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(71) Applicant *(for all designated States except US)*: **ZIMMER SPINE, INC.** [US/US]; 7375 Bush Lake Road, Minneapolis, MN 55439-2029 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **DANT, Jack, A.** [—/US]; 1992 James Avenue, St. Paul, MN 55105-1718 (US).

(74) Agents: **MARKS, Scott, A.** et al.; 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402-3901 (US).

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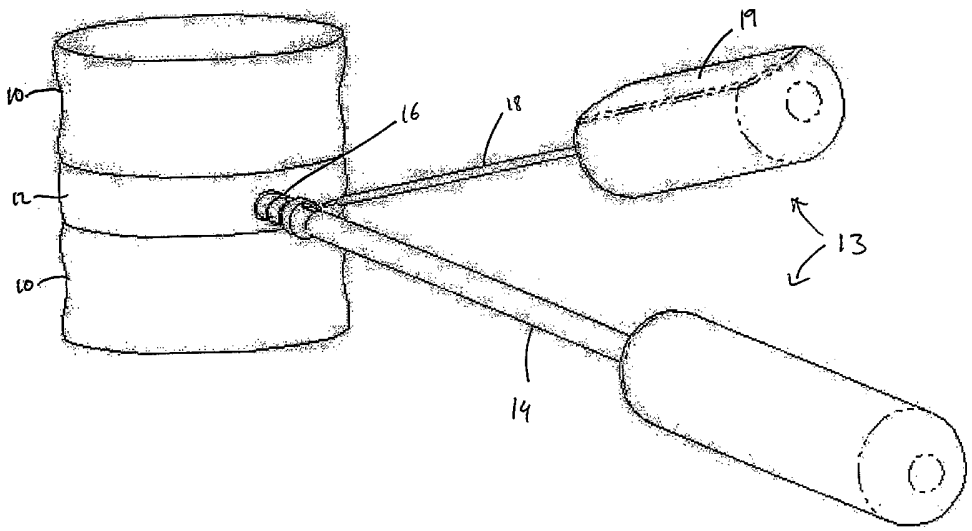
(54) Title: HELICAL SUTURING DEVICE



(57) Abstract: An apparatus for repairing a tear in an annulus fibrosus of a spinal disc (12) includes a hollow, helically-shaped suturing needle (16) and a retriever (18). The needle is used to insert a suture (38) along a helical pathway bridging the tear. The retriever is used to retrieve one end of the suture from the inside of the annulus and bring it close the other end of the suture outside the annulus, where the suture can be tensioned and tied to fixate the tear. In other embodiments, multiple sutures are placed with helically-shaped needles of differing dimensions.

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HELICAL SUTURING DEVICE

TECHNICAL FIELD

[001] The present invention is related to medical devices for suturing. More particularly, it relates to devices for repairing a tear in the annulus fibrosus of a spinal disc.

BACKGROUND

[002] The intervertebral discs are ligaments that connect the vertebrae of the spine together. They provide structural support for the spine and distribute forces exerted on the spinal column. An intervertebral disc consists of three major components: cartilage endplates, nucleus pulposus, and annulus fibrosus. The central portion, nucleus pulposus, is relatively soft and gelatinous, having a consistency similar to that of crabmeat. Surrounding the nucleus is the annulus fibrosus, which has a more rigid consistency and is largely comprised of concentric layers of fibrous tissue. The annular portion serves to provide peripheral mechanical support to the disc, afford torsional resistance, and contain the softer nuclear portion and resist its hydrostatic pressure.

[003] Unfortunately, intervertebral discs are susceptible to injury. Disc herniation occurs when the nucleus begins to extrude through an opening in the annulus, often to the extent that the herniated material impinges on nerve roots in the spine, resulting in pain. One way to address such pain is remove the bulging disk material surgically through a nucleotomy and/or anulotomy, thus relieving pressure on the nerve roots. Further treatment might include the use of intervertebral spacers to reduce the pressure exerted on the disc by the spine. However, very few products are currently available that address the repair of the annulus fibrosus per se. This is true whether the annular tissue has been damaged by herination, or by the creation of surgical access ports in the course of disc repair.

[004] There exists a need for methods and instruments for repair of the annulus fibrosus. Any such methods that are simple and compatible with minimally-invasive surgical techniques would be particularly desirable.

SUMMARY

[005] The present invention, according to one embodiment, is a system for repairing a tear in an annulus fibrosus of a spine. The system includes a substantially helically-shaped suturing needle, a length of suture, and a retriever. The suturing needle is configured to deliver the suture in a helically-shaped path bridging the tear. The retriever is configured to retrieve one end of the suture from the inside of the annulus to the outside, where the two ends of the suture can be tensioned and tied. In other embodiments, multiple systems are used to place multiple sutures.

