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(54) Title: SUTURE AND SOFT ANCHOR ASSEMBLY AND METHOD OF MAKING THE SAME

(57) Abstract: A method of anchoring a suture (20, 24) into a pilot hole (52) in bone (54), utilizing a suture anchor (42). A lumen-defining circular soft wall 16, having a first and second end (22, 26), is slidably engaged to a piece of suture (12), a first length (20) of which extends from the first end of the wall (22) and is threaded through the lumen (18) from the second end (26), and a second length (24) of which extends from the second end (26) and is threaded through the lumen (18) from the first end (22). The suture anchor (42) is introduced into the pilot hole (52) so that the first length (20) and second length (24) of suture material extend out of the pilot hole (52). The first length (20) and second length (24) are pulled on alternately, thereby permitting the suture anchor (42) structure to slide on the piece of suture material (20, 24), and to be compacted evenly by the pulling, until the suture anchor (42) is set in the pilot hole (52).

SUTURE AND SOFT ANCHOR ASSEMBLY AND METHOD OF MAKING THE SAME

Technical Field

This application relates to a suture and soft anchor assembly adapted to anchoring a suture to bone, without the use of a metal piece.

Background Art

In performing various surgical repair operations it is necessary to anchor a suture to bone, typically in order to connect muscle to the bone, in the same manner as a healthy tendon. One apparatus for effecting this anchoring is to provide a suture that has some structure on or about it that can be compacted by a surgeon performing some action, such as drawing on a piece of suture material. The structure is introduced into a pilot hole, and is compacted, so that it forms a hard ball that sets by digging into the sides of the pilot hole, thereby anchoring the suture.

Although the soft suture anchor has a range of advantages over metal anchors, such as screws, the setting action is not always as robust as would be desirable. A poorly set anchor may work its way loose over time, resulting in a slack bone-muscle connection, which could cause a great deal of dissatisfaction on the part of a patient. In the worst case situation, the anchor works its way free of the bone, undoing the bone-to-muscle connection.

Summary

The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope. In various embodiments, one or more of the above-described problems have been reduced or eliminated, while other embodiments are directed to other improvements.

In a first separate aspect, the present invention may take the form of a suture assembly, including a soft anchor made up of a piece of suture material and a soft structure, of greater diameter and a shorter length than the piece of suture material and having a circular soft wall, defining an interior lumen and having a first end and a second end opposed to the first end. The first piece of suture material

extends longitudinally through the circular soft wall in such a manner that the soft structure can slide along the piece of suture material and thereby defines a first length of the piece of suture material, extending from engagement with the circular soft wall at the first end and a second length of the piece of suture material, extending from engagement with the circular soft wall at the second end. Finally, the first length is threaded through the lumen, entering at the second end and the second length is threaded through the lumen, entering at the first end. Accordingly, an anchor is formed, made up of said circular soft wall with said lengths looped about it, and said lengths extend outward, available for attachment to anatomical structures

In a second separate aspect, the present invention may take the form of a method of anchoring a suture into a pilot hole in bone. The method utilizes a suture anchor structure, wherein a lumen-defining circular soft wall, having a longitudinal first end and an opposed second end, is slidably engaged to a piece of suture material, and wherein a first length of the suture material extends from the first end of the wall and is threaded through the lumen from the second end, and a second length of the suture material extends from the second end and is threaded through the lumen from the first end. The suture anchor structure is introduced into the pilot hole so that the first length and second length of suture material extend out of the pilot hole. The first length and second length are pulled on alternately, thereby permitting the suture anchor structure to slide on the piece of suture material, and to be compacted evenly by the pulling, until the suture anchor is set in the pilot hole.

In a third separate aspect, the present invention may take the form of a method of making a suture assembly, including a soft suture anchor, that utilizes a piece of suture material and includes the step of constructing a soft structure about the piece of suture material, such that the soft structure is slidably engaged to the piece of suture material, and wherein the soft structure defines a lumen, separate from the slidable engagement of the soft structure to the piece of suture. Further, the soft structure has a first longitudinal end out of which extends a first length of the piece of suture material and has a second longitudinal end opposed to the first longitudinal, out of which extends a second length of the piece of suture material.

The first length is threaded through the lumen from the second to the first end, such that the first length extends out of the lumen at the first end of the soft structure and the second length is threaded through the lumen, from the first end to the second such that the second length extends out of the lumen at the second end of the soft structure. The soft structure and the portions of the lengths that are looped about it form a soft anchor, and the portion of the lengths extending outwardly from the lumens are available for attachment to anatomical features.

In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed descriptions.

Brief Description of the Drawings

Exemplary embodiments are illustrated in referenced drawings. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

FIG. 1 is a side isometric view of a workpiece representing a step in the production of a suture and soft anchor assembly, according to the present invention.

