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[Continued on next page]

(54) Title: SUTURE BASED TISSUE REPAIR

(57) Abstract: The present invention provides an apparatus for suture-based tissue repair, preferably for the annulus of a spinal disc, that includes a suture loop preferably pre-tied with a sliding knot, a clasp-type component that captures the ends of the suture loop, and an optional plug member that fills the tissue defect. Also disclosed is a method that places the suture loop in a full-thickness stitch encircling the tissue defect, secures the ends of the suture loop to the clasp, and cinches the suture loop to approximate the tissue without the need to tie knots. Also disclosed is a suture passer that enables a suture strand or loop to be passed through the tissue wall, captured, and retrieved. The suture passer may optionally incorporate a clasp in such an arrangement that enables a suture loop passed through the tissue wall to be captured directly by the clasp.

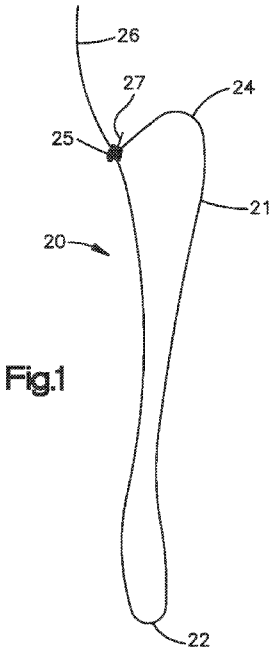

Fig.1

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TITLE OF INVENTION

SUTURE BASED TISSUE REPAIR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/059,584 filed June 6, 2008, entitled "SUTURE BASED ANNULUS REPAIR", the contents of which is incorporated in its entirety by reference herein.

BACKGROUND OF THE INVENTION

[0002] Sciatica, or radicular leg pain, is suffered by millions of Americans. One common cause of sciatica is ruptured or herniated discs of the spine for example, in the lumbar area. That is, when the outer wall of an intervertebral disc (*i.e.,* the annulus fibrosis) becomes weakened, it may tear allowing the soft inner part of the disc (*i.e.,* the nucleus pulposus) to push its way out. Once the nucleus pulposus extends out past the regular margin of the annulus fibrosis, the nucleus pulposus can press against very sensitive nerve tissue in the spine resulting in radicular pain. One treatment for relieving radiculopathy is a discectomy. A discectomy is a surgical procedure performed to remove at least a part of the damaged disc to relieve the pressure on the nerve tissue and alleviate the pain. The surgery generally involves a small incision in the skin over the spine, removal of some ligament and bone material to access the disc and the removal of some of the disc material, e.g., removing herniated nucleus pulposus to achieve neural decompression. Currently, standard discectomy techniques do not repair the defect or incision in the annulus fibrosis. As a result, the remaining nucleus pulposus may extend or push its way out of the opening or damaged annulus fibrosis post-operatively.

Alternatively the surgeon may elect to perform extensive debulking, in which most of the remaining nucleus material is removed in addition to the herniated portion to minimize the risk of post-operative reherniation, but this increases the risk of post-operative disc height collapse and subsequent progression to increased lower back pain.

[0003] Thus there remains a need to provide a tissue repair system and method and more specifically an annulus fibrosis repair system and method to solve the challenges present in current discectomy procedures and the post-operative complications associated therewith.

BRIEF SUMMARY OF THE INVENTION

[0004] The present invention provides an apparatus for suture-based tissue repair, including repairing a defect or opening in the annulus fibrosis of a spinal disc, that comprises a suture loop preferably pre-tied with a sliding knot, and a clasp-type component that captures the ends of the suture loop. An optional plug member that fills the opening in the annulus fibrosis may also be included. Also disclosed is a method that places the suture loop in a full-thickness stitch encircling the annulus defect, secures the ends of the suture loop to the clasp, and cinches the suture loop to approximate the annular tissue without the need to tie knots. Also disclosed is a suture passer that enables a suture strand or loop to be passed through the annulus wall, captured, and retrieved. The suture passer may optionally incorporate a clasp in such an arrangement that enables a suture loop passed through the annulus wall to be captured directly by the clasp.

[0005] In one embodiment a system for spinal disc annulus repair is provided which comprises a strand of suture and a clasp device. The suture preferably has at least one loop and at least one sliding knot, and the clasp device preferably has at least one

eyelet. The eyelet may comprise a closed ring, a C-shape, a U-shape, an S-shape, an O-shape, a coil shape, or other shape having an opening to permit a suture to pass into the eyelet. The system may further comprise a suture passer and retriever instrument that may include a needle having a receptacle for receiving the suture.

[0006] In another embodiment a further system for repairing a defect in the annulus of a spinal disc is provided that may comprise a strand of suture and a clasp device having an eyelet for securing the suture. The suture may have at least one loop having two ends and a sliding knot, and the eyelet of the clasp device may be configured for securing the ends of the suture loop, wherein the suture and clasp device are configured and arranged in combination to surround the annulus defect and approximate the defect with the two ends of the loop extending in opposite directions from the clasp device. The suture and clasp device preferably are in series in forming a loop surrounding the defect of the annulus fibrosis. The system may further comprise a suture passer and retriever instrument. The suture passer may include a needle releasably attached to the suture and preferably for passing the suture through the disc annulus. The retriever instrument is preferably configured to cooperate and preferably work in association with the needle.

[0007] The suture passer and retriever instrument may further comprise a boom arm for capturing the suture. The suture passer and retriever instrument may be releasably coupleable to the clasp device. The system may further comprise a plug member for filling and sealing the annulus defect. The system may further comprise a plurality of barbs, one barb connected to each of the ends of the suture loop, and wherein the clasp device has a plurality of eyelets, each eyelet connectable to the barbs, wherein

the eyelet is expandable and at least a portion of the barb is configured to pass through the eyelet. Alternatively or additionally, the suture passer and retriever instrument may comprise a wire loop for capturing the suture.

[0008] The clasp device may include a two piece clip, the first piece connectable to a first end of the suture loop, a second piece of the clip connectable to a second end of the suture loop, and the first piece coupleable to the second piece. The clasp device may have two hooks having open slots to receive the suture, the hooks being resiliently flexible to collapse to a smaller size and expand to a larger size. The suture passer and retriever instrument may further comprise two needles, each needle connectable to an end of the suture loop and being independently moveable, the clasp device releasably connectable to the suture passer and retriever instrument, the clasp device having an opening for receiving the suture.

[0009] In another embodiment, a method of repairing a defect in an annulus of a spinal disc is provided, the method comprising the steps of: (1) providing a suture having at least one loop and a sliding knot; (2) providing a clasp device for capturing the ends of the suture loop; (3) providing a passing device for attaching to the suture loops, the passing device for passing the suture through a wall of the annulus; (4) attaching a first end of the suture loop to the passing device; (5) inserting the passing device with the suture loop end through the disc annulus wall; (6) inserting the second end of the suture loop through the disc annulus wall; (7) connecting the first end and second end of the suture loop to the clasp device while the suture loop ends and clasp device are outside the spinal disc; (8) inserting the clasp device through the annulus defect so that the suture loop and clasp device form a continuous loop around the annulus defect; and (9)

tightening the suture to tension the suture loop to close the defect, wherein the clasp device and suture loop are in series with each other and both the suture and clasp device approximate and draw the defect closed.

[0010] The method may further include the passing device comprising a needle and the further step of releasably attaching the needle to the suture loop. The method may further include the steps of coupling the passing device to the clasp device, and releasing the clasp device from the passing device. The method may further comprise the steps of: (1) inserting the first end of the suture loop through the annulus wall from the outside to the inside of the disc; (2) retrieving the first end of the suture loop through the defect in the annulus so that the first end of the suture loop is outside the disc space; (3) inserting the second end of the suture loop from the outside to the inside of the disc; and (4) retrieving the second end of the suture loop through the defect in the annulus so that the second end of the suture loop is outside the disc space. The method may further comprise using a multi-piece connectable clip, and connecting a first piece of the multi-piece clip to a second piece of the multi-piece clip. The method may further comprise: connecting a first end of the suture loop to the first piece of the multi-piece clip; and connecting a second end of the suture loop to the second piece of the multi-piece clip.

[0011] It should be understood, however, that the system, kit and method of use is not limited to the precise arrangements, structures, features, embodiments, aspects and instrumentalities shown, and that the arrangements, structures, and features disclosed herein can be used singularly or in combination with other arrangements, structures, features, aspects and instrumentalities.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0012] The foregoing summary, as well as the following detailed description of the preferred embodiments of the application, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the system, device and method of the present application, there is shown in the drawings preferred tissue repair systems, embodiments and techniques. It should be understood, however, that the application is not limited to the precise arrangements, structures, features, embodiments, aspects and instrumentalities shown, and that the arrangements, structures, features, disclosed herein can be used singularly or in combination with other arrangements, structures, features, aspects and instrumentalities. In the drawings:

[0013] Fig. 1 illustrates an embodiment of a preformed suture loop that may be used in the present invention;

[0014] Fig. 2 illustrates a perspective view of an open ring suture clasp in accordance with the present invention.

[0015] Fig. 3 illustrates a perspective view of a closed ring suture clasp in accordance with the present invention.

[0016] Fig. 4 illustrates a double eyelet suture clasp in accordance with the present invention, and an embodiment of an insertion instrument.

[0017] Fig. 5A-E illustrates a tissue repair system and method in accordance with the present invention.

[0018] Fig. 6 illustrates an alternate tissue repair system and method in accordance with the present invention.

[0019] Fig. 7 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 6.

[0020] Fig. 8 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 6.

[0021] Fig. 9 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 6.

[0022] Fig. 10 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 6.

[0023] Fig. 11 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 6.

[0024] Fig. 12 illustrates another alternate tissue repair system and method in accordance with the present invention.

[0025] Fig. 13 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 12.

[0026] Fig. 14 illustrates an additional method step used with the alternate tissue repair system and method shown in Figure 12.

[0027] Fig. 15 illustrates an additional, and preferably last, method step used with the alternate tissue repair system and method shown in Figure 12.

[0028] Fig. 16 illustrates yet another alternate tissue repair system and method in accordance with the present invention.

[0029] Fig. 17A-B illustrates a tissue repair system and method that includes a pair of barbs, in accordance with the present invention.

[0030] Fig. 18 illustrates an alternate embodiment of a suture passing instrument in accordance with the present invention.

[0031] Fig. 19 A-F illustrates an alternative tissue repair system and method in accordance with the present invention;

[0032] Fig. 20 illustrates an alternative tissue repair system in accordance with the present invention;

[0033] Fig. 21 illustrates an alternative tissue repair system in accordance with the present invention;

[0034] Figs. 22A-K illustrates an alternative method for tissue repair using the systems of Figures 20 and 21.

[0035] Fig. 23 illustrates a tissue repair system and method that includes a clasp with multiple suture loops, in accordance with the present invention.

[0036] Fig. 24A-B illustrates a tissue repair system and method that includes a plug, in accordance with the present invention.

[0037] Fig. 25A-D illustrates a tissue repair system and method that includes a knotless suture in accordance with the present invention.

[0038] Fig 26 illustrates an alternative tissue repair system and method including a mulit-loop suture in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0039] Certain terminology is used in the following description for convenience only and is not limiting. The words "right", "left", "lower", "upper", "top", and "bottom", designate directions in the drawings to which reference is made. The words "inwardly" or “distally” and "outwardly" or “proximally” refer to directions toward and away from,

respectively, the geometric center of the intervertebral space. The words, "anterior", "posterior", "superior", "inferior", "lateral" and "medial" and related words and/or phrases designate preferred positions and orientations in the human body to which reference is made and are not meant to be limiting. The terminology includes the above-listed words, derivatives thereof and words of similar import.

[0040] While the tissue repair system and method will be shown and described with reference to repairing a defect in the annulus fibrosis of a spinal disc it should be understood that the tissue repair system and method will have applicability to other bodily tissue and applications. For example, the tissue repair system and method may be used for meniscal repair, rotator cuff repair, gastroplication procedures, inguinal hernia repair, dural repair, *etc*. Moreover, the tissue repair system and method may be used for fixation of an implant to soft tissue, such as, for example, suture fixation of adhesion barriers, hernia meshes, rotator cuff patches, *etc*. In addition, while reference is often made to a defect in the annulus fibrosis of a spinal disc, or annulus defect, the tissue repair system and method is not limited in its application to annulus defects but applies to any incision, opening, wound, herniation, damage or defect in the annulus fibrosis of a spinal disc or bodily tissue. The term "annulus defect" or "tissue defect" and words of similar import should be given a broad, as opposed to a limited, interpretation to cover all such applications unless indicated otherwise.

[0041] A tissue repair system and method is provided, preferably an annulus repair system and method, that preferably includes a suture and a suture clasp. The suture 20, as shown in Figure 1 is preferably a loop 21 of suture material pre-tied with a knot 25 which, in various embodiments can include any type of sliding knot, ratcheting

knot, or locking knot now or hereafter known in the art. In a preferred embodiment, the knot is a ratcheting and/or locking knot that prevents post-operative loosening of the repair construct. The suture preferably includes a first loop end 22, a second loop end 24, and a free length of suture strand 26 adjacent to and extending from the knot 25. In this embodiment, one of the free suture strands 27 is preferably cut adjacent to the knot during manufacture. Alternatively, both free strands extending from the knot can remain, thus allowing the user to tension both strands upon final tissue approximation to promote additional locking of the knot. While the suture 20 may be supplied to the hospital, operating center or operating room with a pre-formed or pre-tied knot and loop, the suture 20 may also be configured in the operating room before or during the surgery to include a loop 21, first loop end 22, second loop end 24, knot 25 and free strand 26.

[0042] The clasp 60, in one embodiment as best shown in Figure 2, is preferably a simple ring 61 of biocompatible material with a slot 62 configured to allow one or more loops of suture material to be secured to the clasp. In one embodiment, the clasp preferably includes a slot 62 that provides the open ring clasp in a C-shape, while in alternate embodiments, the clasp may include a carabiner-type mechanism or spring-loaded retractable sliding member 63 that enables the clasp to open and secure one or more suture loops and then close to form a closed ring configuration. The suture clasp may assume the form of the open ring suture clasp 61 as shown in Figure 2, or may assume the form of a closed ring suture clasp 65, as best shown in Figure 3, or may assume the form of a double eyelet suture clasp 51, as best shown in Figure 4 and described in detail below. The suture clasp may also be U-shaped, S-shaped, C-shaped,

O-shaped, coil shaped, or any other shape that has an opening to permit the loop end of a suture to pass into and be secured to the clasp.

[0043] Referring to Figure 3, clasp 65 has a closed eyelet loop 66 and two lateral integrated cleats 67, 69. In use, the suture 20, and more specifically loop end 22, is passed through the opening 68 in the eyelet loop 66, looped over the cleat 69, and cinched tight to attach the suture loop end 22 to the clasp 65. The other suture loop end 24 is passed through the opening 68 in the eyelet loop 66, looped over the cleat 67, and cinched tight to attach suture end 24 to the clasp 65. Suture loop 24 may additionally or alternatively be passed over cleat 69 holding suture loop 22. Suture clasp 65 may be used with multiple sutures 20, or each suture strand 20 may use a single suture clasp 65.

[0044] Referring to Figure 4, another embodiment of a suture clasp device 51 is provided. The clasp 51 features two oppositely arranged eyelets 52, 54, wherein each eyelet includes a slot 53 through which each end 22, 24 of a suture loop 21 can be routed, preferably such that the final suture loop-clasp construct is a continuous band. The slots 53 can be permanently or temporarily opened to permit the suture loop end to pass within the eyelet. Temporary opening of the slot 53 can be accomplished with a variety of mechanisms, such as a spring-loaded sliding actuate member (similar to a jewelry clamp), a spring-loaded hinged flap (similar to a carabiner), or a hingless elastic eyelet that allows the slot 53 to open under load and close thereafter. These same mechanisms can be utilized in clasps 61 or 65. In use the suture loop end 22 may be inserted through slot 53 in eyelet 52 while the suture loop end 24 may be inserted through slot 53 in eyelet 54 to attach the two ends of the suture loop to the clasp 51. Suture clasp 51 may be used with multiple sutures 20, or each suture strand 20 may use a single suture clasp 51.

[0045] A system and method for repair of a disc annulus using a suture 20 and clasp 60 is illustrated in Figures 5A-E. Clasp 60 may be any one of clasps 51, 61 and 65 shown and described in Figures 2, 3 and 4, or alternative clasps may also be used. In use, a suture, such as, for example, the suture 20 illustrated in Figure 1, is preferably provided that is pre-tied to include a ratcheting, locking, or other sliding knot 25 such that the suture includes a first loop end 22, a second loop end 24, and a free length of suture strand 26 adjacent the knot 25. As shown in Fig. 5A the first loop end 22 of the suture is passed through the annulus wall 5 into the interior 3 of the disc 1 on a first side of an annulus defect 2 while the other end 24 of the suture, including the suture knot 25 and the free strand 26 of suture, remain external 6 to the annulus wall 5. The first loop end 22 of the suture 20 is then retrieved through the annulus defect 2 and held exterior 6 to the annulus wall as shown in Figure 5B.

[0046] The second loop end 24 of the suture 20 as shown in Figure 5C is then passed through the annulus wall 5 into the interior 3 of the disc 1 on a second side of the annulus defect 2 while the first loop end 22 of the suture, the suture knot 25, and the free strand 26 of suture 20 remain external 6 to the annulus 5. As shown in Figure 5D, the second loop end 24 of the suture is then retrieved through the annulus defect 2 and held exterior 6 to the annulus 5 and adjacent the first loop end 22. The clasp 60 is then used to join the first and second loop ends 22, 24. The free strand 26 of suture is then pulled, whereby the clasp 60 and the two loop ends 22 are drawn into the interior 3 of the disc and the annulus defect or opening 2 is approximated and closed as shown in Figure 5E. Alternatively, the clasp 60 may be advanced into the interior of the disc first, then the free strand 26 of suture 20 is pulled to approximate the annulus defect. The free strand 26 of

suture may then be trimmed. The suture can be passed through the body tissue with a needle or other known suture insertion device, or the devices described herein. In the method of Figures 5A-E, the suture loop is passed from the outside or exterior of the disc annulus to the interior of the disc space and thereafter retrieved through the defect so that the suture can be connected to the clasp while both the clasp and suture are exterior to the disc space, and preferably exterior to the patient.

