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

[Continued on next page]

(54) Title: TUBULAR LIGAMENT CUTTING IMPLEMENT

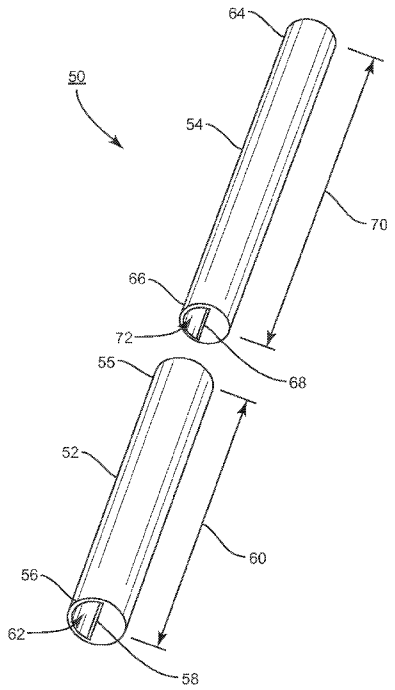

FIG. 2

(57) Abstract: A cutting implement includes a first tubular portion and a second tubular portion. Each tubular portion is hollow and includes a blade element at a distal end. The blade element helps define an aperture that allows access to the interior hollow portion of the tubular portion. A ligament graft element is threaded through the aperture of each tubular portion and the respective tubular portions are interoperated to cut the ligament graft.

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— *with amended claims and statement (Art. 19(1))*

TUBULAR LIGAMENT CUTTING IMPLEMENT

Field of the Disclosure

[0001] The present disclosure relates to a cutting instrument adapted to help a surgeon harvest a replacement tendon for an anterior cruciate ligament (ACL) injury from the quadriceps tendon.

Background

[0002] Most people can go through the majority of their life without ever appreciating the complicated structure of the knee that helps them walk. However, the knee remains a fragile mechanical structure that is readily susceptible to damage. While medical advances have made repairing the knee possible, repair of certain types of injuries results in other long term effects. To assist the reader, Figure 1 is provided with a brief explanation of the components of the knee.

[0003] For the purposes of the present disclosure, and as illustrated, the knee may be composed of the quadriceps muscles 10, the femur 12, the articular cartilage 14, the lateral condyle 16, the posterior cruciate ligament 18, the anterior cruciate ligament 20, the lateral collateral ligament 22, the fibula 24, the tibia 26, the patellar tendon 28, the meniscus 30, the medial collateral ligament 32, the patella 34 (shown slightly displaced to the side - it normally rests in the center of the knee) and the quadriceps tendon 36. Of particular interest for the purposes of the present disclosure is the anterior cruciate ligament (ACL) 20 and what is done to repair the ACL 20.

[0004] ACL tears are common in athletes and are usually season ending injuries. The ACL 20 cannot heal - it must be surgically reconstructed. The reconstruction requires replacement tissue. The most common tissue used is a central slip of the patient's own patellar tendon 28. In practice, the patellar tendon 28 has proven to be generally effective, but the size of the graft that can be used is limited to the size of the patient's own patellar tendon 28. As a rule of thumb, only a third of the patellar tendon 28 may be harvested as a graft. Thus, a doctor will measure the width of the patellar tendon 28, divide by three, and take the middle third of the patellar tendon 28. Such harvested grafts are rarely more than 10 mm wide and may be smaller. Taking this tissue from a person's

patellar tendon 28 also causes significant pain and discomfort in the post operative healing period, which may last up to a year, and up to twenty (20) percent of these patients are left with chronic anterior knee pain.

[0005] Some doctors recommend and use other graft sources, such as cadaver grafts, but cadaver grafts have a higher failure rate. Additionally, there is a non-zero chance of disease transmission or rejection by the patient's immune system. As a final drawback, cadaver grafts are usually quite expensive and may not be covered by some insurance companies.

[0006] Other doctors use hamstring tendons (e.g., the distal semitendinosus tendon) because the scar created during harvesting is relatively small and there is less pain during the rehabilitation, but again, the hamstring tendon has its own collection of disadvantages. The disadvantages include the fact that once the graft is taken, a patient's hamstring will never recover to its previous strength. Further, all hamstring reconstructions stretch and are looser than the original ACL 20. This loosening is particularly problematic in younger female athletes.

[0007] Another alternative graft source is the quadriceps tendon 36. The quadriceps tendon 36 is larger and stronger than either the patellar tendon 28 or the hamstring tendon. The quadriceps tendon 36 is likewise stiffer and less prone to stretching or plastic deformation. However, the qualities that make the quadriceps tendon 36 attractive also contribute to the difficulty in harvesting a graft from the quadriceps tendon 36. Existing surgical implements require a large incision up the longitudinal axis of the femur 12 on the front or ventral/anterior side of the thigh to cut down to the level of the quadriceps tendon 36, resulting in a large post operative scar. Additionally, the quadriceps tendon 36 has a consistency similar to the proverbial shoe leather, making it difficult to cut. However, an ACL 20 repaired with grafts from the quadriceps tendon 36 generally results in almost no anterior knee pain postoperatively over the short or long term and recovers quicker.

[0008] The present inventor's prior application, U.S. Patent Application Serial Number 13/102,562, filed May 6, 2011 (which is hereby incorporated by reference in its entirety), provides a number of devices designed to create a graft from the quadriceps tendon 36 and discloses an element to make the initial cut on the quadriceps tendon 36 as

well as a number of secondary cutting implements to trim the distal end of the graft. While these secondary cutting implements are adequate to perform their intended purpose, alternate devices may be more cost effective or have easier engineering realities.

Summary

[0009] The present disclosure provides a secondary cutting implement that is adapted to trim a distal end of a preliminarily harvested graft from the quadriceps tendon in a minimally invasive manner. Once the quadriceps tendon graft is secured, it may be used in conventional manners to repair the anterior cruciate ligament (ACL).

