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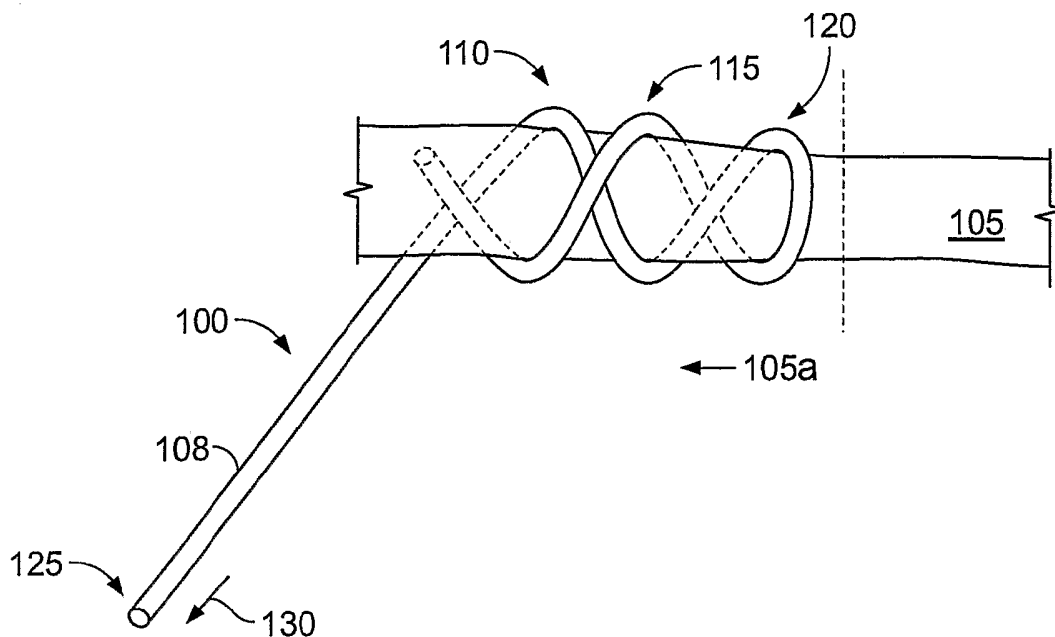
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[Continued on next page]

(54) Title: MEDICAL TISSUE FIXATION DEVICE COMPRISING SUTURE LOOPS



(57) Abstract: A medical device that attaches to tissue without requiring stitching includes a tissue fixation device (100) having a first sub-loop (110) and a second sub-loop (115), and an assisting member (705) disposed through the first sub-loop and through the second sub-loop. The tissue fixation device includes, for example, an adjustable, flexible member formed by inserting one end portion of the flexible member through another end portion of the flexible member, and first and second sub-loops formed by crossing a portion of the flexible member over a different portion of the flexible member.

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TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW,*

BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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MEDICAL TISSUE FIXATION DEVICE COMPRISING SUTURE LOOPS

TECHNICAL FIELD

This invention relates to medical devices, and more particularly to a fixation device.

BACKGROUND

5 To perform a surgical repair, e.g., of a torn anterior cruciate ligament ("ACL"), the surgeon typically connects a length of suture to the replacement ACL soft tissue graft. The suture enables the surgeon to pull the tissue graft through holes formed in the tibia and femur for receiving the tissue graft. Typically, the surgeon attaches the suture to the ACL soft tissue graft using a whipstitch. Stitching the suture to the tissue graft using a whipstitch usually takes over
10 two minutes per tissue graft.

SUMMARY

This invention relates to a fixation device that attaches to a tissue graft without requiring stitching. One advantage is that the time it takes for the surgeon to attach the fixation device to the tissue graft is shorter than the time it takes to whipstitch a suture to the tissue graft. In one
15 aspect, there is a medical device (e.g., tissue fixation device) that includes a member having a first sub-loop and a second sub-loop, where each sub-loop is configured to receive a length of tissue therethrough. In another aspect, there is a medical device including an adjustable loop and an assisting member. The adjustable loop includes a first sub-loop and a second sub-loop configured to receive a length of tissue therethrough. The assisting member is disposed through
20 the first sub-loop and through the second sub-loop. In yet another aspect, there is a medical device including an adjustable, flexible member. The adjustable, flexible member is formed by inserting one end portion of the flexible member through another end portion of the flexible member. The adjustable member is further formed into a first sub-loop and a second sub-loop. Crossing a portion of the flexible member over a different portion of the flexible member forms
25 the first sub-loop and the second sub-loop. The first sub-loop and the second sub-loop are configured to fixate onto tissue. In another aspect, there is a medical device that includes a plurality of adjustable suture members and a cannula. In the plurality of adjustable suture

members, each member includes a first sub-loop, a second sub-loop, and a third sub-loop, where each sub-loop is configured to receive a length of tissue therethrough. The cannula is disposed through the sub-loops of each of the plurality of adjustable suture members.