[0047] Referring to Figure 4, an inserter 50 is provided that enables a surgeon to advance the clasp 51 manually through an annulus defect. The inserter 50 is connected to the clasp, for example, via a threaded interface. The inserter optionally may be cannulated to accept the suture strand(s) and allow cinching of the construct for tissue approximation. In the technique used with inserter 50, the ends 22, 24 of the suture loop 21 are passed through the thickness of the annulus wall 5 from outside to inside and the loops 22, 24 are retrieved through the opening 2 in the annulus as described in the method of Figure 5. With the loop ends 22, 24 exterior to the disc space, the loop ends are hooked to the clasp 51 by inserting the loop ends 22, 24 through the slots 53 in the eyelets 52, 54. The free end 26 of the suture strand is passed up the cannulated shaft of the inserter 50. The clasp inserter 50 with connected suture loops ends 22, 24 is advanced through the defect 2 in the annulus wall 5 and the free end 26 of the suture is pulled to cinch up the loop 21 and draw the ends of the opening in the annulus together. The inserter 50 is detached from the clasp (e.g., unthreaded) and the free strand 26 of the suture 20 is cut as desired. Alternatively, the free strand 26 and knot 25 may be positioned external to the disc as shown in Fig. 11, 15, 18, and 17. The inserter 50 can be

optionally used in conjunction with the methods shown in Figures 5-11, or other methods described herein.

[0048] In the tissue repair system and method of Figures 5A-E, the clasp is in series with the suture loops and forms a continuous strand of suture. Without the clasp in Figures 5A-E the suture would not approximate and close the tissue defect. The system and technique of Figures 5A-E have particular application to a surgical site deep within the body. The suture is reapproximated to the clasp and the clasp and suture in combination cinches and reapproximates the defect (i.e. draws the tissue defect closed). One advantage of the tissue repair system and method is the use of pre-tied sutures which form a loop as shown in Figure 1. Pre-tied sutures facilitate the speed and increases the reliability of the wound closure since a surgeon will not need to form knots with suture strand in a surgical environment and deep within a patient. In a surgical environment where (1) the surgeon is working with surgical gloves, (2) the wound is deep within a patient, (3) the openings to the surgical site are minimized to facilitate speedy recovery and (4) the surgical site has blood and other bodily tissue and fluids making visibility and manual dexterity difficult, tying and manipulating suture strands can be difficult, and the use of pre-tied sutures may be advantageous.

[0049] A tissue repair system and method is provided in Figures 6-11 that may have particular application to repairing a spinal disc annulus, or other body tissue, and that preferably includes a suture 20, a suture passer/retriever instrument 70, and a suture clasp 60. The suture may be as illustrated in Figure 1, and the clasp 60 may be any one of clasps 51, 61 and 65 shown in Figures 2-4, or other clasps that connect the ends of the suture loop. The suture passer/retriever instrument 70 may be configured to allow a

suture loop 21 to pass through an annulus wall 5 on either side of a defect 2 from the external side 6 of the annulus wall to the interior side 3 of the annulus wall 5. The suture passer/retriever instrument 70 may also be configured to retrieve the passed suture loop end 22 from within the interior of the disc to enable a surgeon to secure the suture loop 21 to a clasp 60 located external to the disc space 3. In alternate embodiments discussed in more detail below, the clasp can be loaded into or onto the suture passer/retriever instrument such that the suture loop 21 can be passed through the annulus wall to the interior of the disc space and captured directly by the clasp while within the interior of the disc space.

[0050] The suture passer/retriever instrument 70 includes a frame or housing 75 which further includes a proximal portion 72 (not shown), a distal portion 74 and a longitudinal axis 71 extending therebetween. The proximal portion of the suture passer/ retriever instrument 70 includes a cannulated portion 76 configured to house and direct the movement of a needle 80. The needle 80 has an open slot (see figure 20) through which is passed a strand of the suture 20. The distal portion 74 of the suture passer/retriever instrument 70 is configured for placement through the disc annulus defect and into the interior 3 of the disc space. The distal portion 74 may be characterized by a thin portion 78 that is sized and configured for introduction through an annulus defect and a laterally extending boom arm 77. The boom arm 77 may also include a distally extending obliquely oriented tip 79, as is best shown in Figure 6, that is sized and configured to retrieve the suture once inside the disc space. The boom arm 77 may include a latch or hook that would catch and retain the suture loop as the needle is

withdrawn from the disc annulus. The suture passer/retriever instrument 70 is unidirectional in that the suture only passes in one direction through the disc annulus.

[0051] In use, and with reference to Figures 6-11, the first end 22 of the suture loop 21 is preferably secured to the needle 80 seated within the frame 75 of the suture passer/retriever device 70 and the distal end 74 of the suture passer/retriever device 70 is inserted into the interior 3 of the disc space through a defect 2 within the wall 5 of the annulus, as best shown in Figure 6. The needle 80 carrying the first end 22 of the suture loop 21 then moves through the annulus wall 5 on one side of the defect while the second end 24 of the suture loop 21, knot 25, and free strand 26 of the suture are retained outside of the disc space, as best shown in Figure 7. The needle 80 is then retracted back into the housing 75 of the suture passer/retriever device 70 while, the first end 22 of the suture loop 21 is captured by the boom arm 77. The suture passer/retriever device 70 (with the suture loop 21 captured by the boom arm) then is withdrawn from the disc space 3 through the annular defect 2, as best shown in Figure 8. The first end 22 of the suture loop 21 is then removed from the suture passer/retriever instrument 70 and is held outside of the disc space.

[0052] The second end 24 of the suture loop 21 is secured to the needle 80 and the distal end 74 of the suture passer/retriever device 70 is reinserted into the interior 3 of the disc space through the annulus defect. The suture passer/retriever instrument 70 is manipulated so that the boom arm 77 is located beneath the other side of the annulus defect where the user desires to pass the suture. The needle 80 carrying the second end 24 of the suture loop 21 then translates distally and is guided through the annulus wall 5 on the other side of the annulus defect 2 while the first end of the suture loop 22, knot 25,

and free strand 76 of suture are retained outside of the disc space, as best shown in Figure 9. As best shown in Figure 10, the needle 80 is withdrawn proximally back towards the housing 75 of the suture passer/retriever device 70 and, the second end 24 of the suture loop is captured by the boom arm 77. The suture passer/retriever device 70 with the captured suture loop end 24 then is withdrawn from the disc space through the annulus opening. A suture clasp 60, such as either of the suture clasps 51, 61, 65 shown and described in reference to Figures 2-4, or other clasp type is used to join the first and second ends 22, 24 of the suture loop 21. The free strand 26 of the suture is then pulled, which can in one example be facilitated by using a knot pusher known in the art for use with sliding suture knots, whereby the suture clasp 60 and the two loop ends 22, 24 are drawn into the interior 3 of the disc 1 and the annulus defect 2 is approximated, as is best shown in Figure 11.

[0053] Alternatively, the clasp 60 and loop ends 22, 24 may be advanced into the interior 3 of the disc first, and then the free strand 26 of suture is pulled to approximate the annulus defect. The free strand 26 of suture is then trimmed, while the knot 25 is exterior to the annulus. Alternatively, or additionally, the knot may be fully recessed by advancing it into the annulus, for example, down one of the needle tracts during cinching.

[0054] In the system and method of Figures 6-11, the suture loop is passed from the outside of the disc annulus into the interior of the disc space and thereafter retrieved through the disc annulus defect so that the suture can be connected to the clasp while both the clasp and ends of the suture loop are exterior to the disc space, and preferably exterior to the patient so that the suture can be easily handled and connected to the clasp. In the tissue repair system and method of Figures 6-11, the clasp is in series with the suture loop

and forms a continuous strand of suture. The suture loop is connected to the clasp, and the suture in combination with the clasp cinches and reapproximates the tissue defect. Without the clasp in the method of Figures 6-11, the suture would not reapproximate the tissue defect.

[0055] Referring to Figures 12-15, a tissue repair system and method is provided that preferably includes a suture loop 21 with pre-tied knot 25 as described previously, a suture passer/retriever instrument 70, and suture clasp 60 preloaded onto the suture passer/retriever instrument, thereby saving procedural effort and time. The clasp 60 may be threaded onto, snap fit, or connected to the boom arm 77 by other methods. Preferably the clasp 60 is configured similar to the open ring clasp 61 in Figure 2. The method of operation of Figures 12-15 is similar to that described above in connection with Figures 6-11. During the step shown in Figure 13, however, as the needle translates and is guided downwardly through the annulus wall on one side of the annulus defect, the first end 22 of the suture loop is hooked through the preloaded open ring suture clasp 61 secured to or within the boom arm 77. Similarly, and with reference to Figure 14, as the needle translates and is guided downwardly through the annulus wall on the opposite side of the annulus defect, the second end 24 of the suture loop is hooked through the preloaded open ring suture clasp 61 secured to or within the boom arm 77. During the last step, and with reference to Figure 15, the preloaded open ring suture clasp 60 is manually or automatically ejected from the suture passer/retriever instrument 70, the distal end 74 of the suture passer/retriever instrument 70 is removed from within the disc, the free strand of suture 26 is pulled, the sutures are cinched and drawn tight to close the annulus defect, and the free strand 26 of suture is trimmed. In the embodiment and method described in

Figures 12-15 the clasp and instrument 70 remain within the annulus until both ends of the suture loop are connected to the clasp and then the instrument 70 is removed from the disc. The clasp in the embodiment and method of Figures 12-15 preferably remains inside the disc. A rod (not shown) may be operated by the user to push or eject the clasp from the instrument 70.

[0056] In the embodiment of Figures 12-15 the slots in the open ring clasp may be open when the clasp is attached to the suture passer/retriever instrument 70, and the suture passer/retriever instrument 70 may open the slots as the clasp 60 is attached to the instrument 70. Similarly the slots may close as the clasp is ejected from the suture/passer retriever instrument 70. That is, the clasp 60 may be configured so that the slots are biased or automatically closed unless held open and the suture passer/retriever instrument 70 may have a mechanism that opens and holds open the slots as the clasp is loaded onto the instrument 70. When the clasp is released from the instrument 70 the slots will automatically close.

[0057] While the suture passer/retriever instrument 70 shown and described in Figures 6-11, and 12-15 has been configured to have the needle associated with retaining and moving the suture from the exterior to the interior of the disc other configurations are contemplated. For example, the suture may be retained on the boom arm 77 of the suture passer/retriever instrument and the needle may pass from the exterior to the interior of the disc and as the needle is being withdrawn from the disc it will capture the suture loop and pull it back out through the annulus wall. The same method may apply to the other end of the suture loop and with both suture loop ends outside of the disc a clasp may

thereafter be connected to the suture loop ends and the suture cinched and tightened to close the annulus opening in combination with the clasp.

[0058] Referring to Figures 16 and 17, an annulus repair system and method is provided that includes a suture loop 21 with knot 25, a suture clasp 60 similar or identical to the suture clasp 51 shown and discussed in reference to Figure 4, and a pair of barbs 90. The suture clasp 60, suture 20, and suture barbs 90 are best shown in Figure 17. The suture clasp 60 is preloaded onto the suture passer/retriever instrument 70, and the method is similar to that described above in reference to Figures 12-15.

[0059] The suture barbs 90 preferably have a stem 96 with an eyelet 97 for capturing one end of the suture loop. The barb 90 also preferably has a tip, preferably pointed for piercing and passing through the disc annulus. One of the suture barbs 92 may be connected to the first end 22 of the suture loop 21 and the second suture barb 94 may be connected to the second end 24 of the suture loop 21. The suture and barbs may be supplied preassembled and connected together and in a kit, or the suture connections with the barbs may occur before or during the procedure. With preassembled barbs where the suture loop is connected to the barb the surgeon does not have to tie knots to close the disc annulus opening potentially resulting in a faster procedure and a more reliable closure of the annulus opening. The barb may be mounted to a suture passer instrument 70 similar to the embodiments of Figures 5-11 or 6-12 but adapted to utilize barbs 90 instead of a needle in use.

[0060] The barb 90 is moved through the disc annulus and the tip 98 of the barb 90 moves through eyelet 54 until the stem 96 of the barb is located within the eyelet. More specifically, the proximal end of the tip 98 is larger than the eyelets 52, 54 so that

as tip 98 moves through the eyelet 52, 54 the eyelet as a result of slots 53 expands to a larger size to enable the tip 98 to pass through eyelet 52, 54 whereupon the stem 96 is received in the eyelet 52, 54 and the eyelet returns to its original unflexed state. The barb 90 is thereby captured by the clasp 60. The second barb 90 is inserted through the annulus of the disc at a second location and the tip 94 is passed through the eyelet 54 until the stem 96 is located within the eyelet 54. The clasp 60 is thereafter ejected from the suture passer/retriever instrument as shown in Figure 17A. The suture loop is then tightened by pulling free strand 26 which cinches the sutures, proximating and closing the annulus defect as shown in Figure 17B.

[0061] Depending upon the design of the barbs 90 it may or may not be desirable for the stems 96 of the barbs 90 to extend up and into the wall of the annulus. If it is undesirable for the stems of the barbs to be located within the punctures formed by the barbs upon proximating and closing the opening in the annulus, which may be desirable and necessary to achieve proper reapproximation of the defect, then care should be taken, for example, by insuring that the distance between the punctures in the annulus when the defect in the annulus is closed is greater than the distance of the eyelets in the clasp.

[0062] Referring to Figure 18, an alternate embodiment of a suture passing instrument is provided. The suture passer 30 of Figure 21 includes an axially translatable suture passing needle 31 moveable within a needle housing 35 by a needle knob 36. The needle housing 35 is attached to a guide body 32. The guide body 32 has a handle 37 and also includes a lumen 34 that houses a deployable wire loop 33 configured to snare and retrieve a suture 20 passed through the annulus. The guide body 32 and lumen 34 may be angled at its distal end, preferably towards the projected path of the needle. The suture

passer has a knob 38 for controlling movement of the wire loop 33 which is deployed from the distal end of the guide body 32 in such a way that it encircles or is moveable to encircle the projected path of the needle 31 and/or the passed suture to allow the passed suture to be retrieved using a "blind" technique that does not require direct visualization.

[0063] The needle 31 can be loaded with the suture loop 21. The distal end of the suture passer 30 including the angled lumen of the guide body and the wire loop 33 are inserted through the opening 2 in the annulus to be repaired and the wire loop 33 is manipulated so that it encircles the projected path of needle 31. The needle 31 is advanced through the annulus wall and through the wire loop and the wire loop is used to catch the suture 20. The needle 31 is retracted while the wire loop 33 holds the suture 20. The suture passer 30 is then removed from the annulus with the wire loop holding and retrieving the suture from inside the disc so that the suture passes out of the annulus opening. The same technique is employed with the suture passer 30 in other location(s) surrounding the annulus opening and the suture is retrieved from the interior of the disc space through the opening. The suture ends are then connected to a clasp 60, which can be any one of the clasps 51, 61, 65 shown in Figures 2-4, or any other clasp, and the method of cinching the sutures and closing the opening of the annulus as described and shown in Figures 5D-E, 11 and 15 can be employed. The guide body 32 may alternatively accommodate multiple needles or needle housings arranged about its outer diameter and corresponding deployable wire loops or a single rotationally-indexing wire loop. In one embodiment, the needle may be straight and the lumen may be angled, the lumen projecting towards the opening of the axially deployed wire loop. In another

embodiment, the suture passing needle 31 may be curved at its distal end with the wire loop 33 deploying axially.

[0064] Figures 19A-F illustrates another embodiment of a tissue repair system and method. The tissue repair system of Figures 19A-F includes a suture 20, and a two-piece connector clip 35. The two piece connector clip 35 includes a first clip part 36, having a projecting portion 37, and a second clip part 38 having a receiving portion 39. The first clip part 36 attaches to the second clip part 38. The clip parts 36, 38 may be connected in many ways now known or hereafter developed including threaded connections, snap connections, interlocking flanges and shoulders, etc. Each clip part 36, 38 may further include a channel, hole or eyelet so that the suture can be attached to the clips parts 36, 38.

[0065] The suture 20 and two piece connector clip parts 36, 38 may be provided preassembled for the surgery where a first loop end 22 is associated with and preferably connected to the first clip part 36, and the second loop end 24 is associated with and preferably connected to the second clip part 38 forming a suture loop 21 with a pre-tied knot 25 and free length of suture strand 26. A needle (not shown) is inserted through the annulus wall 5 and the first part 36 of the clip connector 35 is passed through the annulus into the interior of the disc as shown in Figure 19A. The suture 20 is free to slide through the hole in the first clip part 36. The first clip part 36 is retrieved through the defect in the annulus wall so that it is outside or exterior to the disc space as shown in Figure 19 B. Next the needle is inserted through the other side of the defect in the annulus and the second clip part 38 is passed through the annulus 5 as shown in Figure 19C so that it is located in the interior of the disc. The second clip part 38 is then retrieved through the

defect in the annulus so that it is outside or exterior to the disc space as shown in Figure 19D. The two clip parts 36, 38 are clipped together preferably while located exterior to the disc space as shown in Figure 19 E, and preferably exterior of the patient, and the suture knot 25 is pulled tight so the clip 35 is drawn into the disc space as shown in Figure 19 F, and the two sides of the annulus defect are drawn tightly together. Several suture and clip assemblies 35 may be used together to repair the tear, defect, incision, or opening in the annulus of the spinal disc.