[0010] The secondary cutting implement comprises a first hollow tubular element and a second hollow tubular element that telescopingly fits within the first tubular element. The distal ends of each tubular element include an interior blade element positioned perpendicular to a longitudinal axis of the tubular element. The interior blade elements are sized such that the distal end of each tubular portion is at least partially open. That is, the blade elements help define an aperture at the distal end of the tubular hollow elements.

[0011] In use, the quadriceps tendon is cut to a desired length and then the graft portion is threaded through the open distal end of the first tubular element. The graft portion is also threaded through the open distal end of the second tubular element. The tubular elements are rotated in opposite directions causing the interior blade elements to trim the distal end of the graft.

[0012] Those skilled in the art will appreciate the scope of the disclosure and realize additional aspects thereof after reading the following detailed description in association with the accompanying drawings.

Brief Description of the Drawings

[0013] The accompanying drawings incorporated in and forming a part of this specification illustrate several aspects of the disclosure, and together with the description serve to explain the principles of the disclosure.

[0014] Figure 1 illustrates a conventional knee;

[0015] Figure 2 illustrates an exploded perspective view of an exemplary embodiment of the secondary cutting implement of the present disclosure;

[0016] Figures 3A-3F illustrate schematically operation of the secondary cutting element; and

[0017] Figure 4 illustrates a flow chart describing the operation of the secondary cutting element.

Detailed Description

[0018] The embodiments set forth below represent the necessary information to enable those skilled in the art to practice the disclosure and illustrate the best mode of practicing the disclosure. Upon reading the following description in light of the accompanying drawings, those skilled in the art will understand the concepts of the disclosure and will recognize applications of these concepts not particularly addressed herein. It should be understood that these concepts and applications fall within the scope of the disclosure and the accompanying claims.

[0019] Figure 2 illustrates a first exemplary embodiment of a secondary cutting implement 50 according to the present disclosure. The secondary cutting implement 50 is useful for trimming a graft being harvested from the quadriceps tendon 36, such as occurs when the cutting implement of the previously incorporated '562 application is used to cut a graft from the quadriceps tendon 36. The secondary cutting implement 50 has a first element 52, which is hollow and has a first handle end 55 and a first distal end 56. The first distal end 56 includes a first blade element 58. The first blade element 58 is positioned perpendicular to a longitudinal axis 60 of the first element 52. The first blade element 58 may be integrally formed with the body of the first element 52 or fixedly secured thereto. In an exemplary embodiment, the first element 52 is adapted to be reusable while the first blade element 58 is removably affixed thereto such that it can be replaced readily. Thus, the first blade element 58 may be considered disposable or reusable as desired. The first blade element 58 extends, in an exemplary embodiment, approximately halfway across distal end 56 (e.g., covering approximately 45-55% (and in an exemplary embodiment approximately 51%) of the area of the distal end 56) and partially defines a first aperture 62 through which a graft may be threaded as explained in

greater detail below. In an exemplary embodiment, the first element 52 is made from a metal such as surgical stainless steel (e.g., made out of chromium, nickel, molybdenum, and/or titanium) such as 316L, 316LVM and/or compliant with ASTM F138. In an alternate embodiment, the first element 52 is made from a polymer based material. The first blade element 58 may be made from surgical steel, glass, obsidian, diamond, or the like as desired. In an exemplary embodiment, the first element 52 may be approximately 100 mm long.

[0020] The second element 54, which is hollow and has a second handle end 64 and a second distal end 66. The second distal end 66 includes a second blade element 68. The second blade element 68 is positioned perpendicular to a longitudinal axis 70 of the second element 54. The second blade element 68 may be integrally formed with the body of the second element 54 or fixedly secured thereto. In an exemplary embodiment, the second element 54 is adapted to be reusable while the second blade element 68 is removably affixed thereto such that it can be replaced readily. Thus, the second blade element 68 may be considered disposable or reusable as desired. The second blade element 68 extends, in an exemplary embodiment, approximately halfway across second distal end 66 (e.g., covering approximately 45-55% (and in an exemplary embodiment approximately 51%) of the area of the distal end 66) and at least partially defines a second aperture 72 through which a graft may be threaded as explained in greater detail below. In an exemplary embodiment, the second element 54 is made from a metal such as surgical stainless steel (e.g., made out of chromium, nickel, molybdenum, and/or titanium) such as 316L, 316LVM and/or compliant with ASTM F138. In an alternate embodiment, the second element 54 is made from a polymer based material. The second blade element 68 may be made from surgical steel, glass, obsidian, diamond, or the like as desired. In an exemplary embodiment, the second element 54 may be approximately 120 mm long and 23 mm in interior diameter. The first element 52 may be sized such that its interior diameter is just large enough to fit around the exterior diameter of second element 54.

[0021] By design, the first element 52 is shorter than the second element 54, and the second element 54 telescopingly fits within the first element 52 such that the second

handle end 64 extends out past the first handle end 55 so as to facilitate manipulation of the second element 54 within the first element 52.

[0022] In an exemplary embodiment, the handle ends 55 and 64 may be abraded, knurled, or otherwise textured to provide a firm gripping surface. In an alternate embodiment, there may be an explicit handle attached to or formed on the handle ends 55 and 64 to make manipulation and grip more natural.

[0023] Figures 3A-3F illustrate a technique of using the secondary cutting implement 50 as further explained in the flowchart of Figure 4. The process 100 of harvesting the graft 80 begins with the incision being made (block 102) and the tendon being cut to form the graft 80 (block 104). As explained in the previously incorporated '562 application, the graft 80 may be created from the quadriceps tendon 36.

[0024] Once the graft 80 is cut from the quadriceps tendon 36, the cutting implement is removed and the first element 52 is threaded through the first aperture 62 (block 106), through the hollow portion of the first element 52 and out the first handle end 55. Thus, the interior dimensions of the hollow portion of the first element 52 should be sized so as to accommodate the graft 80 and the bit of patella 82. Likewise, the size of the first aperture 62 should be sufficient to pass both the graft 80 and the bit of patella 82.