In other embodiments, the medical device can include one or more of the following
5 features:

The member includes suture. The member further includes a third sub-loop configured to receive a length of tissue therethrough. The medical device includes an assisting member disposed through the first sub-loop and through the second sub-loop. The assisting member includes a medical grasping device. The assisting member comprises a cannula. The member is
10 a first member, where the medical device also includes a second adjustable member including a first sub-loop and a second sub-loop. The assisting member is further disposed through the first sub-loop of the second adjustable tissue fixation device and through the second sub-loop of the second adjustable tissue fixation device. The member is an adjustable member formed by inserting one end portion of the adjustable member through another end portion of the adjustable
15 member. The adjustable member is further formed into a first sub-loop and a second sub-loop. Crossing a portion of the adjustable member over a different portion of the adjustable member forms the first sub-loop and the second sub-loop. The first sub-loop and the second sub-loop are configured to fixate onto tissue. In other examples, the sub-loops are configured to fixate on ligament or tendon tissue.

In another aspect, there is a method for making a medical device. The method includes
20 inserting one end portion of a flexible member through another end portion of the flexible member to form an adjustable loop. The method further includes locating a first portion of the adjustable loop over a second portion of the adjustable loop to form a first sub-loop and a second sub-loop, where the sub-loops configured to receive a length of tissue.

In one example, the method also includes locating a first portion of the second sub-loop
25 over a second portion of the second sub-loop to form a third sub-loop. In another example, the flexible member comprises suture. In another example, the method also includes locating further comprises rotating a portion of the adjustable loop approximately 180 degrees of rotation. In

another example, the method also includes sliding the first portion of the adjustable loop over the second portion of the adjustable loop to form a first sub-loop and a second sub-loop.

In yet another example, the method also includes locating a first portion of an assisting member within the first sub-loop and a second portion of the assisting member within the second sub-loop. In one example, the assisting member includes a medical grasping device. In another example, the assisting member comprises a cannula. In another example, the flexible member is a first flexible member. In this example, the method also includes inserting one end portion of a second flexible member through another end portion of the second flexible member to form a second adjustable loop, locating a first portion of the second adjustable loop over a second portion of the second adjustable loop to form a first sub-loop and a second sub-loop and locating a fourth portion of the assisting member within the first sub-loop of the second flexible member and a fifth portion of the assisting member within the second sub-loop of the second flexible member.

In another aspect, there is a method for attaching a fixation device to tissue. The method includes moving a first sub-loop and a second sub-loop of the fixation device over a portion of the tissue and pulling an end portion of the fixation device to reduce the size of the sub-loops to fixate the fixation device to the portion of the tissue. In one example, the method also includes moving a third sub-loop over the portion of tissue. In another example, the method also includes grasping tissue with an assisting member located within the first and second sub-loops. In another example, the method also includes sliding the first sub-loop and the second sub-loop off of the assisting member. In another example, the fixation device comprises suture. In another example, the tissue comprises ligament or tendon graft.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1 is a side view of a fixation device connected to tissue.

FIG. 2 is a side view of an adjustable loop.

FIG. 3 is a perspective view of the adjustable loop.

5 FIG. 4 is a side view of two sub-loops formed from the adjustable loop.

FIG. 5 is a side view of three sub-loops formed from the adjustable loop to produce the fixation device.

FIG. 6 is a side view of an alternative embodiment of three sub-loops formed from the adjustable loop of FIG. 2 to produce the fixation device.

10 FIG. 7A is a side view of the fixation device over a cannula.

FIG. 7B is a side view of a plurality of fixation devices over a cannula.

FIG. 8 is a side view of the fixation device over a cannula being used with a medical grasping device.

FIG. 9 is a side view of the fixation device over a medical grasping device.

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DETAILED DESCRIPTION

Referring to FIG. 1, a fixation device 100 includes a length of flexible material, e.g., a suture 108 formed into a first sub-loop 110, a second sub-loop 115, and a third sub-loop 120. As described in more detail below, sub-loops 110, 115, and 120 are formed and wrapped around tissue 105 such that when a surgeon pulls an end 125 of suture 108 in a direction indicated by arrow 130, sub-loops 110, 115, and 120 constrict around and thus fixate on a portion 105a of tissue 105. This allows the surgeon to pull tissue 105 by pulling end 125 of fixation device 100 and provides a limitless gripping force in that as the tension applied to 125 increases, the constriction of the loops around tissue 105 increases. In other words, the harder the surgeon pulls, the tighter sub-loops 110, 115, and 120 constrict around portion 105a of tissue 105. Tissue

105 includes, for example, a replacement ligament or tendon. Suture 108 includes, for example, medical grade suture suitable for use in a surgical procedure.

Referring to FIGS. 2 and 3, fixation device 100 is constructed by initially forming suture 108 into an adjustable loop 205. Adjustable loop 205 is formed by passing end 125 of suture 108 through an opposite end 210 of suture 108. For example, suture end 125 is pushed through end 210 such that portions 108a and 108b of suture end 210 define a hole 305. Alternatively, hole 305 is preformed in suture end 210 and suture end 125 is passed through the hole. As constructed, suture 108 easily slides through hole 305 to increase or decrease the size of adjustable loop 205. This mechanism also allows the surgeon to increase and decrease the size of any sub-loops formed from adjustable loop 205 when the surgeon pulls on end 125.

Referring to FIG. 4, rotating adjustable loop 205 one-half turn, approximately 180 degrees, around an axis 400 generates sub-loops 110 and 115. As illustrated, the rotation is in a direction indicated by arrow 405. This rotation causes a first portion 410 of adjustable loop 205 to cross and overlap a second portion 415 of adjustable loop 205. The overlapping portions 410 and 415 define part of the boundaries of sub-loops 110 and 115. Axis 400 also represents how tissue 105 (FIG. 1) passes through sub-loops 110 and 115. As illustrated, tissue 105 goes into the center of second sub-loop 115, under (with respect to the illustrated viewing angle) overlapping portions 410 and 415, and out of the center of the first sub-loop 110.

