and extending through a second hole in the synovial membrane to the inside of the

membrane above the meniscus. The loops are used to retain the elongate member in position along the peripheral edge portion of the meniscus, as described.

In a further aspect, the present invention provides an apparatus for forming one or loops of suture material at the periphery of a meniscus of the knee joint, the apparatus comprising:

an introducer having a longitudinal bore extending therethrough, the distal end of the introducer comprising a guide portion extending at an angle to the axis of the longitudinal bore of the introducer;

whereby a needle extended through the longitudinal bore in the introducer contacts the guide portion and extends from the distal end of the introducer at an angle to the axis of the bore of the introducer.

In use, the introducer is introduced into the knee joint below the meniscus, for example from an anterior arthroscopic portal in the knee tissue. The needle is inserted into the bore in the introducer and moved in the distal direction. The tip of the needle contacts the guide portion at the distal end of the introducer and is directed upwards as it emerges from the distal end of the longitudinal bore of the introducer. In this way, the needle can be directed through the synovial membrane so as to introduce a length of suture material to form the aforedescribed loops. The needle is preferably provided with means for releasably holding the suture material, for example an eye at its distal end.

The guide portion may extend at any suitable angle to the longitudinal axis of the bore in the introducer. Preferably, the guide portion extends substantially perpendicular to the axis of the longitudinal bore, whereby the needle emerges from the distal end of the introducer and extends substantially perpendicular to the longitudinal axis of the introducer. In this way, the introducer may be positioned substantially horizontally beneath the meniscus and the needle may be extended substantially vertically upwards past the peripheral edge of the meniscus and through the synovial membrane, as described above.

Embodiments of both the method and apparatus of the present invention will now be described, by way of example only, having reference to the accompanying drawings, in which:

Figure 1 is a diagrammatical representation of a transverse section through a knee joint viewed from above showing healthy mensci;

Figure 1a is a vertical cross-sectional representation in the coronal plane of the medial edge portion of the knee joint of Figure 1;

Figure 2 is a diagrammatical representation of a transverse section through a knee viewed from above showing a medial meniscus displaced from the articular surface of the tibia;

Figure 2a is a vertical cross-sectional representation in the coronal plane of the medial portion of the knee joint of Figure 2;

Figure 3 is diagrammatical representation of a transverse section through the knee of Figure 2, with an elongate member installed around the periphery of the medial meniscus according to the method of the present invention;

Figure 3a is a vertical cross-sectional representation in the coronal plane of the medial edge portion of the knee joint of Figure 3 showing the position of the elongate member adjacent the medial meniscus;

Figure 4 is a diagrammatical representation of a vertical section through the knee of Figure 3 in the sagittal plane showing the anterior and posterior anchoring of the elongate member to the tibia;

Figures 5a to 5d, illustrate a sequence of steps for the first phase of installing an elongate member around the medial meniscus of the knee joint shown in Figure 2 according to an embodiment of the present invention;

Figures 6a to 6e, illustrate a sequence of steps for the second phase of installing an elongate member around the medial meniscus of the knee joint shown in Figure 2 according to the embodiment of the present invention;

Figures 7a to 7h, illustrate a series of steps for installing an elongate member according to an alternative embodiment of the present invention;

Figure 8a is a perspective view of an apparatus according to one embodiment of the present invention;

Figure 8b is a front view of the apparatus of Figure 8a;

Figure 8c is a side view of the apparatus of Figure 8a; and

Figure 9 is a perspective view of a needle for use with the apparatus of Figure 8a.

As discussed hereinbefore, Figure 1 shows a transverse view of a knee joint in a healthy condition, with the lateral and medial menisci, 4, 6 properly located between the opposing articular surfaces of the tibia 8 and the femur 9. A vertical cross-sectional representation of the knee joint (coronal section) of Figure 1 is shown in Figure 1a, showing the medial meniscus 6 in place between the tibia 8 and the femur 9.

A meniscal subluxation of the knee joint of Figures 1 and 1a is shown in Figures 2 and 2a, in which the medial meniscus 6 is displaced transversely from the position shown in Figure 1, exposing the articular surface of the tibia 8. As a result of the subluxation, increased contact stresses occur and the contact are between the tibia and femur is reduced. Over time, damage to the knee joint occurs, as the articular cartilage wears and fails.

Referring to Figure 3, there is shown a transverse view of the knee joint of Figure 2, with an elongate member provided around the periphery 20 of the medial

meniscus by a procedure according to the present invention. The elongate member, generally indicated as 52, comprises a band of woven or braided polyester fibres. Forming the elongate member from braided fibres, such as polyester fibres, is particularly preferred for many embodiments. The elongate member 52 has a first end comprising a first fixation portion 54 and second end comprising a fixation portion 56 and a central working portion 58. The band has a generally elliptical cross section having opposing major surfaces 60, one of which faces and contacts the surface of the periphery 20 of the medial meniscus 6. The elongate member 52 is anchored to the tibia 8 at each of its first and second ends 54, 56, as described in more detail below. The procedure for installing the elongate member 52 applies tension to the member, causing the member to apply a radially inwards or confining force on the meniscus 6, as indicated by arrows A in Figures 3 and 3a. Sufficient tension is applied to the elongate member 52 that the meniscus 6 is drawn back into position between the articular surfaces of the tibia 8 and the femur. The elongate member 52 further acts to hold the meniscus in this position. The elongate member also restores and acts to maintain the appropriate shape of the meniscus 6.

Figure 4 is a sagittal view of the knee joint of Figure 3. As shown, the fixation portion at the first end 54 of the elongate member is attached to the tibia adjacent the transverse ligament. A blind bore 70 is formed in the tibia, in known manner, with the first end portion 54 of the elongate member 52 anchored within the blind bore by an interference screw 72, in known manner. A diagonal bore 74 is drilled in the tibia having a first opening 76 in the posterior surface of the tibia 8 adjacent the posterior attachment of the meniscus 6 and a second opening 78 in the anterior face 80 of the tibia 8. The second end portion 56 of the elongate member 52 extends into the first opening 76, through the bore 74 and is anchored at the second opening 78 of the bore 74 by means of an endobutton 82, as is known in the art. Other similar means for anchoring the second end 56 of the elongate member 52 may also be employed, such as an interference screw.

To install the elongate member 52 as shown in Figures 3 and 4, the diagonal bore 74 and the blind bore 70 are drilled in the tibia 8, in known manner. The elongate member 52 is inserted into the knee joint 2 so as to have its working portion 58 lying in contact with the periphery of the meniscus 6. The second end 56 of the

elongate member 52 is passed through the bore 74 from the first opening 76 to the second opening 78. The second end 56 of the elongate member is then anchored to the tibia 8 by way of the endobutton 82, as known in the art. Tension is applied to the second end portion 56 of the elongate member, as required to relocate the meniscus 6 between the tibia 8 and the femur 9. The first end 54 of the elongate member 52 is then anchored to the tibia 8 by means of the screw 72 in the blind bore 70, again in known manner.

Referring to Figures 5a to 5d, there is shown a sequence of steps for the first phase of installing an elongate member around the medial meniscus of the knee joint shown in Figure 2. Referring to Figure 5a, a guide, generally indicated as 102, comprises a guide support block 104 having a handle 106 and an arcuate guide member 108 extending therefrom. In the position shown in Figure 5a, the guide member 108 has been inserted into the knee joint through a medial portal formed by an incision in the medial portion of the tissue surrounding the knee joint. As shown, the guide member 108 is in position to extend around the periphery of the meniscus 6, with the distal end 110 of the guide member 108 being adjacent the posterior horn of the meniscus. A first bore 112 has been drilled in the tibia in known manner and extends from adjacent the posterior attachment of the meniscus 6 diagonally through the tibia in like manner to the bore 74 shown in Figure 4.

Turning to Figure 5b, a needle assembly, generally indicated as 120 and comprising a handle 122 and an arcuate needle 124, is aligned with the guide block 104 and the guide member 108 and the needle 124 is inserted into the knee joint adjacent the guide member 108. Figure 5c shows the needle 124 in the fully inserted position.

The final step in the first phase is shown in Figure 5d, with a first suture 130 being put in place. The needle 124 is provided with a longitudinal bore therethrough, and the suture 130 is passed through the bore to the distal end of the needle 124. The suture 130 is then captured by a suitable grasping device (not shown for clarity), as is known in the art, inserted through the bore 112 in the tibia (similar to the bore 74 shown in Figure 4) to enter the knee joint. The grasper is used to pull the suture

130 through to the anterior knee, exiting through the opening in the anterior face of the tibia (opening 78, shown in Figure 4)..

Referring to Figures 6a to 6e, there is shown a sequence of steps for the second phase of installing an elongate member around the lateral meniscus of the knee joint shown in Figure 2. The suture 130 shown in Figure 5d has been omitted from Figure 6a for clarity. It is also to be understood that the first and second phases of the procedure as described herein may be carried out in the reverse order, that is with the posterior suture being positioned first.

Figure 6a shows the guide 102 and the needle assembly 120 inserted into the knee joint through the medial portal, with the guide member 108 and the needle 124 extending anterior of the medial portal to the anterior horn of the meniscus 6. As shown in Figure 6a, a second bore 140 has been drilled in the tibia in the anterior portion of the tibial plateau.

A second suture 150 is introduced into the knee joint, as indicated in Figure 6b, with the suture extending from the second bore 140 to the medial portal. The suture 150 is introduced in similar manner to that described above for the suture 130, using the hollow needle and an arthroscopic grasper.

The two sutures 130, 150 are tied to respective ends of an elongate member 160, as shown in Figure 6c. The sutures 130, 150 are tensioned, as indicated by arrows B in Figures 6c and 6d, to draw the elongate member 160 through the medial portal and into position around the peripheral edge of the meniscus 6, as shown in Figure 6e. The elongate member 160 is tensioned and anchored as described hereinbefore and shown in Figure 4. It is to be noted that the elongate member 160 is installed under the medial collateral ligament (MCL) 170 as indicated in Figure 6e.

Referring to Figures 7a to 7h, there is illustrated a series of steps for installing an elongate member according to an alternative embodiment of the present invention. Referring to Figure 7a, a knee meniscus 202 is shown in plan view. A needle 204 having a tip 206 in an introducer 208 is shown inserted beneath the meniscus 202, with the tip 206 of the needle 204 extending beyond the outer edge of

the meniscus. The introducer 208 is first inserted to the position shown in Figure 7a. Thereafter, the needle 204 is extended from the introducer, such that the needle tip 206 punctures the synovial membrane 230 both below and above the meniscus 202 at points X and Y indicated in Figure 7b. In this way, the needle 204 forms a path from within the lower portion of the synovial cavity, out through the synovial membrane 230 at point X and into the upper portion of the synovial cavity through the membrane 230 at point Y.

The introducer 208 and needle 206 are used to insert a length of suture material 210. As shown in Figure 7c, repeated insertions and withdrawals of the introducer 208 and the needle 206 to and from the position shown in Figure 7b allow loops of the suture material 210 to be formed both above and below the meniscus within the synovial cavity. In particular, a plurality of upper loops 212 and a plurality of lower loops 214 (indicated by a dotted line in Figure 7c) are formed about the meniscus 202.

Once the loops 212, 214 have been formed above and below the meniscus 202, the elongate member 220 is introduced into the knee joint within the synovial cavity so as to pass through the upper loops, as shown in plan view in Figure 7d. Figure 7e shows a vertical sectional view of the knee joint of Figure 7d, with the elongate member 220 in position within the upper loops 212.

Finally, the suture 210 is tensioned, drawing the loops 212, 214 closed, in particular drawing the upper loops 212 around the elongate member 220. Continued tensioning of the suture 210 draws the elongate member 220 down and against the periphery of the meniscus 202, as shown in Figure 7f. The elongate member 220 is then tensioned and anchored as described above, to relocate and retain the meniscus between the tibia and the femur. The suture 220 acts to hold the elongate member 220 in place against the meniscus 202, limiting or preventing the elongate member becoming displaced.

Referring to Figures 7g and 7h, there is shown steps of an alternative procedure for forming the loops 212, 214 of suture material at the peripheral edge of the meniscus. The steps of Figures 7g and 7h are analogous to those of Figures 7a

and 7b described above, but using a preferred embodiment of an instrument for introducing the suture material and forming the loops. The instrument comprises a generally tubular introducer 280 having a longitudinal bore extending therethrough. The introducer 280 is provided with a guide portion 282 at its distal end, the guide portion extending substantially perpendicular to the longitudinal axis of the introducer, as shown in Figure 7h. A needle 284, extended into the introducer in the distal direction contacts the guide portion 282 and is diverted as shown in Figure 7h. In this way, the needle 284 may be caused to pass upwards at the periphery of the meniscus 202 and through the synovial membrane. The needle 284 is provided with an eye 286 at its distal end for holding a length of suture material 288. The procedure for forming the loops of suture material is as described above.

Turning to Figure 8a, there is shown a perspective view of an apparatus according to one embodiment of the present invention. Figures 8b and 8c show front and side views respectively of the apparatus of Figure 8a. The apparatus is of use in the aforedescribed procedure for installing an elongate member around the meniscus of a knee joint.

The apparatus, generally indicated as 302, comprises an elongate, generally cylindrical handle 304 having a support member 306 mounted at one end thereof. The support member 306 is formed as a generally rectangular block. The support member 306 comprises a guide means, in the form of channels 308 formed therein, one either side of the handle 304, as shown in Figure 8b. Each channel 308 has a generally rectangular cross-section, as shown in Figure 8b, with the floor 310 of the channel being curved to accept a needle, as described in more detail below.

A guide member 312 extends from one side of the support member 306 from between the channels 308. The guide member 312 is tubular in form having a bore 314 extending therethrough opening at the distal end 316 of the guide member 312. The guide member 312 is curved in an arc, as shown in Figure 8c. As shown in Figures 8b and 8c, the distal end 316 of the guide member 312 is generally conical in form. The central bore in the guide member 312 aligns with a bore 318 extending through the support member 306, as shown in Figure 8a. In this way, suture material or materials to form the elongate member may be passed along the guide member

312 for placement within the knee joint, as described in the aforementioned procedure.

Referring to Figure 9, there is shown a needle for use with the apparatus of Figures 8a to 8c. The needle, generally indicated as 352, comprises an elongate handle 354. An arcuate blade 356 extends from the distal end of the handle 354. The blade 356 and the handle 354 form the first and second portions of the needle, as hereinbefore generally described.

The blade 356 is generally rectangular in cross-section and has a longitudinal bore 358 extending therethrough, as shown in the Detail B of Figure 9. In this way, material to form the elongate member and/or suture material may be introduced through the blade 356 of the needle.

The blade 356 is generally arcuate, extending through an arc of about 60°, as shown in Figure 9.

In use, the needle 352 is combined with the apparatus of Figures 8a to 8c by placing the blade 356 of the needle into one of the channels 308 in the support member 306. The floor of the channel 308 is curved and has the same radius of curvature of the blade 356. Similarly, the radius of curvature of the guide member 312 is the same as the radius of curvature of the blade 356. Use of the apparatus 302 and the needle 352 is as shown in Figures 5 and 6 and described above. In particular, the guide member 312 is first introduced into the tissue of the knee along the upper peripheral edge of the meniscus, as shown. Thereafter, the blade 356 of the needle 352 is introduced into the knee tissue below the guide member 312, using the channel 308 in the support member 306 and the guide member 312 as a guide.