[0025] Note that as used herein "threaded through" or similar phrases draws analogy to threading a needle, and does not refer to the threads on a screw.

[0026] The graft 80 may then be threaded through the second aperture 72 and the second element 54 (block 108 and Fig. 3C). Note that if the apertures 62 and 72 are aligned and the second element 54 is already positioned within the first element 52, the graft 80 may be threaded through the first and second elements concurrently. As is seen in Figure 3C, the second handle end 64 extends past the first handle end 55. Likewise, at least initially, the apertures 62 and 72 are aligned to allow the graft 80 to pass therethrough.

[0027] The second element 54 is then rotated relative to the first element 52 (block 110, Figures 3D & 3E). As the two elements 52 and 54 are rotated relative to one another, the blade elements 58 and 68 rotate to one another and effectively close the aperture through which the graft 80 has been passed. This allows the blade elements 58

and 68 to scissor together, thereby cutting the graft 80. Once the rotation has been effectuated sufficiently, the graft 80 is severed (block 112).

[0028] The graft 80 is then removed (block 114) as well as the cutting implement 50 (block 116, Fig. 3F). Then the graft 80 may be used to repair the ACL as desired.

[0029] Those skilled in the art will recognize improvements and modifications to the embodiments of the present disclosure. All such improvements and modifications are considered within the scope of the concepts disclosed herein and the claims that follow.

Claims

What is claimed is:

1. A surgical instrument comprising:

a first hollow element comprising a first distal end and a first handle end, the first distal end comprising a first blade element; and

a second hollow element comprising a second distal end and a second handle end the second distal end comprising a second blade element; and

wherein the first hollow element is sized relative to the second hollow element such that the second hollow element telescopingly fits within the first hollow element and is adapted to rotate therewithin in such a manner that rotation of the second hollow element relative to the first hollow element causes the first and second blade elements to interoperate to cut a workpiece.

2. The surgical instrument of claim 1 wherein the first hollow element is tubular.

3. The surgical instrument of claim 1 wherein the second hollow element is tubular.

4. The surgical instrument of claim 1 wherein the first blade element at least partially defines a first aperture on the first hollow element such that the workpiece may be threaded through the first aperture.

5. The surgical instrument of claim 1 wherein the second blade element at least partially defines a second aperture on the second hollow element such that the workpiece may be threaded through the second aperture.

6. The surgical instrument of claim 1 wherein the first hollow element is formed from a material selected from the group consisting of: a metal and a polymer.

7. The surgical instrument of claim 1 wherein the second hollow element is formed from a material selected from the group consisting of: a metal and a polymer.

8. The surgical instrument of claim 1 wherein the second hollow element is longer than the first hollow element.

9. The surgical instrument of claim 1 wherein the workpiece is a quadriceps tendon and the blade elements are adapted to cut the quadriceps tendon.

10. The surgical instrument of claim 1 wherein the first and second hollow elements are adapted to be inserted within a human body.

11. A method of using a surgical implement comprising:

threading a workpiece through a first hollow element;

threading the workpiece through a second hollow element

telescopingly fitting the second hollow element inside the first hollow element; and

rotating the first hollow element relative to the second hollow element such that respective blade members interoperate to cut the workpiece.

12. The method of claim 11 wherein the first hollow element is tubular.

13. The method of claim 11 wherein the second hollow element is tubular.

14. The method of claim 11 further comprising at least partially defining a first aperture with a first blade element of the respective blade members such that the workpiece may be threaded through the first aperture.

15. The method of claim 11 further comprising at least partially defining a second aperture with a second blade element of the respective blade members such that the workpiece may be threaded through the second aperture.

16. The method of claim 11 wherein the first hollow element is formed from a material selected from the group consisting of: a metal and a polymer.

17. The method of claim 11 wherein the second hollow element is formed from a material selected from the group consisting of: a metal and a polymer.

18. The method of claim 11 wherein the second hollow element is longer than the first hollow element.

19. The method of claim 11 wherein the workpiece is a quadriceps tendon and the respective blade elements are adapted to cut the quadriceps tendon.

20. The method of claim 11 further comprising inserting the first and second hollow elements into a human body.

AMENDED CLAIMS
received by the International Bureau on 05 November 2013 (05.11.2013).

1. A surgical instrument comprising:

a first hollow element comprising a first distal end and a first handle end, the first distal end comprising a first blade element; and

a second hollow element comprising a second distal end and a second handle end, the second distal end comprising a blunt edge; and

wherein the first hollow element is sized relative to the second hollow element such that the second hollow element telescopingly fits within the first hollow element and is adapted to rotate therewithin in such a manner that rotation of the second hollow element relative to the first hollow element causes the first blade element and the blunt edge to interoperate to cut a workpiece.

2. The surgical instrument of claim 1 wherein the first hollow element is tubular.

3. The surgical instrument of claim 1 wherein the second hollow element is tubular.

4. The surgical instrument of claim 1 wherein the first blade element at least partially defines a first aperture on the first hollow element such that the workpiece may be threaded through the first aperture and wherein the first aperture comprises a cut out portion.

5. The surgical instrument of claim 1 wherein the blunt edge at least partially defines a second aperture on the second hollow element such that the workpiece may be threaded through the second aperture and wherein the second aperture comprises a cut out portion.

6. The surgical instrument of claim 1 further comprising a third hollow element sized to fit in the first hollow element.

7. The surgical instrument of claim 6 wherein the second hollow element is sized to fit in the third hollow element.

8. The surgical instrument of claim 1 wherein the second hollow element is longer than the first hollow element.

9. The surgical instrument of claim 1 wherein the workpiece is a quadriceps tendon and the blade elements are adapted to cut the quadriceps tendon.

10. The surgical instrument of claim 1 wherein the first and second hollow elements are adapted to be inserted within a human body.

STATEMENT UNDER ARTICLE 19 (1)

Applicant has submitted amendments under Article 19 for the above-referenced application.