FIG. 2 is a side isometric view of the workpiece of FIG. 1 at a further stage in the production process, wherein a soft structure having a lumen and a pair of suture lengths extending therefrom have been defined.

FIG. 3 is a side isometric view of the workpiece of FIG. 2 at a further stage of the production process, wherein a first suture length is in the process of being pulled through the lumen.

FIG. 4 is a side isometric view of the workpiece of FIG. 3 at a further stage in the production process, wherein the first suture length has been pulled through the lumen.

FIG. 5 is a side isometric view of the workpiece of FIG. 4 at a further stage of the production process, wherein the second suture length is in the process of being pulled through the lumen.

FIG. 6 is a side isometric view of the workpiece of FIG. 5 at a further stage of the production process, wherein the second suture length has been pulled through the lumen, completing assembly having a soft anchor and suture lengths.

FIG. 7 is a side isometric view of the assembly of FIG. 6, wherein the two suture lengths have been pulled, thereby collapsing and compacting the anchor.

FIG. 8 is a sectional view of a pilot hole in bone showing the assembly of FIG. 6 inserted using an insertion tool.

FIG. 9 is a sectional view of a pilot hole in bone showing the assembly of FIG. 6, and wherein the anchor has been deployed by pulling on the lengths.

FIG. 10 is a side isometric view of the production of an alternative embodiment, showing the assembly of FIG. 6, and also showing an additional piece of suture in the process of being threaded through the lumen.

FIG. 11 is a side isometric view of a finished alternative embodiment of a suture and soft anchor assembly having four lengths of search extending from the soft anchor.

Best Modes of Carrying Out the Invention

Referring to FIGS. 1 and 2, in one preferred embodiment, construction of a suture and anchor assembly begins with a workpiece 10 that is formed by feeding a size 2 piece of suture 12 together with a set of thinner ultra high molecular weight polyethylene UHWMPE fibers (for example smaller diameter suture material, such as 4-0 suture material) into a suture braiding machine in such a manner that the size 2 piece of suture 12 becomes one of the warp ends (longitudinally running elements) of the resultant workpiece 10. Suture piece 12, together with the remainder of the braid 14 (not including suture piece 12), form a circular wall 16 defining a lumen 18. Workpiece 10 is formed when the product of the braiding machine is cut into a piece that can range in length, depending on the specific application. Then, the remainder 14 is cut on both ends with a cauterizing blade or scissors, so that it now forms a soft structure 14, as showing in FIG. 2, including a circular wall 16, defining a lumen 18, that only extends along, and is slidingly engaged to, a portion of suture piece 12. As a result, a first length 20 of suture piece

12 extends from a first end 22 of soft structure 16 and a second end 24 extends from a second end 26 of soft structure 16.

Referring to FIGS. 3 through 6, a lacing tool 30 is then used to pull the first length 20 through lumen 18, entering at the second end 26, and thereby forming a loop as shown, and exiting at the first end 22. Then, lacing tool 30 is used to pull the second length 24 through lumen 18, entering at the first end 22, and therefore forming an additional loop as shown, and exiting at the second end 26.

Workpiece 10 has now become a finished suture and soft anchor assembly 40, having a soft anchor 42, made up of the circular wall 16 and loops formed by a portion of first length 20 and second length 24. Also, first length 20 and second length 24 extend outwardly for deploying anchor 42 and also for attachment to anatomical structures. Referring to FIG. 7, when first length 20 and second length 24 are pulled, anchor 42 knots up, thereby forming a relatively hard, compacted knot.

FIGS. 8 and 9 show the use of assembly 40, with an insertion tool 50 used to place anchor 42 into a pilot hole 52 that has been drilled into bone 54. While tool 50 is being used to retain anchor 42 in stationary position in hole 52, length 20 and 24 are pulled in alternating order. This causes anchor 42 to form a hard knot, digging into bone 54, thereby setting anchor 42 into bone 54 and providing lengths 20 and 24 to be used to retain muscle or to connect to whatever internal structure is desired.

Referring to FIGS. 10 and 11, in an alternative preferred embodiment an additional piece of suture material 60 is threaded through lumen 18, looped about and rethreaded through, so that it is retained, to provide additional lengths 62 and 64 for tying to other structures, such as muscle or bone, within the body. In further embodiments, further pieces of suture material are also threaded through lumen 18, looped about and rethreaded, to provide still more lengths, for forming further suture connections within the body.