As shown in Figures 8a to 8c, the support member 306 is provided with two channels 308, allowing the apparatus 302 to be reversed for use in the treatment of either meniscus of the knee joint and providing support and guidance for the proper positioning and insertion of the needle 352.

CLAIMS

1. A method for treating a damaged or displaced meniscus of the knee of a subject, the method comprising:

providing an elongate retaining member having a first end and a second end;

extending the retaining member along at least a portion of the outer periphery of the meniscus;

anchoring each of the first and second ends of the retaining member;

whereby tension is applied to the retaining member, thereby applying a radially confining force on the outer periphery of the meniscus.

2. The method according to claim 1, wherein the elongate member is extended along a major portion of the outer periphery of the meniscus.

3. The method according to claim 2, wherein the elongate member is extended along substantially all of the outer periphery of the meniscus.

4. The method according to any preceding claim, wherein the elongate member is placed under tension sufficient to restore the shape of a misshapen meniscus.

5. The method according to claim 4, wherein the elongate member is placed under tension sufficient to restore a displaced meniscus to its correct position.

6. The method according to any preceding claim, wherein the elongate member is permanent.

7. The method according to any preceding claim, wherein the elongate member is formed from a fibrous material.

8. The method according to claim 7, wherein the elongate member is formed from a plurality of fibres, the fibres being arranged by weaving, braiding or stitching.

9. The method according to any preceding claim, wherein the elongate member comprises a material that encourages tissue ingrowth.

10. The method according to claim 9, wherein the elongate member comprises polyester.

11. The method according to any preceding claim, wherein the elongate member conforms to and accommodates the peripheral surface of the meniscus.

12. The method according to any preceding claim, wherein the elongate member comprises a major substantially flat surface for contacting the peripheral surface of the meniscus.

13. The method according to any preceding claim, wherein the elongate member comprises a fixation portion at one or both ends.

14. The method according to any preceding claim, wherein a first end of the elongate member is anchored to the tibia.

15. The method according to claim 14, wherein the first end is anchored to an anterior region of the tibia.

16. The method according to claim 15, wherein the first end is anchored at a location on the tibia adjacent the transverse ligament.

17. The method according to any of claims 14 to 16, wherein the first end is anchored to the tibia by means of a screw installed in a blind bore formed in the tibia.

18. The method according to any preceding claim, wherein a second end of the elongate member is anchored to the tibia.

19. The method according to any preceding claim, wherein the elongate member is in the form of a loop.

20. The method according to any preceding claim, wherein a bore is formed in the tibia, a portion of the elongate member at the second end extending through the bore.

21. The method according to claim 20, wherein the bore extends through the tibia.

22. The method according to claim 21, wherein the bore has a first opening adjacent the posterior attachment of the meniscus.

23. The method according to claim 22, wherein the bore has a second opening in an anterior region of the tibia.

24. The method according to claim 23, wherein the bore extends upwards from the second opening in a posterior direction to the first opening.

25. The method according to claim 24, wherein the elongate member extends through the bore from the first opening and is anchored by an anchoring means at or adjacent the second opening in the bore.

26. The method according to claim 25, comprising:

forming the bore in the tibia;

positioning the elongate member adjacent the outer periphery of the meniscus;

securing the first end of the elongate member to the tibia at the anterior location;

passing the second end of the elongate member through the bore in the tibia;

applying tension to the elongate member from the second opening of the bore; and

securing the second end of the elongate member to the tibia.

27. The method according to claim 25, comprising:

forming the bore in the tibia;

positioning the elongate member adjacent the outer periphery of the meniscus;

passing the second end of the elongate member through the bore in the tibia;

securing the second end of the elongate member to the tibia;

applying tension to the elongate member; and

securing the first end of the elongate member to the tibia at the anterior location.

28. The method according to any preceding claim, wherein the elongate member is disposed on the inside of the synovial membrane.

29. The method according to of claims 1 to 27, wherein the elongate member is disposed on the outside of the synovial membrane.

30. The method according to any preceding claim, wherein the elongate member is retained adjacent the meniscus at one or more points along its length.

31. The method according to claim 30, wherein the elongate member is drawn into a fold of the synovial membrane adjacent the outer periphery of the meniscus.

32. The method according to either of claims 30 or 31, wherein the means for retaining the elongate member comprises one or more retaining sutures.

33. The method according to claim 32, wherein the retaining suture is formed with a plurality of loops, the elongate member extending through the loops of the suture, whereby tension is applied to the suture to draw the elongate member into position adjacent the meniscus.

34. The method according to claim 33, wherein the loops extend from beneath the meniscus from a starting point on the inside of the synovial membrane, extend through a first hole in the synovial membrane, extend outside the synovial membrane upwards behind the meniscus, and extend through a second hole in the synovial membrane onto the inside of the membrane above the meniscus.

35. The method according to any of claims 32 to 34, wherein the suture is introduced into the knee from an anterior arthroscopic portal.

36. The method according to any preceding claim, wherein one or more introducing sutures are first installed in the knee joint, the free ends of the introducing suture are attached to a respective end of the elongate member, and tension is applied to the introducing suture to draw the elongate member into position in the knee joint.

37. An apparatus for applying an elongate member at the periphery of a meniscus of the knee joint of a subject, the apparatus comprising:

a needle for insertion into the knee joint for introducing the elongate member into the knee joint;

a support member comprising a guide means for supporting and orienting the needle for insertion into the knee joint; and

a guide member for insertion into the knee joint adjacent the peripheral edge of the meniscus.

38. The apparatus according to claim 37, wherein at least the portion of the needle for insertion into the knee tissue is arcuate in the longitudinal direction.

39. The apparatus according to claim 38, wherein the arcuate portion of the needle has a radius of curvature of from 20 to 50 mm.

40. The apparatus according to either of claims 38 or 39, wherein the arcuate portion of the needle extends through an arc of from 20 to 70°.

41. The apparatus according to any of claims 37 to 40, wherein the needle has a cross-section that is generally circular or rectangular.

42. The apparatus according to any of claims 37 to 41, wherein the distal end portion of the needle is bevelled.

43. The apparatus according to any of claims 37 to 42, wherein the needle is provided with an eye in its distal end portion.

44. The apparatus according to any of claims 37 to 43, wherein the portion of the needle for introducing into the tissue of the knee joint comprises a longitudinal bore extending therethrough.

45. The apparatus according to any of claims 37 to 44, wherein the guide means of the support member restricts the translation and/or rotation of the needle.

46. The apparatus according to claim 45, wherein the guide means restricts both translation and rotation of the needle in two perpendicular planes, while allowing movement of the needle in a third plane.

47. The apparatus according to claim 46, wherein, in use, the third plane is a lateral plane extending through knee from the anterior side to the posterior side.

48. The apparatus according to any of claims 37 to 47, wherein the guide means comprises a groove or channel formed therein for accepting the needle.

49. The apparatus according to claim 48, wherein the groove or channel has a cross-section that matches that of the needle.

50. The apparatus according to either of claims 48 or 49, wherein the groove or channel is generally rectangular in cross-section.

51. The apparatus according to any of claims 48 to 50, wherein the floor of the groove or channel is arcuate.

52. The apparatus according to claim 51, wherein the radius of curvature of the floor is the same as the radius of curvature of the arcuate portion of the needle.

53. The apparatus according to any of claims 37 to 52, wherein the guide member is fixed in relation to the support member.

54. The apparatus according to claim 53, wherein the guide member is rigidly mounted to the support member.

55. The apparatus according to any of claims 37 to 54, wherein the guide member is arcuate.

56. The apparatus according to claim 55, wherein the guide member has a radius of curvature the same as that of the arcuate portion of the needle.

57. The apparatus according to either of claims 55 or 56, wherein the radius of curvature the guide member is from 20 to 50 mm.

58. The apparatus according to any of claims 55 to 57, wherein the guide member extends through an arc of from 20 to 70°.

59. The apparatus according to any of claims 37 to 58, wherein the guide member is generally circular in cross-section.

60. The apparatus according to any of claims 37 to 59, wherein the guide member has a longitudinal bore extending therethrough.

61. An apparatus for forming one or loops of suture material at the periphery of a meniscus of the knee joint, the apparatus comprising:

an introducer having a longitudinal bore extending therethrough, the distal end of the introducer comprising a guide portion extending at an angle to the axis of the longitudinal bore of the introducer;

whereby a needle extended through the longitudinal bore in the introducer contacts the guide portion and extends from the distal end of the introducer at an angle to the axis of the bore of the introducer.

62. The apparatus according to claim 61, wherein the guide portion extends substantially perpendicular to the axis of the longitudinal bore of the introducer.