The new claims correspond to those claims found in priority document US Patent Application Serial Number 13/832,638, filed March 15, 2013.

Regards,

Taylor M. Davenport

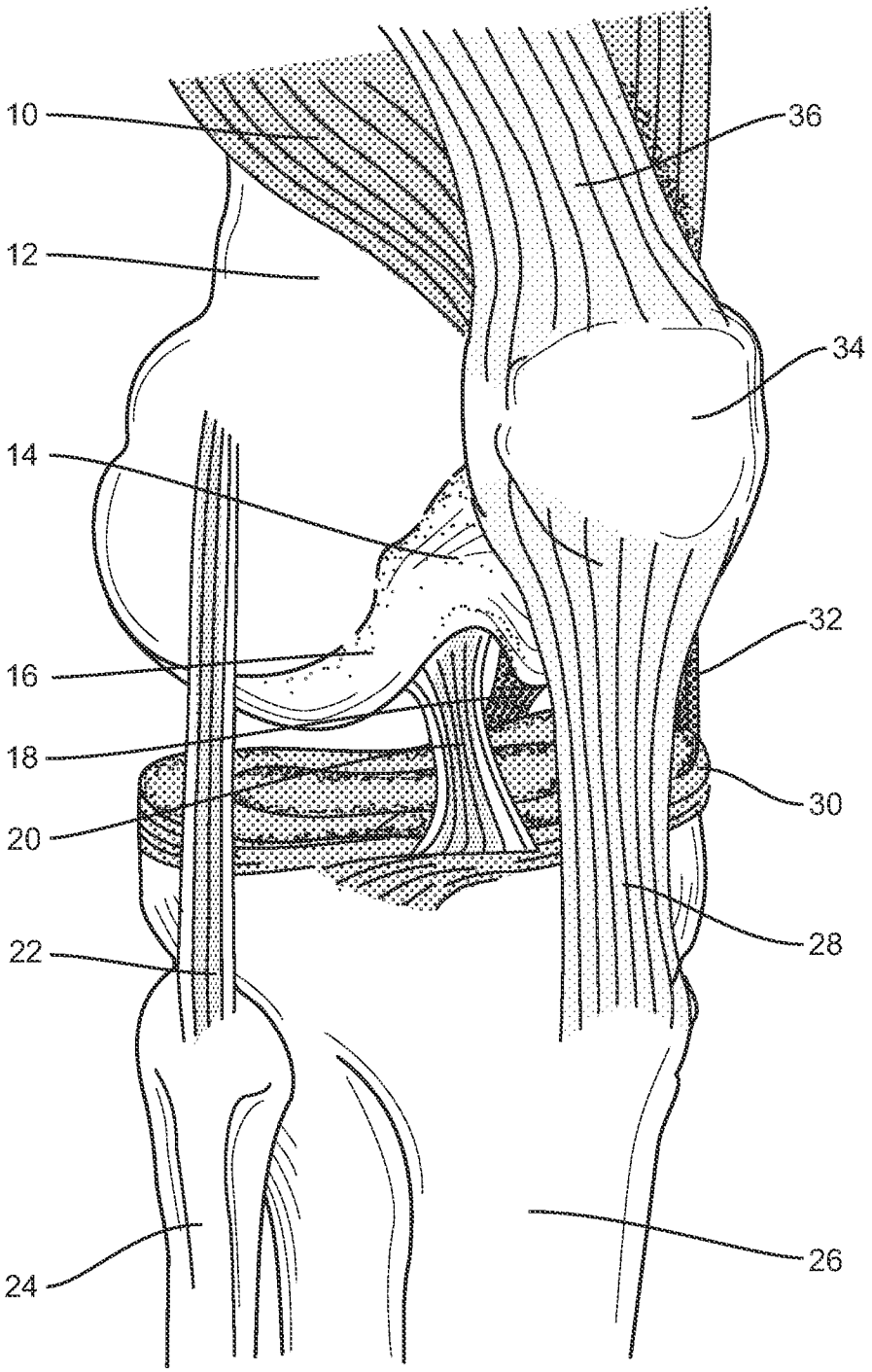

FIG. 1
(PRIOR ART)

