



(51) International Patent Classification:
A61B 17/00 (2006.01) A61B 17/04 (2006.01)

(21) International Application Number:
PCT/US2010/024472

(22) International Filing Date:
17 February 2010 (17.02.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/389,847 20 February 2009 (20.02.2009) US

(71) Applicant (for all designated States except US):
BOSTON SCIENTIFIC SCIMED, INC. [US/US]; One
Scimed Place, Maple Grove, Minnesota 55311 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **HANSEN, James, G.**
[US/US]; 12776 Verdun Street NW, Coon Rapids, Min-
nesota 55448 (US).

(74) Agent: **SEAGER, Glenn, M.**; 1221 Nicollet Avenue,
Suite 800, Minneapolis, Minnesota 55403 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD,
SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: LOCKING ELEMENT FOR VASCULAR CLOSURE DEVICE

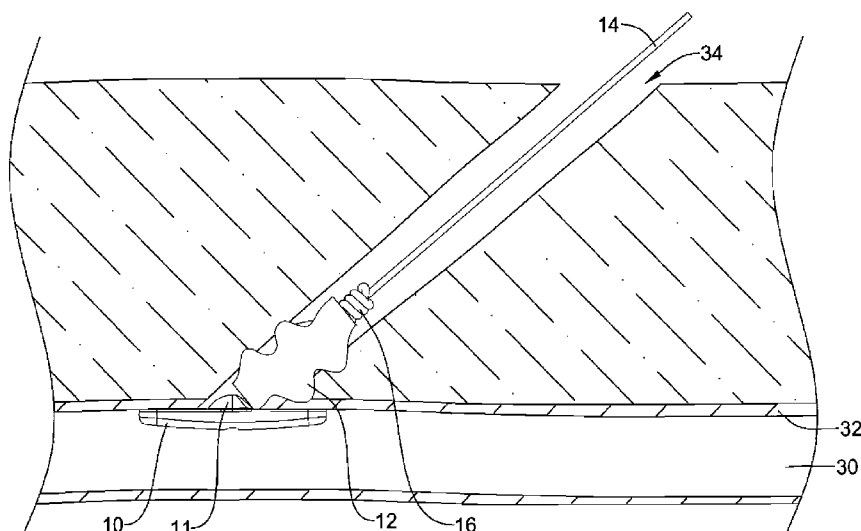


Figure 1

(57) Abstract: In one illustrative example, a device for sealing an opening in a vessel wall and/or tissue tract may include an anchor (10), a filament (14), a plug (12), and a knot (16). The anchor may be configured to be disposed adjacent to an interior surface of the vessel wall adjacent the opening in the vessel wall. The filament may have a distal end coupled to the anchor and may be configured to extend proximally through the vessel opening and/or tissue tract. The plug may be disposed about at least a portion of the filament member. The knot may be disposed about the filament proximal of the plug and may be configured to move over the filament and secure the plug relative to the anchor. The knot may be independent of the filament member.

LOCKING ELEMENT FOR VASCULAR CLOSURE DEVICE

Field

The present disclosure relates generally to medical devices and more particularly to methods and devices for closing and/or sealing punctures in tissue.

Background

In many medical procedures, such as, for example, balloon angioplasty and the like, an opening can be created in a blood vessel or arteriotomy to allow for the insertion of various medical devices which can be navigated through the blood vessel to the site to be treated. For example, a guidewire may first be inserted through the tissue tract created between the skin, or the epidermis, of the patient down through the subcutaneous tissue and into the opening formed in the blood vessel. The guidewire is then navigated through the blood vessel to the site of the occlusion or other treatment site. Once the guidewire is in place, an introducer sheath can be slid over the guide wire to form a wider, more easily accessible, tract between the epidermis and the opening into the blood vessel. The appropriate medical device can then be introduced over the guidewire through the introducer sheath and then up the blood vessel to the site of the occlusion or other treatment site.