In a first preferred embodiment, a suture assembly, including a soft anchor, includes a piece of suture material and a soft structure, of greater diameter and a shorter length than the piece of suture material and having a circular soft wall, defining an interior lumen and having a first end and a second end opposed to the

first end. Further, the first piece of suture material extends longitudinally through the circular soft wall in such a manner that the soft structure can slide along the piece of suture material and thereby define a first length of the piece of suture material, extending from engagement with the circular soft wall at the first end and a second length of the piece of suture material, extending from engagement with the circular soft wall at the second end. Finally, the first length is threaded through the lumen, entering at the second end, thereby forming a loop, and the second length is threaded through the lumen, entering at the first end, thereby forming a loop and thereby forming an anchor made up of the circular soft wall and the loops and the first and second lengths extending outward and thereby being available for attachment to anatomical structures. In this embodiment, the soft structure may be a braid of fibers, forming a circular soft wall that defines the lumen, of which the piece of suture material forms a warp end. Further, the fibers of the soft structure may be at least 90% UHWMPE. In addition, the first length may extend at least 10 cm from the lumen at the soft structure first end and the second length extends at least 10 cm from the lumen at the soft structure second end. In further addition, the piece of suture material may be at least 90% UHWMPE by weight. Further, the additional suture piece may be threaded through the lumen, thereby providing additional possible suture attachment points and yet another suture piece may be threaded through the lumen, thereby providing yet additional possible suture attachment points.

In a second embodiment, the invention may take the form of a method of anchoring a suture into a pilot hole in bone, using a suture anchor structure, wherein a lumen-defining circular soft wall, having a longitudinal first end and an opposed second end, is slidably engaged to a piece of suture material, and wherein a first length of the suture material extends from the first end of the wall and is threaded through the lumen from the second end, and a second length of the suture material extends from the second end and is threaded through the lumen from the first end. This suture anchor structure is introduced into the pilot hole so that the first length and second length of suture material extend out of the pilot hole, and the first length and second length are pulled alternately, thereby permitting the suture anchor structure to slide on the piece of suture material, and

to be compacted evenly by the pulling, until the suture anchor is set in the pilot hole. In this method the soft structure may be a braid of fibers, forming a circular soft wall that defines the lumen, of which the piece of suture material forms a warp end. Further, the fibers of the soft structure may be at least 90% UHWMPE. In addition, the first length may extend at least 10 cm from the lumen at the soft structure first end and the second length extends at least 10 cm from the lumen at the soft structure second end. In further addition, the piece of suture material may be at least 90% UHWMPE by weight. Further, the first length may be attached to an anatomical structure and the second length may be attached to an anatomical structure. Also, a yet additional suture piece may be threaded through the lumen. and this piece may have a first end and a second end and in the method the yet additional piece first end may be attached to a first anatomical structure and the yet additional piece second end may be attached to a second anatomical structure

In a third embodiment, the present invention may take the form of a method of making a soft suture assembly, including a soft suture anchor, utilizing a piece of suture material. Beginning by constructing a soft structure about the piece of suture material, such that the soft structure is slidably engaged to the piece of suture material, and wherein the soft structure defines a lumen, separate from the slidable engagement of the soft structure to the piece of suture. Further, the soft structure has a first longitudinal end out of which extends a first length of the piece of suture material and has a second longitudinal end opposed to the first longitudinal, out of which extends a second length of the piece of suture material. Then the first length is threaded through the lumen from the second to the first end, thereby forming a loop,such that the first length extends out of the lumen at the first end of the soft structure. Then, threading the second length through the lumen, from the first end to the second, thereby forming a loop, such that the second length extends out of the lumen at the second end of the soft structure. Accordingly, a soft anchor is formed, made up of the soft structure and the loops, and with the first and second lengths extending outwardly for attachment to anatomical structures. In this method the step of constructing a soft structure about the piece of suture material may be accomplished by, first placing suture material in a suture braiding machine and braiding it together with a set of fibers so that it forms a warp end of a resultant

braided suture extent. Then, cutting a length of the resultant braided suture extent, the length being comprised of the piece of suture material and a remainder made of the fibers. Finally, cutting away from the remainder on either longitudinal side of a portion of the remainder, thereby creating a soft structure formed by the portion of the remainder, which is slidably engaged to the piece of suture material. In this method, the fibers of the soft structure may be at least 90% UHWMPE. Also, the piece of suture material may be a number 2 suture. In addition, the first length may extend at least 10 cm from the lumen at the soft structure first end and the second length extends at least 10 cm from the lumen at the soft structure second end. Further, the piece of suture material may be at least 90% UHWMPE by weight. Further, an additional suture piece may be threaded through the lumen, thereby providing additional possible suture attachment points. And, in this instance, yet another suture piece is threaded through the lumen, thereby providing yet additional possible suture attachment points.

Industrial Applicability

The present invention finds application in the production of suture assemblies for use in surgery.