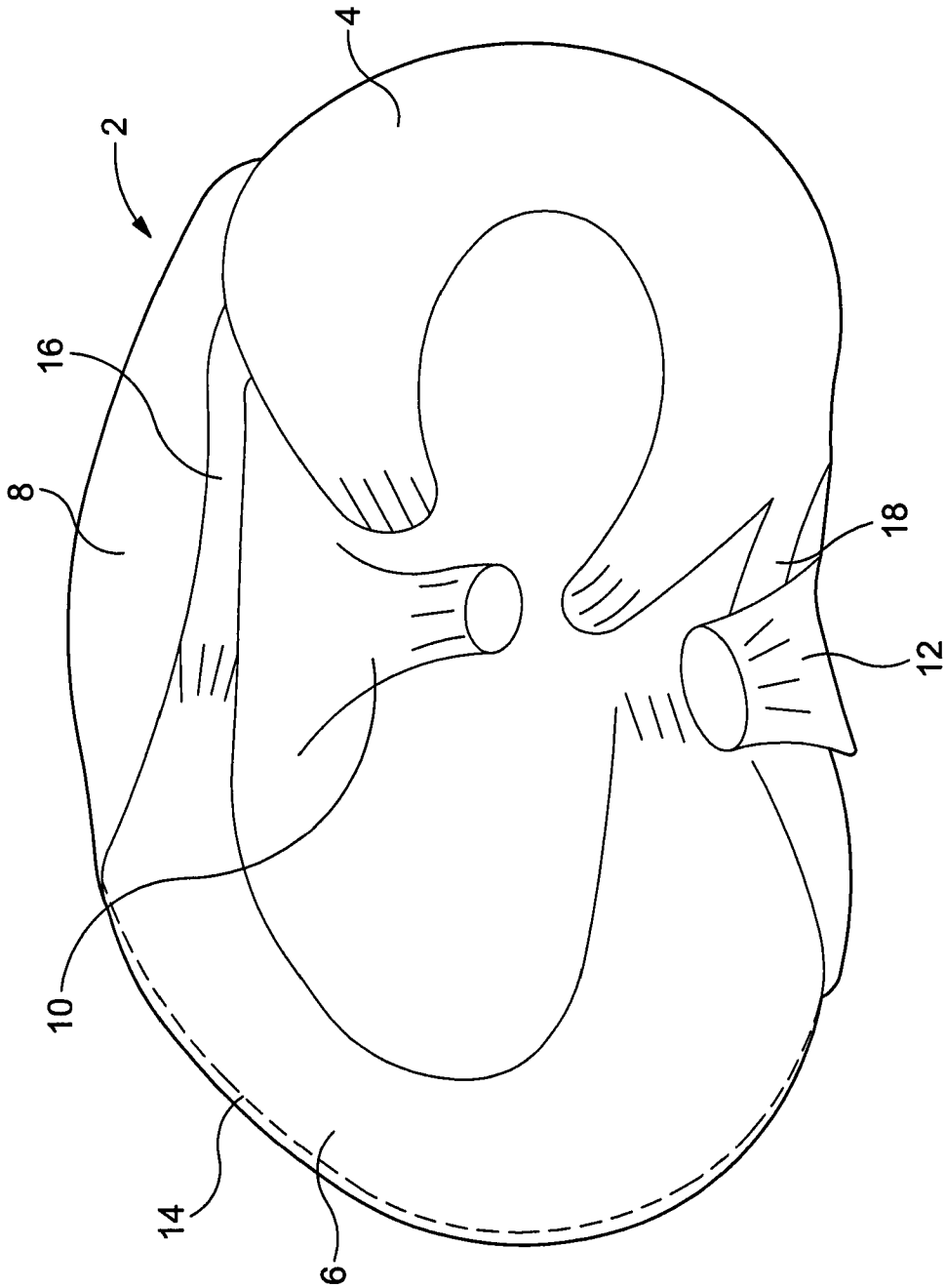

Figure 1

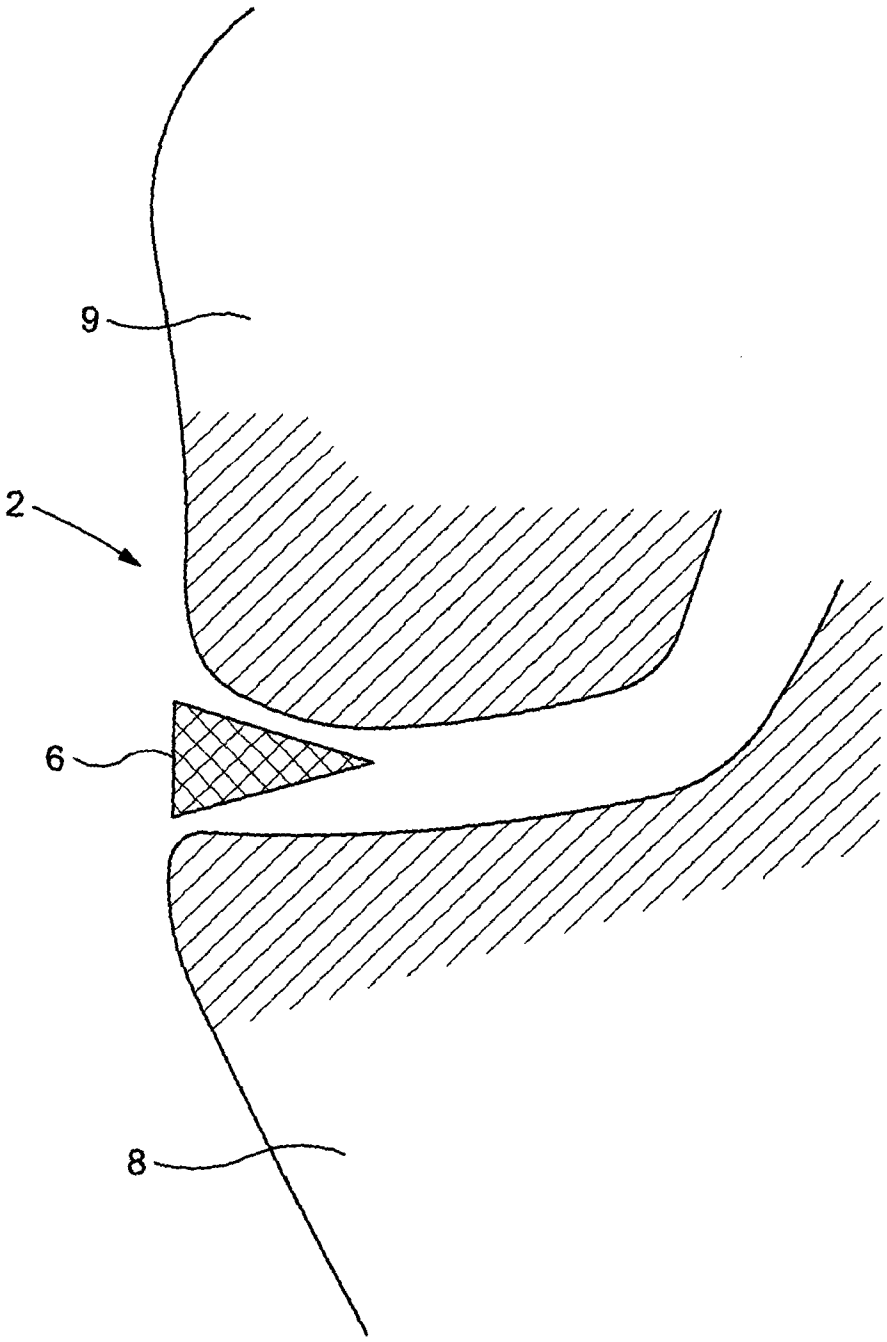

Figure 1a

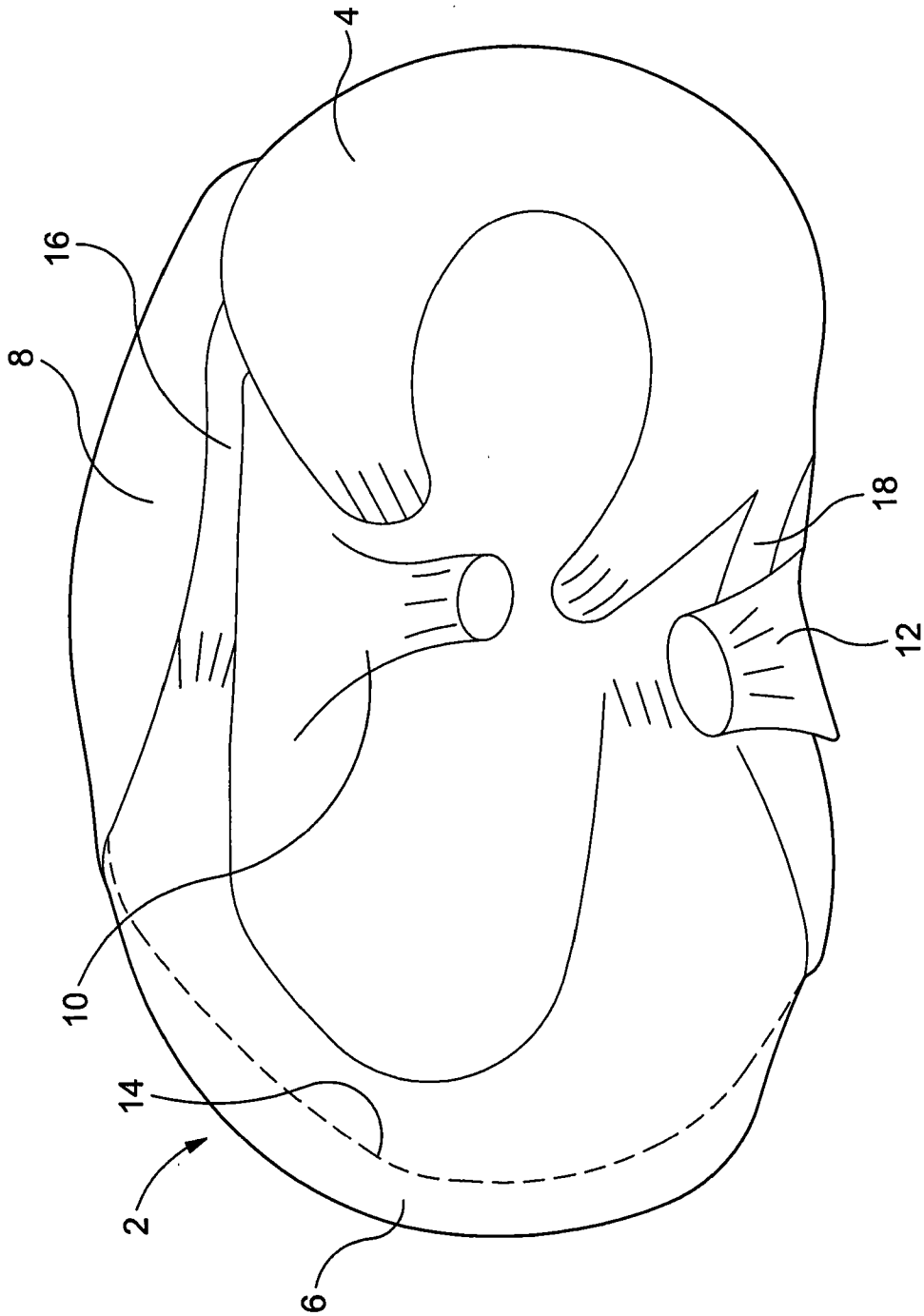

Figure 2

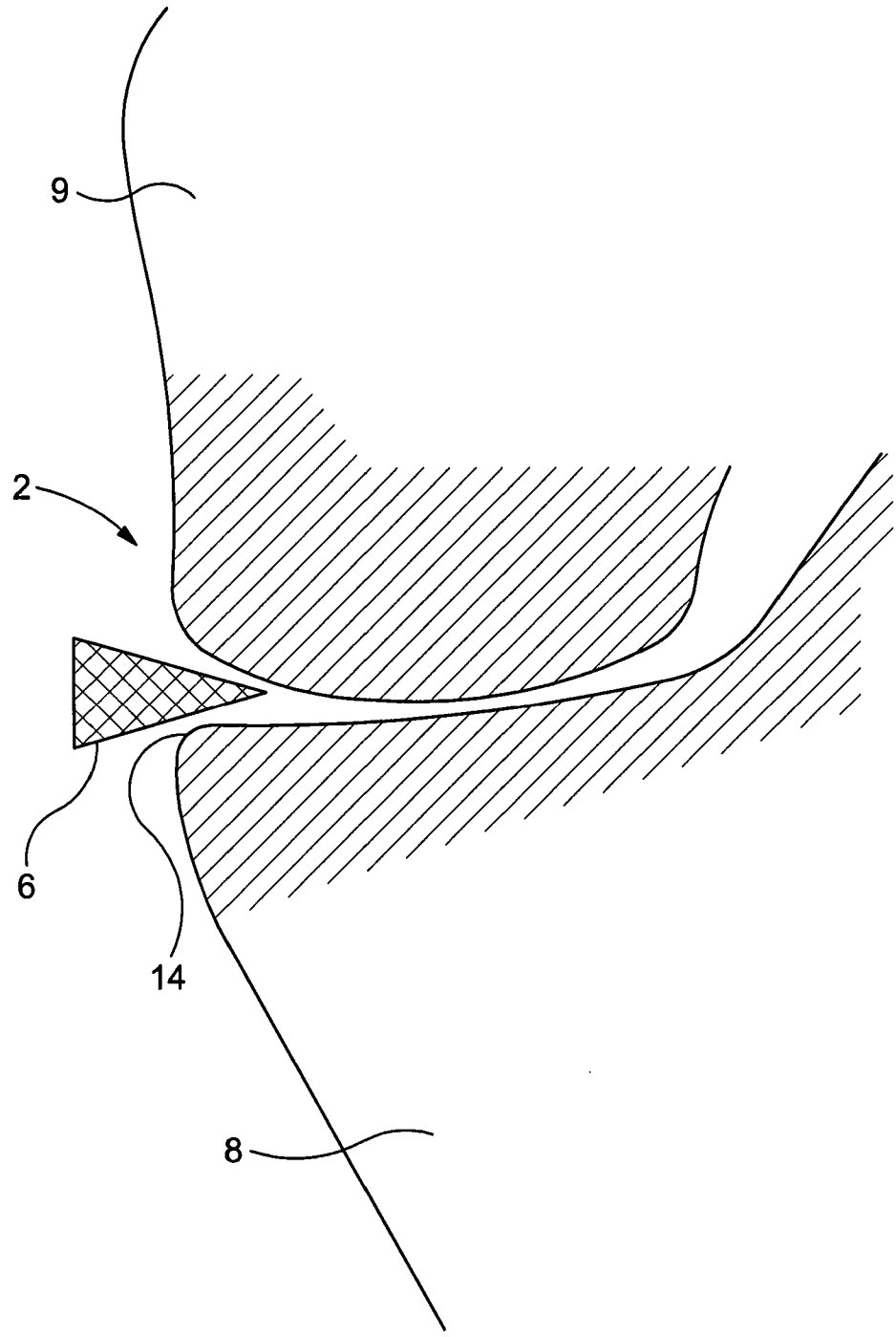

Figure 2a

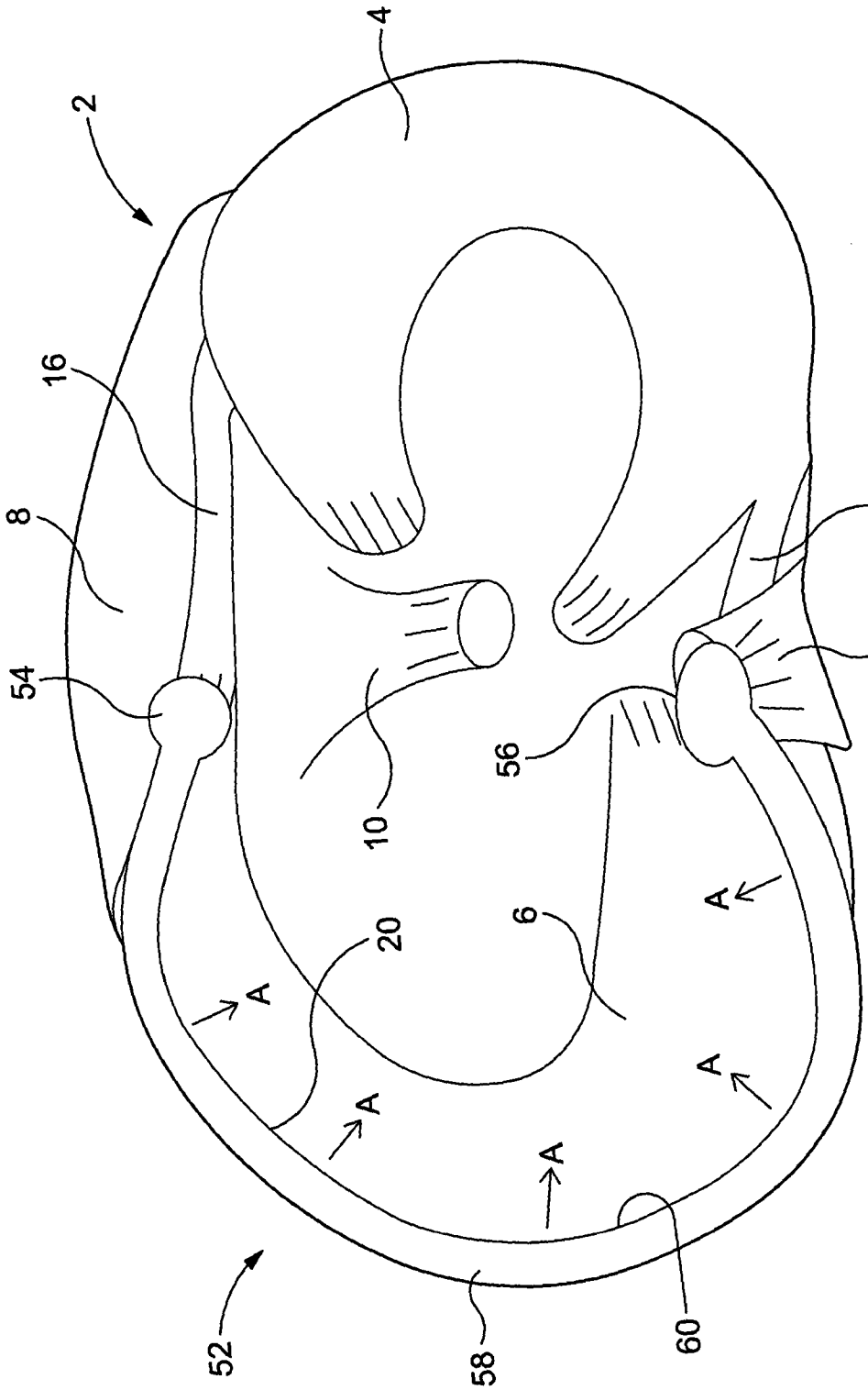

Figure 3

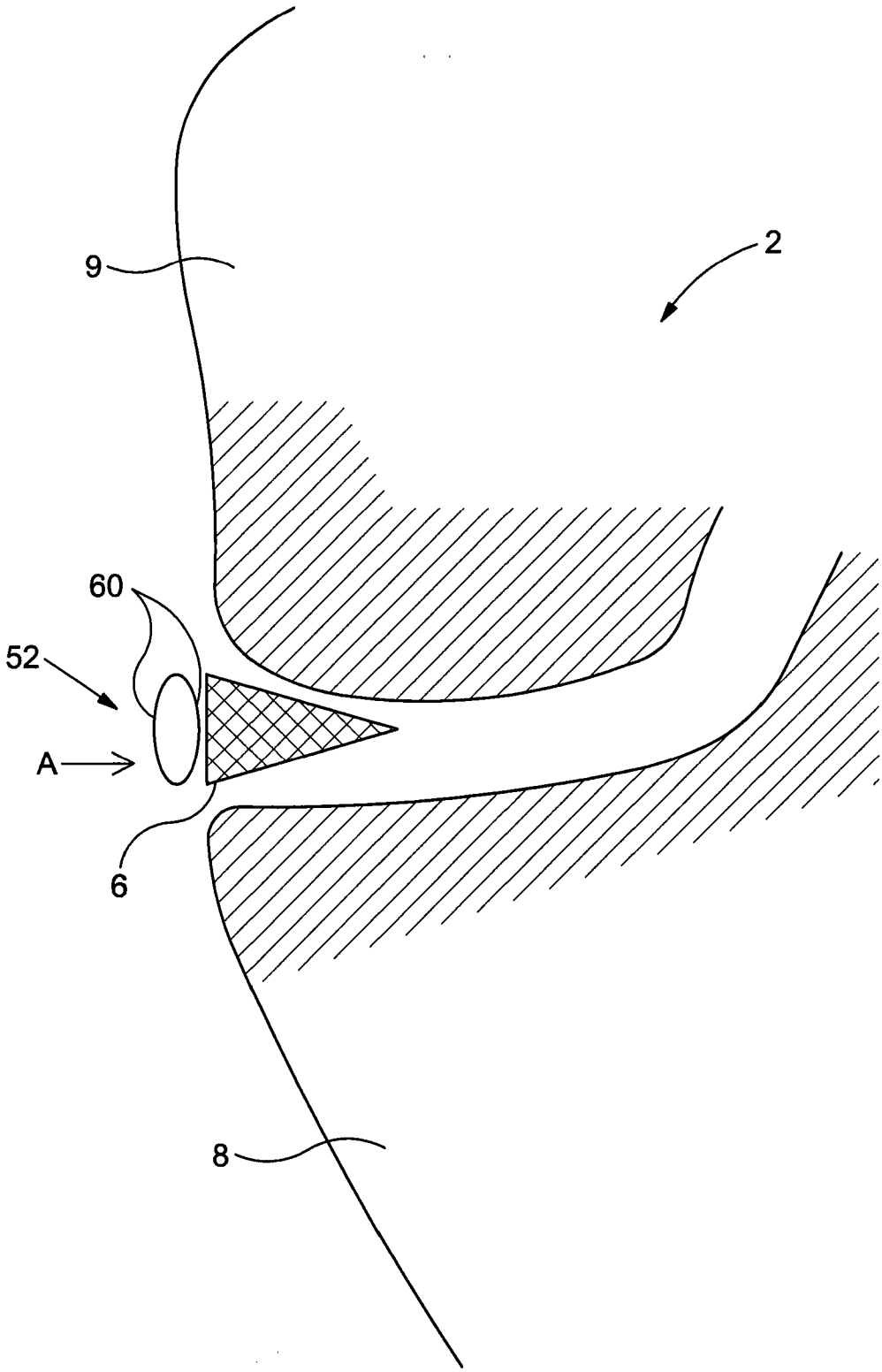

Figure 3a

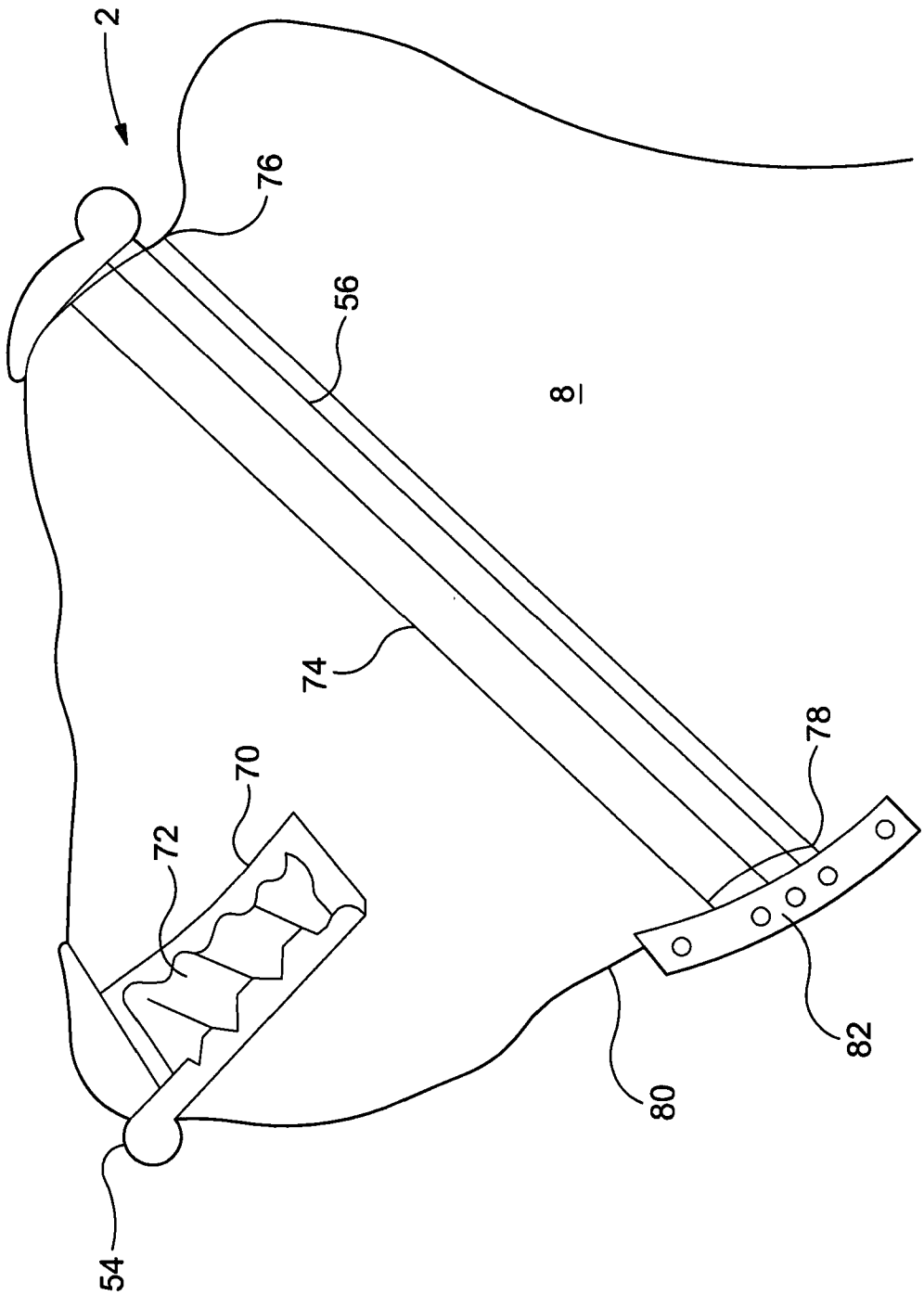

Figure 4

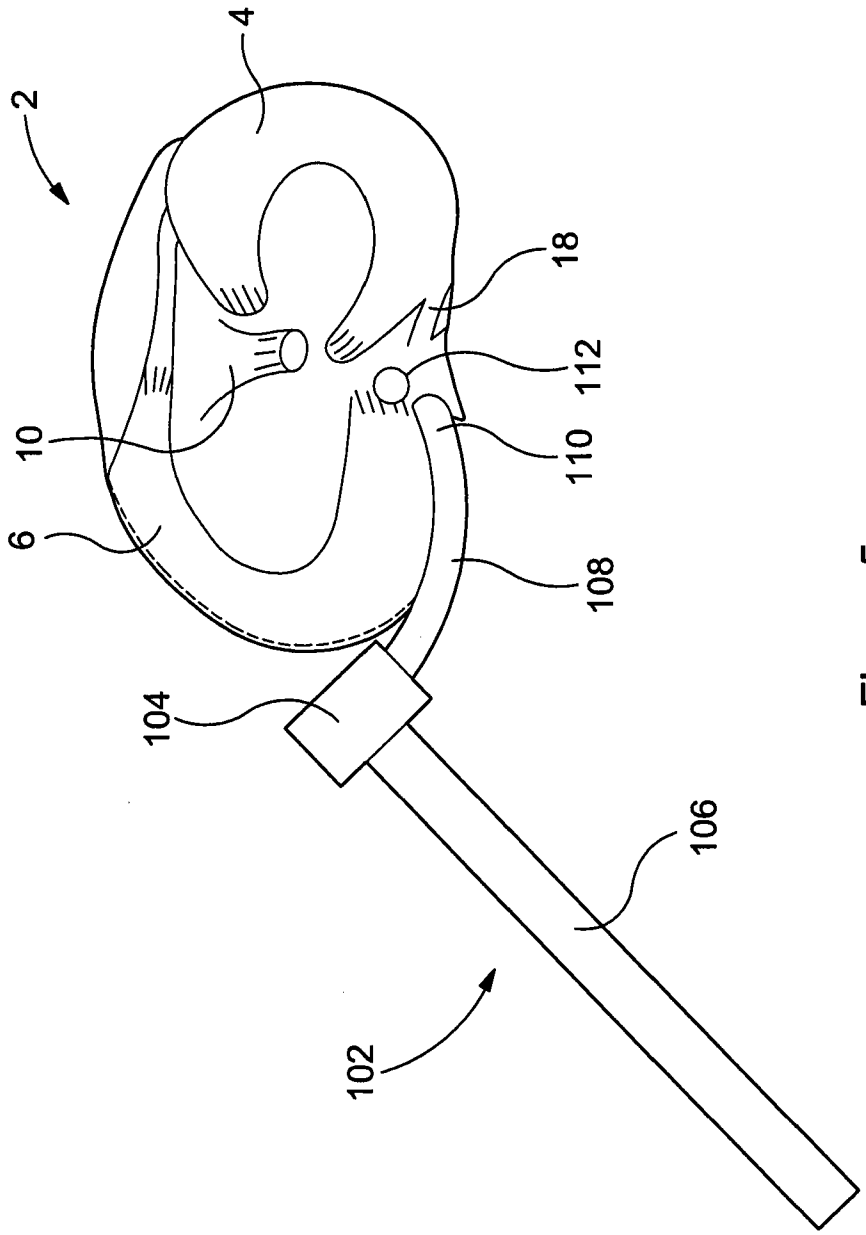

Figure 5a

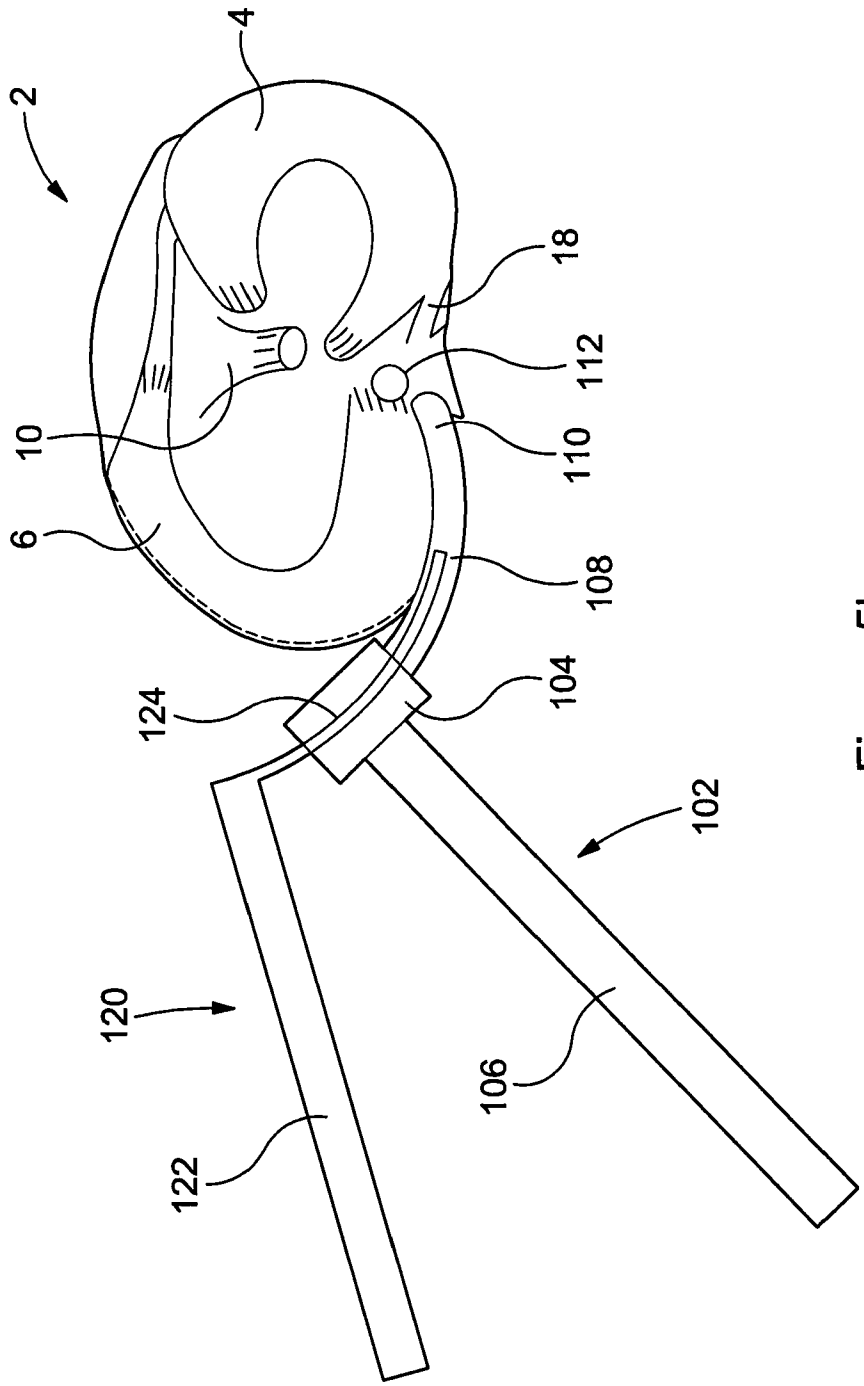

Figure 5b

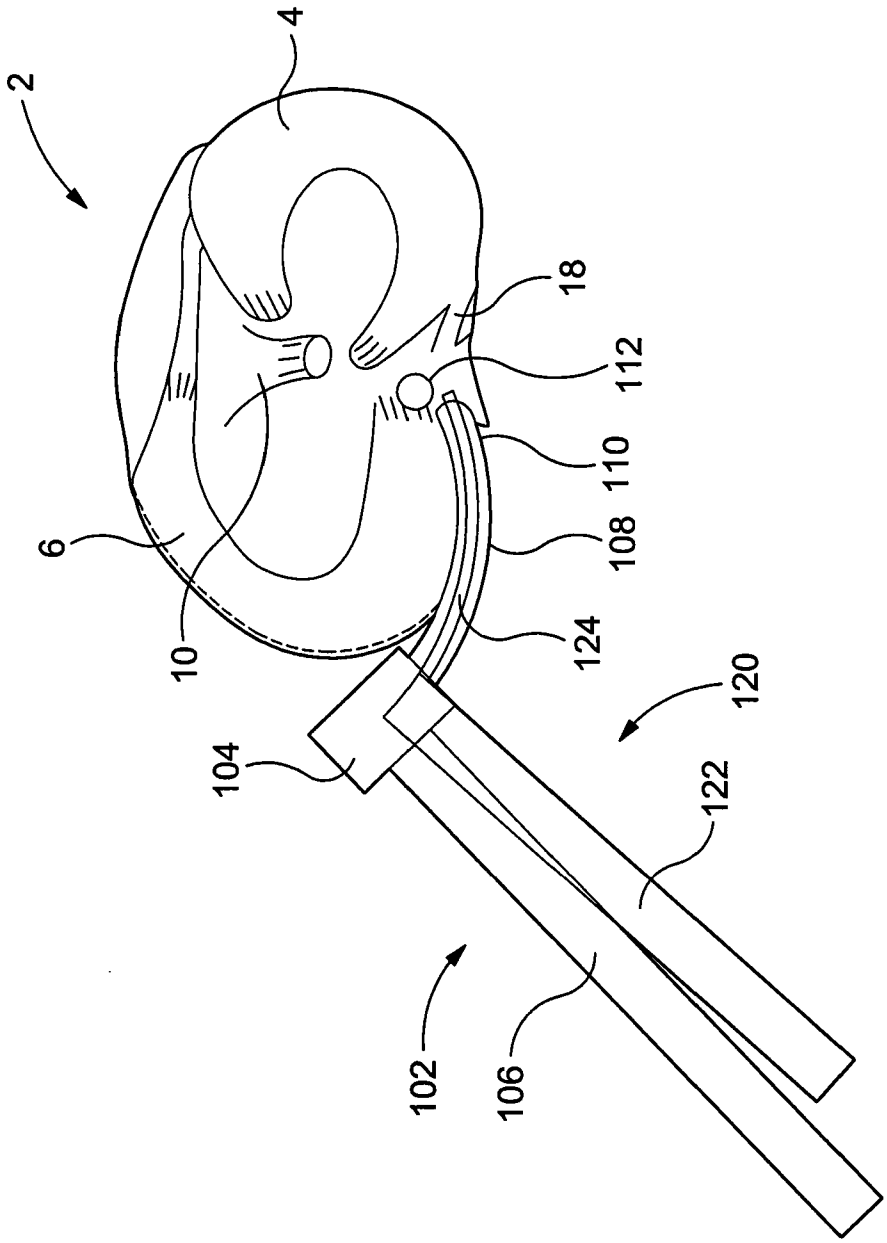

Figure 5c

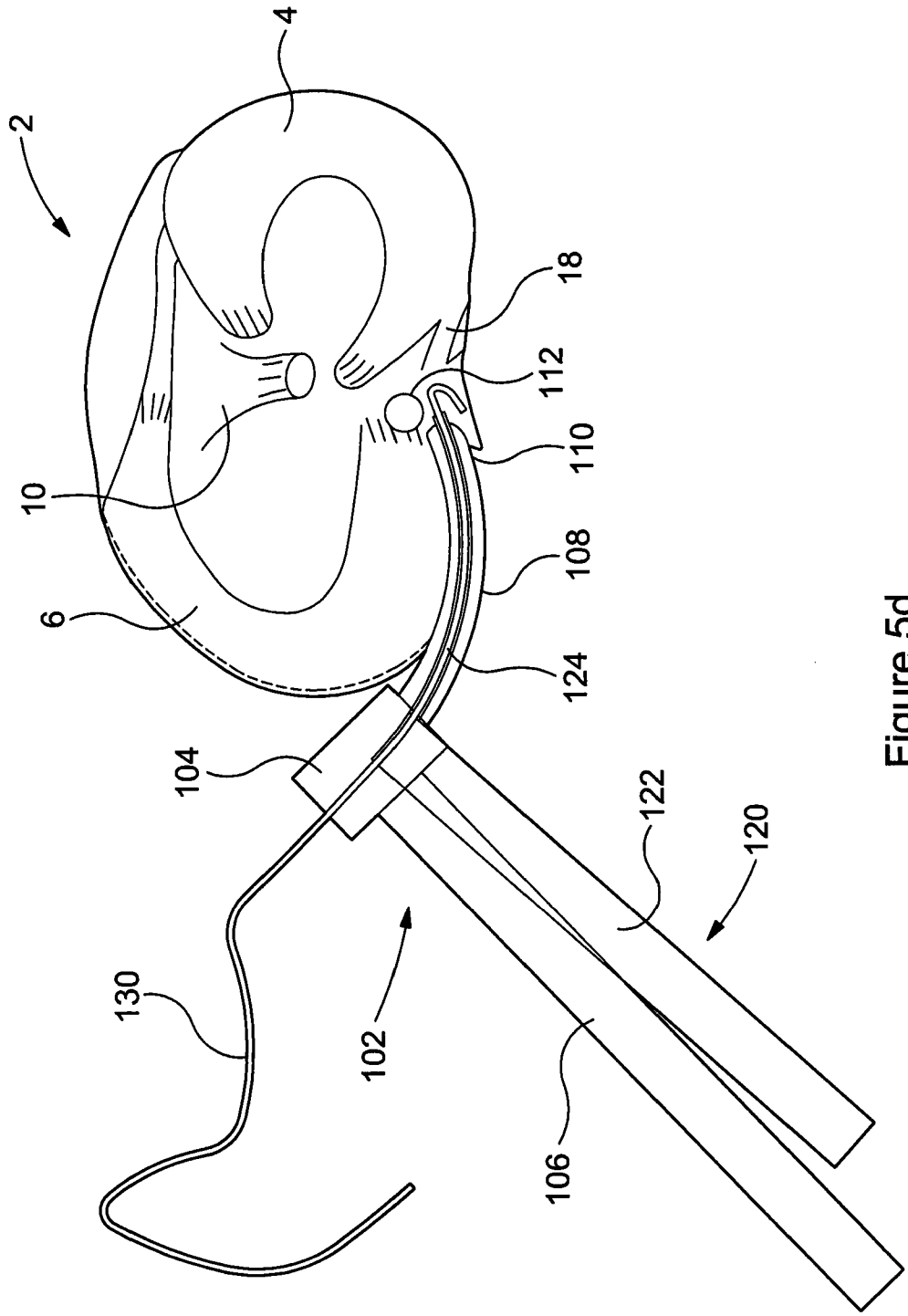