[0066] In the system and method of Figures 19A-E the suture loop is passed from the outside of the disc annulus into the interior of the disc space and thereafter retrieved through the disc annulus so that the clips can be connected while both the clips and ends of the suture loop are exterior to the disc space, and preferably exterior to the patient so that the suture can be easily handled and the clips connected together. In the tissue repair system and method of Figures 19A-F, the clips are in series with the suture loop and forms a continuous construct. The suture is connected to the clips, and the suture in combination with the clips cinches and reapproximates the tissue defect. Without the clips in the method of Figures 6-11, the suture would not approximate and draw the tissue defect closed.

[0067] A further embodiment of a suture based tissue repair system and method is shown in Figures 20-22. The suture based tissue repair system of Figure 20 includes a needle 81 configured and adapted to hold and connect to a suture 20, a clasp 60 and a clasp inserter 45. The needle 81 may be independent of the clasp 20 and clasp inserter 45 or may be part of an integrated design as illustrated and described with reference to Figure 21. The needle has an opening or notch 82 in its distal end and a channel 83 for

guiding and maintaining the suture across the needle opening. A further channel 84 may be provided to retain the suture along the length of the needle. The guide channel 83, opening 82 and clasp 60 are configured so that the suture 20 can be inserted through the slot in the clasp 60 and looped over the open end of the clasp 60.

[0068] Figure 21 illustrates an alternative suture assembly and clasp instrument 110. The suture inserter and clasp assembly instrument 110 has a first needle 112 and a second needle 114 located within and slidable relative to housing 115. Housing 115 is cannulated and has an inserter 120 located within cannulated bore 116. The inserter 120 is moveable relative to the housing 115 and preferably slidable within bore 116 in housing 115. A clasp 60, similar to clasp 60 in Figure 20, is connected to the distal end of the inserter 120. First needle 112 and second needle 114 each may be structured and configured similar to needle 81 in Figure 20. A suture 20 is threaded across an opening in the first and second needles 112, 114 similar to Figure 20. The first and second needles 112, 114 each have a handle 118 that extends through a slot located in housing 115 and are each independently operable by a user to move each respective needle relative to the housing so the distal end of the needle extends from the housing. A first loop end 22 of the suture 20 extends around the first needle 112 and a second loop end 24 of the suture 20 extends around the second needle 114. The suture knot 25 preferably is located within the housing and the free strand 26 of the suture extends out the bore 116 of the housing 115.

[0069] The use of the needle 81 and the clasp inserter 45 of Figure 20, and the use of the suture inserter and clasp assembly instrument 110 of Figure 21, is shown in Figures 22A-K. The inserter 45, 110 and clasp 60 is inserted through the defect in the annulus of

a spinal disc. If the assembly 110 of Figure 21 is used, the tip of the cannula 119, which houses the inserter 120 and clasp 60 assembly, is inserted through the annulus defect as shown in Figure 22A and the inserter 120 is then moved in housing 115 so the clasp 60 extends outside the cannula 119 and into the interior of the disc space as shown in Figure 22B. The clasp 60 preferably expands to a larger or different size as it exits the cannula 119 as shown in Figure 22B. The inserter/clasp assembly may be moved toward the first side of the annulus as shown in Figure 22C and the needle 81, or first needle 112 may be inserted through the annulus. Next the suture end 22 is looped over the clasp as shown in Figure 22D and the needle 81, 112 is withdrawn from the annulus with the first loop end 22 of the suture wrapped around the clasp 60 as shown in Figure 22E. The inserter/clasp assembly instrument 110 is moved to the other side of the annulus defect, shown in Figure 22F, and the needle 81, second needle 114 is inserted through the second side of the annulus, shown in Figure 22G, and the needle is moved over the clasp 60 so that the suture is hooked onto and held by the clasp as shown in Figure 22H. The needle 81, second needle 114 is withdrawn from the annulus with the suture held by the clasp 60 as shown in Figure 22I. The inserter 45, 120 is then disconnected from the clasp 60, shown in Figure 22J, and the inserter is withdrawn from the annulus defect. The suture 20 is then drawn tight so that the opening in the annulus is closed and drawn tightly together and the free end of the suture is cut as desired.

[0070] The systems and methods described above can be further adapted for use with more than one suture loop, as shown in Fig. 23. In this embodiment, the ends of each suture loop could be secured by the same clasp, or optionally a separate clasp could be used for each suture loop. The suture loops could be passed through the annulus and

around the annular defect in configurations known in the prior art or hereafter discovered. Examples of these configurations, which are commonly used in clinical practice, would be a cruciate configuration (shown) or a stacked mattress configuration.

[0071] Additionally, or alternatively, the systems and methods described above may utilize two suture loops (each with its own sliding knot and free strand) on the same strand of suture. For example, referring to Figure 26 a suture based tissue repair system and method is disclosed which includes a multi-loop suture 20 and a suture clasp 60. In Figure 26 only two loops 21, 21' are illustrated but more than two loops may be possible. The loops 21, 21', 21", etc. may be pre-tied with one or more knots 25, 25', 25", etc. which, in various embodiments can include any type of sliding knot, ratcheting knot, or locking knot now or hereafter known in the art. In a preferred embodiment, the knots are a ratcheting and/or locking knot that prevents post-operative loosening of the repair construct. Each suture loop 21, 21', 21", etc. preferably includes a first loop end 22, 22', 22", etc., a second loop end 24, 24' 24", etc., and a free length of suture strand 26, 26', 26", etc. adjacent to and extending from the knot 25, 25', 25", etc. In this embodiment, the free suture strand 27 adjacent the knot 25 extends to the adjacent knot 25'. The clasp 60 in Figure 26 may be any one of the clasps, or clips described or illustrated herein , or additional or alternative clasps or clips. The multi-loop suture may be utilized as described in the methods herein, and preferably the suture loops and the clasp or clip in combination work in series to close the tissue gap and reapproximate the tissue. While the multi-loop suture 20 may be supplied to the hospital, operating center or operating room with a pre-formed or pre-tied knot and multiple loops 21, 21', 21", etc., the suture 20 may also be configured in the operating room before or during the surgery to include

loops 21, 21'; first loop ends 22, 22'; second loop ends 24, 24'; knots 25, 25' and free strands 26, 26'.

[0072] Referring to Figure 24, an alternate system and method similar to that shown and described when referring to Figure 4 is shown. The system and method of Figure 24 includes the clasp 51 of Figure 4 and further includes a plug 55 for occluding the annular defect, which is well suited for circumstances in which the annular defect is too large to allow adequate reapproximation using only the sutures and clasps described above. The plug 55 preferably is formed of a compliant biocompatible material, such as collagen, cellulose, hydrogels, etc., and may serve as a scaffold to facilitate healing. The plug 55 is connected to clasp construct 60, and the plug 55 can be attached to the clasp 60 via direct means, such as adhesive, or may be attached using connecting bands or sutures or any additional means. In use, the plug is positioned in the annulus defect and encircled by the suture loop and clasp. The plug/clasp assembly can be implanted and used as described in connection with Figures 4 and 5A-E, where the suture loop ends are connected to the clasp while outside of the disc space as shown in Figure 24A and then the plug/clasp assembly is drawn into the annulus defect with the plug preferably remaining at least partially within the annulus opening as shown in Figure 24B.

[0073] Alternatively, the plug can include a suture-locking mechanism that eliminates the need for a suture loop with a pre-tied knot. In such an embodiment, one strand of suture is passed through a full-thickness stitch encircling the annulus defect and the free strands of the suture are routed through the suture-locking mechanism within the defect or within the disc space. The suture-locking mechanism can be, for example, a locking dowel within an outer cylindrical sheath as described below in connection with

Figure 25. The suture-locking mechanism can optionally be surrounded by a biomaterial to provide a scaffold and fill the annulus defect. The suture-locking mechanism can optionally be located within the disc (i.e. not within the annulus defect).

[0074] Referring to Figure 25, an annulus repair system and method is provided that includes a suture 20, a locking anchor 85, and an inserter instrument 40 that further includes an inserter shaft 42 and a trigger-activated plunger 44. The locking anchor 85 further includes a locking sheath 46 and a locking dowel 48. The locking anchor may be pre-loaded onto the inserter instrument. Using a suture passer and retriever instrument similar to that previously described, a continuous strand of suture is passed through the annulus such that its free ends are retrieved through the defect, similar in configuration to Fig. 10, with the exception that a single strand of suture is passed, rather than a suture loop with a pre-tied sliding knot. The free ends of the suture are then threaded through the locking sheath of the locking anchor, which is loaded onto the inserter instrument. The locking anchor 85 and inserter instrument 40 are then passed into or through the annulus defect, the free strands are tensioned to reapproximate the annular defect, and the trigger-activated plunger 44 is advanced to allow the locking dowel 48 to engage the locking sheath 46, thereby locking the free strands of suture 20 within the locking anchor 85. The inserter tool 50 is then disengaged from the locking anchor 85, and the free strands of suture are cut.

[0075] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, and features and structures may be used singularly or

in combination, and it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

CLAIMS

We claim:

1. A system for bodily tissue repair comprising:

a strand of suture having at least one loop and at least one knot;

a clasp device for securing the at least one loop of suture and having at least one at least partially closed eyelet.

2. The system of claim 1 wherein the eyelet comprises a closed ring.

3. The system of claim 1 wherein the eyelet is C-shaped, U-shaped, S-shaped, O-shaped, coil shaped, or other shape having an opening to permit a suture to pass into the eyelet.

4. The system of claim 1 further comprising a suture passer and retriever instrument further including a needle having a receptacle for receiving the suture.

5. A system for repairing a defect in the soft tissue comprising:

a strand of suture having at least one loop having two ends and a sliding, locking, or ratcheting knot;

a clasp device having an at least partially closed eyelet for securing the two ends of the loop, wherein the suture and clasp device are configured in combination to surround the tissue defect and at least partially approximate the defect with the two ends of the loop extending in opposite directions of the clasp device.

6. The system of claim 5 wherein the suture and clasp device are in series in forming a loop surrounding the tissue defect.

7. The system of claim 5 further comprising a needle for releasably attaching to the suture and for passing the suture through the soft tissue.

8. The system of claim 7 further comprising a suture passer and retriever instrument, the suture passer and retriever instrument configured to cooperate with the needle.

9. The system of claim 8 wherein the suture passer and retriever instrument further comprises a boom arm for capturing the suture.

10. The system of claim 9 wherein the suture passer and retriever instrument is releasably coupleable to the clasp device.

11. The system of claim 5 further comprising a plug member for filling and sealing the tissue defect.

12. The system of claim 5 further comprising a plurality of barbs, one barb connected to each of the ends of the suture loop, and wherein the clasp device has a plurality of eyelets, each eyelet connectable to the barbs, wherein the eyelet is expandable and at least a portion of the barb is configured to pass through the eyelet.

13. The system of claim 8 wherein the suture passer and retriever instrument comprises a wire loop for capturing the suture.

14. The system of claim 5 wherein the clasp device includes a two piece clip, the first piece connectable to a first end of the suture loop, a second piece of the clip connectable to a second end of the suture loop and the first piece coupleable to the second piece.

15. The system of claim 8 wherein the clasp device has two hooks having open slots to receive the suture, the hooks being resiliently flexible to collapse to a smaller size and expand to a larger size.

16. The system of claim 8 wherein the suture passer and retriever instrument further comprises two needles, each needle connectable to an end of the suture and being independently moveable, the clasp device releasably connectable to the suture passer and retriever instrument, the clasp device having an opening for receiving the suture.

17. The system of claim 1, wherein the clasp device and suture strand are configured and sized for repairing a defect in the annulus of a spinal disc.

18. A method of repairing a defect in an annulus of a spinal disc comprising:

providing a suture having at least one loop and a sliding, locking, or ratcheting knot;

providing a clasp device for capturing the ends of the suture loop;

providing a passing device for attaching to the at least one suture loop, the passing device for passing the suture through a wall of the annulus;

attaching a first end of the suture loop to the passing device;

inserting the passing device with the first suture end through the disc annulus wall;

inserting second end of the suture loop through the disc annulus wall;

connecting the first end and second end of the suture loop to the clasp device while the suture loop ends and clasp device are outside the spinal disc;

inserting the clasp device through the annulus defect so that the suture loop and clasp device form a continuous loop around the annulus defect; and

tightening the suture to tension the suture loop to at least partially close the defect, wherein the clasp device and suture loop are in series with each other and both the suture and clasp device approximate and draw the defect closed.

19. The method of claim 18 wherein the passing device comprises a needle and further comprising releasably attaching the needle to the suture loop.

20. The method of claim 18 wherein the passing device is coupled to the clasp device, and further comprising releasing the clasp device from the passing device.

21. The method of claim 18 further comprising:

inserting the first end of the suture loop through the annulus wall from the outside to the inside of the disc;

retrieving the first end of the suture loop through the defect in the annulus so that the first end of the suture loop is outside the disc space;

inserting the second end of the suture loop from the outside to the inside of the disc;

retrieving the second end of the suture loop through the defect in the annulus so that the second end of the suture loop is outside the disc space.

22. The method of claim 21 wherein the clasp device comprises a multi-piece connectable clip, further comprising

connecting a first piece of the multi-piece clip to a second piece of the multi-piece clip.

23. The method of claim 22 further comprising:

connecting a first end of the suture loop to the first piece of the multi-piece clip; and

connecting a second end of the suture loop to the second piece of the multi-piece clip.

24. The method of claim 23 wherein the suture loop is connected to at least one of the first and second pieces of the multi-piece clip before the first or second end of the suture loop is inserted through the disc annulus wall.