While a number of exemplary aspects and embodiments have been discussed above, those possessed of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

CLAIMS

1. A suture assembly, including a soft anchor, comprising:

(a) a piece of suture material;

(b) a soft structure, of greater diameter and a shorter length than said piece of suture material and having a circular soft wall, defining an interior lumen and having a first end and a second end opposed to said first end;

(c) wherein said first piece of suture material extends longitudinally through said circular soft wall in such a manner that said soft structure can slide along said piece of suture material and thereby defining a first length of said piece of suture material, extending from engagement with said circular soft wall at said first end and a second length of said piece of suture material, extending from engagement with said circular soft wall at said second end; and

(d) wherein said first length is threaded through said lumen, entering at said second end, thereby forming a loop, and said second length is threaded through said lumen, entering at said first end, thereby forming a loop and thereby forming an anchor made up of said circular soft wall and said loops and said first and second lengths extending outward and thereby being available for attachment to anatomical structures..

2. The assembly of claim 1, wherein said soft structure is a braid of fibers, forming a circular soft wall that defines said lumen, of which said piece of suture material forms a warp end.

3. The assembly of claim 2, wherein said fibers of said soft structure are at least 90% UHWMPE.

4. The assembly of claim 1, wherein said first length extends at least 10 cm from said lumen at said soft structure first end and said second length extends at least 10 cm from said lumen at said soft structure second end.

5. The assembly of claim 1, wherein said piece of suture material is at least 90% UHWMPE by weight.

6. The assembly of claim 1, wherein an additional suture piece is threaded through said lumen, thereby providing additional possible suture attachment points.

7. The assembly of claim 6, wherein yet another suture piece is threaded through said lumen, thereby providing yet additional possible suture attachment points.

8. A method of anchoring a suture into a pilot hole in bone:

(a) providing a suture anchor structure, wherein a lumen-defining circular soft wall, having a longitudinal first end and an opposed second end, is slidably engaged to a piece of suture material, and wherein a first length of said suture material extends from said first end of said wall and is threaded through said lumen from said second end, and a second length of said suture material extends from said second end and is threaded through said lumen from said first end;

(b) introducing said suture anchor structure into said pilot hole so that said first length and second length of suture material extend out of said pilot hole;

(c) pulling alternately on said first length and second length, thereby permitting said suture anchor structure to slide on said piece of suture material, and to be compacted evenly by said pulling, until said suture anchor is set in said pilot hole.

9. The method of claim 8, wherein said soft structure is a braid of fibers, forming a circular soft wall that defines said lumen, of which said piece of suture material forms a warp end.

10. The method of claim 9, wherein said fibers of said soft structure are at least 90% UHWMPE.

11. The method of claim 8, wherein said first length extends at least 10 cm from said lumen at said soft structure first end and said second length extends at least 10 cm from said lumen at said soft structure second end.

12. The method of claim 11, wherein said first length is attached to an anatomical structure and said second length is attached to an anatomical structure.

13. The method of claim 8, wherein said piece of suture material is at least 90% UHWMPE by weight.

14. The method of claim 8, wherein an additional suture piece is threaded through said lumen, and wherein said additional piece has a first end and a second end and wherein during said method said first end is attached to a first anatomical structure and said second end is attached to a second anatomical structure.

15. The method of claim 14, wherein a yet additional suture piece is threaded through said lumen. and wherein said yet additional piece has a first end and a second end and wherein during in said method said yet additional piece first end is attached to a third anatomical structure and said yet additional piece second end is attached to a fourth anatomical structure

16. A method of making a soft suture assembly, including a soft suture anchor, comprising:

(a) providing a piece of suture material;

(b) constructing a soft structure about said piece of suture material, such that said soft structure is slidably engaged to said piece of suture material, and wherein said soft structure defines a lumen, separate from said slidable engagement of said soft structure to said piece of suture and wherein said soft structure has a first longitudinal end out of which extends a first length of said piece of suture material and has a second longitudinal end opposed to said first longitudinal, out of which extends a second length of said piece of suture material;

(c) threading said first length through said lumen from said second to said first end, thereby forming a loop, and such that said first length extends out of said lumen at said first end of said soft structure and threading said second length through said lumen, from said first end to said second, thereby forming a loop, such that said second length extends out of said lumen at said second end of said soft structure, and thereby forming a soft anchor made up of said soft structure and said loops, and with said first and second lengths extending outwardly for attachment to anatomical structures.

17. The method of claim 16, wherein said step of constructing a soft structure about said piece of suture material is accomplished by:

(a) placing suture material in a suture braiding machine and braiding it together with a set of fibers so that it forms a warp end of a resultant braided suture extent;

(b) cutting a length of said resultant braided suture extent, said length being comprised of said piece of suture material and a remainder made of said fibers; and

(c) cutting away from said remainder on either longitudinal side of a portion of said remainder, thereby creating a soft structure formed by said portion of said remainder, which is slidably engaged to said piece of suture material.