Figure 5d

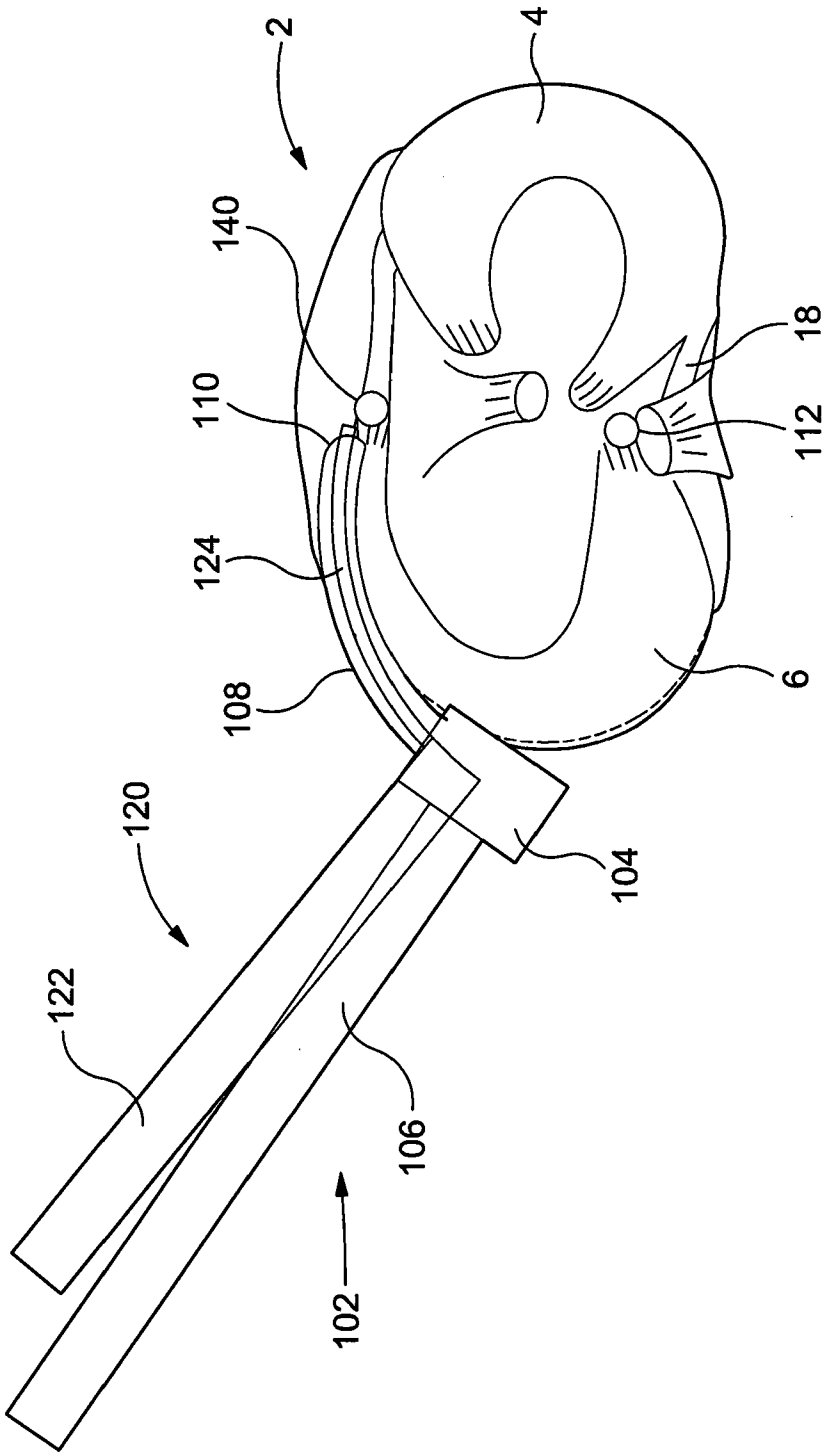

Figure 6a

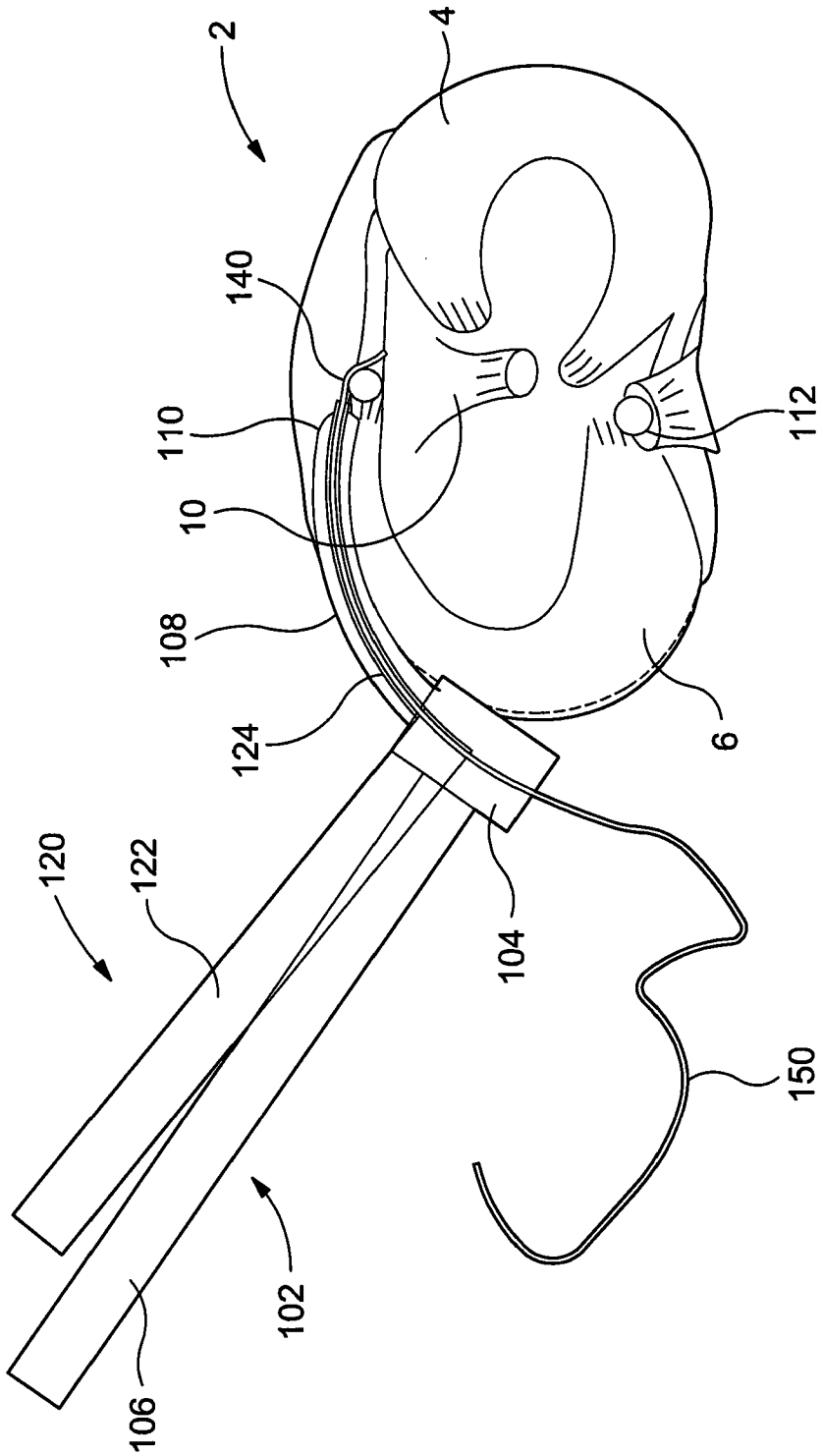

Figure 6b

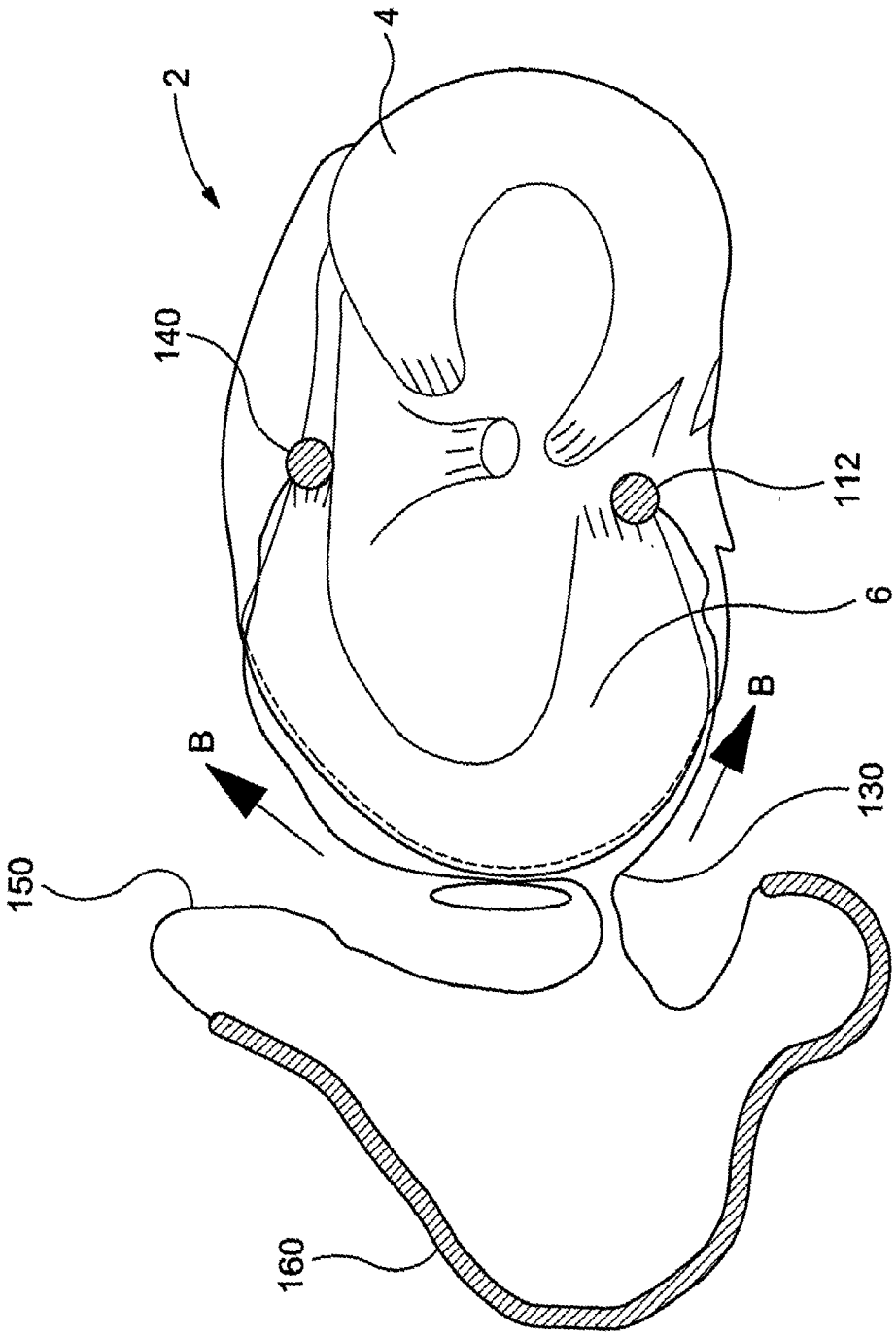

Figure 6c

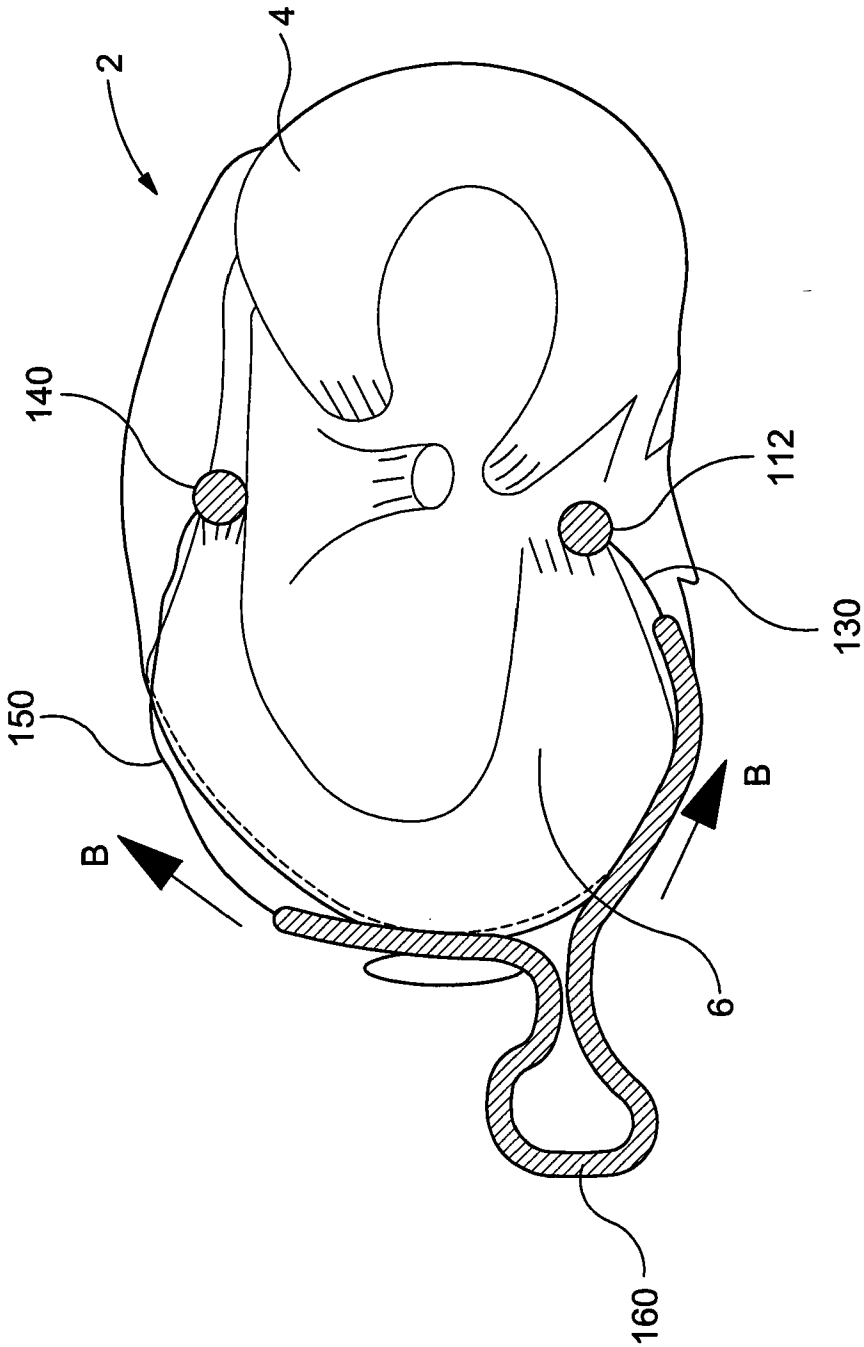

Figure 6d

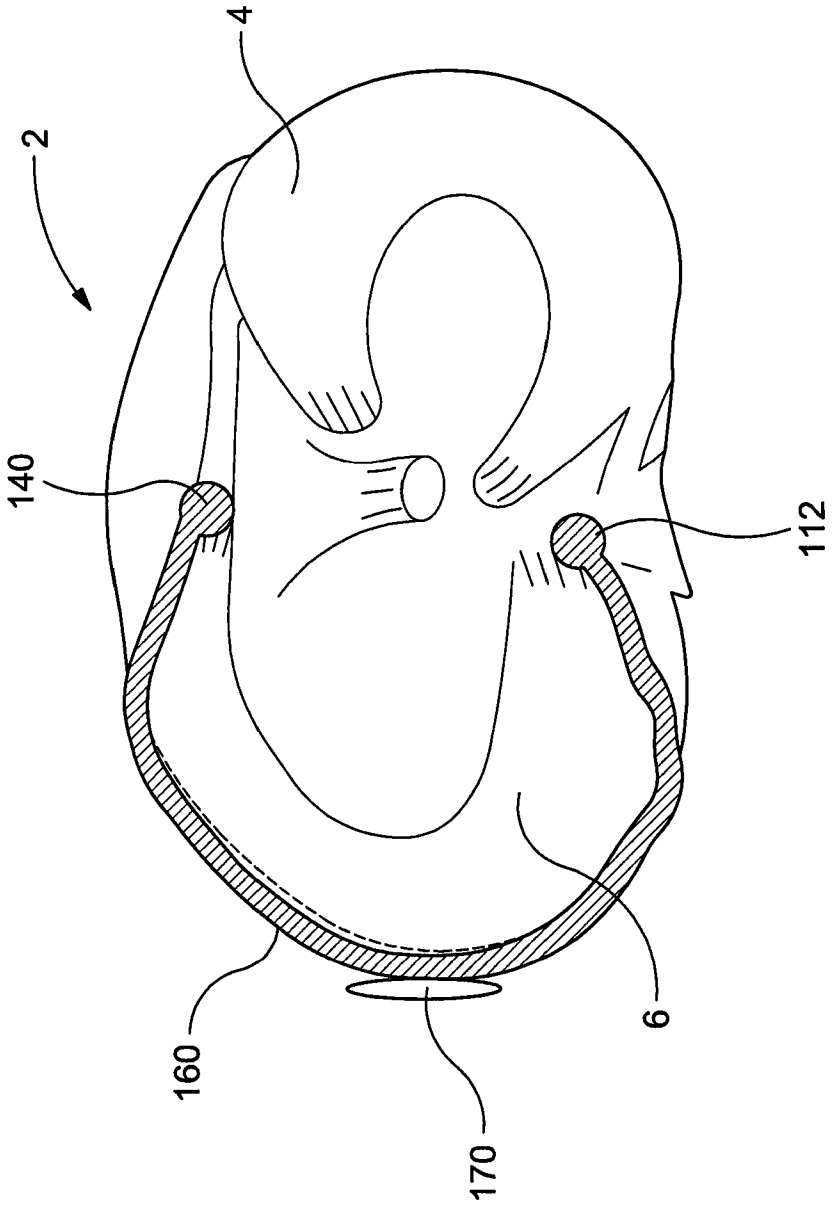

Figure 6e

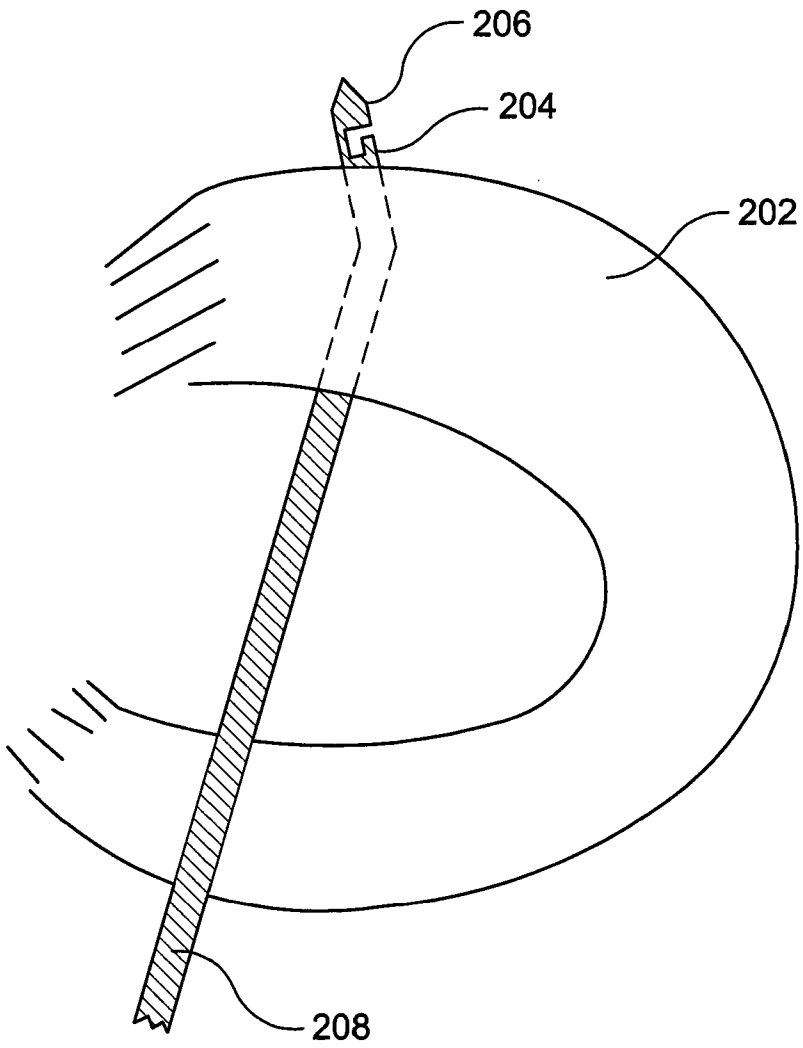

Figure 7a

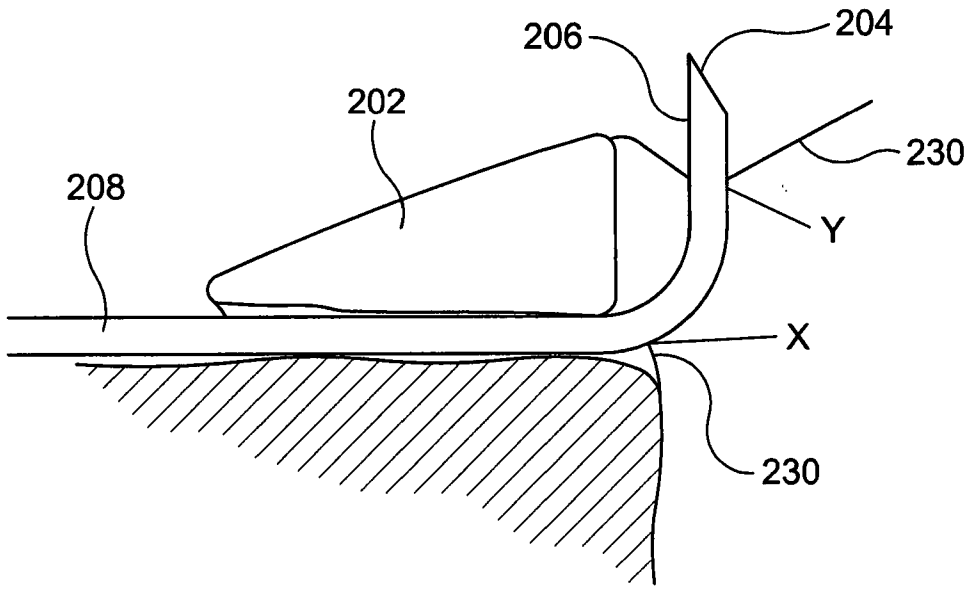

Figure 7b

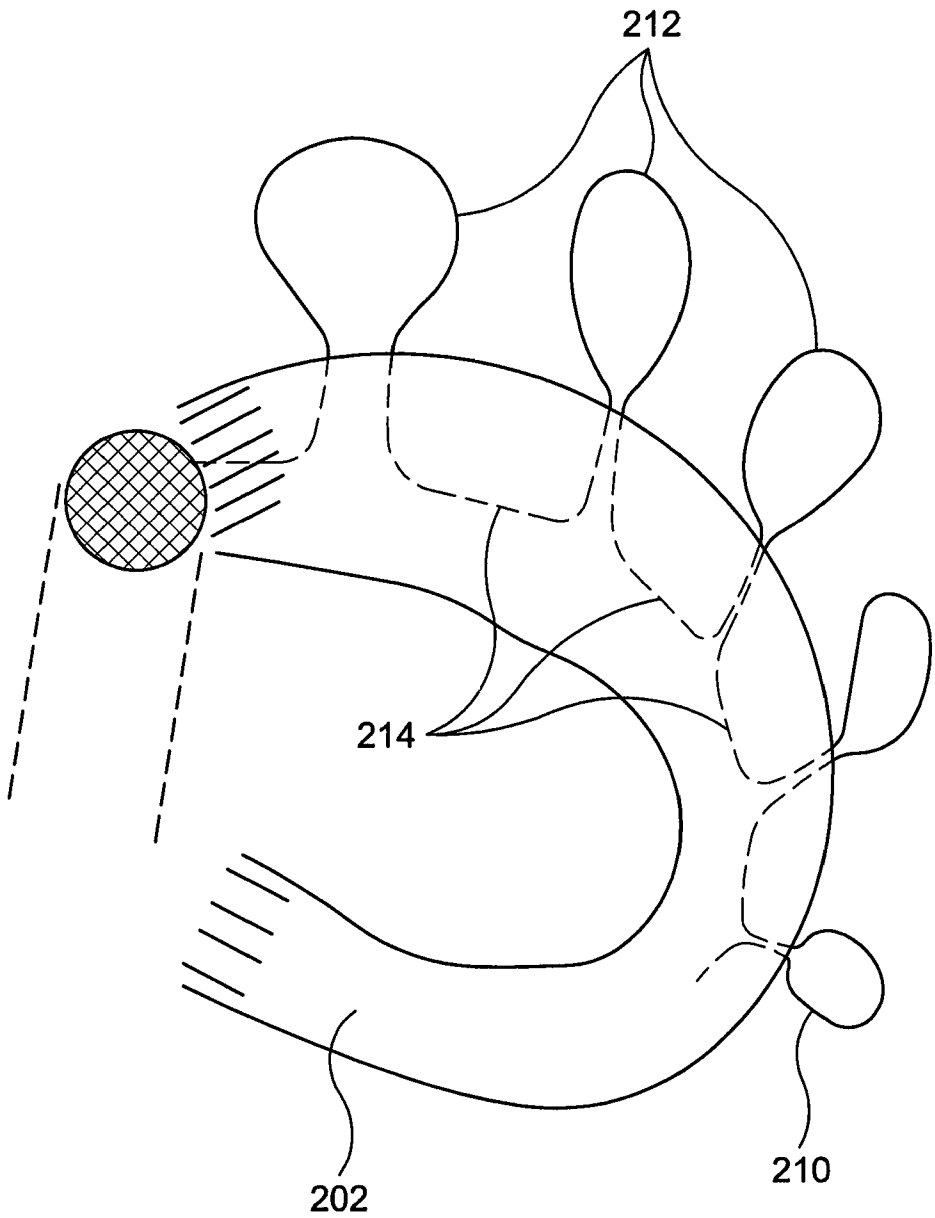

Figure 7c

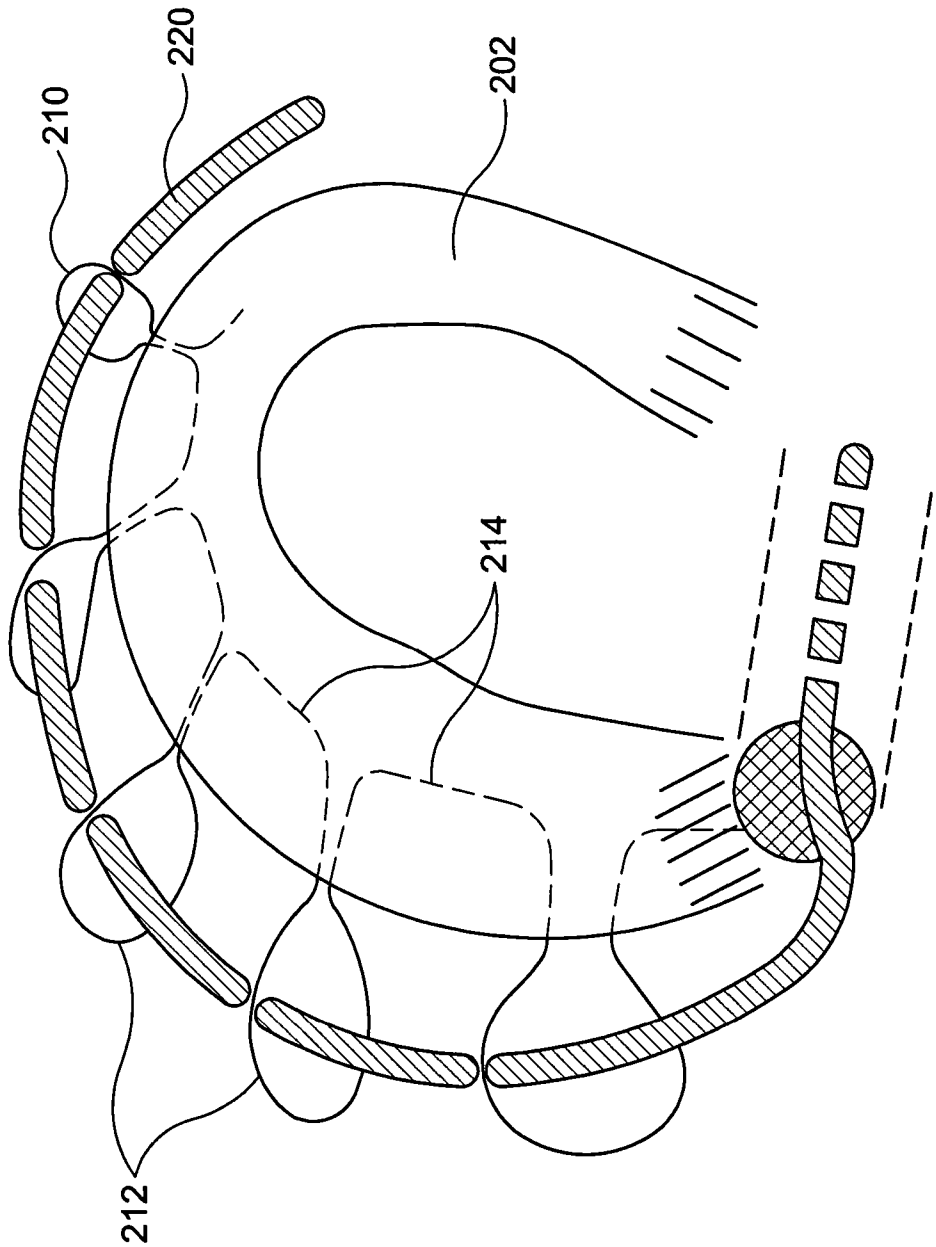

Figure 7d

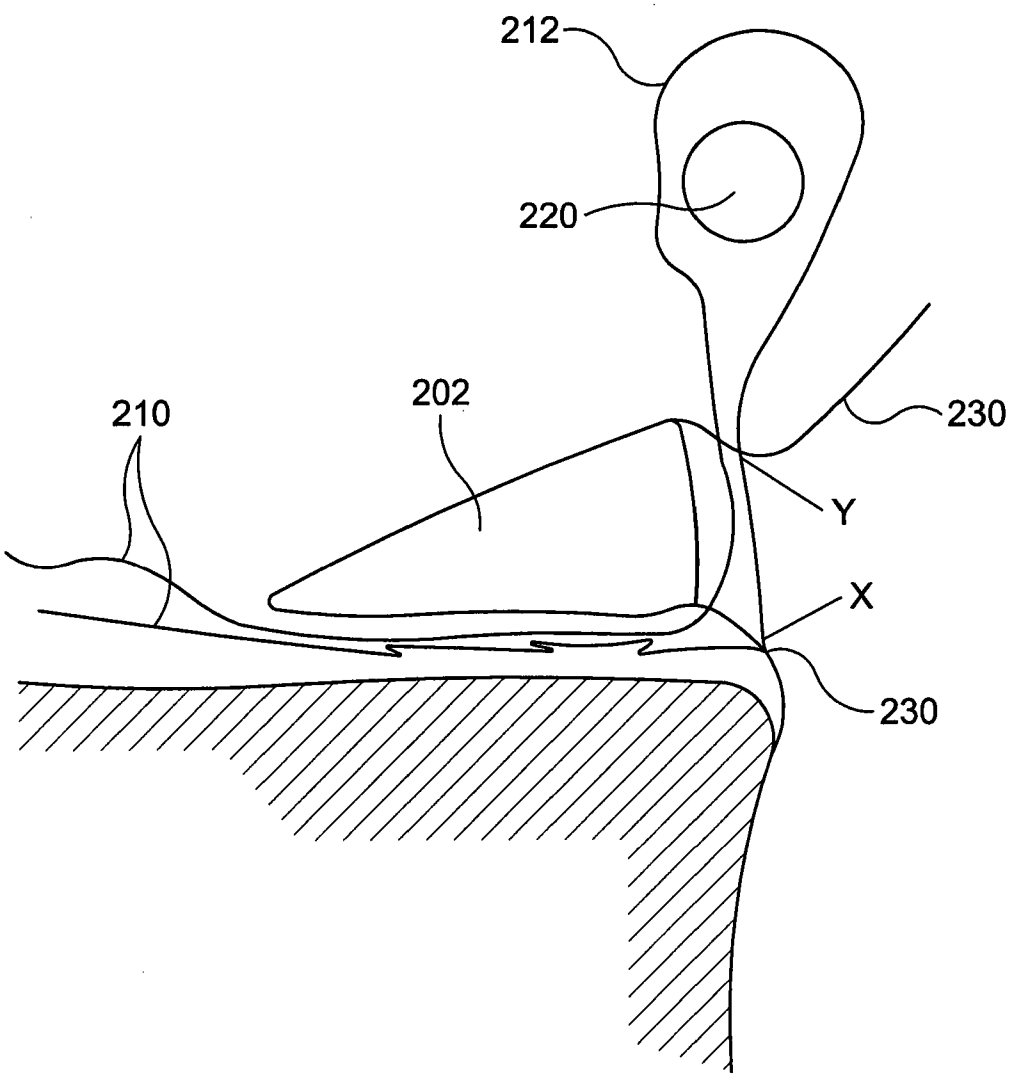

Figure 7e