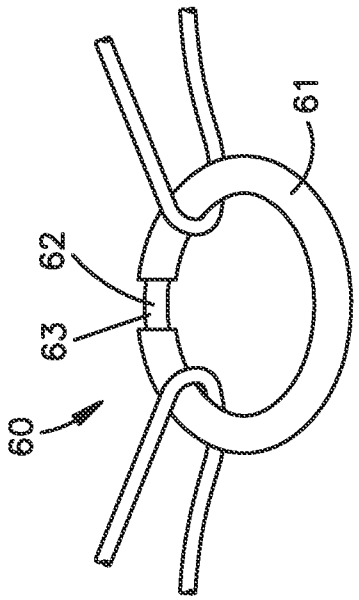

Fig.2

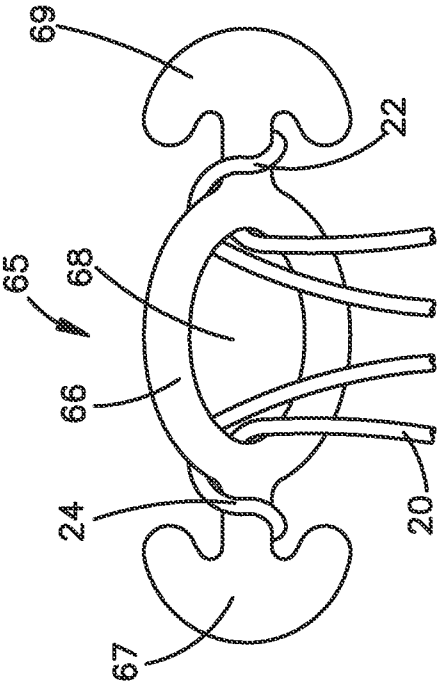

Fig.3

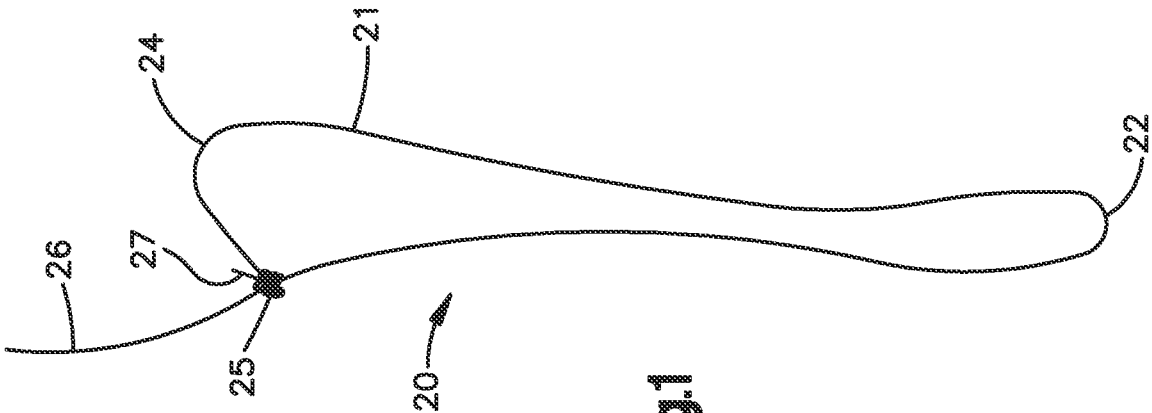

Fig.1

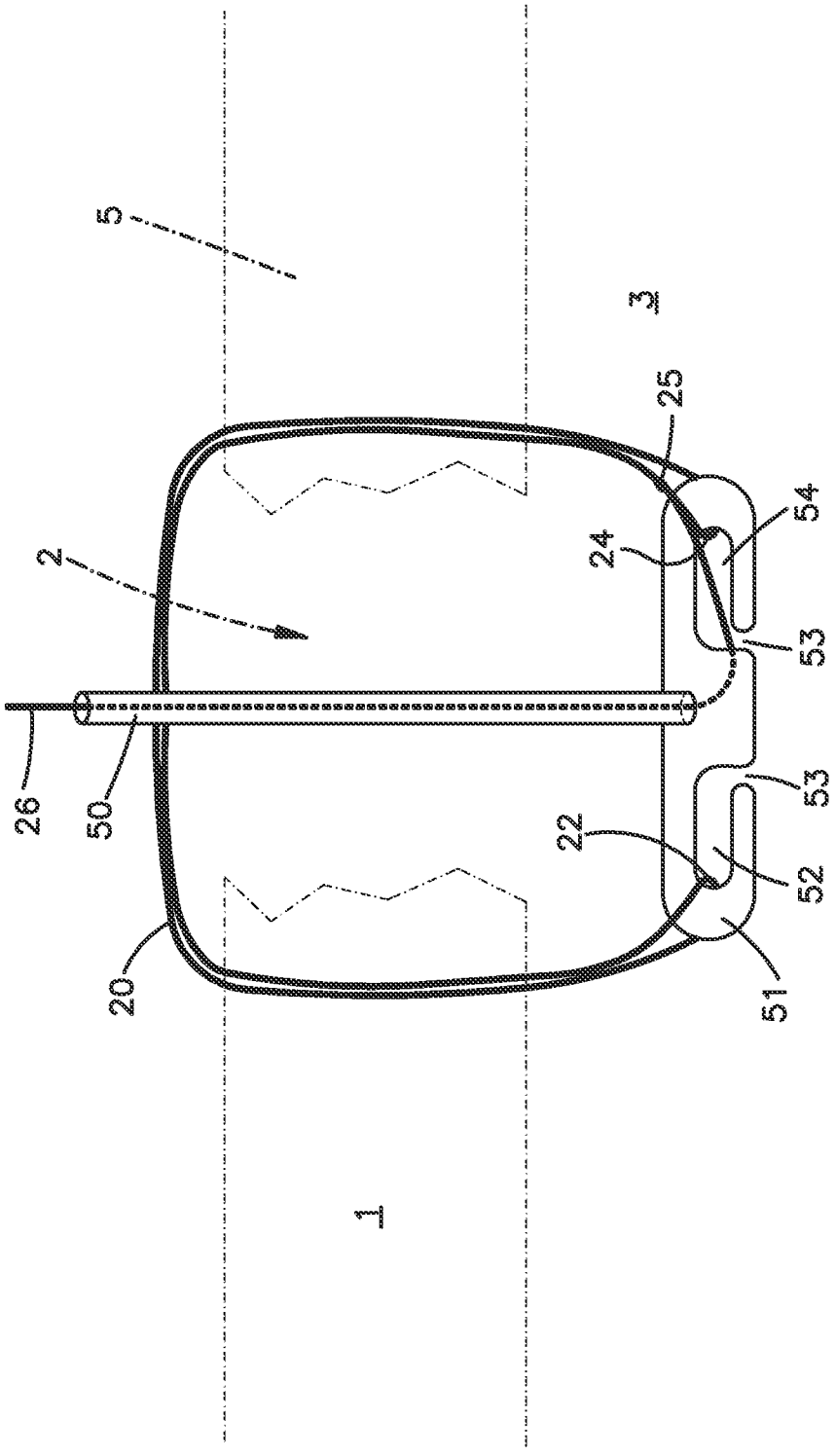

Fig.4

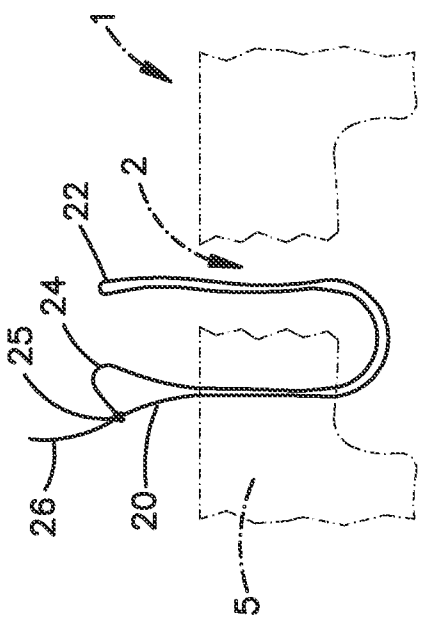

Fig.5B

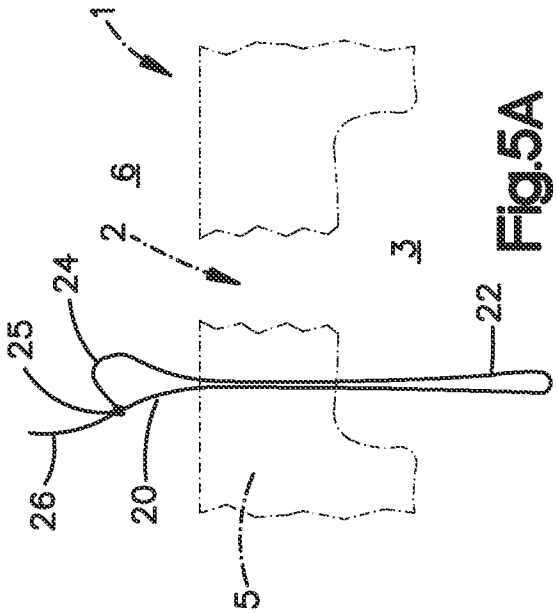

Fig.5A

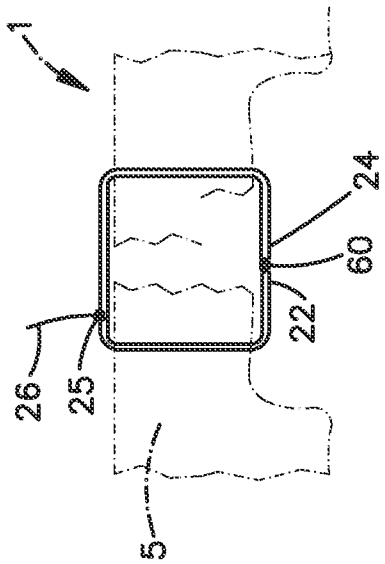

Fig.5E

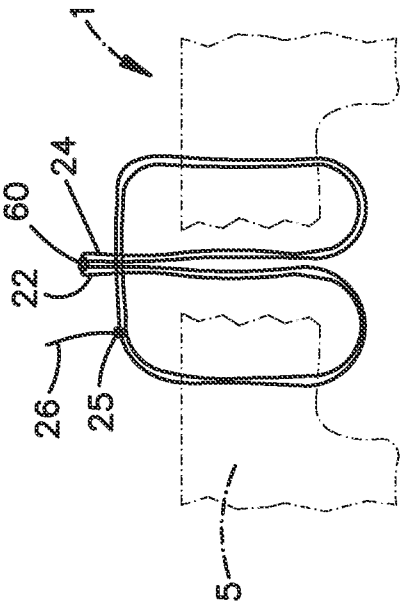

Fig.5D

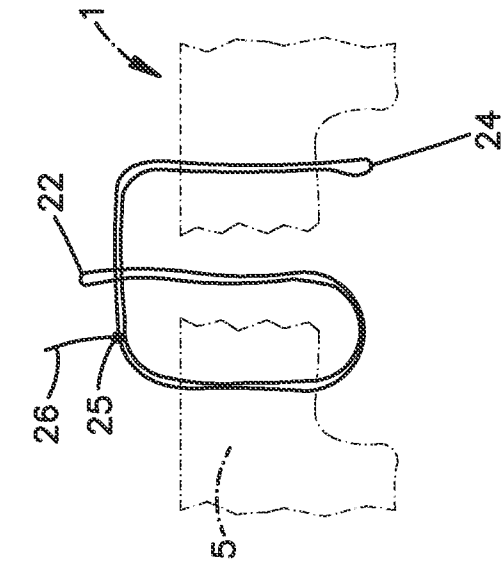

Fig.5C

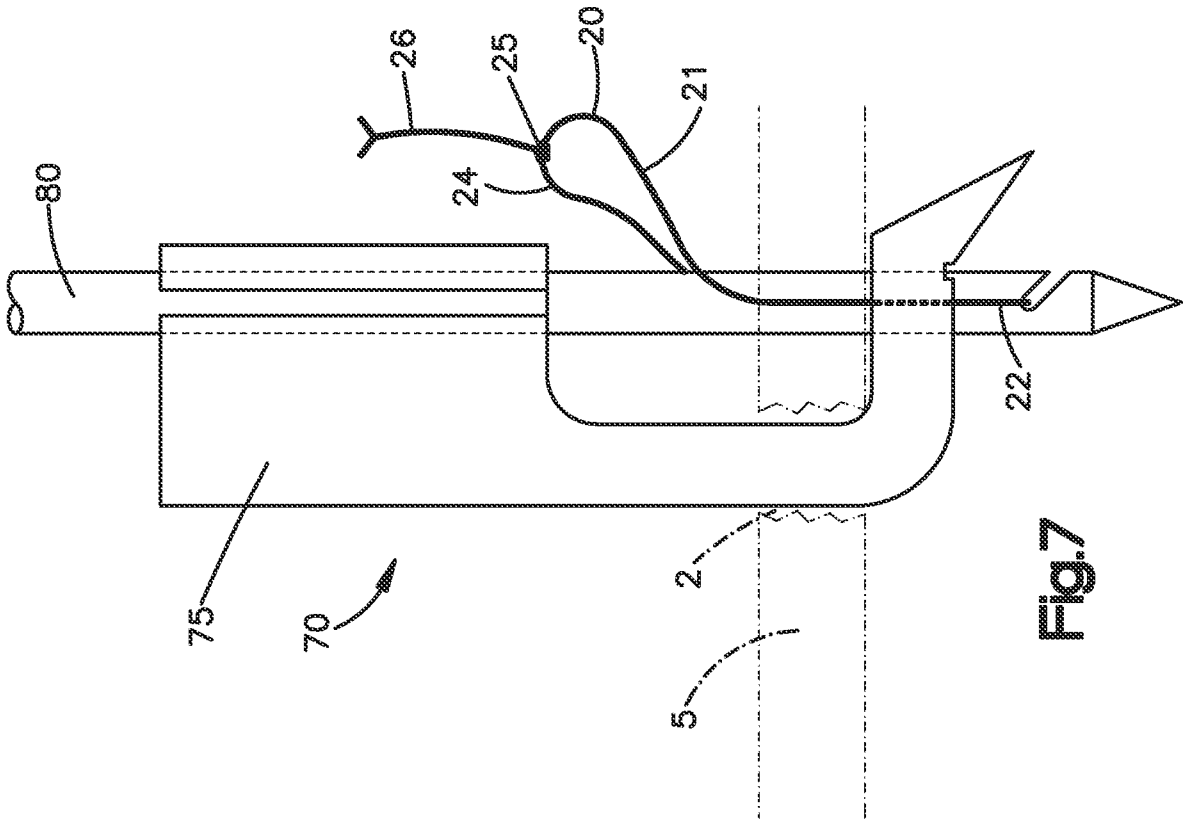
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Fig.7

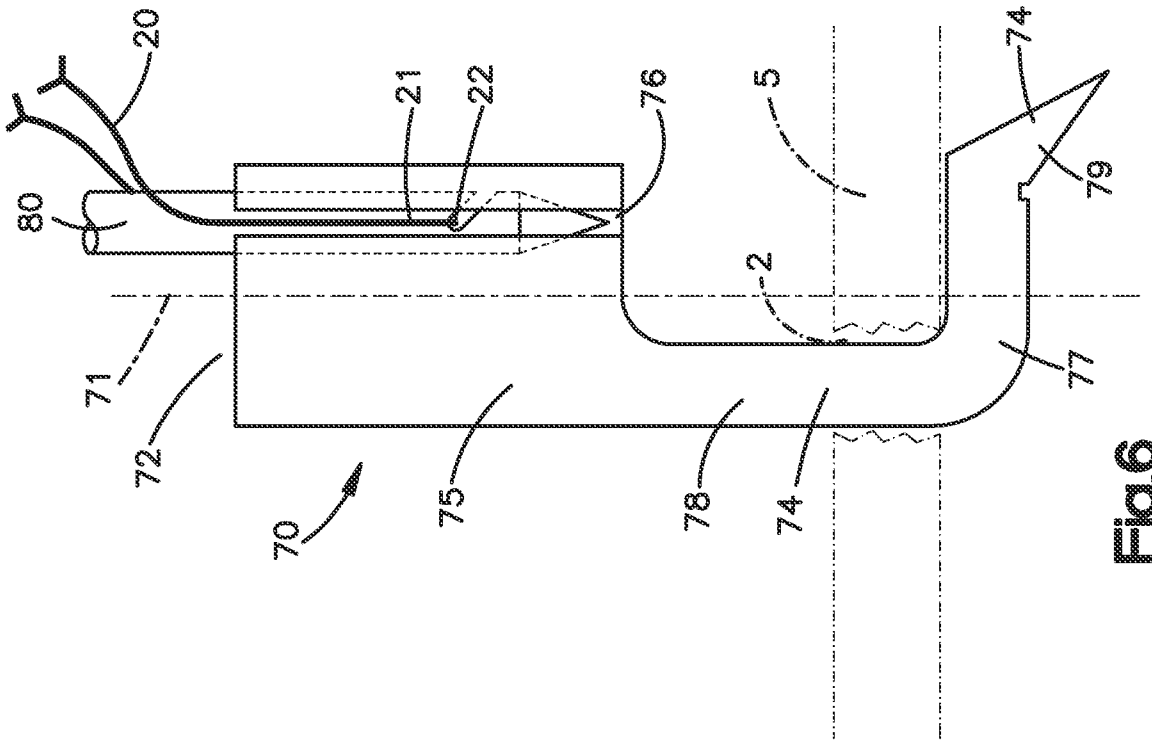
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Fig.6