18. The method of claim 17, wherein said fibers of said soft structure are at least 90% UHWMPE.

19. The method of claim 16, wherein piece of suture material is a length number 2 suture.

20. The method of claim 16, wherein said first length extends at least 10 cm from said lumen at said soft structure first end and said second length extends at least 10 cm from said lumen at said soft structure second end.

21. The method of claim 16, wherein said piece of suture material is at least 90% UHWMPE by weight.

22. The method of claim 16, wherein an additional suture piece is threaded through said lumen, thereby providing additional possible suture attachment points.

23. The method of claim 21, wherein yet another suture piece is threaded through said lumen, thereby providing yet additional possible suture attachment points.

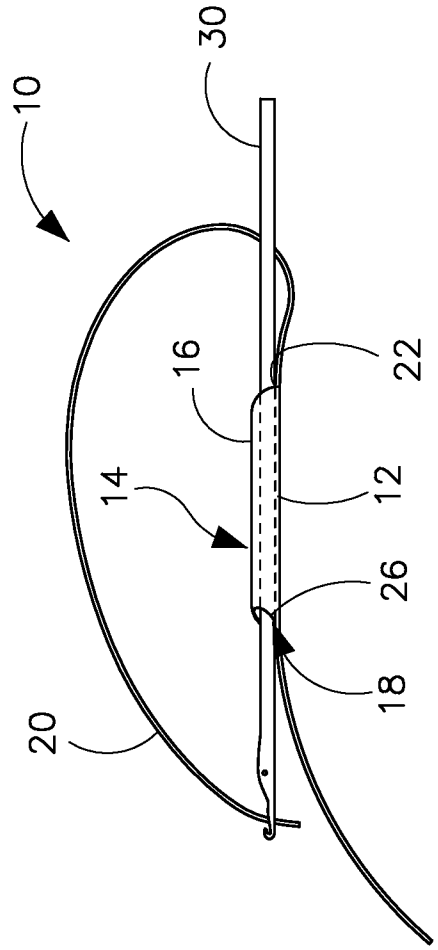

FIG. 3

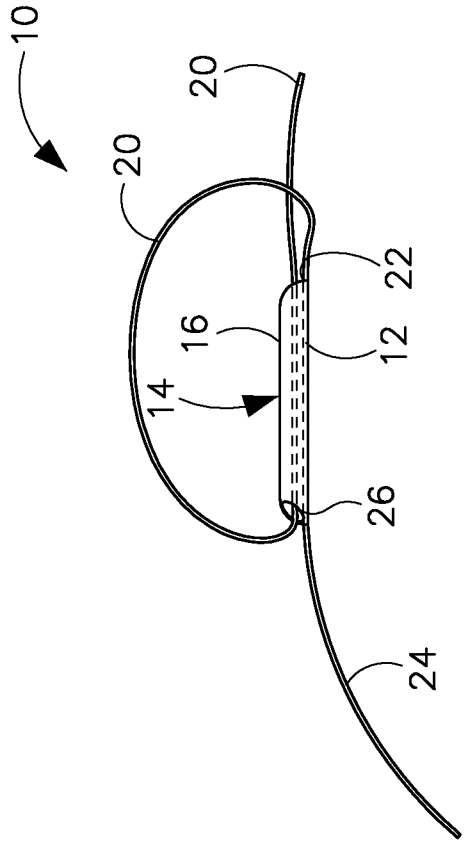

FIG. 4

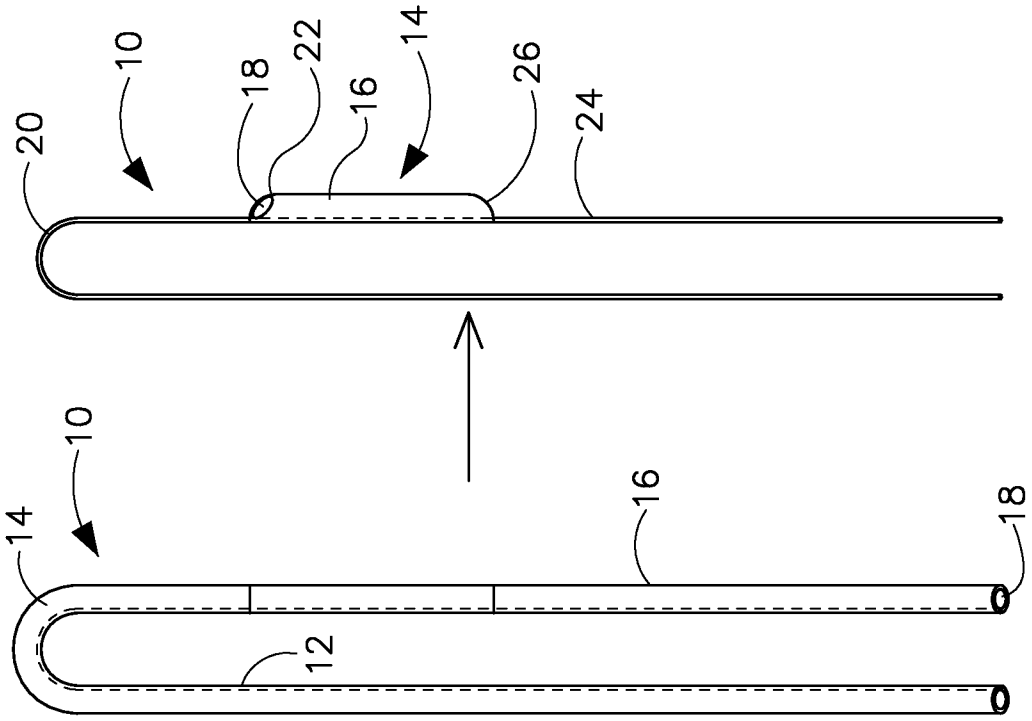

FIG. 2

FIG. 1

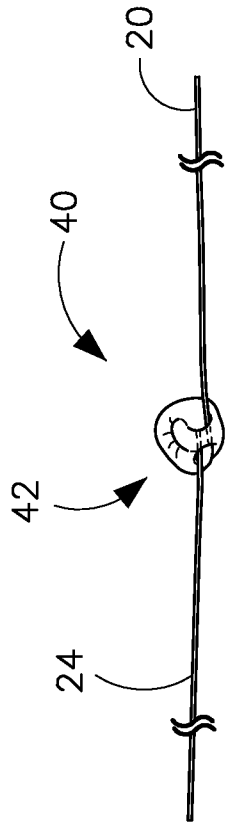

FIG. 7

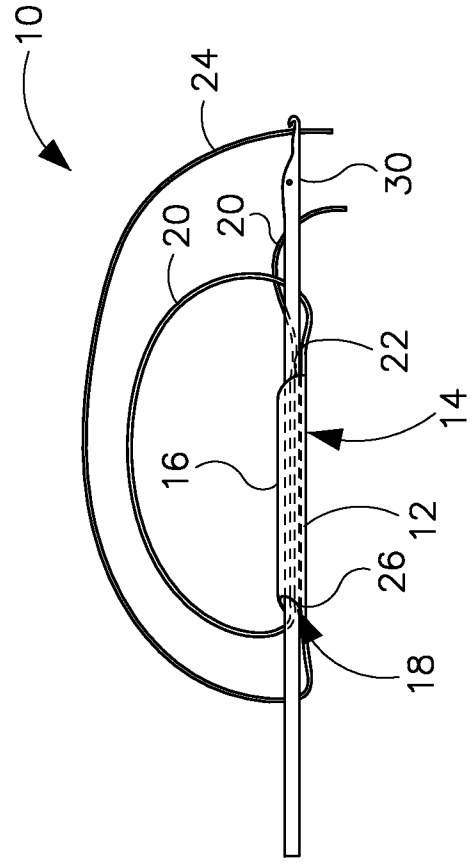

FIG. 5

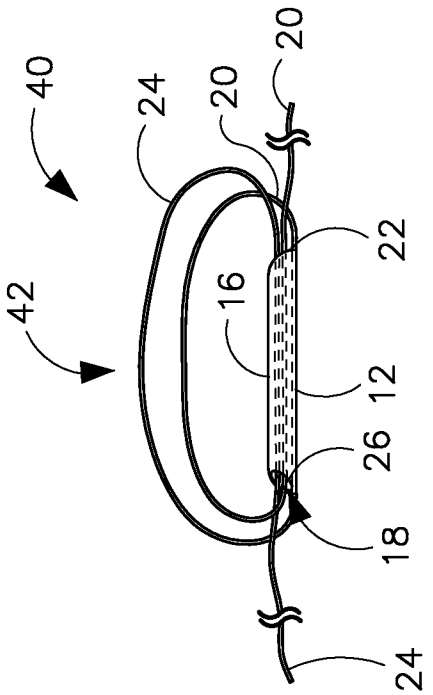

FIG. 6

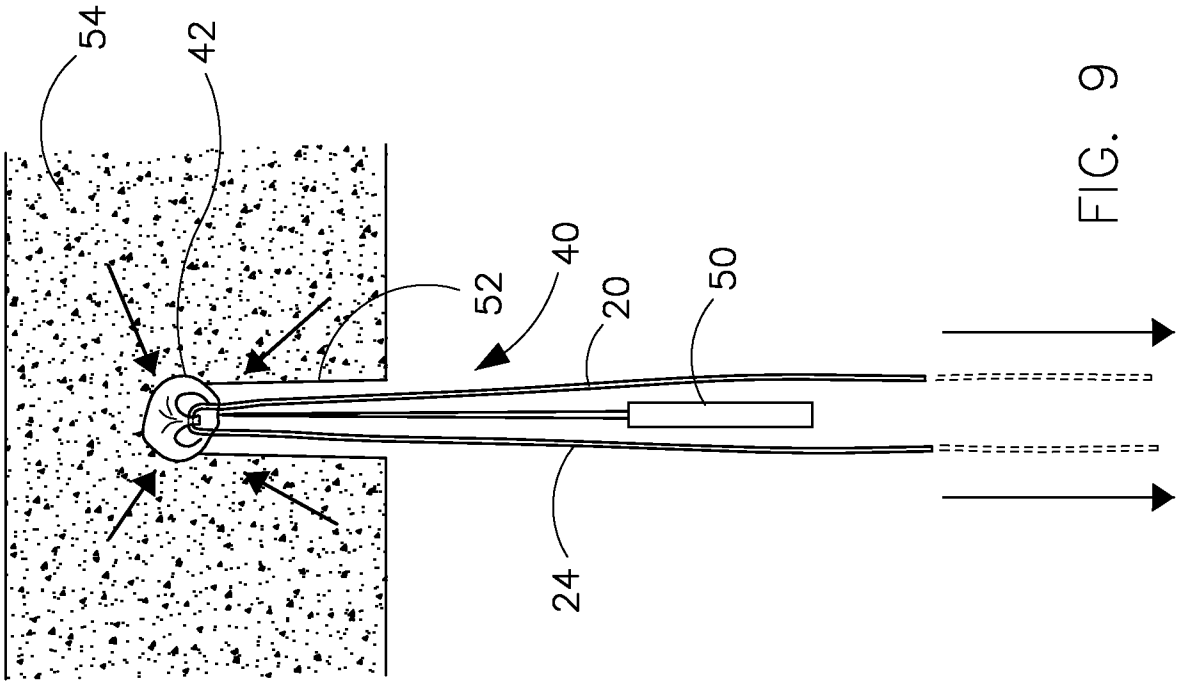

FIG. 9

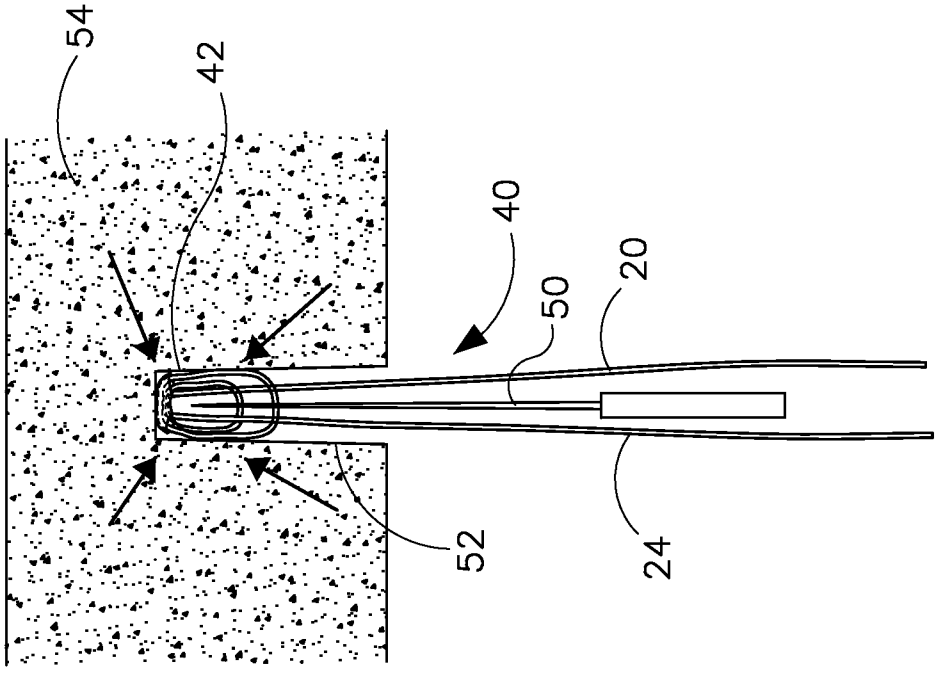

FIG. 8

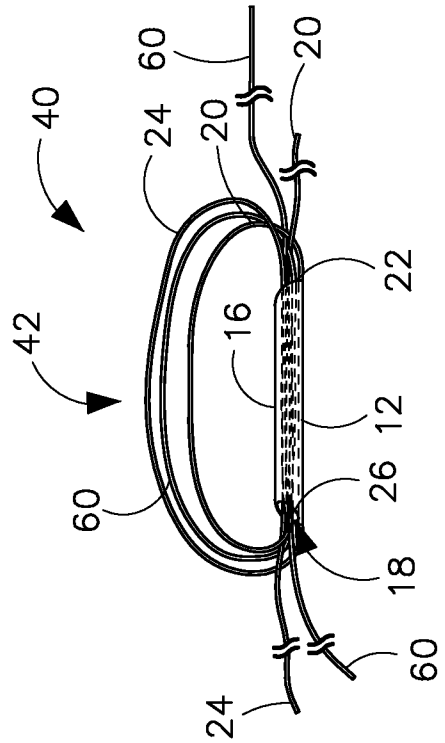
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FIG. 11

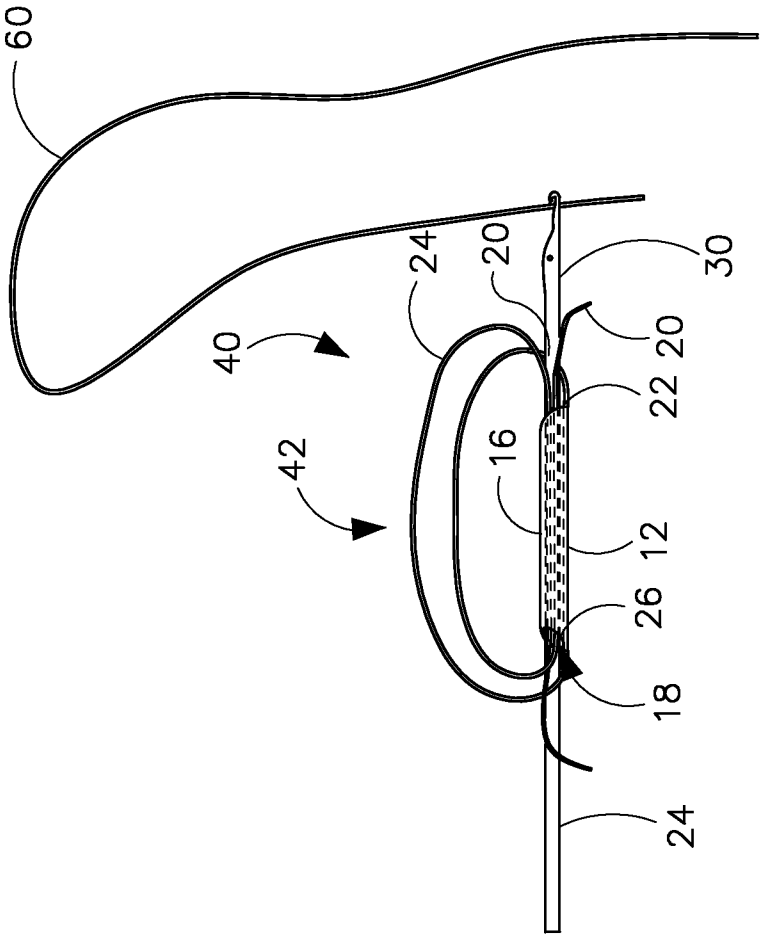