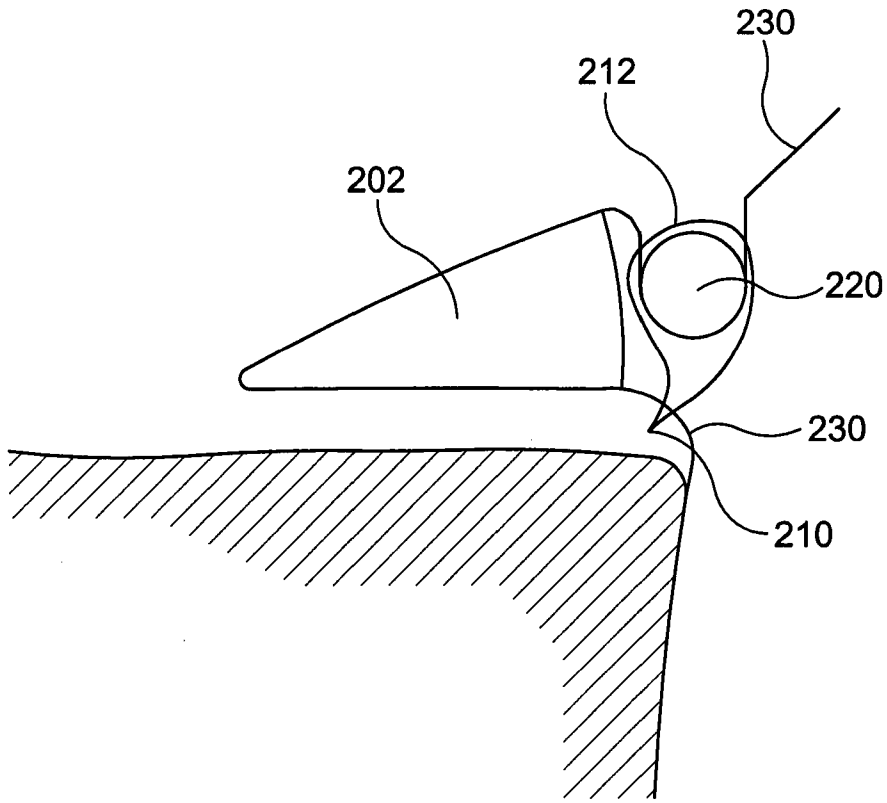

Figure 7f

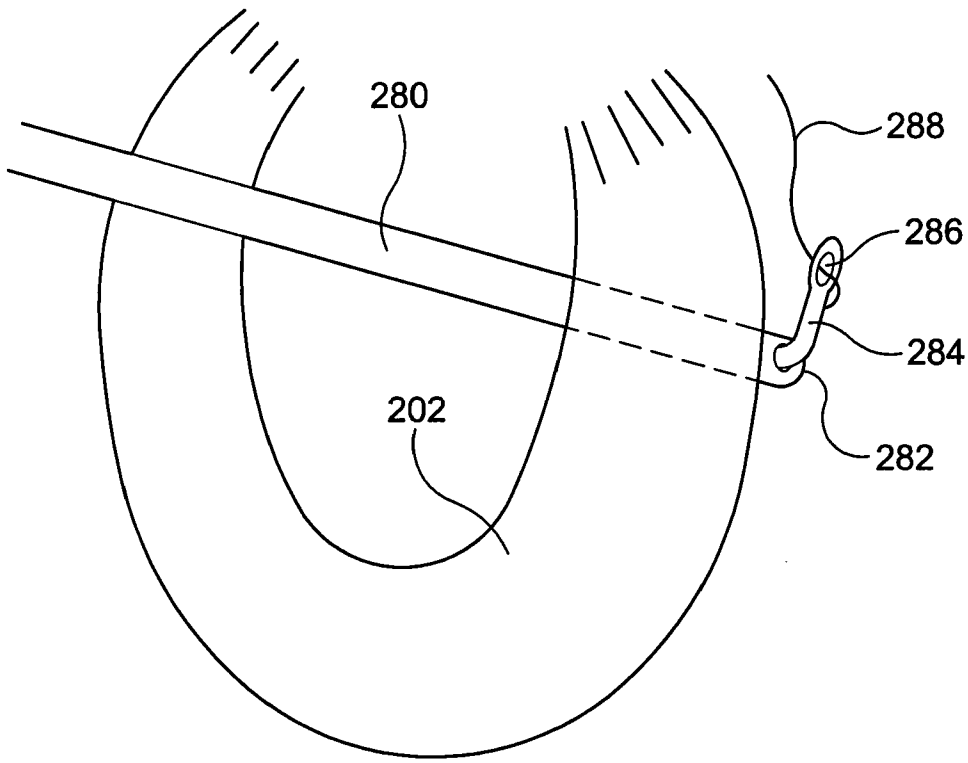

Figure 7g

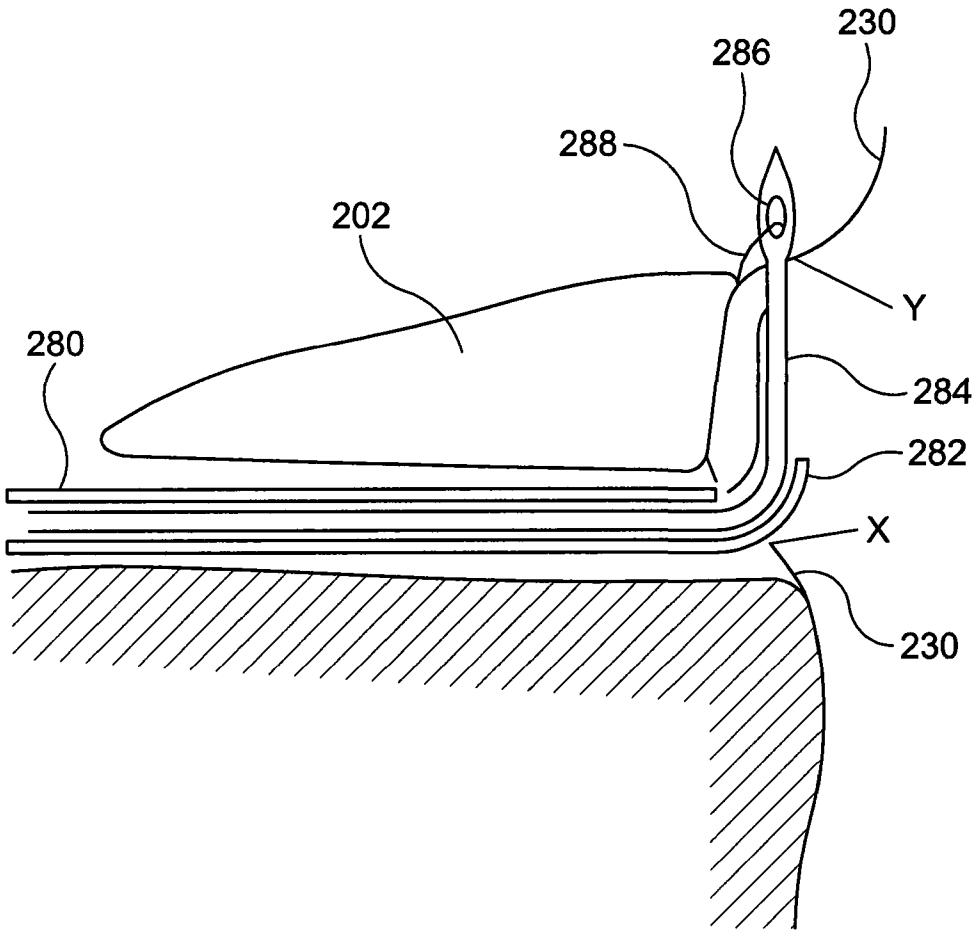

Figure 7h

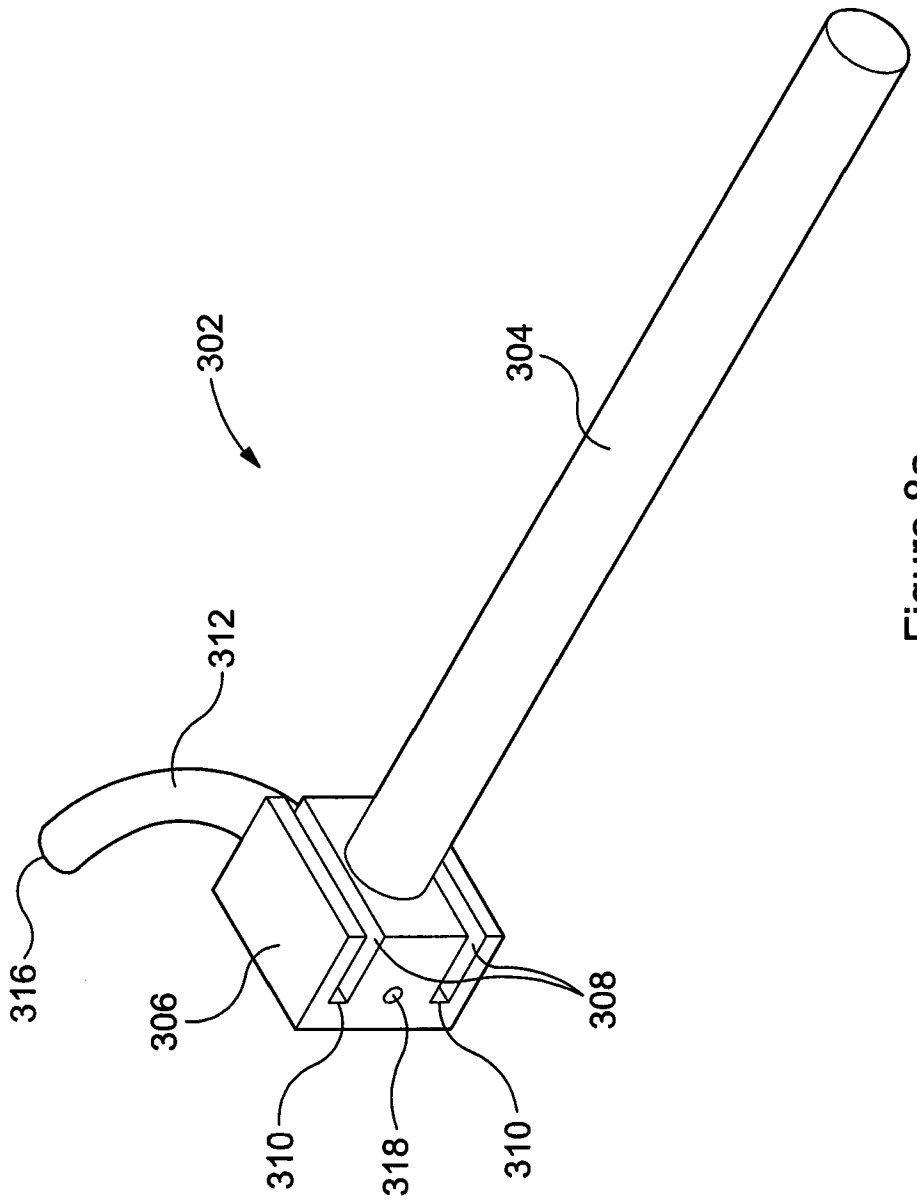

Figure 8a

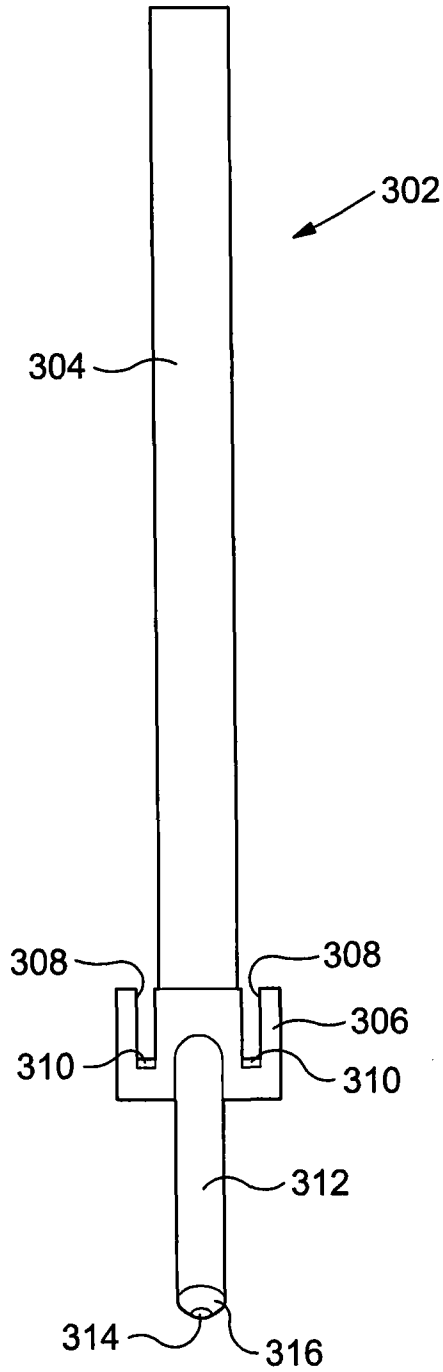

Figure 8b

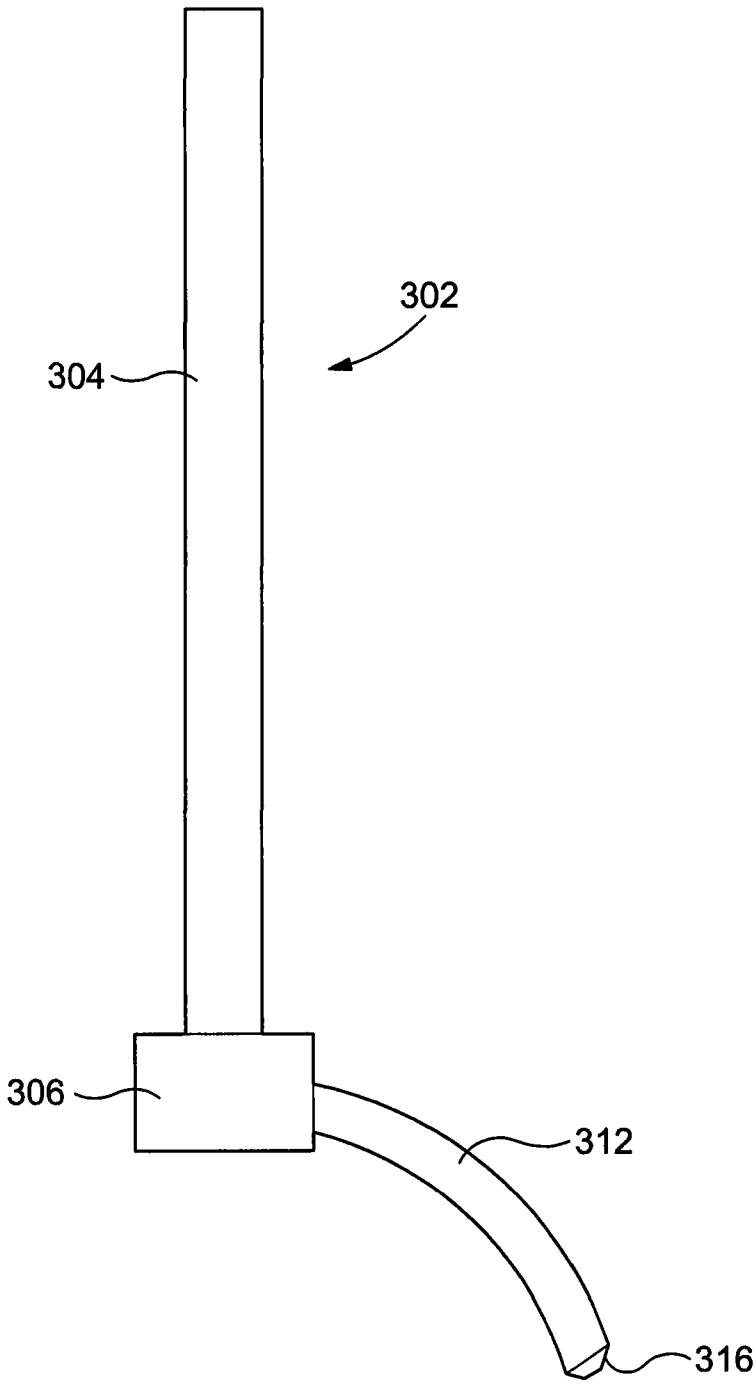

Figure 8c

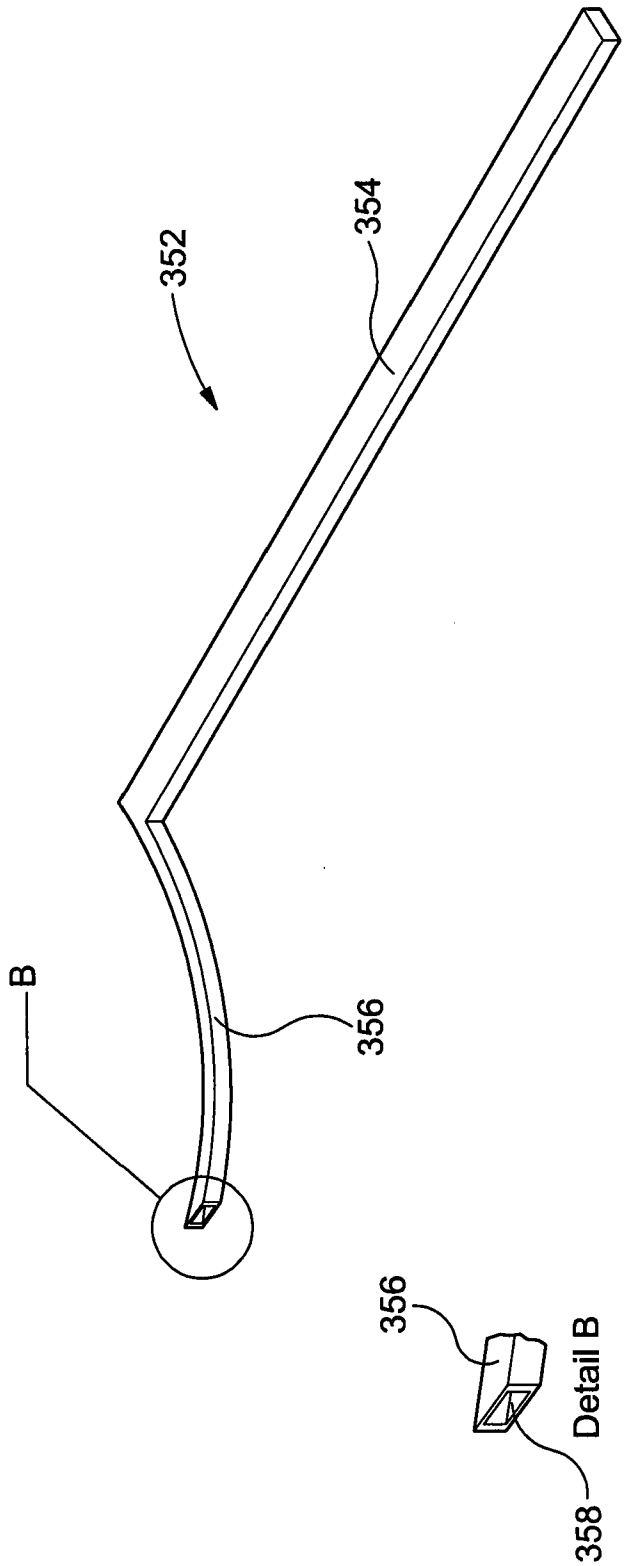

Figure 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2013/000416

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61B17/062
ADD.

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/192545 A1 (WORKMAN WILLIAM BUCHANAN [US]) 30 July 2009 (2009-07-30)	37-42, 45-49, 51-61