[006] This summary is not intended to describe each embodiment or every implementation of the present invention. A more complete understanding of the invention will become apparent upon review of the detailed description and listing of embodiments in conjunction with the accompanying drawings. As will be realized, the invention is capable of modifications in various obvious aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[007] Fig. 1 is an illustration of a representative section of human spine having two vertebrae and a disc with a set of tools for suturing the disc according to one embodiment of the present invention.

[008] Fig. 2 is a perspective detail view of the helically-shaped suturing needle and needle handle shown in Fig. 1.

[009] Fig. 3 is a detailed view of the the distal end of the helically-shaped suturing needle shown in Fig. 1 and 2.

[010] Fig. 4 is a flowchart describing a method of repairing an annulus fibrosus according to one embodiment of the present invention.

[011] Fig. 5 illustrates a helically-shaped needle, needle handle, and retriever in relation to each other and a representative disc undergoing repair.

[012] Fig. 6 is a detailed view of the distal ends of the helically-shaped needle and retriever illustrated in Figs. 1-4.

[013] Fig. 7 is a set of detailed views of an alternate distal end for the retriever.

DETAILED DESCRIPTION

[014] The present invention, in one embodiment, is directed to the repair of tears, cuts, voids, or like tissue damage in discs of the spine. Fig. 1 illustrates a simplified representation of a section of spine including two vertebrae 10 between which is seen an annulus fibrosus 12 of a spinal disc. Major components of an apparatus 13 for repairing an annulus 12 are also shown. A needle handle 14 manipulates a helical suturing needle 16 engaged with the annulus 12. A suture retriever 18 is shown above the needle handle 14. The suture retriever 18 has a flat 19 to indicate its rotational orientation.

[015] Fig. 2 is a perspective view of a distal end 20 of the needle handle 14 attached to a helical suturing needle 16. The helical needle 16 can be characterized by a longitudinal depth 22, a diameter 24, and a pitch 26. In one embodiment, the needle 14 is hollow, having a central lumen that communicates with three bores in the needle, a first bore (not shown) at a proximal end (not shown; located in the needle handle 14) of the needle, a second bore 30 at a distal end 32, and a third bore 34 near the distal end. (See Fig. 3 for an enlarged view of the bores 30, 34.) The needle handle 14 also features a retriever guide 36 that facilitates use of the suture retriever 18.

[016] The chosen values of the depth 22, diameter 24, and pitch 26 of a helical suturing needle 16 will vary with the particular injury to be repaired, the location of the disc along the spine, and the particularities of the individual patient. According to one embodiment, the depth 22 of the needle 16 will have a value ranging from about 3mm to about 25mm, the diameter 24 will have a value ranging from about 2mm to about 13mm, or, alternatively, from about 2mm to about 19mm, and the pitch 26 will have a value ranging from about 2mm per turn to about 7mm per turn. According to another embodiment, the needle 16 has a depth 22 of about 11mm and a diameter 24 of about 7mm. According to still another embodiment, the needle 16 has a depth 22 of about 5mm and a diameter 24 of about 3mm.

[017] Fig. 3 is an enlarged perspective view of the distal end 32 of the helical needle 16. Prior to use, a length of suture 38 is loaded in the helical needle 16

such that it runs from the first bore (not shown) up the needle to the second bore 30, exits the needle there and reenters the needle at the third bore 34, whereupon it runs down the needle back to the first bore. The suture 38 may be loaded during the manufacturing of the helical needle 16 or may be inserted by the surgeon using a push rod (now shown) or some other method of passing the suture 38 through the helical needle 16. In this configuration, both a first end 40 and a second end 42 of the suture 38 extend out of the first bore of the helical needle near the distal end 20 of the needle handle 14, where they can be manipulated by a surgeon (see Fig. 2). The second 30 and third 34 bores of the helical needle hold the suture 38 such that a capturable segment 44 of the suture is formed.

[018] A method 50 for using the present invention according to one embodiment to repair an annulus fibrosus 12 is summarized in the flowchart of Fig. 4. The method may be better understood by referring also to Fig. 5, which illustrates the situation mid-way through the procedure at block 56, and Fig. 6, an enlarged view of the distal ends (32, 46) of the helical needle 16 and suture retriever 18, along with this description.