Referring to FIG. 5, rotating sub-loop 115 another one-half turn, approximately 180 degrees, around axis 400 generates the third sub-loop 120. This rotation causes a third portion 510 of adjustable loop 205 to cross and overlap a fourth portion 515 of adjustable loop 205. The overlapping portions 510 and 515 define part of the boundaries of sub-loops 115 and 120. Axis 400 also represents how tissue 105 (FIG. 1) passes through sub-loops 110, 115 and 120. As illustrated, tissue 105 goes into the center of third sub-loop 120 and over (with respect to the illustrated viewing angle) overlapping portions 510 and 515. Tissue 105 also goes into the center of second sub-loop 115, under (with respect to the illustrated viewing angle) overlapping portions 410 and 415, and out of the center of the first sub-loop 110. This process can be repeated multiple times to generate multiple sub-loops from adjustable loop 205. An advantage

to having three sub-loops over two sub-loops, as depicted in FIG. 4, is that additional loops provide greater tissue to suture purchase, along with greater capacity for load distribution.

Rotating adjustable loop 205, or a portion thereof, is one way to generate sub-loops 110, 115, and 120. There are, however, other processes to generate sub-loops 110, 115, and 120. FIG. 6 illustrates one of those alternative processes to generate sub-loops 110, 115, and 120. As illustrated in FIG. 6, starting with the adjustable loop 205 of FIG. 2, one side of adjustable loop 205 is moved in the direction of arrow 605 while an opposite side of adjustable loop 205 is moved in the direction of arrow 610. The moving sides eventually overlap at portions 410, 415, 510, and 515, generating sub-loops 110, 115, and 120. In this process, unlike the rotation process illustrated in FIG. 5, fourth portion 515 of adjustable loop 205 crosses and overlaps third portion 510 of adjustable loop 205 (with respect to the illustrated viewing angle).

Referring to FIG. 7A, to aid in positioning sub-loops 110, 115, and 120 around tissue 105, a device, e.g., 705 is placed through sub-loops 110, 115, and 120 along axis 400. Referring to FIG. 7B, cannula 705 can include a plurality of fixation devices 100 and 100'. In another example (not shown), cannula 705 includes four fixation devices 100.

Referring to FIG. 8, to transfer fixation device 100 from cannula 705 onto tissue 105, a surgeon uses a grasping device 805, inserted through cannula 705, to grasp tissue 105. With tissue 105 located at an end 810 of cannula 705, the surgeon manually slides sub-loops 110, 115, and 120 in a direction indicated by arrow 815. Sub-loops 110, 115, and 120 slide off of cannula 705 and onto tissue 105. As illustrated, fixation device 100 slides off of cannula 705, onto grasping device 805 and then onto tissue 105.

In an alternative example, the surgeon can locate end 810 of cannula 705 directly over tissue 105 so that when fixation device 100 slides off of cannula 705, it falls directly onto tissue 105. In yet another alternative example, with a plurality of fixation devices 100 located on cannula 705, after attaching a first fixation device to tissue 105, the surgeon grasps another piece of tissue and slides second fixation device onto the other piece of tissue without the need to reload a fixation device between attachments.

Referring to FIG. 9, cannula 705 can be eliminated and the fixation device 100 located directly on the grasping device 805. Like FIG. 8, the surgeon slides sub-loops 110, 115, and 120 in a direction indicated by arrow 815. Sub-loops 110, 115, and 120 slide off of grasping device 805 and onto tissue 105.

5 In use, fixation device 100 allows a surgeon to easily fix suture 108 to tissue 105 so the surgeon can manipulate and direct tissue 105 as needed using suture end 125. As described above, while the surgeon pulls end 125 to direct tissue 105 during a surgical procedure, the sub-loops 110, 115, and 120 formed from adjustable loop 205 constrict and grip the tissue 105 tighter. The surgeon is able to pull and move tissue 105 to direct tissue 105, for example,
10 through holes for receiving the tissue formed in a bone or other soft tissue. When the surgeon is done, the surgeon typically cuts off tissue portion 105a from tissue 105 and discards portion 105a.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope
15 of the invention. For example only and not limit the alternatives the following are some variations to the above examples. For example, other materials can be used in addition to suture for a flexible member. Also, the number of sub-loops and the process used to generate those sub-loops can vary. Also, any device can be used to help temporarily hold the fixation device so that a surgeon can locate the sub-loops onto the tissue. Also, although the term surgeon was used for
20 clarity, any medical personnel can use the fixating device. Accordingly, other embodiments are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A medical device comprising:

a member including a first sub-loop and a second sub-loop, each sub-loop configured to receive a length of tissue therethrough

- 5 2. The medical device of claim 1 wherein the member comprises suture.

3. The medical device of any of the claims 1 to 2 wherein the member further comprises a third sub-loop configured to receive a length of tissue therethrough.

4. The medical device of any of claims 1 to 3 wherein the member is an adjustable member,

10 the adjustable member formed by inserting one end portion of the adjustable member through another end portion of the adjustable member, and the first sub-loop and the second sub-loop formed by crossing a portion of the adjustable member over a different portion of the adjustable member,

wherein the first sub-loop and the second sub-loop are configured to fixate onto tissue.