Y	paragraph [0025] - paragraph [0029] paragraph [0036] - paragraph [0038] figures 1,2,5,9,10	44
X	US 2 833 284 A (SPRINGER HENRY A) 6 May 1958 (1958-05-06)	37,38, 41,43, 45,48, 49, 51-56, 59-61
	column 2, line 5 - line 36 figures 1,3	

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" 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
7 January 2014	16/01/2014

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2013/000416

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/118757 A1 (PIERCE JAVIN C [US]) 19 May 2011 (2011-05-19) paragraph [0062] paragraph [0067] - paragraph [0069] paragraph [0071] figures 1-5	37,38, 41, 45-49, 51-56, 59-62
Y	US 5 368 595 A (LEWIS ROYCE [US]) 29 November 1994 (1994-11-29) abstract column 4, line 57 - line 66 figures	44

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2013/000416

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009192545 A1	30-07-2009	NONE	
US 2833284 A	06-05-1958	NONE	
US 2011118757 A1	19-05-2011	EP 2004069 A2	24-12-2008
		US 2011118757 A1	19-05-2011
		WO 2007111986 A2	04-10-2007
		WO 2007123610 A2	01-11-2007
US 5368595 A	29-11-1994	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2013/000416

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

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

1. [X] Claims Nos.: 1-36
because they relate to subject matter not required to be searched by this Authority, namely:

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

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

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

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.