Once the procedure is completed, the medical devices or other equipment introduced into the vessel can be retracted through the blood vessel, out the opening in the blood vessel wall, and out through the tissue tract to be removed from the body. The physician or other medical technician is presented with the challenge of trying to close the opening in the blood vessel and/or the tissue tract formed in the epidermis and subcutaneous tissue. A number of different device structures, assemblies, and methods are known for closing the opening in the blood vessel and/or tissue tract, each having certain advantages and disadvantages. However, there is an ongoing need to provide new and improved device structures, assemblies, and/or methods for closing and/or sealing the opening in the blood vessel and/or tissue tract.

Brief Summary

The following summary is provided to facilitate an understanding of some of the innovative features unique to the present disclosure and is not intended to

be a full description. A full appreciation of the disclosure can be gained by taking the entire specification, claims, drawings, and abstract as a whole.

The present disclosure relates generally to medical devices and more particularly to methods and devices for closing and/or sealing punctures in tissue. In one illustrative embodiment, a device for sealing an opening in a vessel wall and/or tissue tract may include an anchor, a filament, a plug, and a knot. The anchor may be configured to be disposed adjacent to an interior surface of the vessel wall adjacent the opening in the vessel wall. The filament may have a distal end coupled to the anchor and may be configured to extend proximally through the vessel opening and/or tissue tract. The plug may be disposed about at least a portion of the filament member. The knot may be disposed about the filament proximal of the plug and may be configured to move over the filament and secure the plug relative to the anchor. The knot may be independent of the filament member.

In some cases, the knot may include a suture member having a first end, a second end, and an intermediate portion having a number of turns defining a lumen, wherein the first end and second end are passed through the lumen. In some cases, the knot may be configured to exert a compressive force on the filament.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

Figure 1 is a schematic diagram of an illustrative embodiment of an anchor, a plug, a filament, and a locking element for closing and/or sealing an opening in a blood vessel and/or adjacent tissue tract;

Figure 2 is a schematic diagram of the illustrative knot of Figure 1 loosely disposed about the filament shown in Figure 1;

Figure 3 is a schematic diagram of the illustrative knot of Figure 1 tightly disposed about the filament shown in Figure 1; and

Figures 4 and 5 are schematic diagrams of an illustrative embodiment of a device for sliding the knot along the filament to deploy the plug within the opening of the vessel wall and/or tissue tract.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will

be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms “about” may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Figure 1 is a schematic diagram of an illustrative embodiment of an anchor 10, a plug 12, a filament 14, and a locking element 16 for closing and/or sealing an opening in a blood vessel 30 and/or adjacent tissue tract 34 that was created to gain access to the vessel to perform a medical procedure. In the illustrative embodiment, the anchor 10 may be configured to engage an interior surface of the vessel wall 32. In some cases, the anchor 10 may be configured to partially or completely occlude the opening in the vessel wall 32, as desired. The anchor 10 may include a biodegradable material so that, over time, the anchor 10 is degraded, eroded, and/or absorbed in the body. In some cases, the anchor 10 may include a PLGA, PLLA, PGA or other degradable or erodable polymers, such as polyesters, polysaccharides, polyanhydrides, polycaprolactone, and various combinations thereof. In some cases,

the anchor 10 may include a combination of the previously mentioned materials to impart a variable strength and/or degradation time profile in the anchor 10. One example anchor 10 that is configured to rapidly absorb and/or degrade is disclosed in Application Serial No. 61/031,456, filed February 26, 2008, which is hereby incorporated by reference. However, it is contemplated that any suitable anchor 10 may be used, as desired.

Filament 14 may include a proximal end, a distal end, with a length extending therebetween. The distal end of the filament 14 may be coupled to the anchor 10 with the filament 14 extending proximally therefrom and through the tissue tract 34. In some cases, the anchor 10 may include a raised portion including an eyelet to facilitate attachment of the distal end of the filament 14 to the anchor. In other cases, the distal end of the filament 14 may be molded into the anchor 10, passed through an opening in the anchor 10, or otherwise attached, connected, or secured to the anchor 10, as desired.