[019] Standard surgical techniques are used to gain access to the annulus fibrosus 12, and if necessary, a nucleotomy and/or an anulotomy are performed to remove bulging disc tissue (block 52). Any appropriate conventional or otherwise known techniques can be used for these purposes. A surgeon inserts a helical suturing needle 16, preloaded with suture 38, along a tear (not shown for clarity) in the manner of a corkscrew by rotating the needle handle 14 such that the helix is centered on the tear and the needle penetrates tissue along opposing sides of the tear (block 54). The insertion is continued until the distal end 32 of the needle 16 reaches an interior region 70 of the annulus fibrosus 12.

[020] After the insertion of the needle 16, the suture retriever 18 is advanced into the annulus 12 (block 56), guided by the retriever guide 36 of the needle handle 14. During this step, the surgeon holds the first 40 and second 42 ends of the suture 38 taut to maintain the capturable segment 44 in a well-defined position relative to the needle 16 and handle 14. The retriever 18 and guide 36 are tightly toleranced such that the distal end 46 of the suture retriever 18 is reliably brought to the capturable segment 44. A hook 48 at the distal end 46 of the retriever 18 captures the capturable segment 44 (block 58).

[021] To aid in this capture process, in some embodiments, the retriever 18 and guide 36 include corresponding structures to stop the motion of the retriever in the distal direction once the distal end 46 of the retriever reaches the capturable segment 44. Also in some embodiments, the retriever 18 and guide 36 include corresponding structures to restrict the rotational orientation of the retriever relative to the needle handle 14 and helical suturing needle 16.

[022] In another embodiment of the present invention, illustrated in Fig. 7, a suture retriever 18' has double opposing hooks 74 for capturing the suture at its distal end 46'. In this version, the retriever 18' is advanced so that the suture 38 fully enters the slot 72. The surgeon then rotates the retriever 18' about 90 degrees and withdraws it. The hooks 74 ensure that the suture 38 remains captured during the withdrawal.

[023] Following capture of the suture 38, the surgeon releases the first end 40 of the suture while maintaining a grip on the second end 42. Then he or she withdraws the retriever 18, which pulls the first end 40 of the suture 38 out of the annulus fibrosus 12 along the interior of the helical pathway defined by the suturing needle 16 (block 60). The surgeon then grips the first end 40, releases the second end 42, and retracts the helical suturing needle 16 in a reverse screwing motion, leaving suture 38 along its path (block 62).

[024] With the helical needle 16 completely removed from the annulus fibrosus 12, the suture 38 remaining in the needle is freed by further withdrawal of the needle, or alternately the suture is simply cut between the needle and the annulus. The surgeon starts tying the suture 38 with an overhand knot, carefully applies tension to draw the tear of the annulus 12 together, completes the knot as per standard surgical technique, and cuts off the excess suture (block 64).

[025] While the preceding method describes repair of a tear in an annulus fibrosus oriented in a predominantly radial direction, the present invention may also be used to repair tears with other orientations, such as parallel to the outer surface of an annulus. Furthermore, the present invention may be usefully employed in other anatomies as well.

[026] The present invention leaves only suture as the final implanted material. Suture is equally distributed over the entire depth of the tear, and acts to

close the tear from all directions. The present invention offers improved resistance to recurrence of herniation over prior suturing methods.

[027] In other embodiments of the present invention, the above described procedure is performed more than once on the same tissue, with different helical suture needles 16, and hence, different paths for the sutures 38, potentially resulting in more secure fixation. For example, two sutures 38 may be concentrically placed with two diameters 24 of needles 16. Alternately, two sutures 38 may be placed with two needles 16 of identical dimensions 22, 24, 26 but having differing right- and left-handed helical shapes. In these embodiments, associated sets of sutures 38 and tools 14, 18 may be given corresponding visual appearances (e.g., colors) to assist surgeons with identification.

[028] In yet other embodiments of the present invention, the suture material includes a bioactive material. The bioactive material may be used to deliver a drug therapy. It may include antibiotic and/or antiviral medications. It may include drugs that promote regenerative growth of the tissues of the annulus fibrosus or other tissues. It may include cultured cells to enhance the healing process.

[029] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the disclosure, together with all equivalents thereof.

CLAIMS

1. An apparatus for fixation of a soft tissue tear comprising:

a length of flexible material having a first end and a second end;

a substantially helically-shaped needle including a plurality of helical loops between a distal end and a proximal end, the loops defining an interior region and an exterior region, the needle further adapted for forming a capturable segment of the flexible material at or near its distal end; and

a retriever including a distal end configured for capturing the capturable segment of the flexible material.