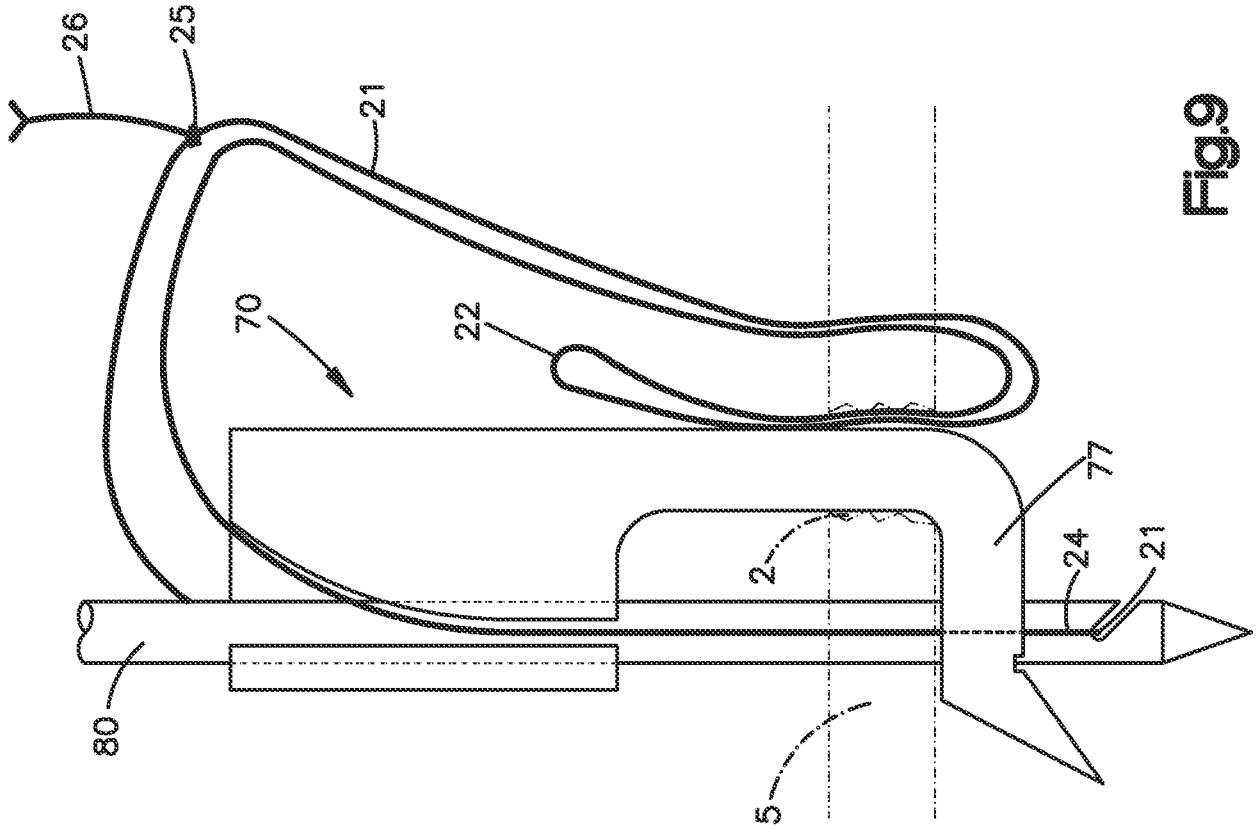

Fig.9

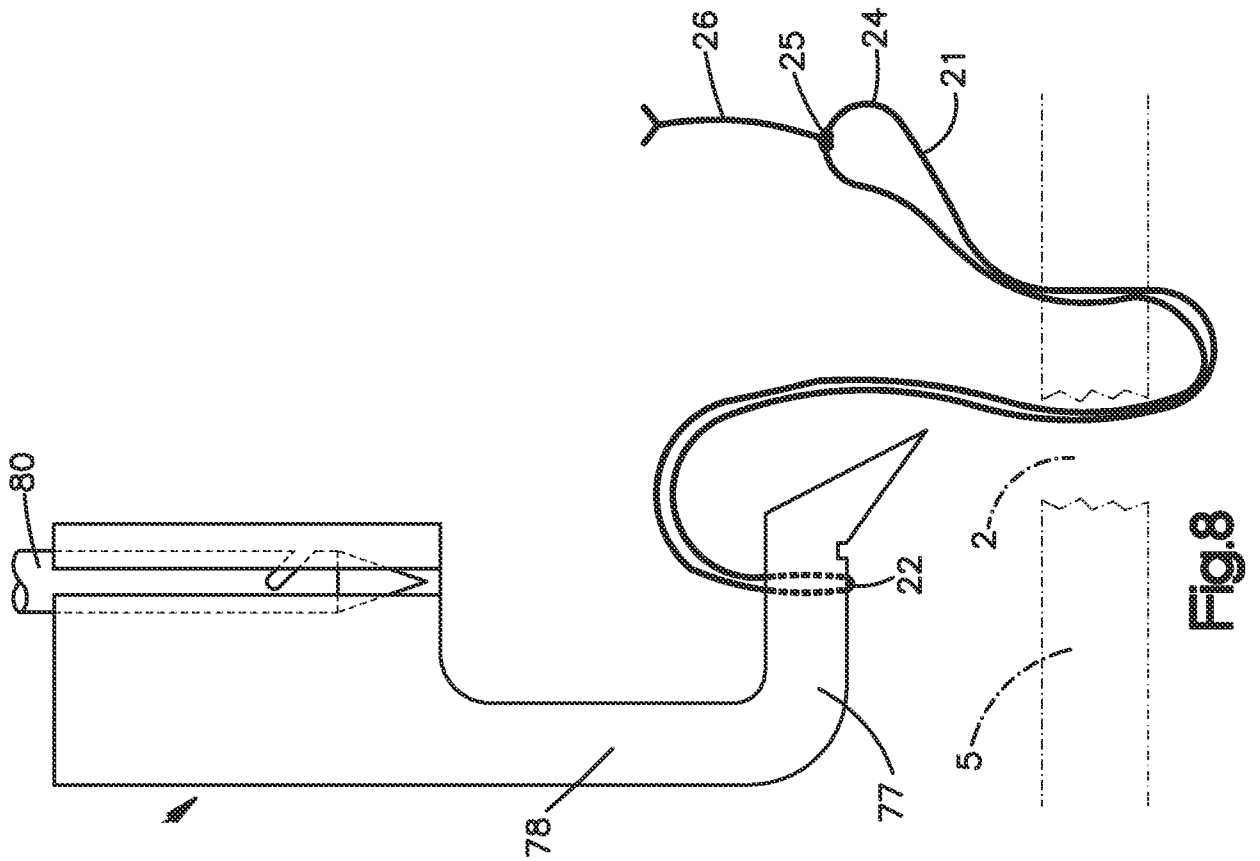

Fig.8

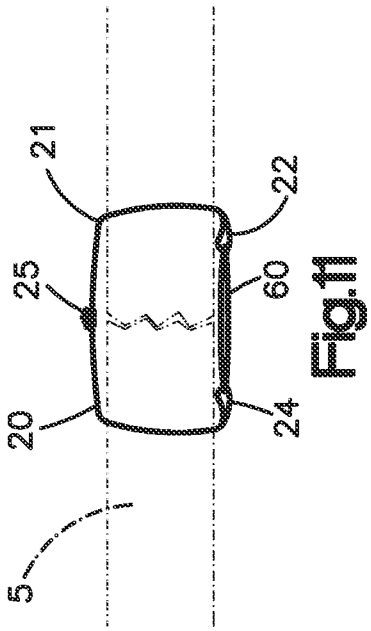

Fig.11

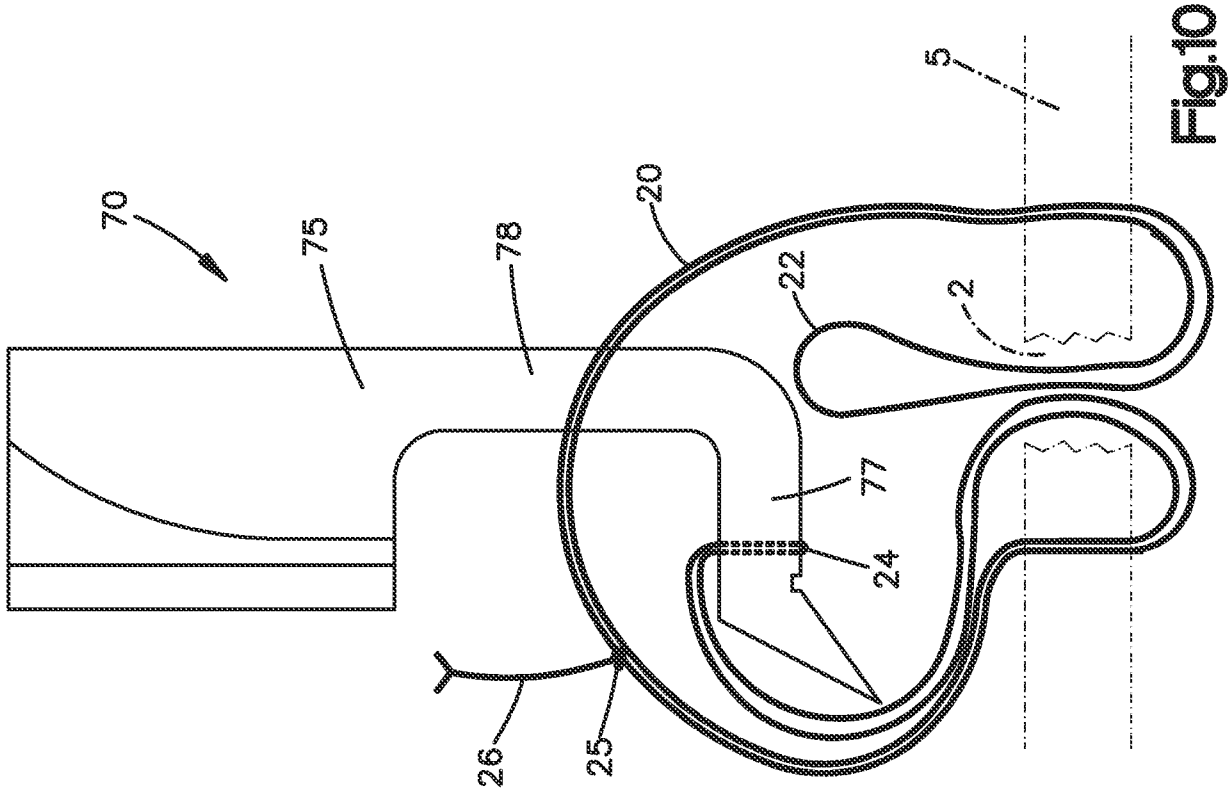

Fig.10

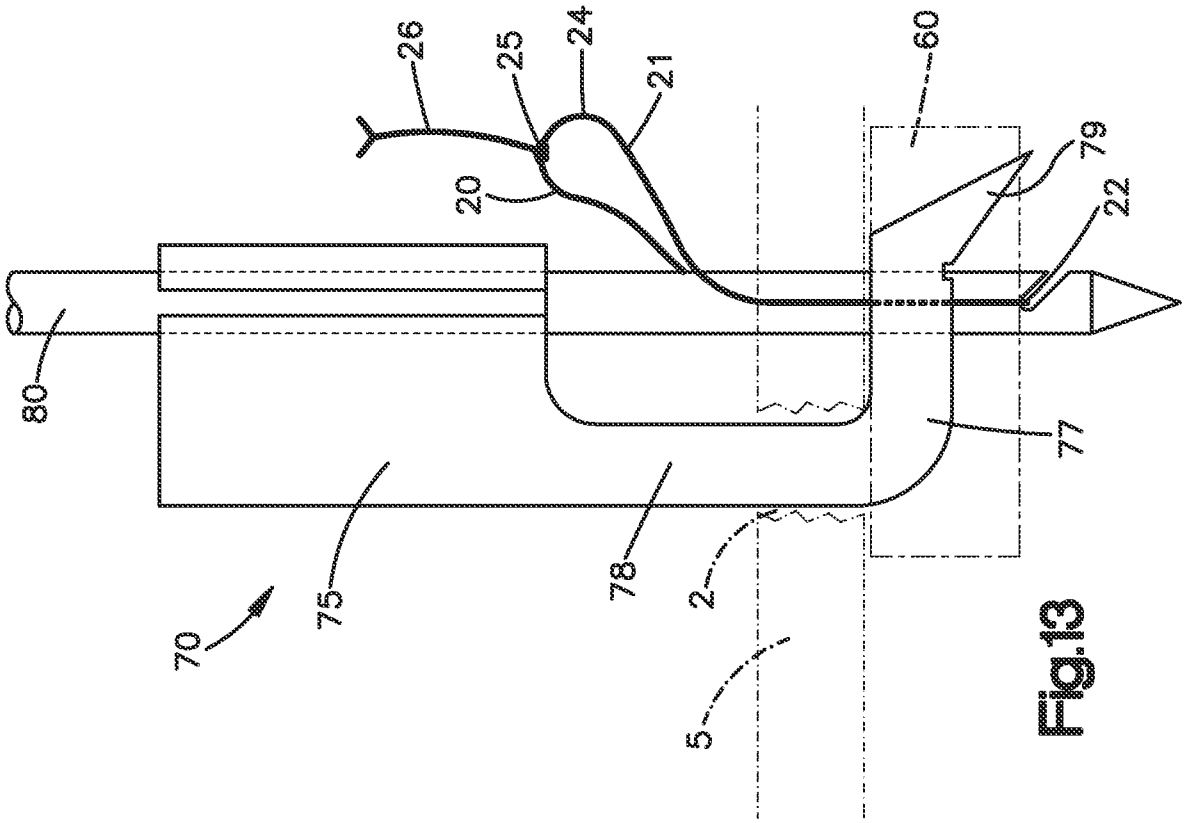
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Fig.13

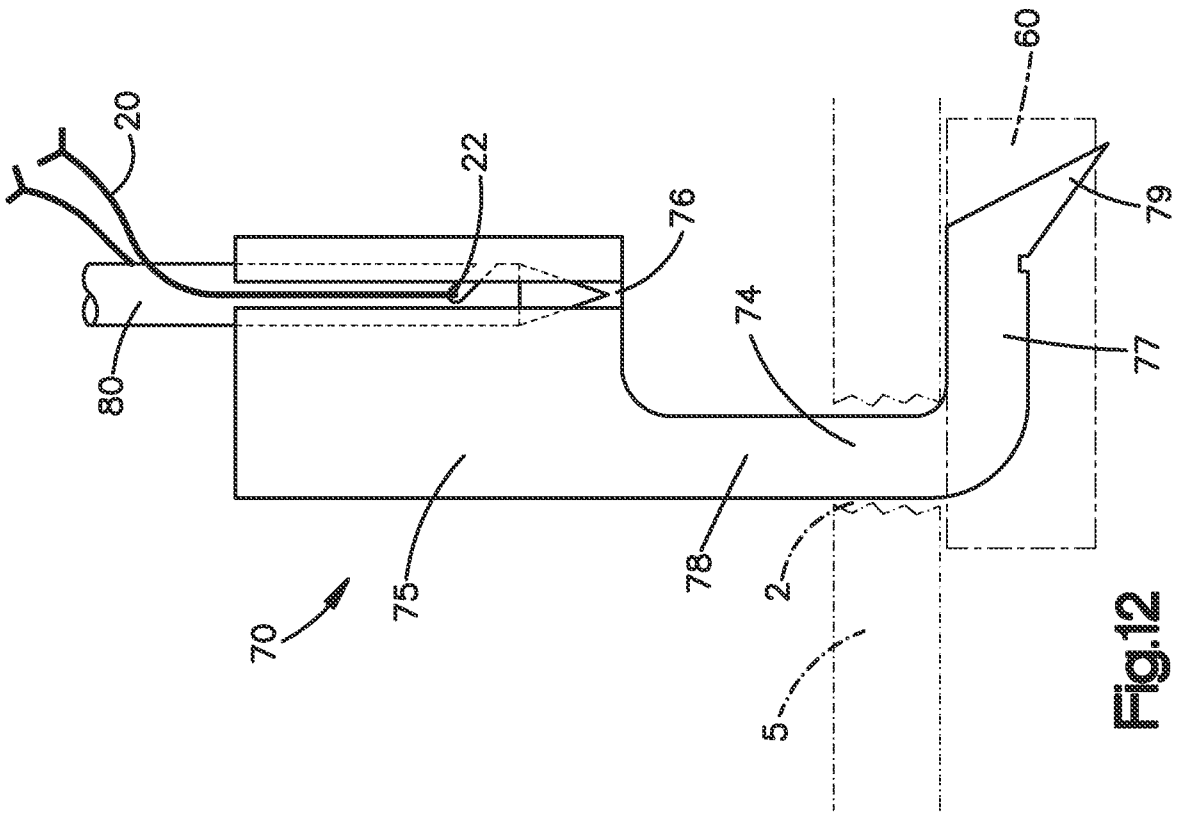
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Fig.12