The filament 14 may include a biodegradable material so that, over time, the filament 14 is degraded, eroded, and/or absorbed in the body. In some cases, the filament 14 may include a PLGA, PLLA, PGA or other degradable or erodable polymers, such as polyesters, polysaccharides, polyanhydrides, polycaprolactone, and various combinations thereof. In some cases, the filament 14 can include a suture material, which may be a biodegradable suture.

In the illustrative embodiment, the plug 12 can be disposed about at least a portion of the filament 14 adjacent to the anchor 10 in the tissue tract 34 and/or opening of the vessel wall 32. The plug 12 may be configured to fill the space in the tissue tract 22 adjacent to the vessel 30 and/or the opening in the vessel wall 32 to close and/or seal the vessel 30 opening and/or tissue tract 34. In some example, the plug 12 may include a material that swells to fill space in the tissue tract 34 and/or vessel wall 32 opening, such as by elastic expansion, fluid absorption, chemical reaction, as well as any other suitable swelling and/or expansion. The plug 12 can be configured to promote hemostasis and/or clotting adjacent to the vessel 30. In one example, the plug may include a collagen, gelatin foam, PEG, starch powder, any suitable hemostatic material, any suitable clot-promoting material, as well as any other suitable material, as desired. In some cases, other materials can be used to provide control of thrombogenicity or hydration. The plug 12 may include a

biodegradable material so that, over time, the plug 12 is degraded, eroded, and/or absorbed in the body.

In the illustrative embodiment, the plug 12 may be generally cylindrical in shape with a lumen extending therethrough. As illustrated, the plug 12 is shown in an axially compressed state after it has been deployed in the tissue tract 20.

Some examples of plugs and plug materials that may be used in the closure device are disclosed in Application Serial No. 12/390,298 (Attorney docket No. 1001.2424101), filed February 20, 2009, which is hereby incorporated by reference. In some cases, the plug 12 can include one or more voids, notches, slits, or other modifications to provide a desired axial compression of plug 12. Examples of plugs that may include voids, notches, slits, or other modification are disclosed in Application Serial No. 12/389,960, (Attorney docket No. 1001.2235101), filed February 20, 2009, which is hereby incorporated by reference. In some cases, the illustrative plug 12 can be processed to have desired expansion characteristics. For example, the plug 12 can be tenderized to break down cell walls to increase the rate of expansion of the plug 12. Examples of plugs that have been tenderized or otherwise processed and methods of tenderizing or otherwise processing are disclosed in Application Serial No. 12/390,067, (Attorney docket No. 1001.2236101), filed February 20, 2009, which is hereby incorporated by reference.

In the illustrative embodiment, the locking element 16 can be a knot. The knot 16 can be used to help secure the plug 12 relative to the anchor 10. In one example, a knot 16 can be disposed about at least a portion of the filament 14 proximal of the anchor 10. The knot 16 can be configured to slide over the filament 14 and compress the plug 12. In some cases, the knot 16 can be slide distal over the filament 14 to compress the plug 12. In some cases, the knot 16 may be a compression knot exerting a radial force on the filament 14. As such, the knot 16 may be configured to have a corresponding friction force of 0.5 pounds, 1.0 pound, 1.5 pounds, 2.0 pounds, 2.5 pounds, 3.0 pounds, or any other friction force, as desired. For example, the knot 16 may have a friction force of at least 0.5 pounds. In another example, the knot 16 may have a friction force of at least one pound, two pounds, three pounds, or any other friction force, as desired. In any event, the knot 16 may be configured to have a friction force greater than the rebound force of the plug 12 to prevent the plug 12 expanding after compression. The rebound force of the plug 12

may be the force of the plug 12 trying to expand in the axial direction after compression.

In the illustrative embodiment, the knot 16 may be independent of the filament 14. The knot 16 may include a suture that is independent of the filament 14. In some cases, the knot 16 may include a suture that has a larger radial diameter than the filament 14 so that the knot 16 has a sufficient size to contact the proximal end of the plug 12 for axial compression and not penetrating into the plug 12.