- 15 5. The medical device of any of the claims 1 to 4 comprising:

an assisting member disposed through the first sub-loop and through the second sub-loop.

6. The medical device of claim 5 wherein the member is a first member, the medical device further comprising,

20 a second adjustable member including a first sub-loop and a second sub-loop,

wherein the assisting member is further disposed through the first sub-loop of the second adjustable tissue fixation device and through the second sub-loop of the second adjustable tissue fixation device. The medical device of claims 5 or 6 wherein the assisting member comprises a medical grasping device.

7. The medical device of claims 5, 6, or 7 wherein the assisting member comprises a cannula.
8. The medical device of any of claims 1 to 5 wherein the member is a first adjustable member, the medical device further comprising a second adjustable member including a first sub-loop and a second sub-loop.
- 5 9. The medical device of any of claims 1 to 9 wherein the sub-loops are configured to fixate on ligament or tendon tissue.
10. A method for making a medical device, comprising:
 - inserting one end portion of a flexible member through another end portion of the flexible member to form an adjustable loop; and
 - 10 locating a first portion of the adjustable loop over a second portion of the adjustable loop to form a first sub-loop and a second sub-loop, the sub-loops configured to receive a length of tissue.
11. The method of claim 11 further comprising:
 - 15 locating a first portion of the second sub-loop over a second portion of the second sub-loop to form a third sub-loop.
12. The method of any of claims 11 to 12 wherein the flexible member comprises suture.
13. The method of any of claims 11 to 13 wherein locating further comprises rotating a portion of the adjustable loop approximately 180 degrees of rotation.
14. The method of any of claims 11 to 14 wherein locating further comprises sliding the first
20 portion of the adjustable loop over the second portion of the adjustable loop to form a first sub-loop and a second sub-loop.
15. The method of any of claims 11 to 15 further comprising locating a first portion of an assisting member within the first sub-loop and a second portion of the assisting member within the second sub-loop.

16. The method of claim 16 wherein the assisting member comprises a medical grasping device.

17. The method of claim 16 or 17 wherein the assisting member comprises a cannula.

18. The method of any of claims 16 to 18 wherein the flexible member is a first flexible member, the method further comprising:

5 inserting one end portion of a second flexible member through another end portion of the second flexible member to form a second adjustable loop;
 locating a first portion of the second adjustable loop over a second portion of the second adjustable loop to form a first sub-loop and a second sub-loop; and
 locating a fourth portion of the assisting member within the first sub-loop of
10 the second flexible member and a fifth portion of the assisting member within the second sub-loop of the second flexible member.

19. A method for attaching a fixation device to tissue, the method comprising:

 moving a first sub-loop and a second sub-loop of the fixation device over a portion of the tissue; and
15 pulling an end portion of the fixation device to reduce the size of the sub-loops to fixate the fixation device to the portion of the tissue.

20. The method of claim 20 wherein moving further comprises moving a third sub-loop over the portion of tissue.

21. The method of any of claims 20 to 21 further comprising grasping tissue with an assisting
20 member located within the first and second sub-loops.

22. The method of claim 22 further comprising sliding the first sub-loop and the second sub-loop off of the assisting member.