2. The apparatus of claim 1 wherein the soft tissue tear includes a tear in an annulus fibrosus.

3. The apparatus of claim 1 wherein the length of flexible material is suture material.

4. The apparatus of claim 1 wherein the length of flexible material includes bioactive material.

5. The apparatus of claim 1 wherein the needle further comprises:

a lumen extending substantially from the distal end to the proximal end; and

three bores communicating with the lumen, a first bore at or near the proximal end, a second bore at or near the distal end, and a third bore between the first and second bores and essentially adjacent to the second bore.

6. The apparatus of claim 5 wherein the flexible material enters the lumen of the needle at the first bore, extends within the lumen from the first bore to the second bore, exits the needle at the second bore, reenters the lumen at the third bore, further extends within the lumen to the first bore, and exits the needle at the first bore, arranged so that both the first and second ends of the flexible material protrude from the first bore at or near the proximal end of the needle, and when the first and

second ends of the flexible material are held taut, the second and third bores of the needle support the capturable segment of the flexible material.

7. The apparatus of claim 1 wherein the retriever further comprises an elongated rod having a distal end and a proximal end.

8. The apparatus of claim 1 wherein the retriever includes a hook at or near the distal end of the retriever.

9. The apparatus of claim 1 wherein the retriever includes double opposing hooks at or near the distal end of the retriever.

10. The apparatus of claim 7 further comprising a needle handle, the needle handle fitted to the proximal end of the needle and having a retriever guide slidably connectable to the retriever and formed to constrain the motion of that the distal end of the elongated rod of the retriever along a path within the interior region of the helical loops of the needle up to a point at or near the distal end of the needle, where the distal end of the retriever may capture the capturable segment of the flexible material.

11. The apparatus of claim 10 wherein the retriever guide and retriever include corresponding structures to prevent the distal end of the retriever from sliding beyond the distal end of the needle.

12. The apparatus of claim 10 wherein the retriever guide and retriever include corresponding structures to restrict the possible rotational orientations of the retriever relative to the retriever handle.

13. The apparatus of claim 1 wherein the retriever includes a structure marking its rotational orientation.

14. The apparatus of claim 1 wherein the helically-shaped needle has a longitudinal depth ranging from about 3mm to about 25mm.

15. The apparatus of claim 1 wherein the helically-shaped needle has a longitudinal depth of about 5mm.

16. The apparatus of claim 1 wherein the helically-shaped needle has a longitudinal depth of about 11mm.

17. The apparatus of claim 1 wherein the helically-shaped needle has a diameter of the helical shape ranging from about 2mm to about 13mm.

18. The apparatus of claim 1 wherein the helically-shaped needle has a diameter of about 3mm.

19. The apparatus of claim 1 wherein the helically-shaped needle has a diameter of about 7mm.

20. The apparatus of claim 1 wherein the helically-shaped needle has a pitch of the helical shape ranging from about 2mm per turn to about 7mm per turn.

21. The apparatus of claim 1 wherein the needle forms a right-handed helical shape.

22. The apparatus of claim 1 wherein the needle forms a left-handed helical shape.

23. The apparatus of claim 1 wherein the flexible material has a distinctive visual appearance.

24. The apparatus of claim 10 wherein the needle handle has a distinctive visual appearance corresponding to the longitudinal depth, diameter, pitch, and handedness of the needle; and

the retriever further includes a handle having a distinctive visual appearance corresponding to the needle handle to which it is associated.

25. An apparatus for fixation of a soft tissue tear comprising:

a substantially helically-shaped suturing needle including:

a plurality of helical loops between a distal end and a proximal end, the loops defining an interior region and an exterior region, dimensioned such that when the needle is inserted in the manner of a corkscrew along the tissue tear, at least some of the loops will bridge the tear and the majority of the tear will reside in the interior region of the helical loops;

a lumen extending substantially from the distal end to the proximal end; and

three bores communicating with the lumen, a first bore at or near the proximal end, a second bore at or near the distal end, and a third bore between the first and second bores and essentially adjacent to the second bore;

a length of suture material having a first end and a second end, the suture material positioned so that it enters the lumen of the needle at the first bore, extends within the lumen from the first bore to the second bore, exits the needle at the second bore, reenters the lumen at the third bore, further extends within the lumen to the first bore, and exits the needle at the first bore, arranged so that both the first and the second ends of the suture material protrude from the first bore at or near the proximal end of the needle, and when the first and second ends of the suture material are held taut, the second and third bores of the needle support a capturable segment of the suture material;

a retriever comprising an elongated rod including a distal end and a proximal end, the distal end having a hook capable of capturing the capturable segment of the suture material; and

a needle handle fitted to the proximal end of the needle, the needle handle having a retriever guide, the retriever guide slidably connectable to the retriever and formed to constrain the motion of the distal end of the elongated rod of the retriever along a path within the interior region of the helical loops of the needle up to a point at or near the distal end of the needle, where the hook of the rod of the retriever may capture the capturable segment of the suture material.