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FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2014/065638

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/04 *(2006.01)*
A61L 17/00 *(2006.01)*

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 17/04, A61L 17/00

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), DWPI, Espacenet, Google, Rambler, Yandex

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0296934 A1 (DEPUY MITEK, INC.) 07.11.2013, claims 1-5, 9, 11-14, fig. 3A-3D, 4, 5A-5H, 6, 10, 11A-11J, paragraphs [0013], [0040], [0043]-[0051], [0053], [0055]-[0059], [0076], [0078]-[0079]	1, 4, 6-8, 14, 16, 17, 22
Y		2, 3, 5, 9-13, 15, 18-21, 23
Y	US 2013/0096612 A1 (ARTHREX, INC.) 18.04.2013, paragraphs [0021], [0025], [0032], [0074]-[0075]	2, 3, 5, 9, 10, 13, 18, 21, 23
Y	US 2010/0016892 A1 (WILLIAM KAISER et al.) 21.01.2010, fig. 10, 11, paragraphs [0061]-[0063]	11, 12, 19, 20
Y	US 2002/0111653 A1 (OPUS MEDICAL, INC.) 15.08.2002, fig. 1A, 1B, 2A-2C, paragraphs [0053]-[0055], [0057], [0066], [0068], [0071]	15

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

☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2015 (18.02.2015)	19 March 2015 (19.03.2015)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer E. Nosova Telephone No. 8(495)531-64-81

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