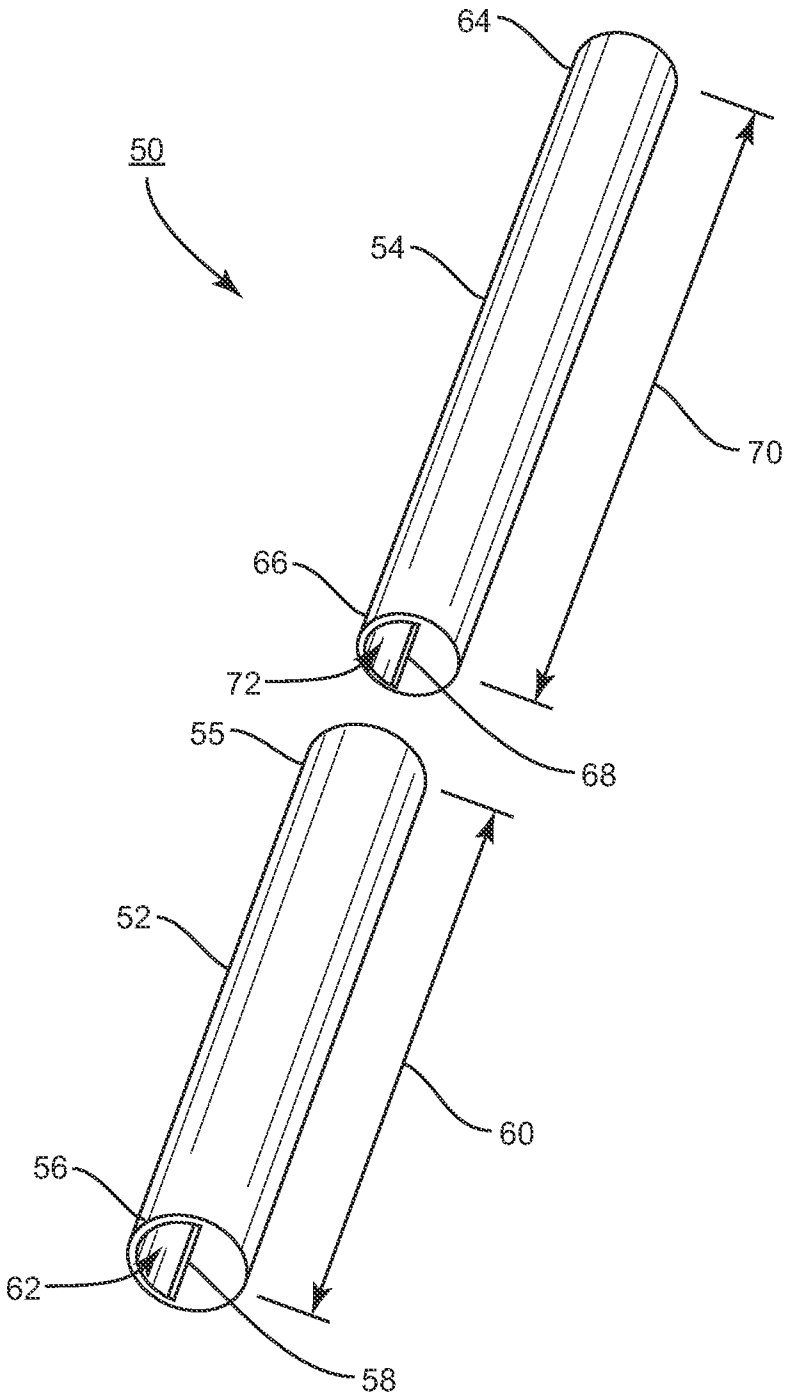

FIG. 2

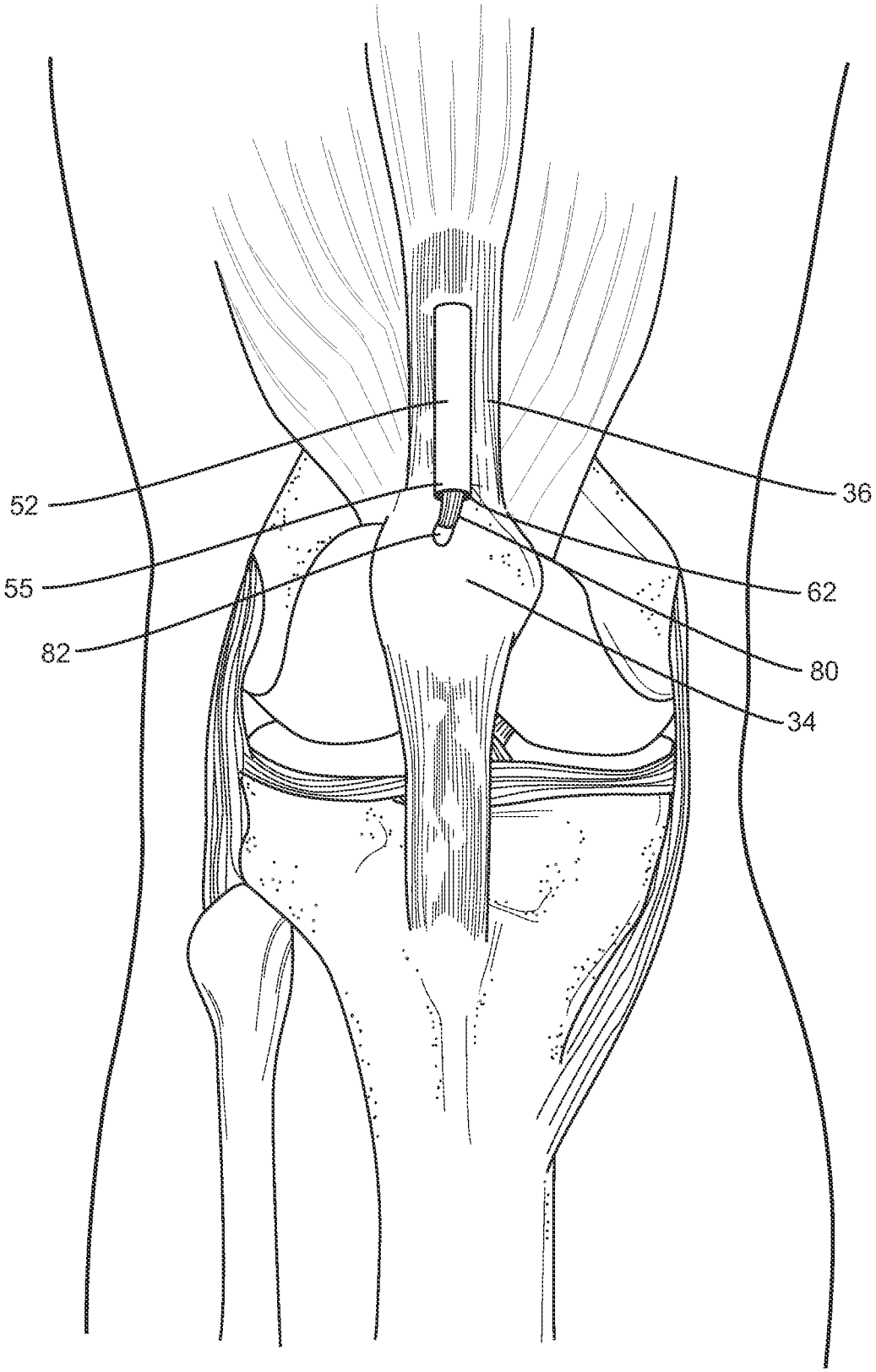

FIG. 3A

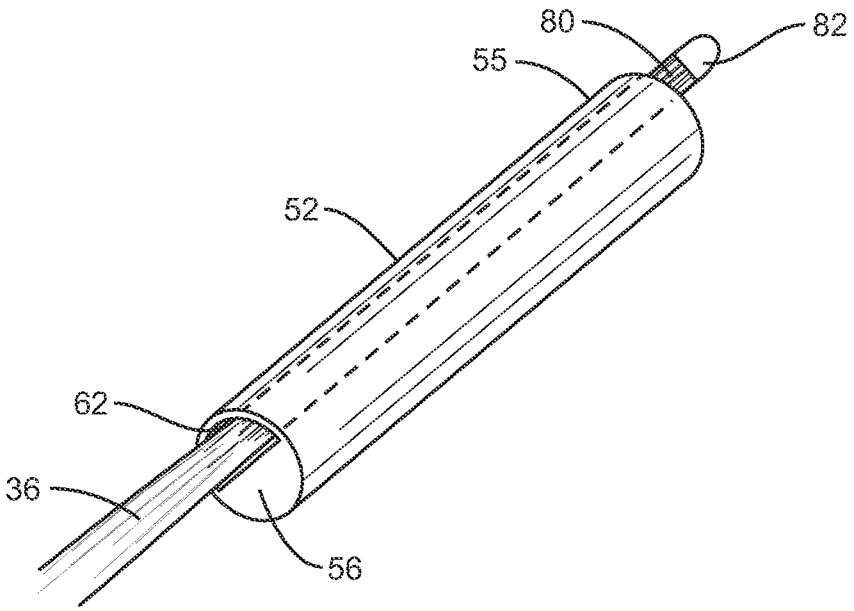

FIG. 3B

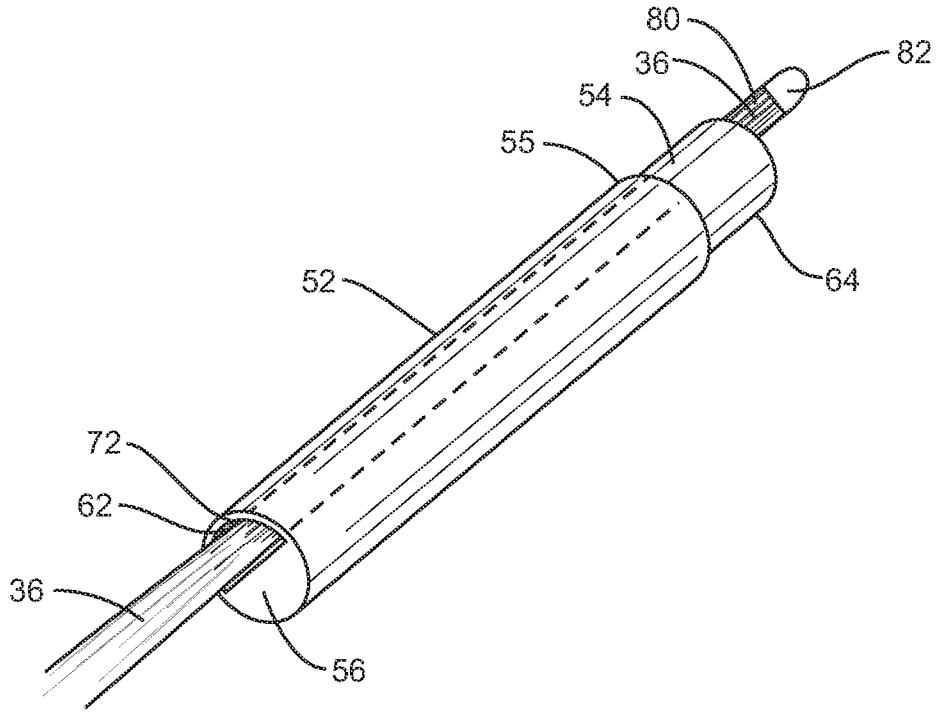

FIG. 3C

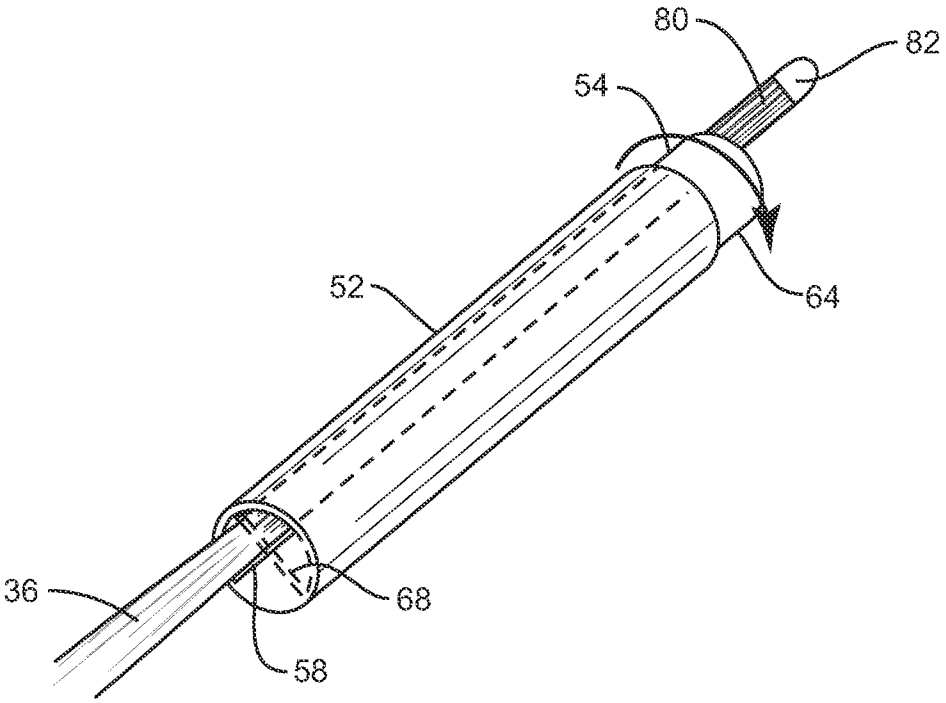

FIG. 3D

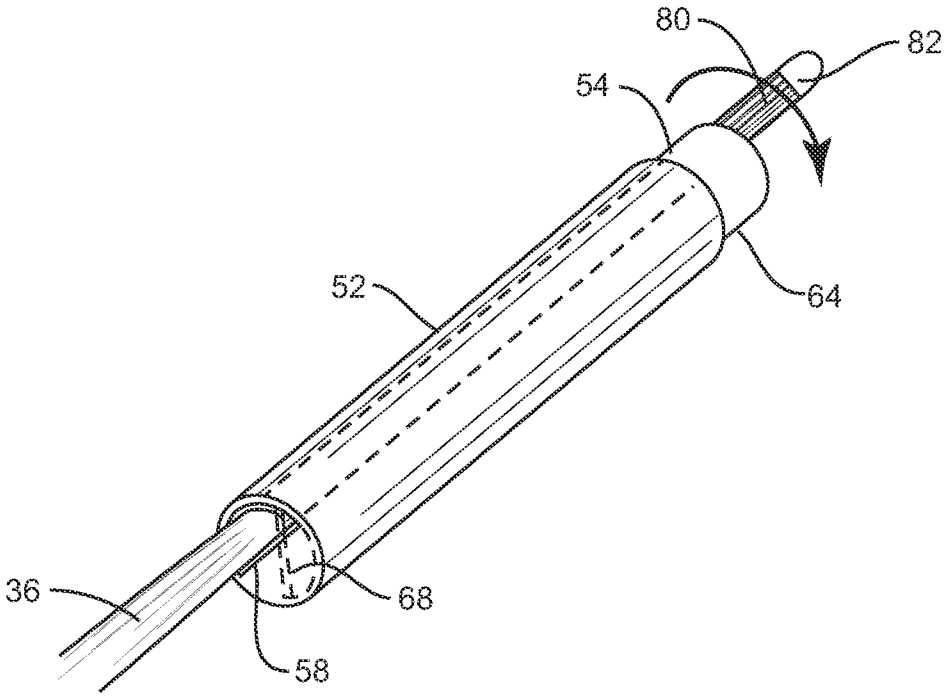

FIG. 3E

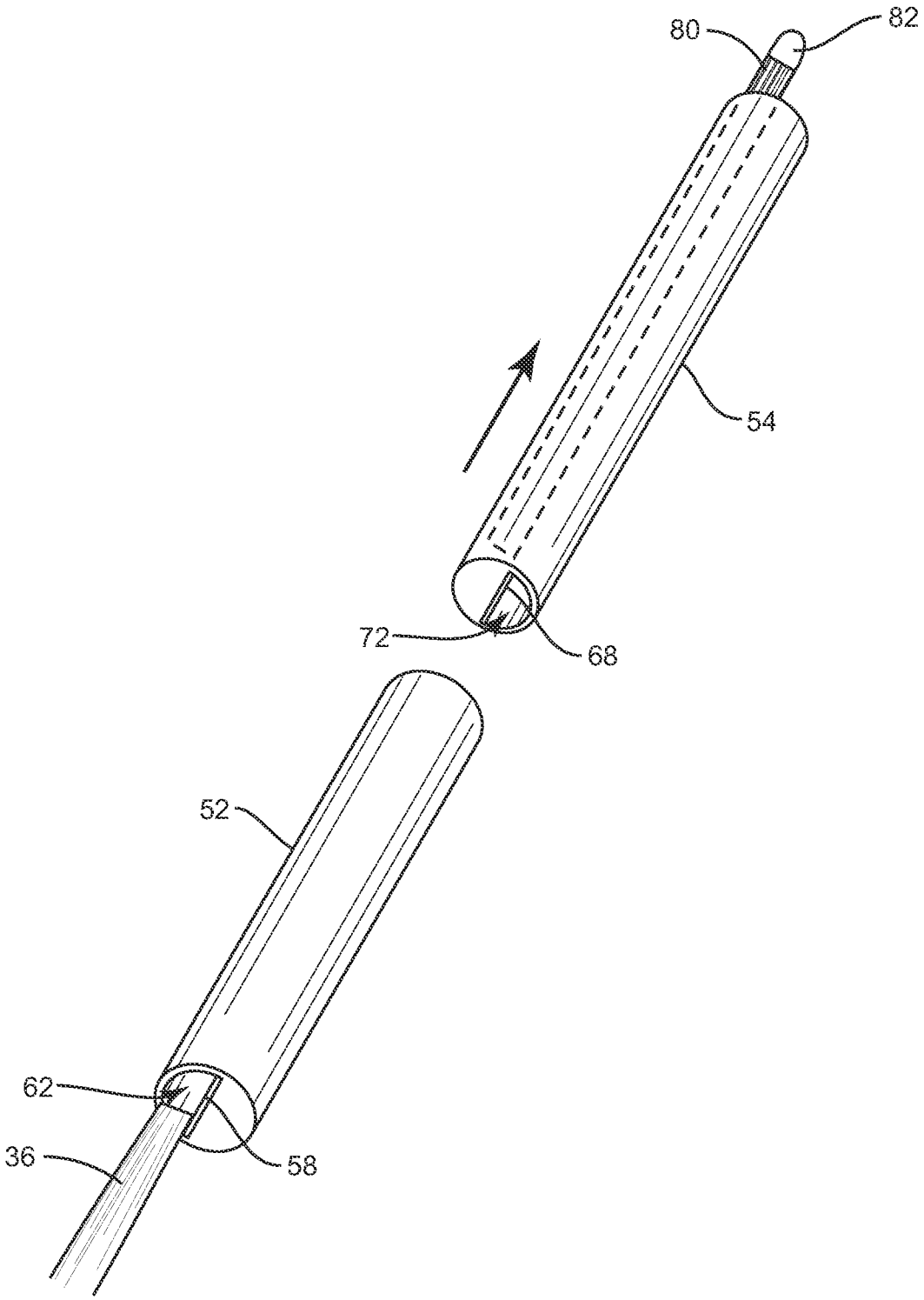

FIG. 3F

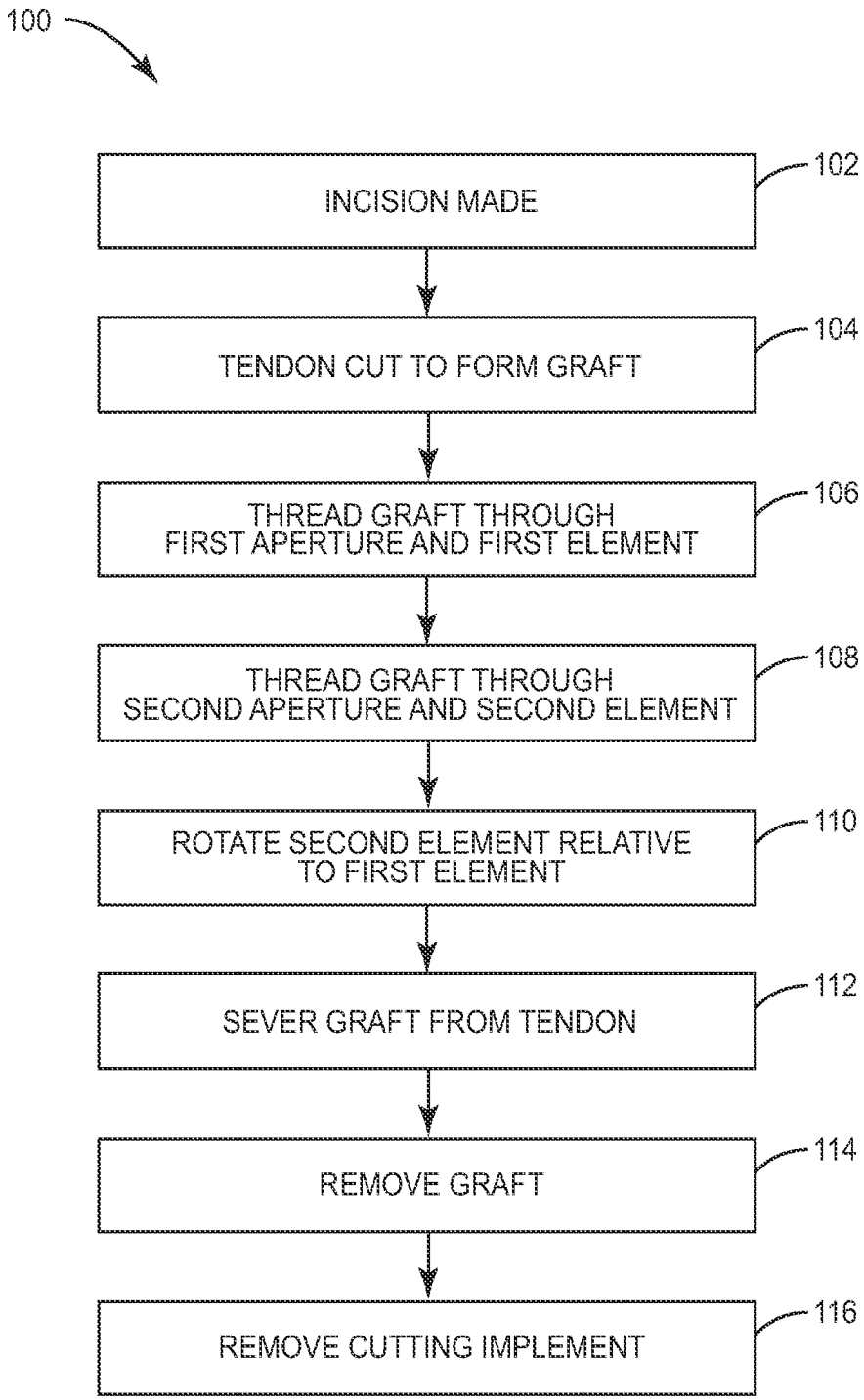
100
INCISION MADE
102
TENDON CUT TO FORM GRAFT
104
THREAD GRAFT THROUGH FIRST APERTURE AND FIRST ELEMENT
106
THREAD GRAFT THROUGH SECOND APERTURE AND SECOND ELEMENT
108
ROTATE SECOND ELEMENT RELATIVE TO FIRST ELEMENT