23. The method of any of claims 20 to 23 wherein the fixation device comprises suture.

24. The method of any of claims 20 to 24 wherein the tissue comprises ligament or tendon graft.

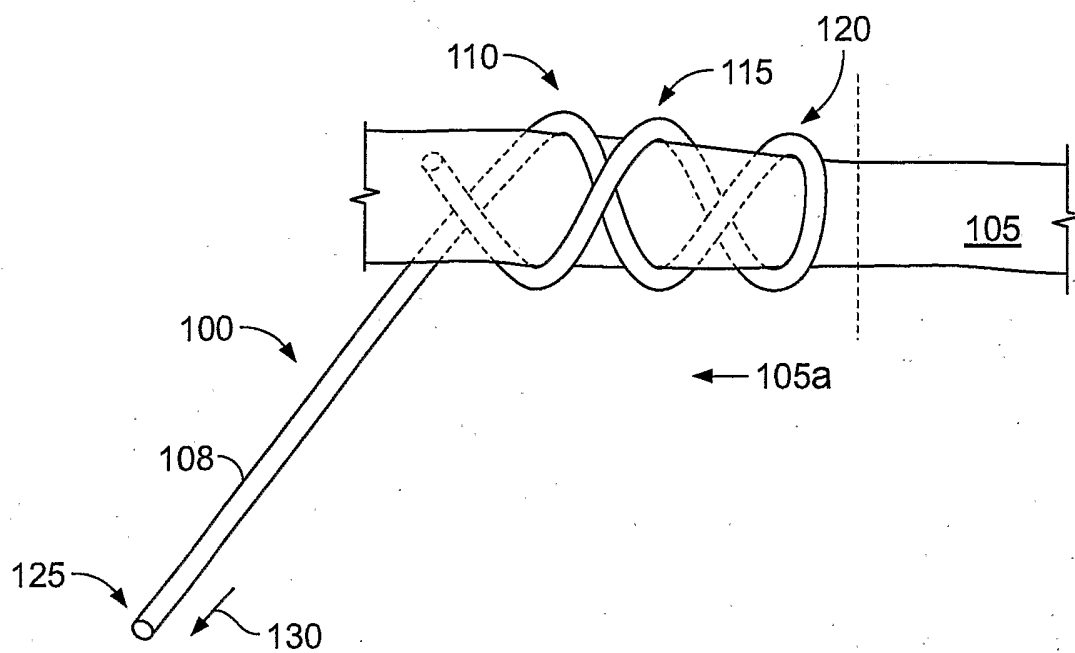


FIG. 1

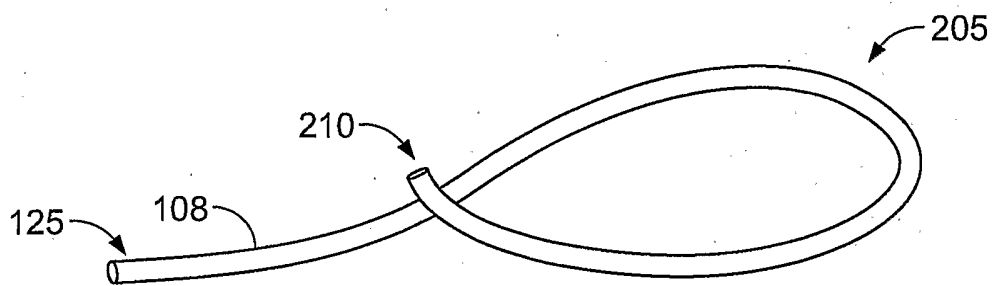


FIG. 2

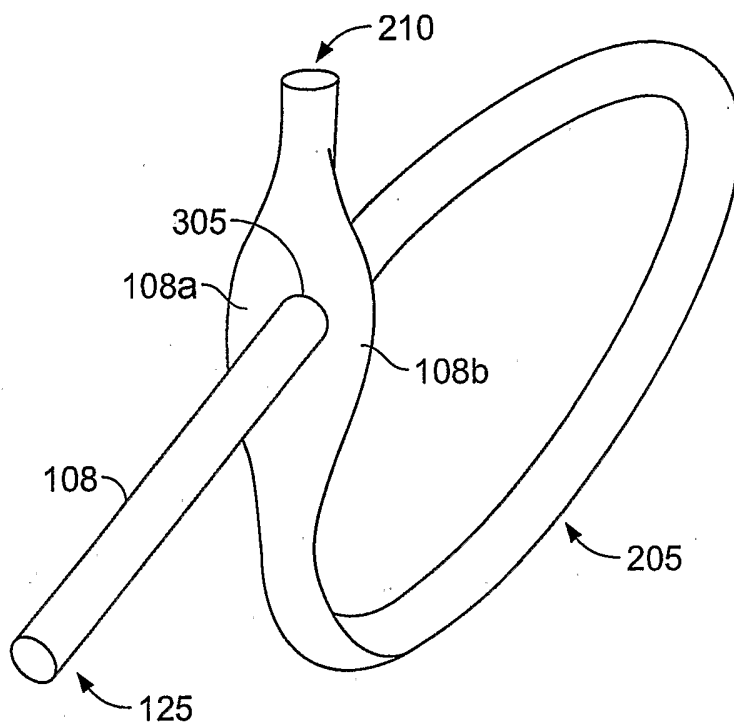


FIG. 3

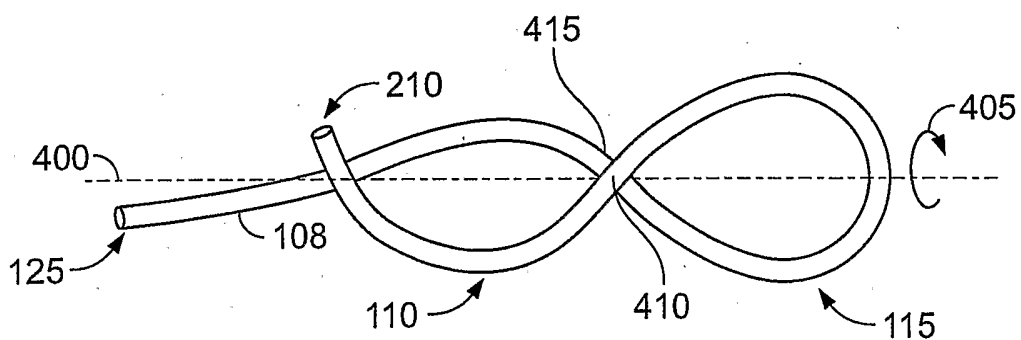


FIG. 4

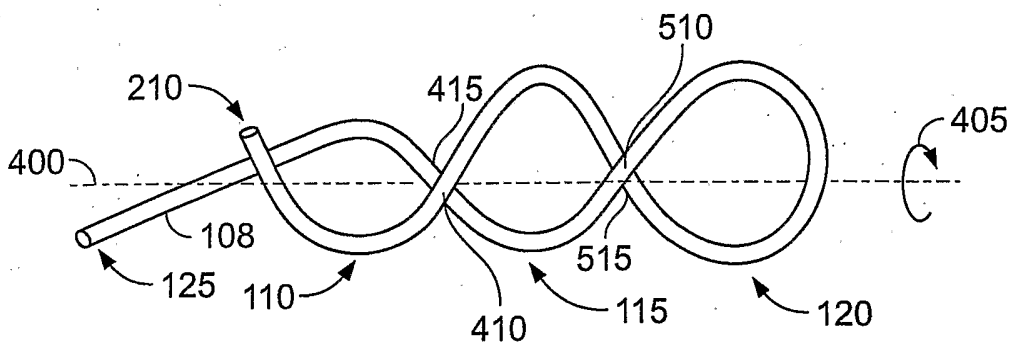


FIG. 5

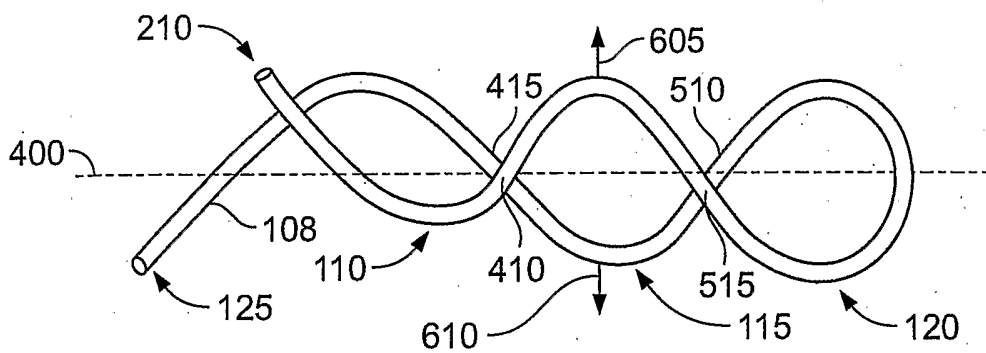


FIG. 6

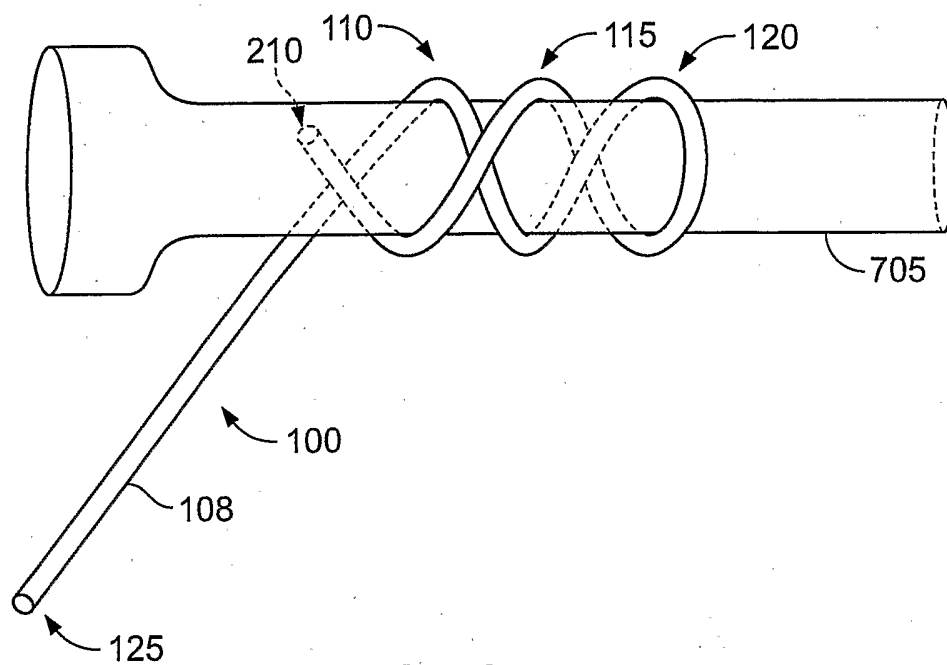


FIG. 7A

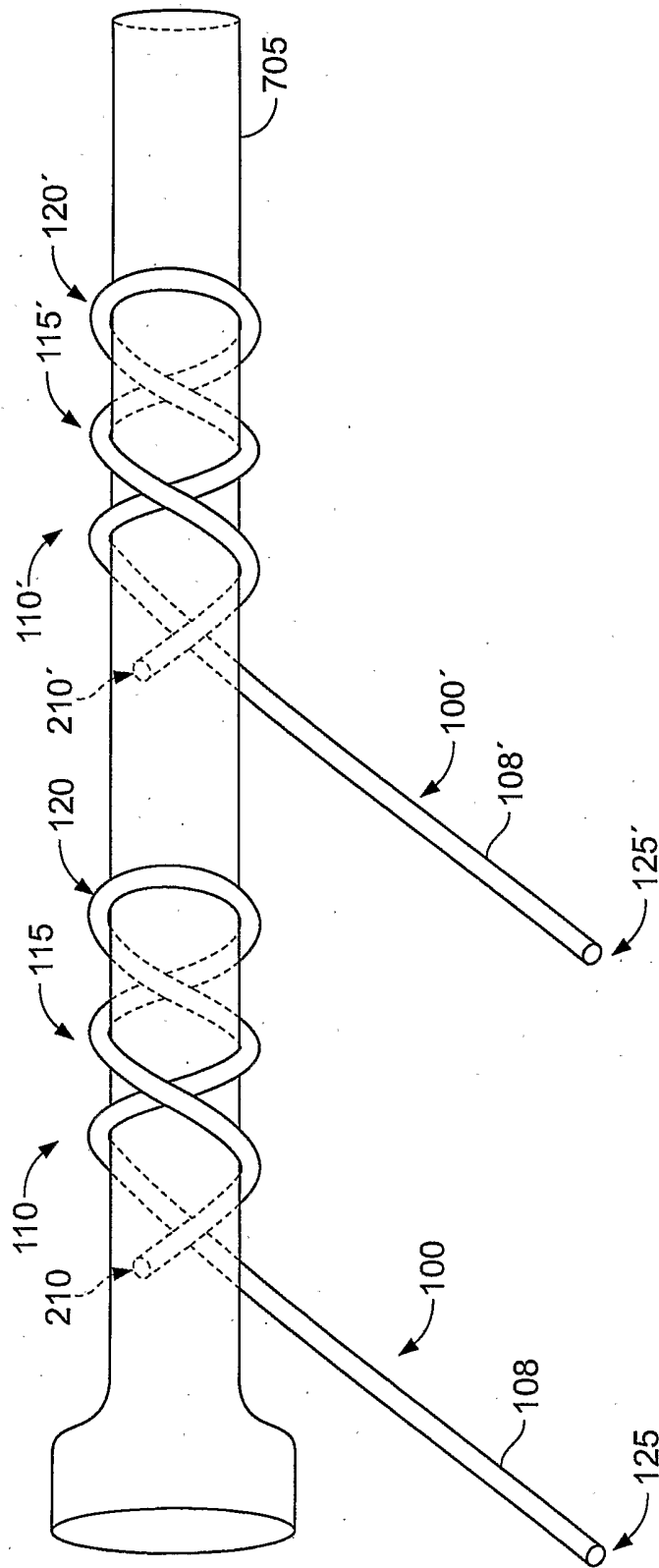