26. A method of repairing a soft tissue tear comprising:

inserting a helically-shaped needle containing a suture along the soft tissue tear, the suture protruding from a portion of the helically-shaped needle;

advancing a retriever into the soft tissue tear and through an interior region of the helically-shaped needle;

capturing the protruding portion of the suture with the retriever;

withdrawing the retriever with the protuding portion of the suture;

withdrawing the helically-shaped needle;

exerting a desired tension on the suture; and

tying the suture.

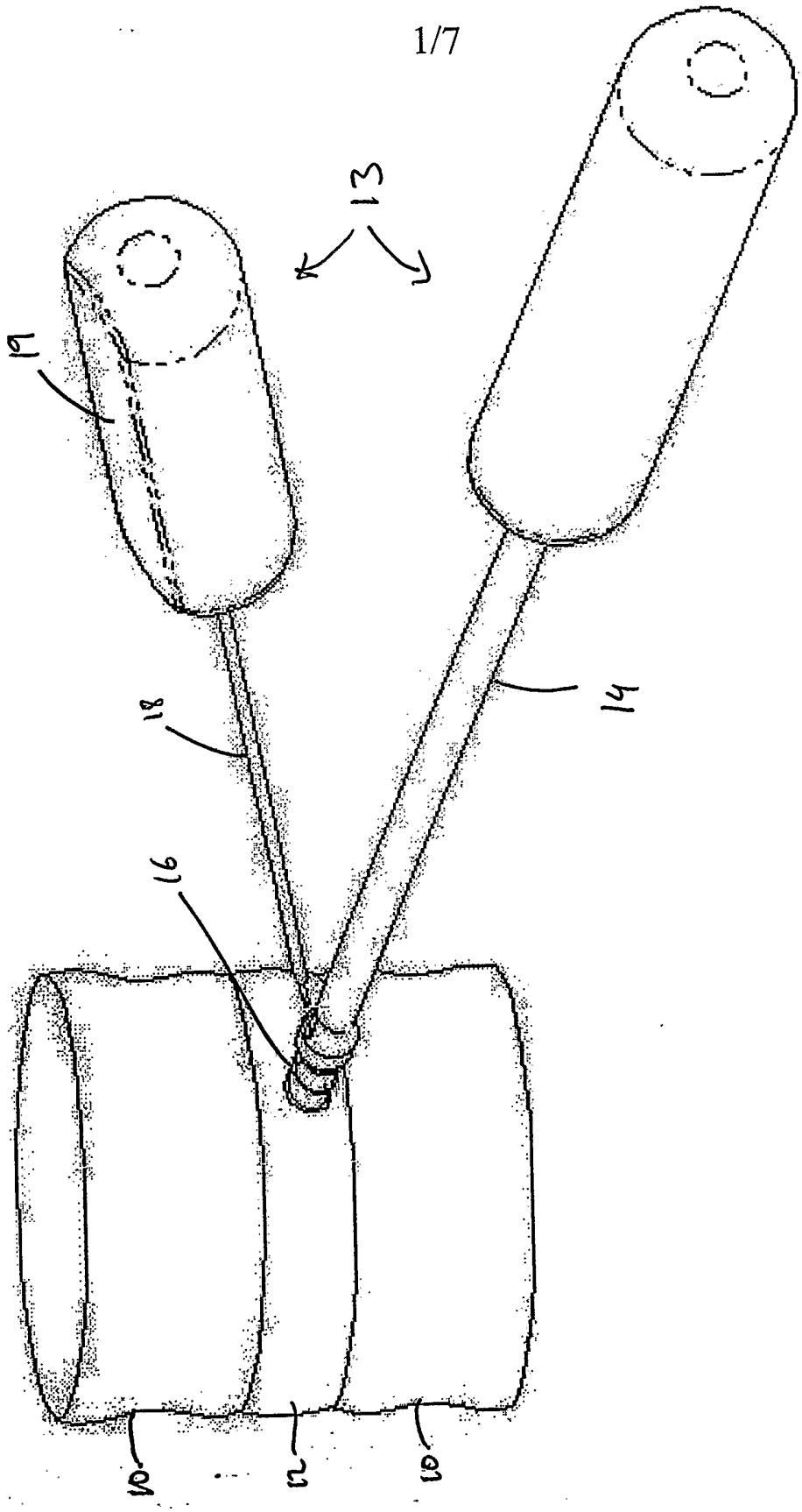


Fig. 1

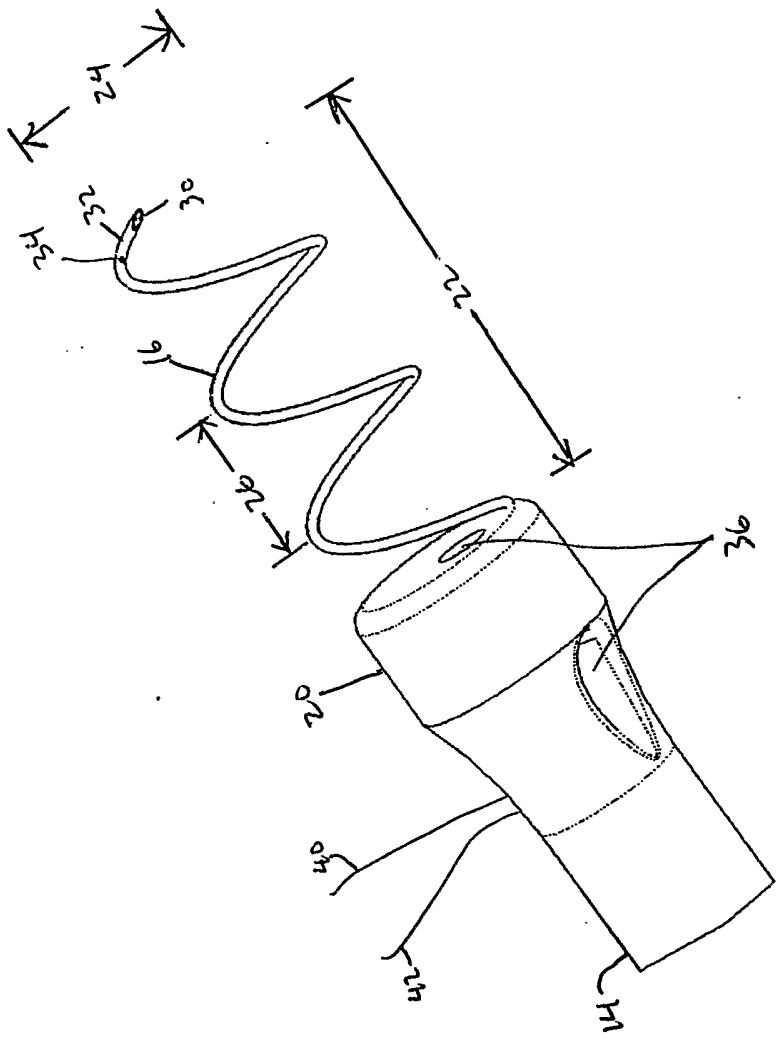


Fig. 2