110
SEVER GRAFT FROM TENDON
112
REMOVE GRAFT
114
REMOVE CUTTING IMPLEMENT
116

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/044973

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/32(2006.01)i, A61B 17/3209(2006.01)i, A61B 17/56(2006.01)i, A61L 31/02(2006.01)i, A61L 31/04(2006.01)i

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 17/32; A61B 17/00; A61F 5/00; A61B 017/34; A61B 17/3209; A61B 17/56; A61L 31/02; A61L 31/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: cutting, tissue, hollow, blade, second, graftt, ACL, BTB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0087260 A1 (SEIPEL, P. and HUNN, D.) 14 April 2011 See claims 1-4, 11, 12, 18; paragraphs [0024]-[0033]; Figures 1-8.	1-10
A	US 2010-0069944 A1 (MURAKAMI, H. et al.) 18 March 2010 See claims 5, 13, 15, 19; Figures 1-13.	1-10
A	US 2011-0306483 A1 (IANNARONE, R. C.) 11 December 2008 See the entire document.	1-10
A	US 5391169 A (MCGUIRE, D. A.) 21 February 1995 See the entire document.	1-10
A	US 2005-0149092 A1 (DUNN, R. M.) 07 July 2005 See the entire document.	1-10

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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
05 September 2013 (05.09.2013)	**05 September 2013 (05.09.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
HAN In Ho
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/044973

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. ☒ Claims Nos.: 11-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 11-20 pertain to methods for treatment of human body and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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 addtional 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 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.

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