FIG. 7B

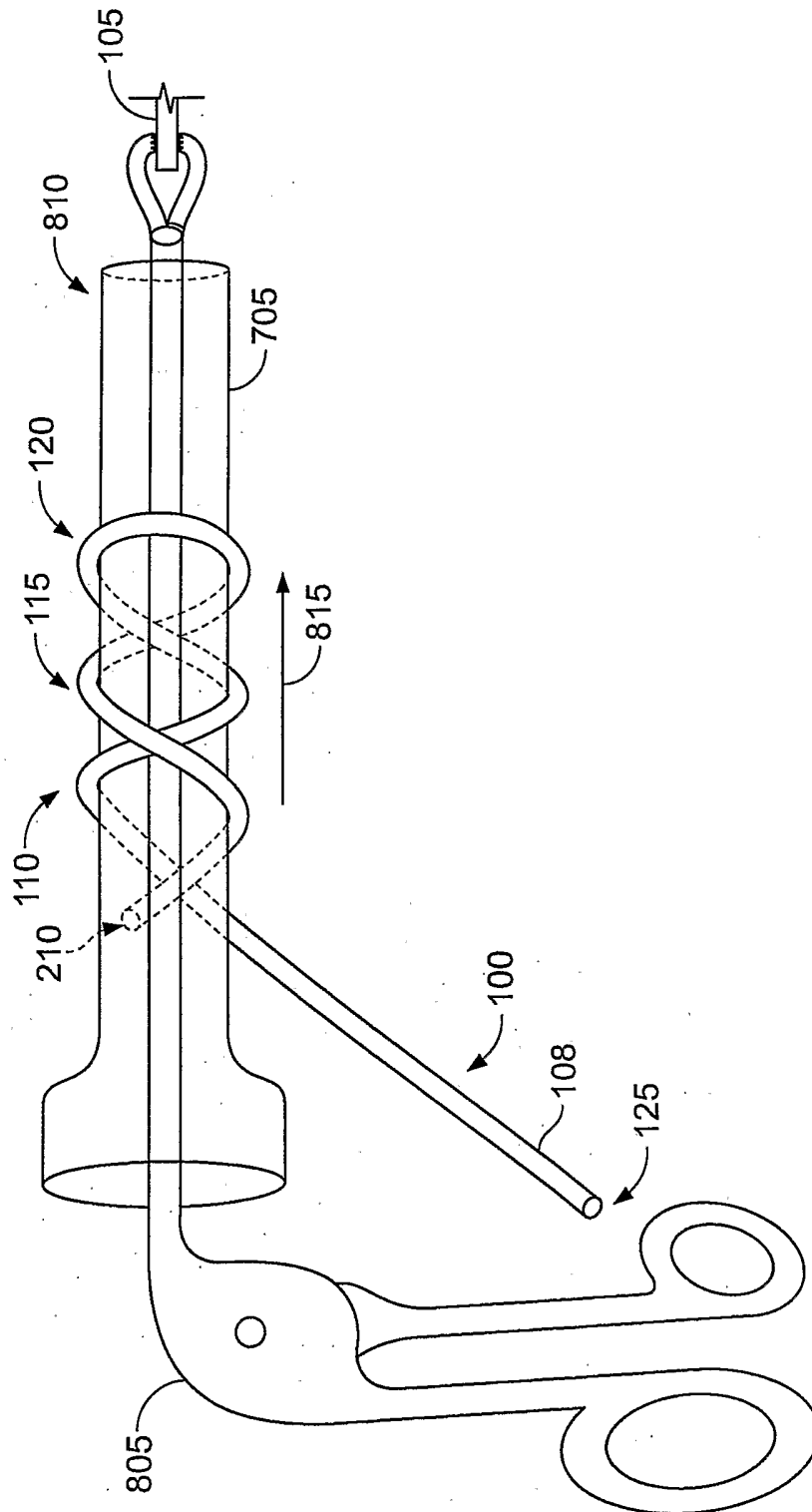


FIG. 8

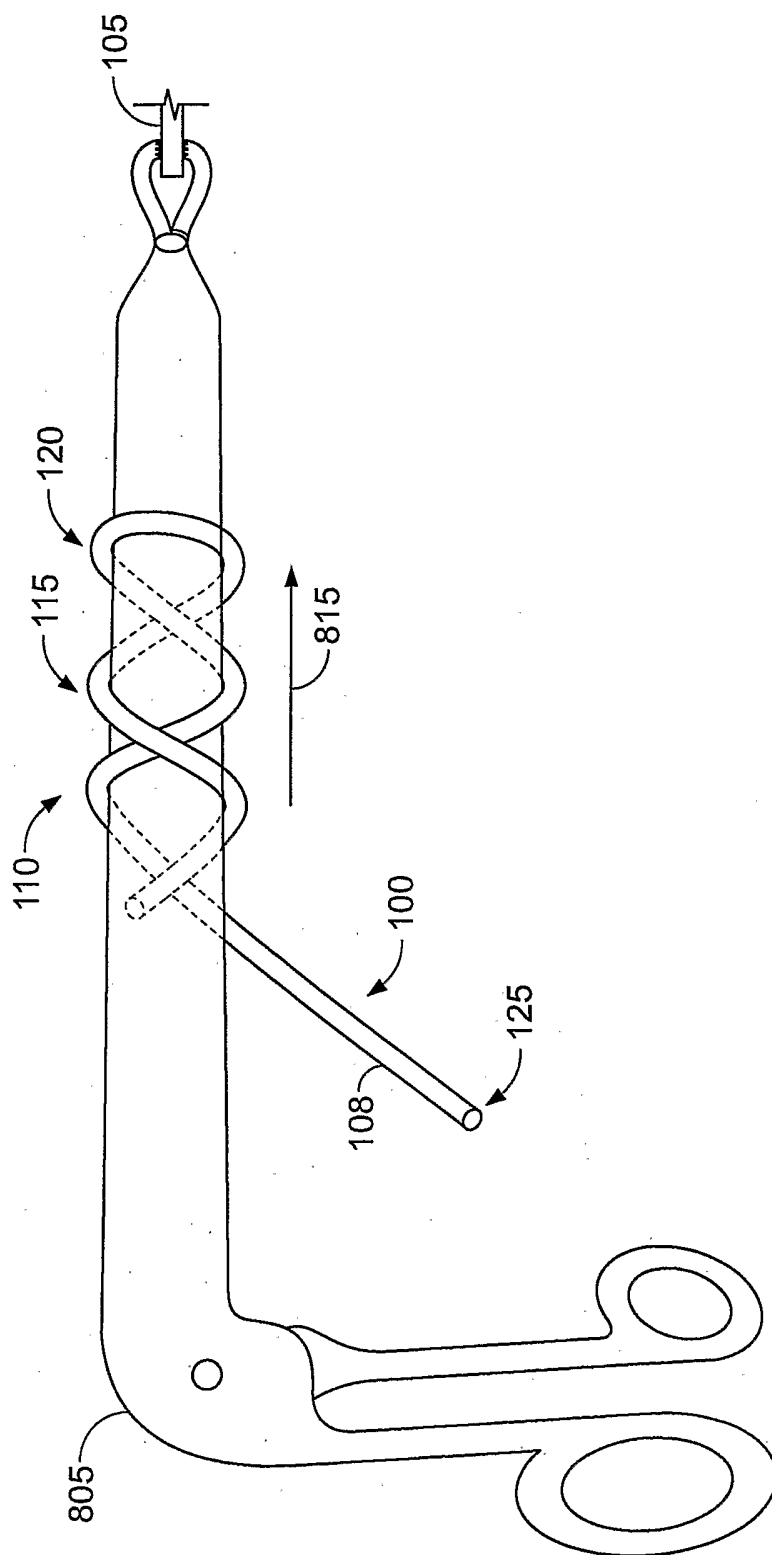


FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/010807A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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)
IPC 7 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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 144 961 A (CHEN CHAO ET AL) 8 September 1992 (1992-09-08) figures 1,2 ----	1-3,5-18
X	US 5 769 862 A (CHEN CHAO ET AL) 23 June 1998 (1998-06-23) figures 3,4 ----	1-3,5-18
X	US 2003/055438 A1 (HIRATA MINORU) 20 March 2003 (2003-03-20) figure 22 ----	1-3
X	US 2002/173788 A1 (TORRIE PAUL A ET AL) 21 November 2002 (2002-11-21) figure 1 ----- -/--	1

 Further documents are listed in the continuation of box C. 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
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- *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.
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Date of the actual completion of the international search

13 August 2004

Date of mailing of the international search report

30/08/2004

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/010807

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ASHLEY, CLIFFORD W.: "Das Ashley-Buch der Knoten" 1982 , MARITIM , HAMBURG XP002292309 page 85 page 225 -----	1-3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/010807

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. Claims Nos.: 19-24
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 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

Information on patent family members

International Application No
PCT/US2004/010807

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