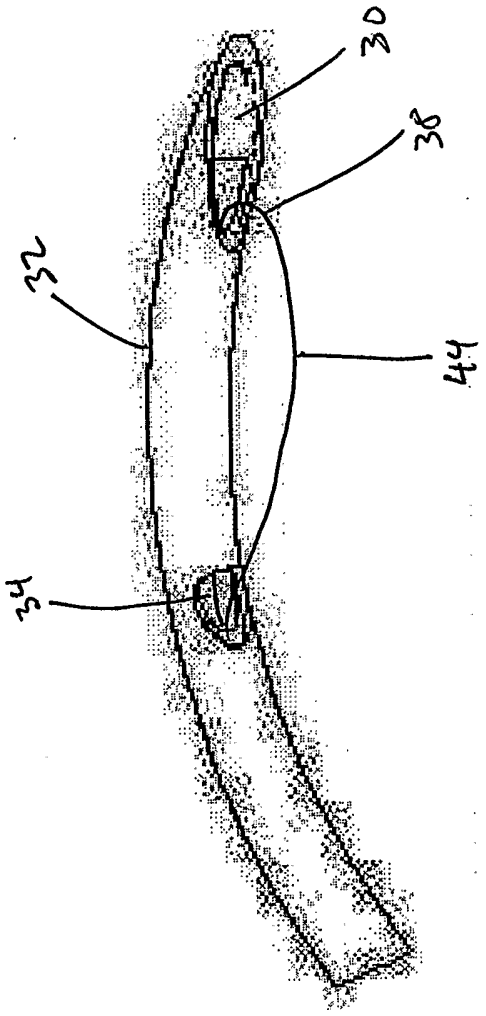


Fig. 3

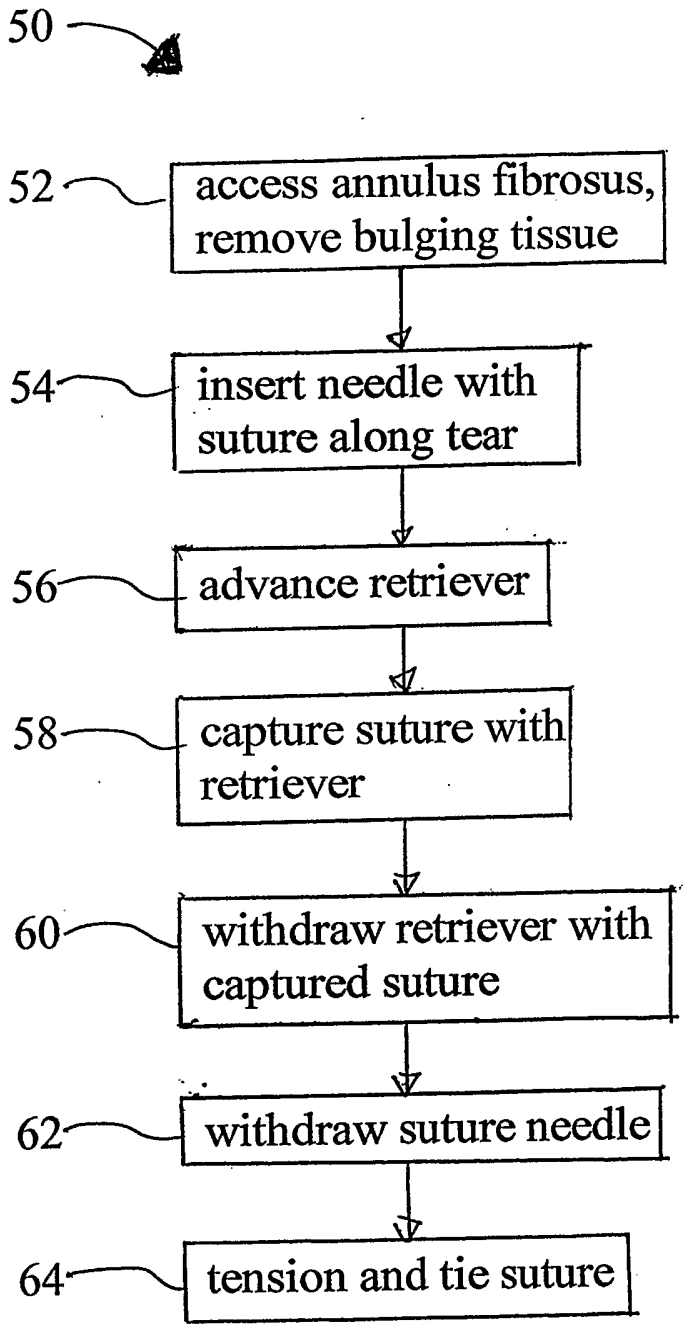

50
52
access annulus fibrosus, remove bulging tissue
54
insert needle with suture along tear
56
advance retriever
58
capture suture with retriever
60
withdraw retriever with captured suture
62
withdraw suture needle
64
tension and tie suture