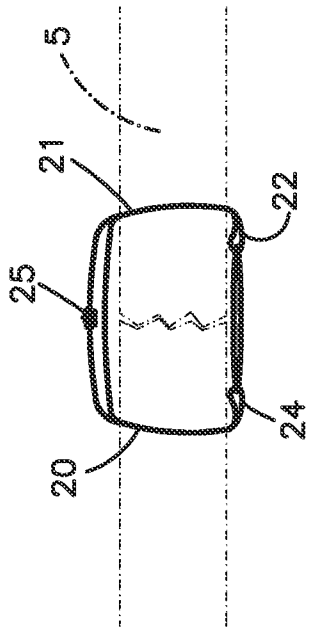

Fig.15

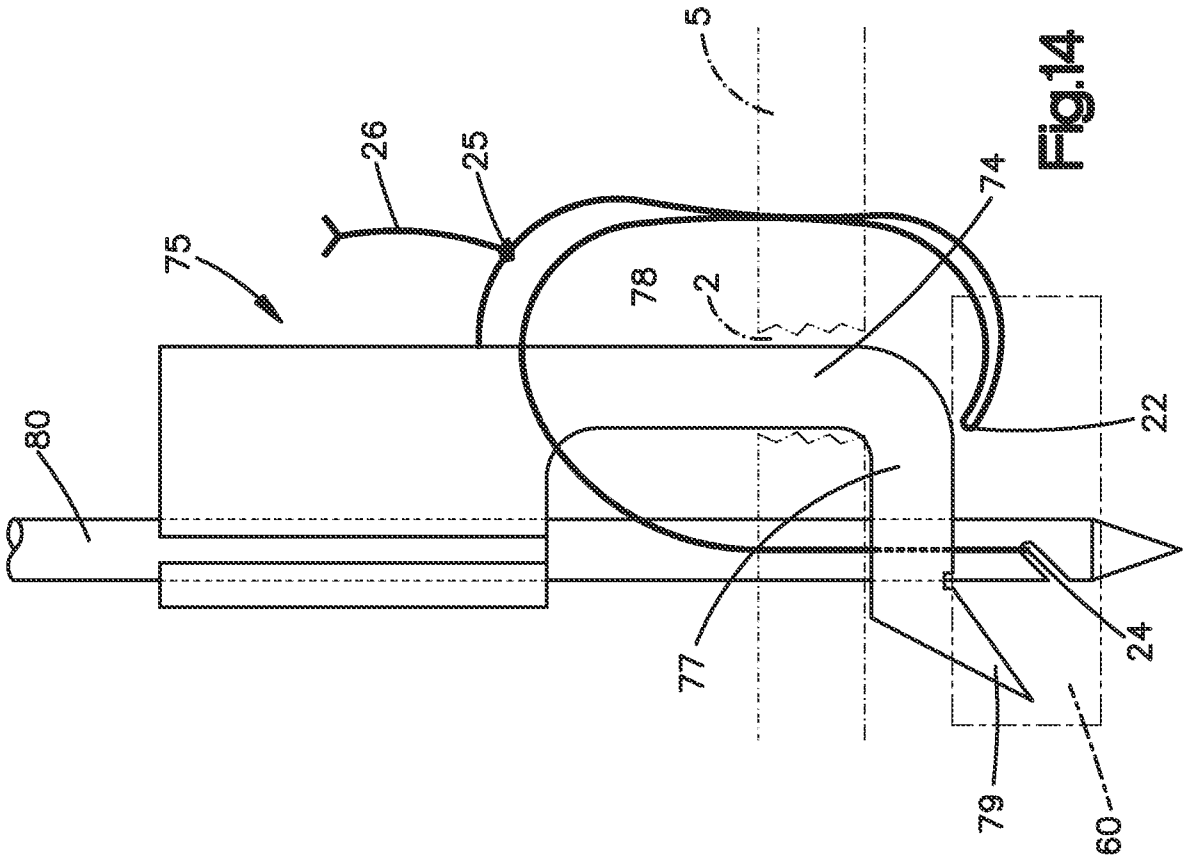

Fig.14

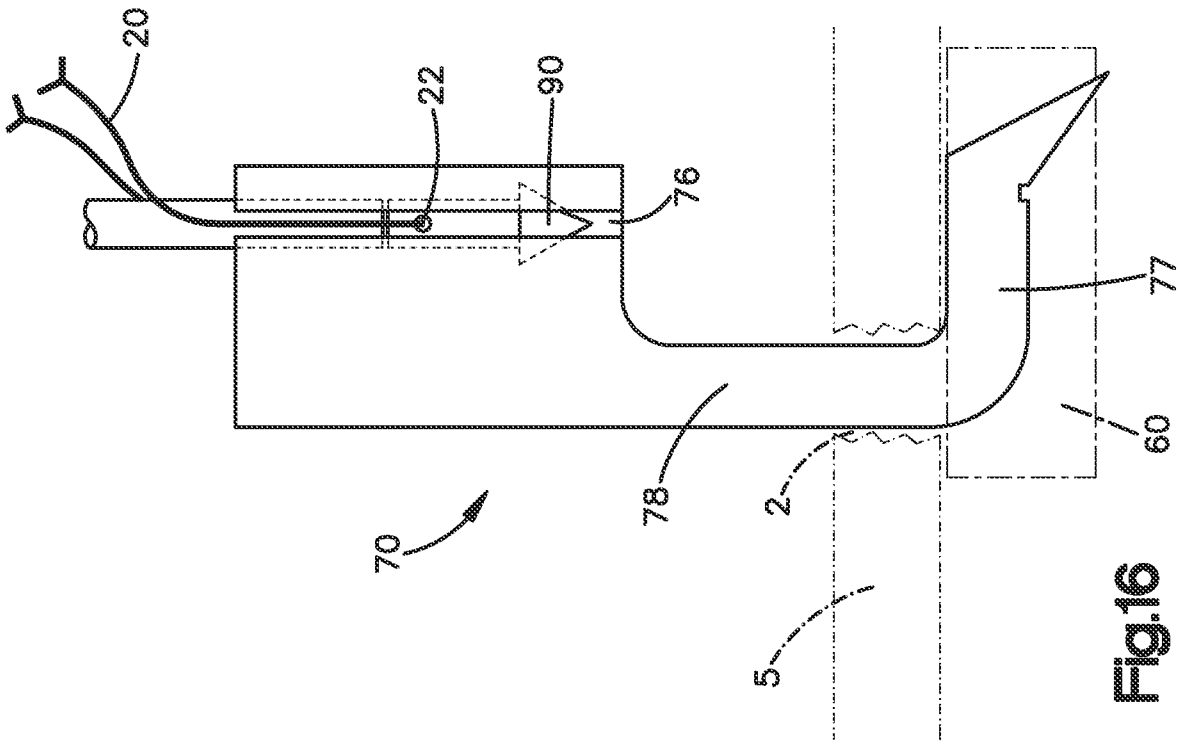

Fig.16

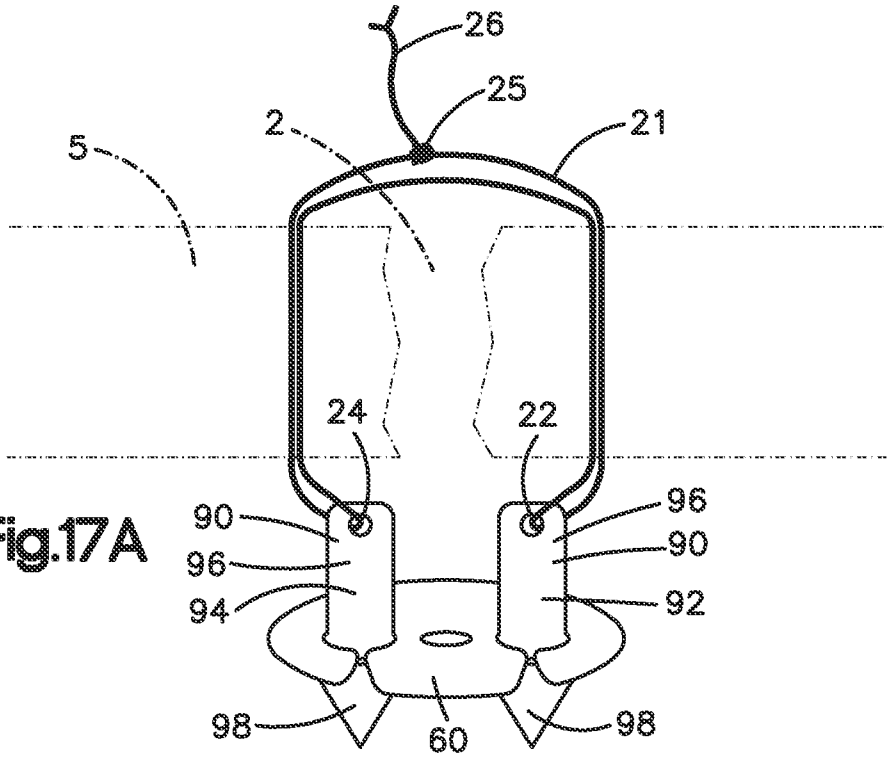

Fig.17A

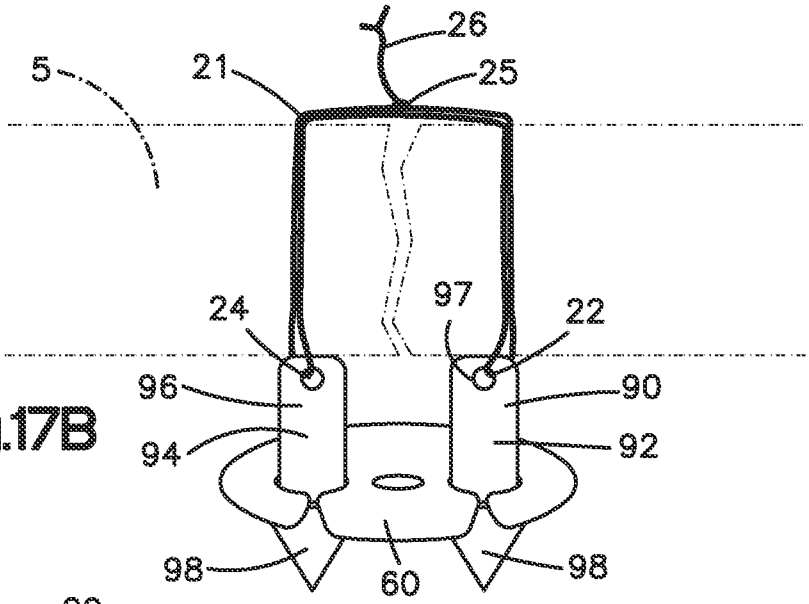

Fig.17B

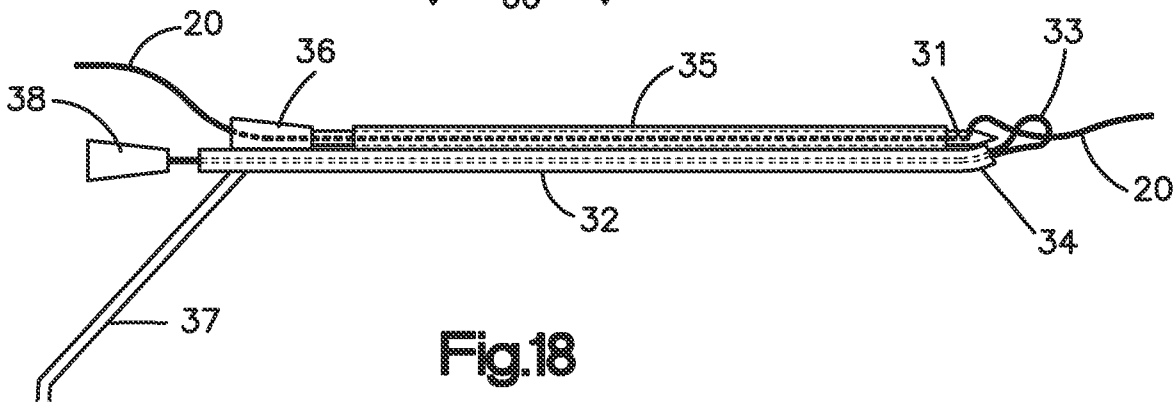

Fig.18

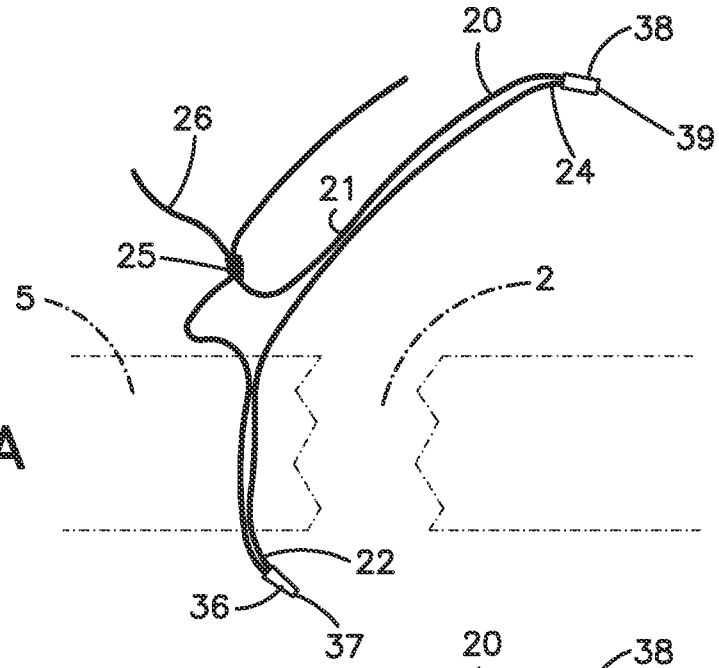

Fig.19A

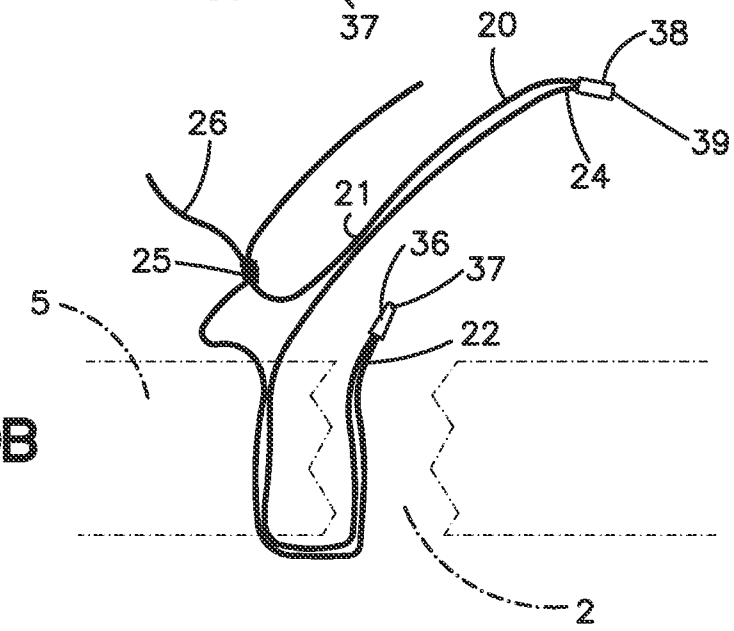

Fig.19B

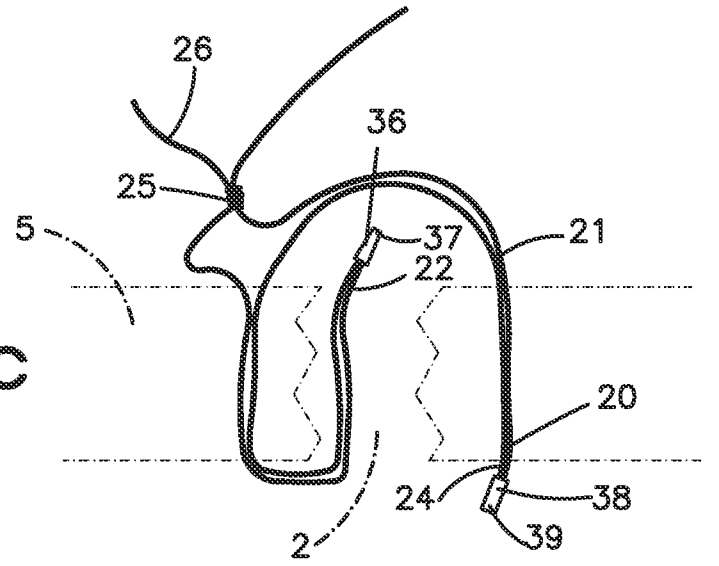

Fig.19C

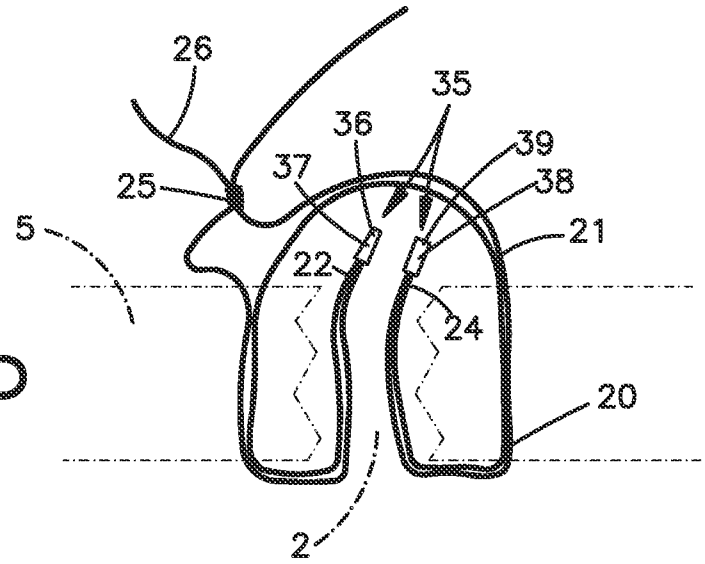

Fig.19D

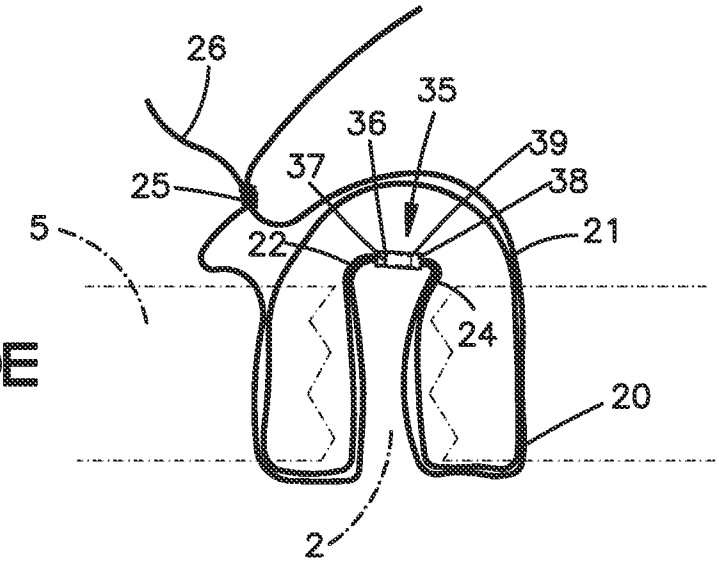

Fig.19E

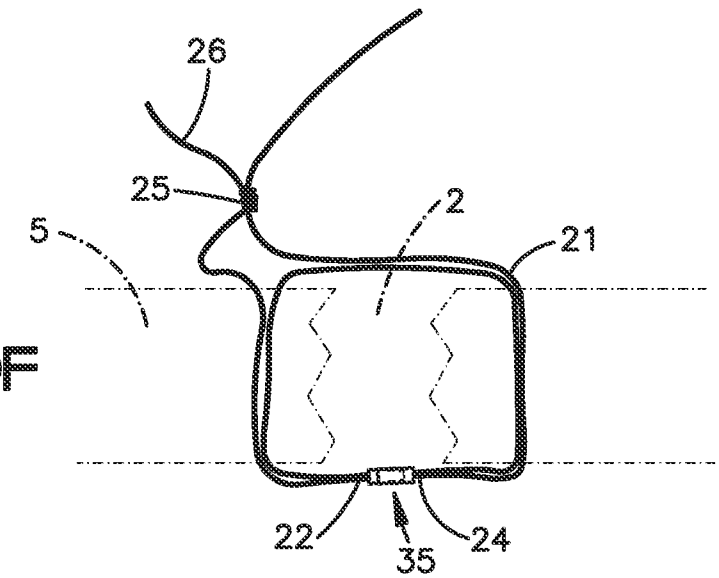

Fig.19F

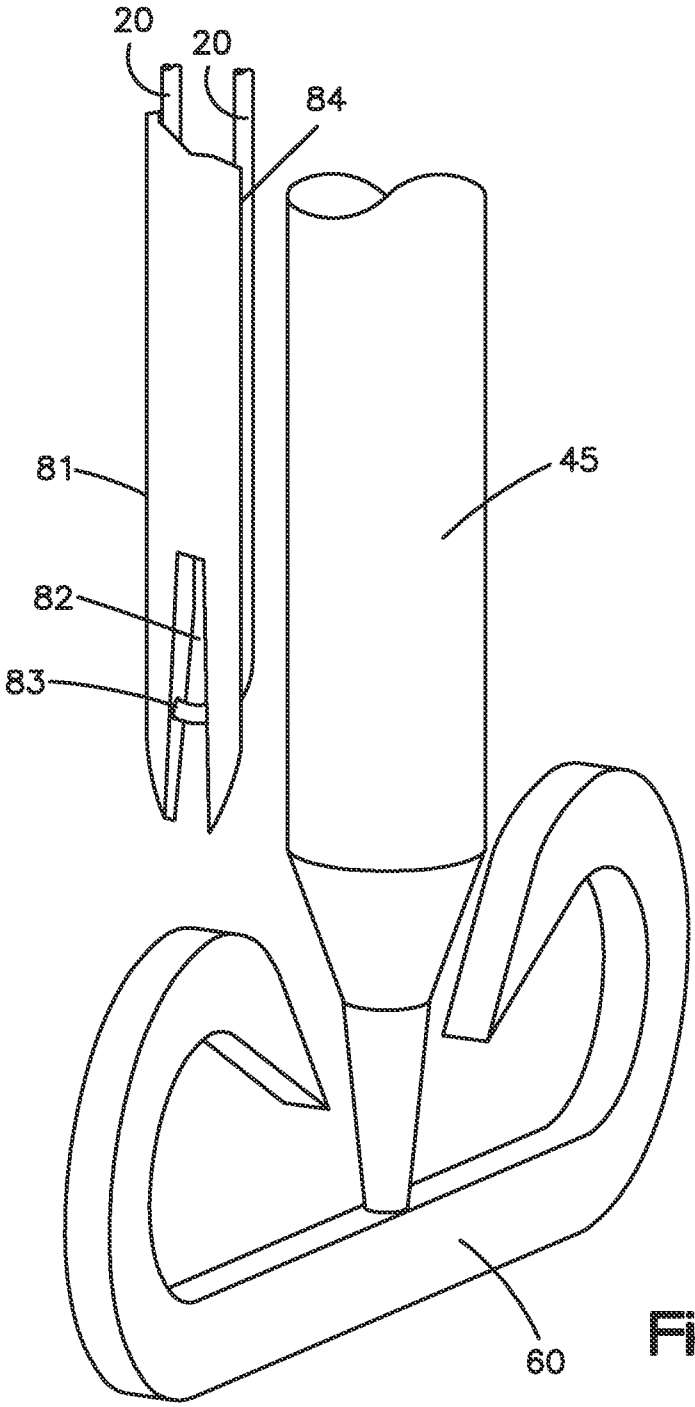

Fig.20

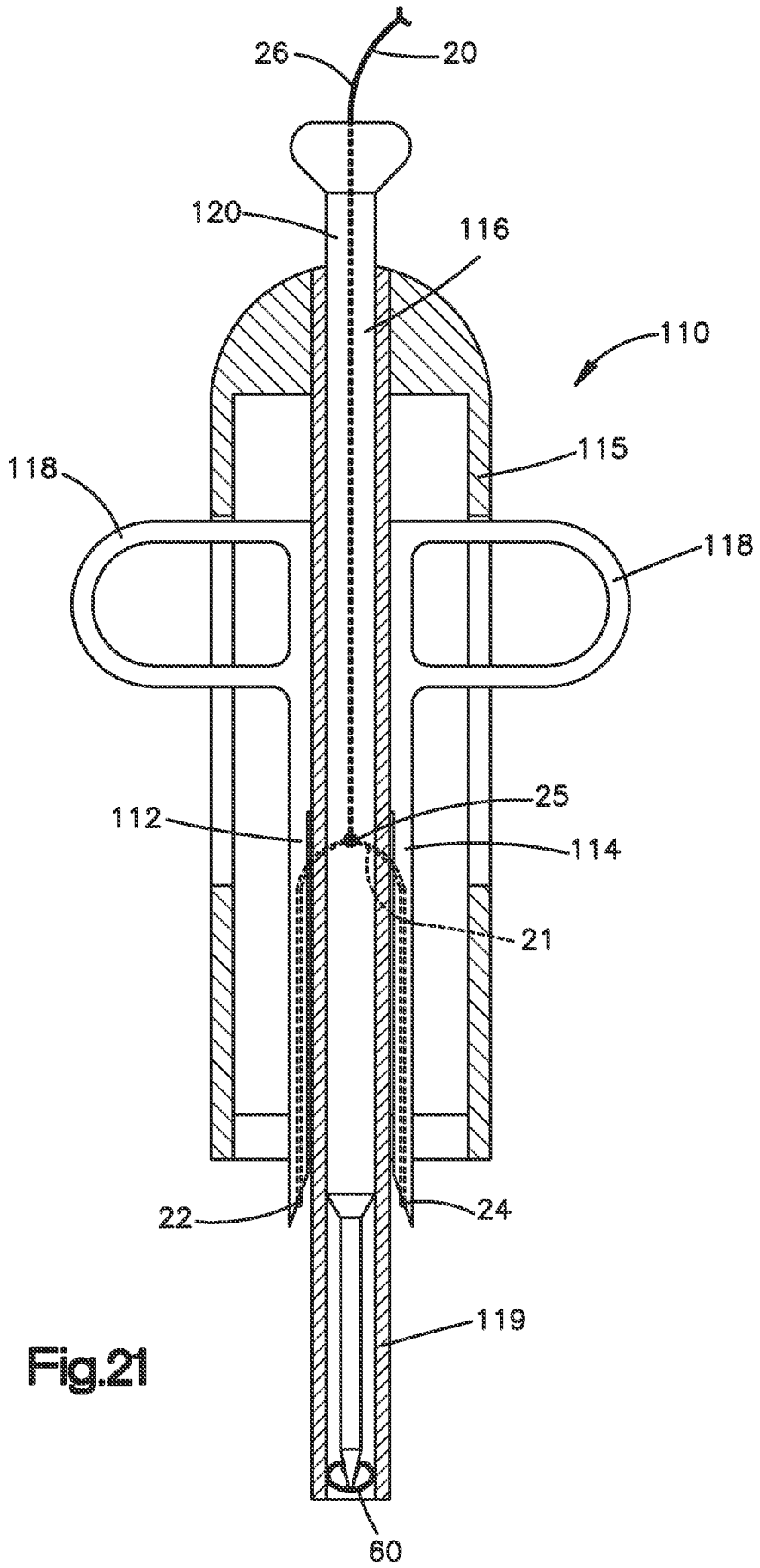

Fig.21

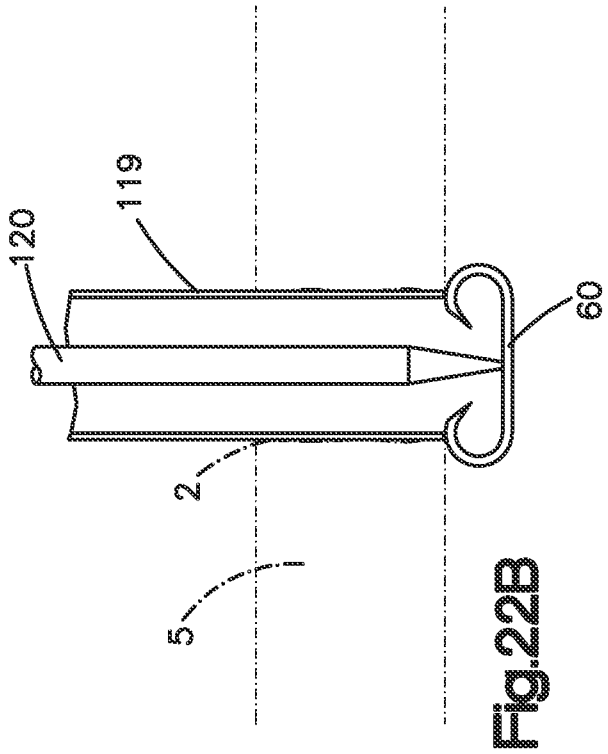

Fig.22B

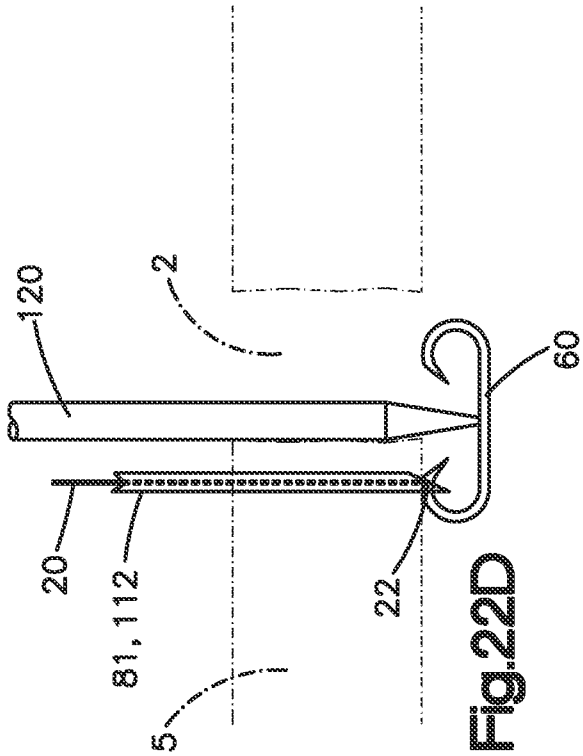

Fig.22D

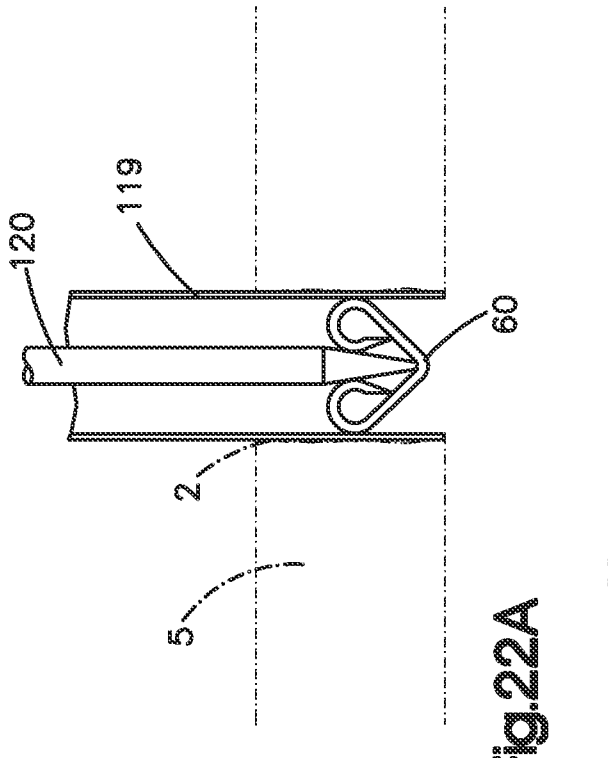

Fig.22A

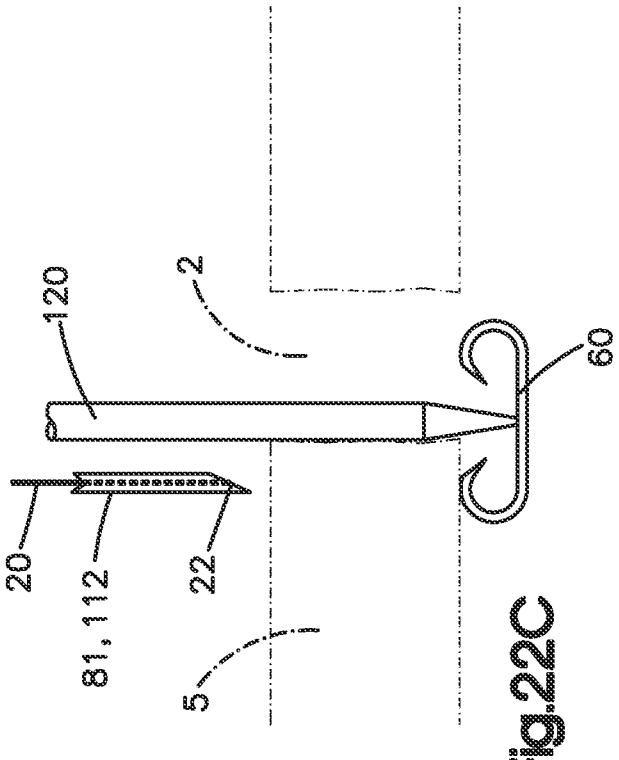

Fig.22C

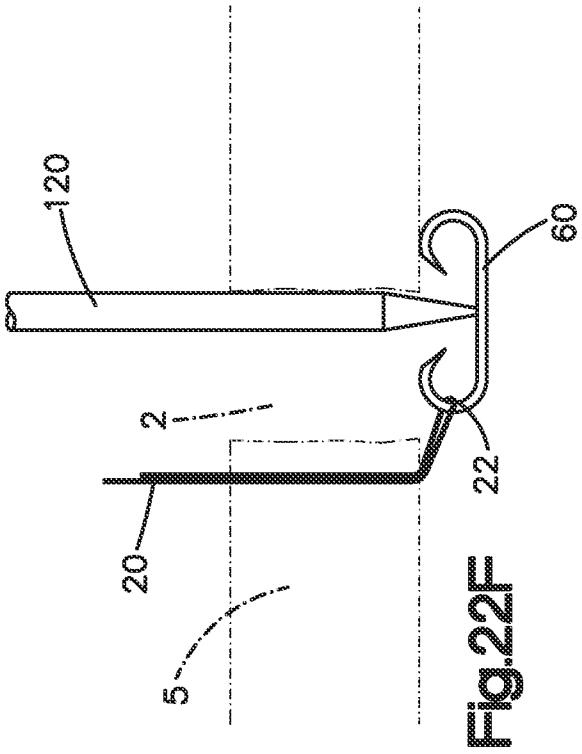

Fig.22F

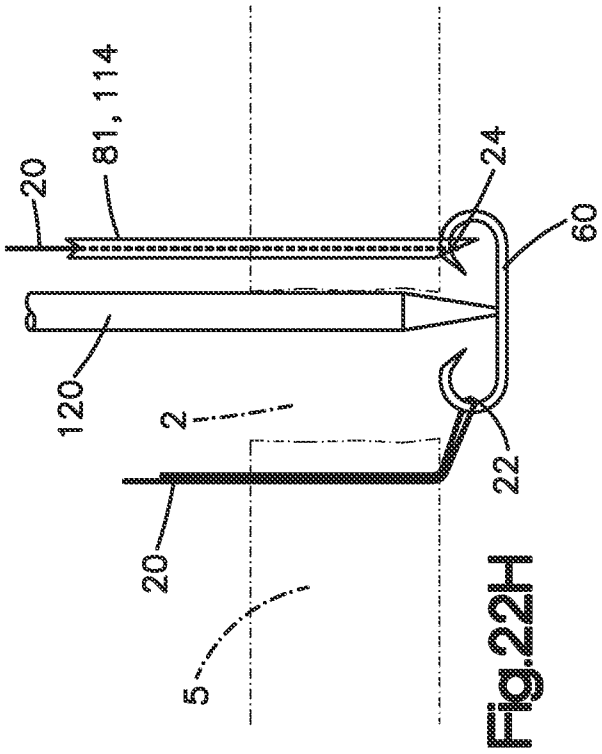

Fig.22H

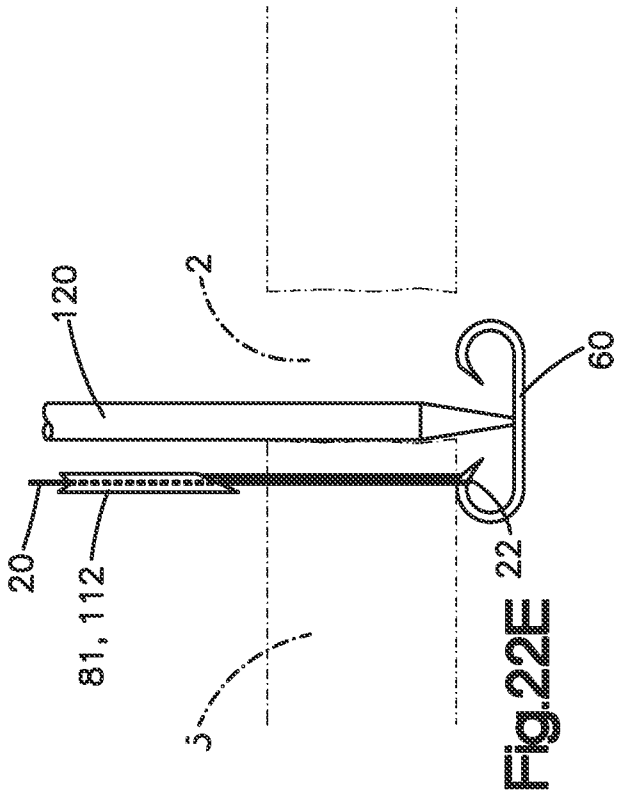

Fig.22E

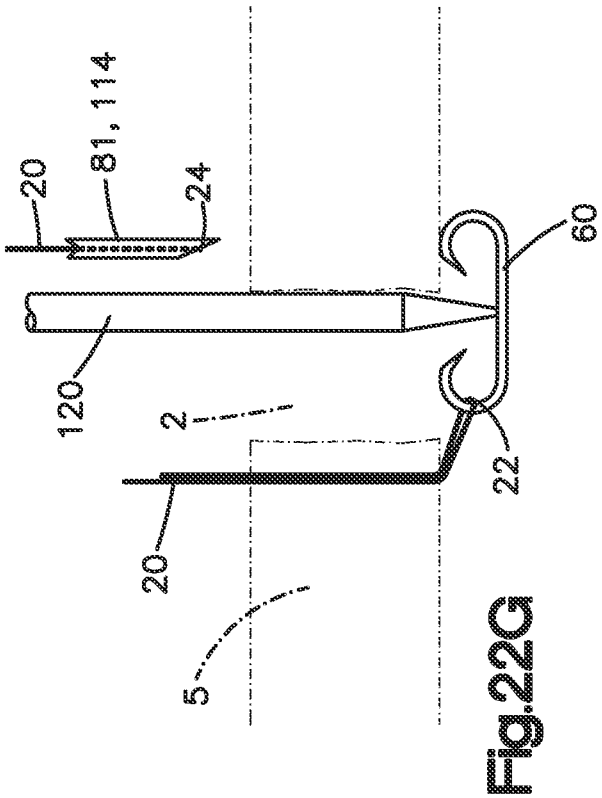

Fig.22G

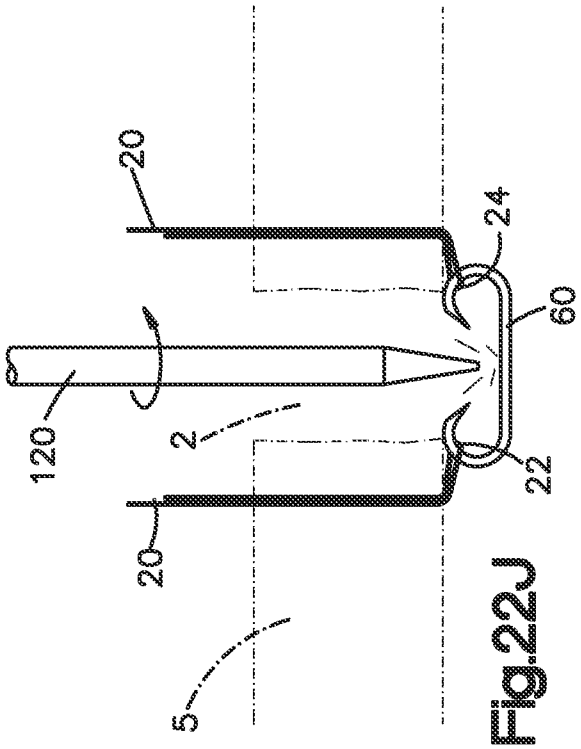

Fig.22J

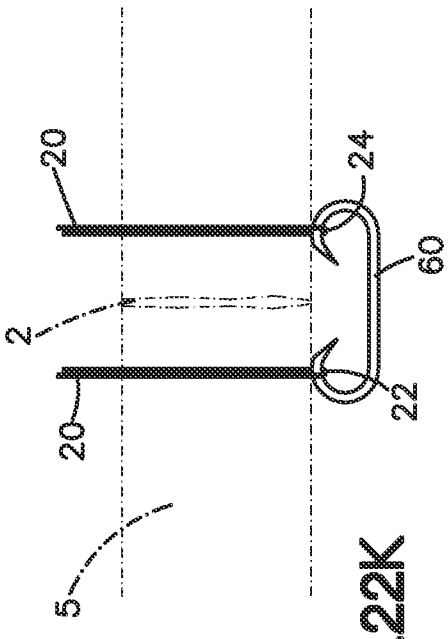

Fig.22K

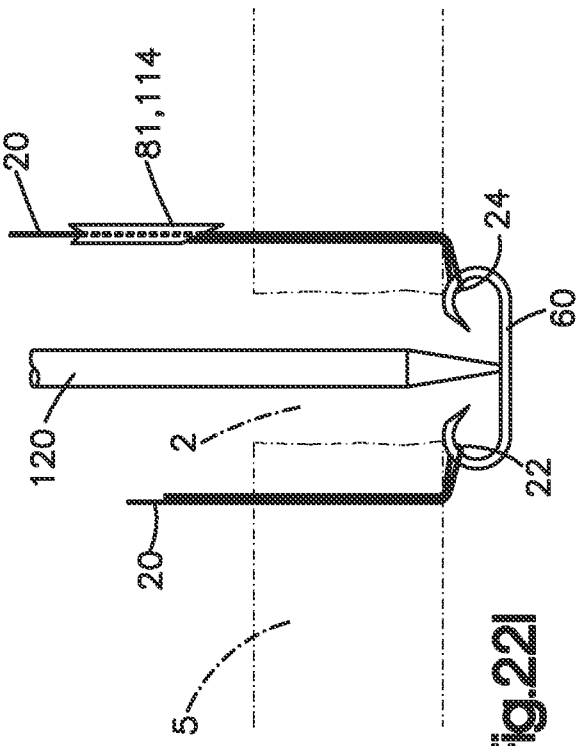

Fig.22I

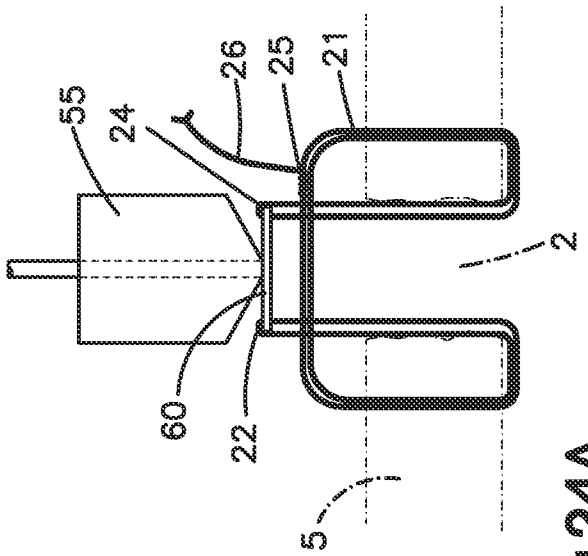

Fig.24A

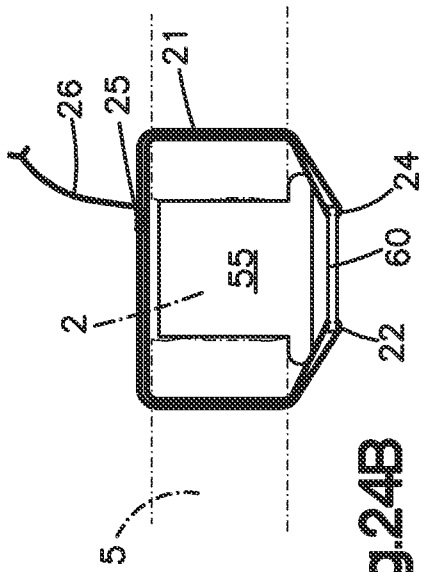

Fig.24B

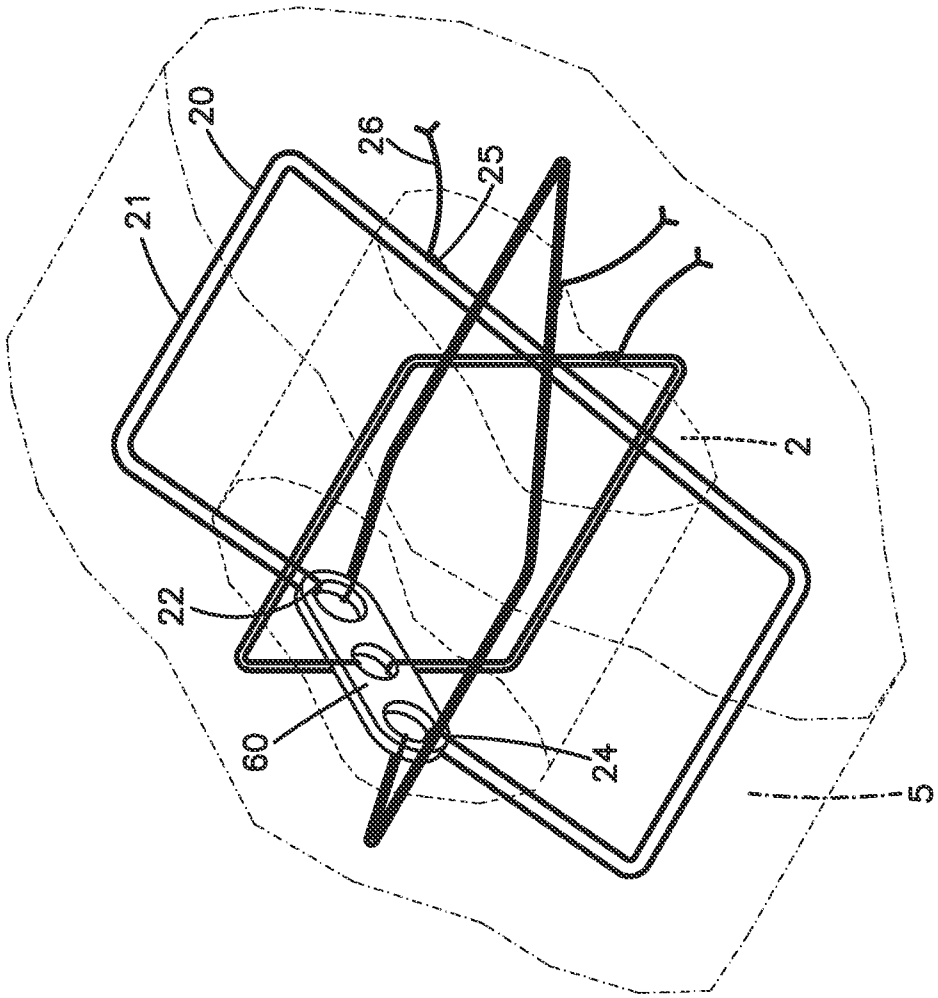

Fig.23

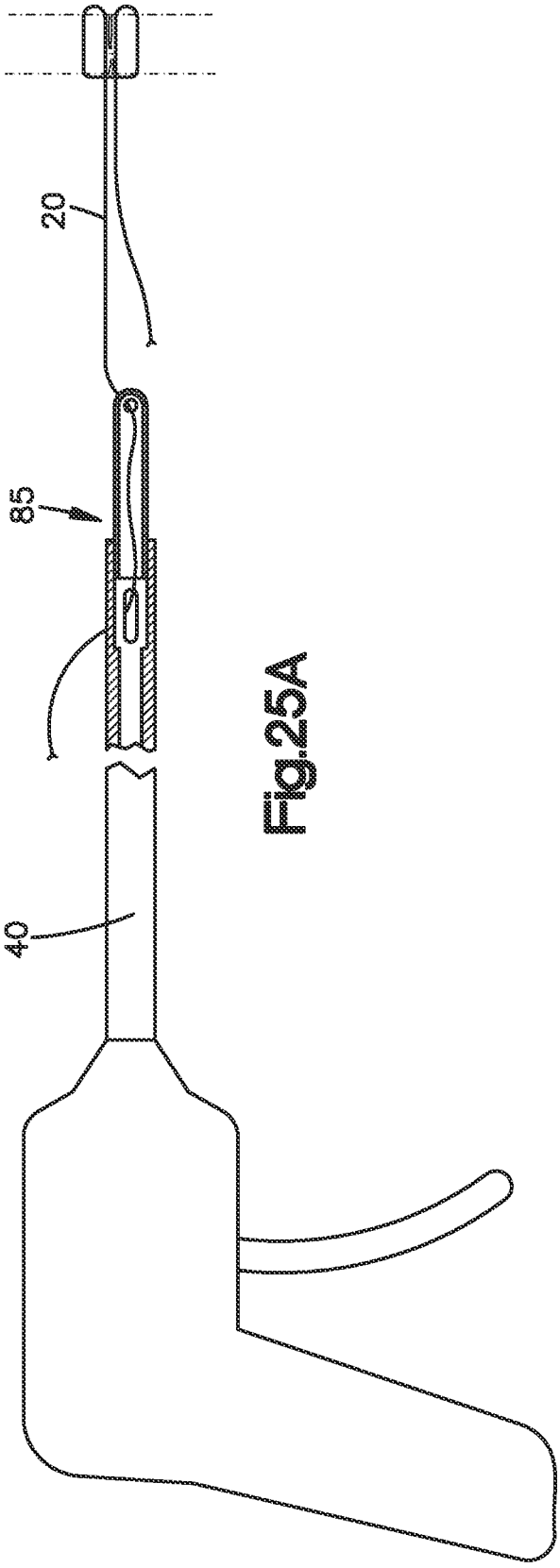

Fig.25A

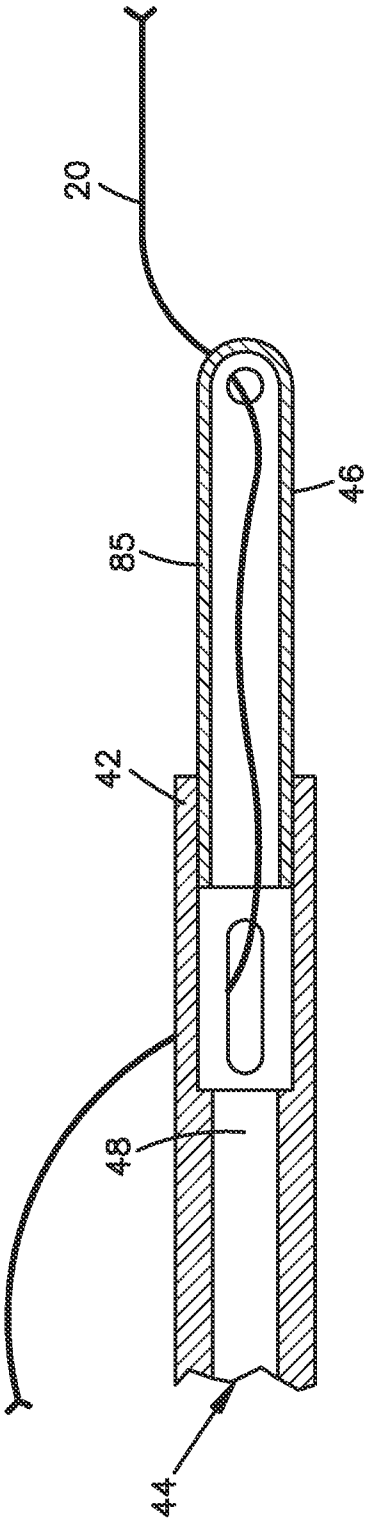

Fig.25B

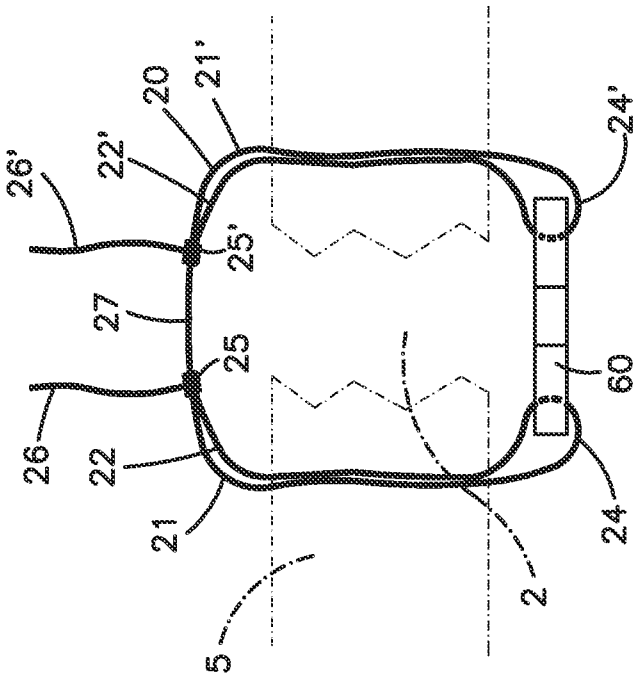

Fig.26

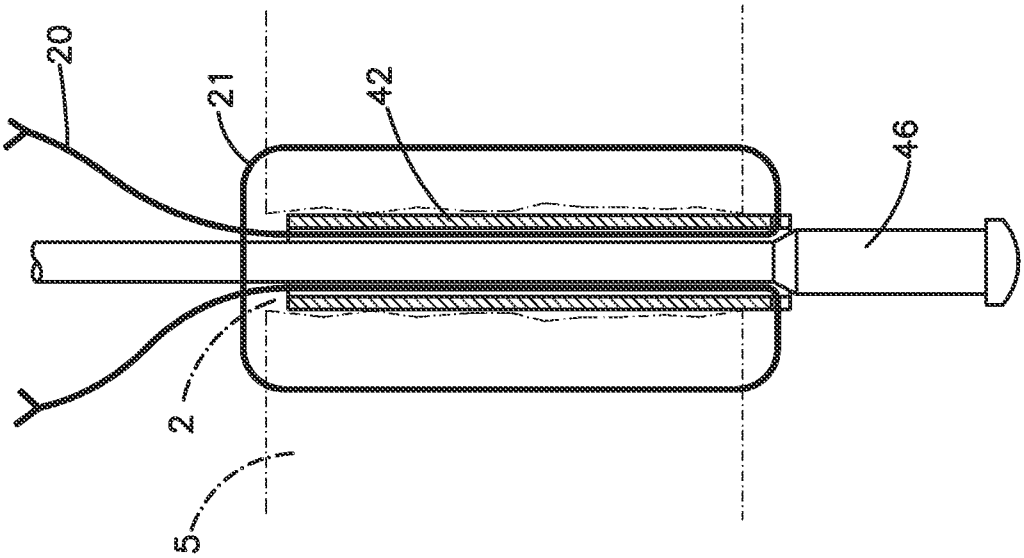

Fig.25D

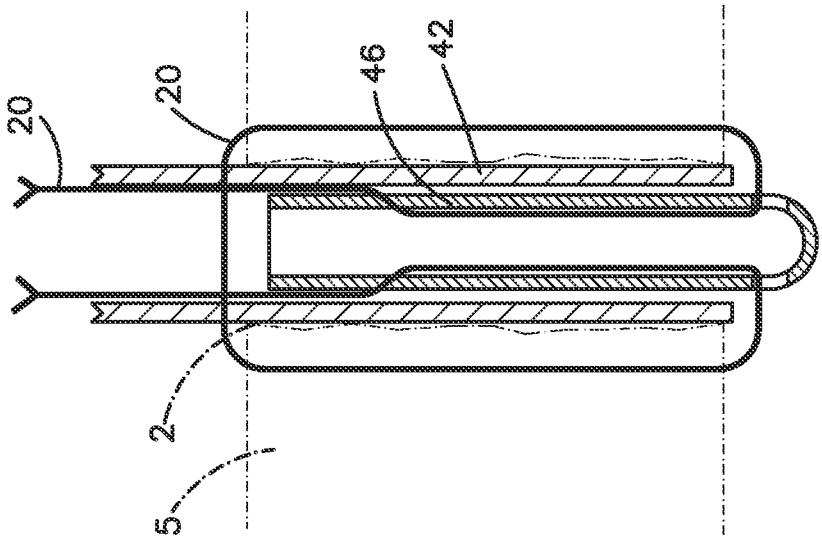

Fig.25C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/046624

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 821 285 B2 (LAUFER ET AL.) 23 November 2004 (2004-11-23) abstract; figures 6B-8 column 7, lines 19-59	1-3,5-7
Y		11,12,17
Y	US 2006/142784 A1 (KONTOS) 29 June 2006 (2006-06-29) paragraph [0092]; figures 7A-11	11
Y	US 2007/100348 A1 (CAUTHEN, III ET AL.) 3 May 2007 (2007-05-03) abstract; figures paragraph [0099]	12,17
X	EP 1 908 408 A (COVIDIEN AG) 9 April 2008 (2008-04-09) the whole document	1,3-10, 13-16

-/--

[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 document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 September 2009	17/09/2009

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	Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/046624

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 568 326 A (DEPUY MITEK, INC.) 31 August 2005 (2005-08-31) abstract; figures	1-3
A	FR 2 717 065 A (CALLAPE) 15 September 1995 (1995-09-15) page 5, line 7 - page 6, column 16; figures	1-3,5,15
P,X	WO 2008/079826 A (OVALIS, INC.) 3 July 2008 (2008-07-03) abstract; figures 8A-8E paragraph [0131]	1,3-10, 13,16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/046624

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.: 18-24
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 allsearchable 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 reportcovers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/046624

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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