Fig. 4

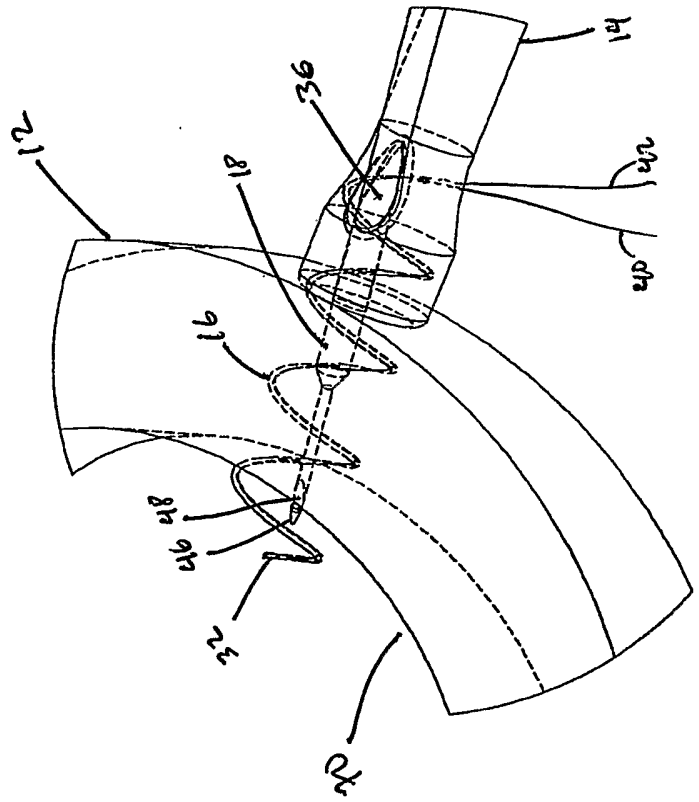


Fig. 5

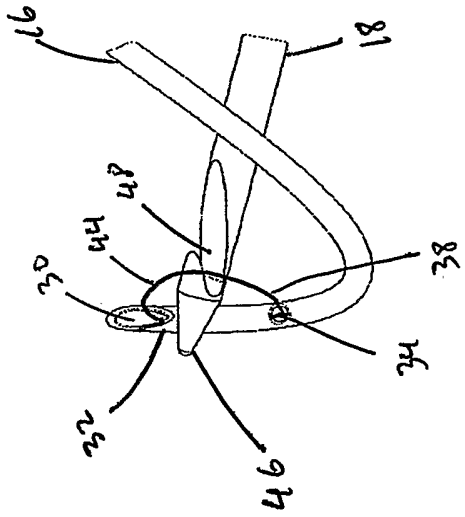
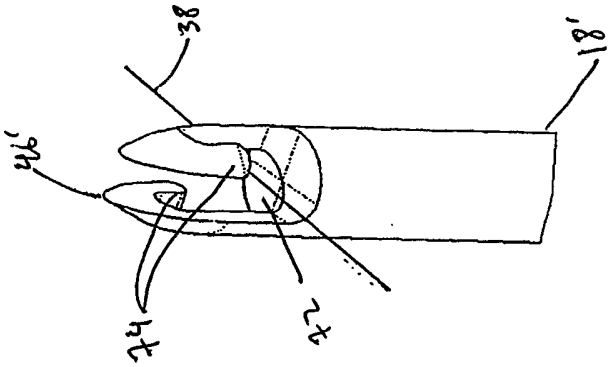
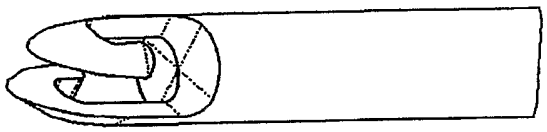


Fig. 6





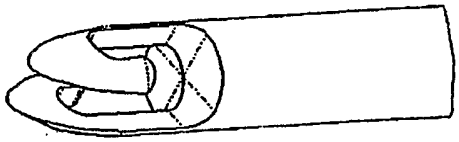


Fig. 7

INTERNATIONAL SEARCH REPORT

PCT/US2005/028442

A. CLASSIFICATION OF SUBJECT MATTER
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 5 709 692 A (MOLLENAUER ET AL) 20 January 1998 (1998-01-20)	1-3,6-24
Y	column 1, line 10 - line 11 column 4, line 54 - column 5, line 26 column 6, line 1 - line 13 column 8, line 23 - line 24 column 10, line 12 - line 26	4
A	figures 1,4,6,9-11,13	5,25
Y	EP 0 557 894 A (ETHICON INC) 1 September 1993 (1993-09-01) page 2, lines 3,4 page 5, lines 25,26	4

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

[X] Patent family members are listed in 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
30 November 2005	15/12/2005

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Louka, M

INTERNATIONAL SEARCH REPORT

PCT/US2005/028442

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 152 769 A (BABER ET AL) 6 October 1992 (1992-10-06) column 3, lines 24-55 figures 4,8,10,15	1,3,5,7, 8,10,11, 25
A	WO 03/099137 A (NDO SURGICAL, INC; CERIER, JEFFREY, C; CRUZ, AMOS; O'KEEFE, JONATHAN;) 4 December 2003 (2003-12-04) figures 12a,12b,12d,14a,14b page 21, line 21 - line 25 page 23, line 14 - line 29	1,9,10, 25
A	US 2002/007218 A1 (CAUTHEN JOSEPH C) 17 January 2002 (2002-01-17) page 2, paragraph 30-33	1,2
A	US 6 626 917 B1 (CRAIG H. RANDALL) 30 September 2003 (2003-09-30) figures 2a,2b	1,25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/028442

Box 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.: 26
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 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 fee, this Authority did not invite payment of any additional fee.

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.

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

INTERNATIONAL SEARCH REPORT

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