In the illustrative embodiment, the knot 16 may include a degradable material so that over time, it is degraded or eroded and no longer present in the body. In some cases, the locking element 16 may include a PLGA, PLLA, PGA or other degradable or erodable polymers, such as polyesters, polysaccharides, polyanhydrides, polycaprolactone, and various combinations thereof.

Figures 2 and 3 are schematic diagrams of the illustrative knot 16 of Figure 1 disposed about the filament 14. As shown in Figure 2, the knot 16 can be formed by loosely wrapping a suture 17 around the filament 14 a number of times to define a lumen therethrough. As illustrated in Figure 2, the suture 17 can be wrapped around the filament 14 five times. However, it is contemplated that the suture 17 may be wrapped around the filament 14 one time, two times, three times, four times, five times, six times, seven times, eight times, nine times, ten times, or any number of times, as desired. Then, both ends of the suture 17 may be passed through the lumen defined by the turns of the knot 16.

Suture 17 ends can then be pulled to tighten the knot 16 as shown in Figure 3. In other words, a tensioning force can be applied to the ends of the suture 17 to tighten the knot 16. The tensioning force to tighten the knot 16 may correspond to the compressive force that the knot 16 exerts on the filament. For example, the greater the tensioning force, the greater the compressive force exerted by the knot 16 on the filament 14. With the knot 16 tightly tied, the ends of the suture 17 can be removed from the knot 16.

In the illustrative embodiment, the suture 17 of knot 16 may be separate and distinct from the filament 14. In other words, the knot 16 may be independent of the filament 14. Further, in some cases, the knot 16 may be constructed of a suture 17 that has a different radial diameter than the suture used for the filament 14. In one illustrative example, the filament 14 may have a diameter of about 0.014 to 0.016 millimeters and the suture 17 of the knot 16 may have a diameter of about 0.016 to

0.018 millimeters. However, it is contemplated that any combination of suture sizes may be used, as desired. In this illustrative example and when five turns are used, the length of the knot 16 may be about 0.0890 to 0.091 millimeters. In addition, in this example, the diameter of the loose knot 16 may be about 0.069 millimeters and the diameter of the tight knot 16 may be about 0.0511 to 0.0532 millimeters. However, any suitable length or width may be used, as desired.

Figures 4 and 5 are schematic diagrams of an illustrative embodiment of a device for sliding the knot 16 along the filament 14 to deploy the plug 12 within the opening of the vessel wall 32 and/or tissue tract 34. In the illustrated embodiment, an insertion sheath 18 may be disposed at least partially in the tissue tract 34 for providing access to the opening in the vessel wall 32. The device for delivery the anchor 10, plug 12, filament 14, and knot 16 can include a device sheath 20 configured to pass into the insertion sheath 18. As shown, the device may include a push rod 22 having a distal end coupled to a plunger compression bead 24. The plunger compression bead 24 may be disposed adjacent to the knot 16. In the illustrative example, the push rod 22 can include one or more coils configured to slide over the filament 14.

In the illustrative example, the device may include an automatic filament release mechanism. This mechanism may include a collet 36 coupled to the filament 14 and a collet locking ring 38 configured to releasably engage the filament 14. As the push rod 22 is advanced distally, a filament release bead 40 disposed in the push rod 22 and about the collet 36, may be advanced distally over the collet 36 and engage the collet locking ring 38. As the push rod 22 continues to advance distally, the filament release bead 40 may disengage the collet locking ring 38 from the collet 36 releasing the filament 14 from the device. An example of an implantation device that may be used with the illustrative anchor 10, plug 12, filament 14, and knot 16 is disclosed in Application Serial No. 12/390,241 (Attorney Docket No. 1001.2426101), filed February 20, 2009, which is hereby incorporated by reference.

As illustrated in Figure 4, the anchor 10 is seated against the interior of the vessel wall 32 or arteriotomy. The filament 14 is coupled to the anchor 10 and extends proximally through the tissue tract 34. The plug 12 is disposed over the filament 14 adjacent the anchor 10 and the knot 16 is disposed about the filament 14 proximal of the plug 12. The plug 12, filament 14, and knot 16 may be disposed, at least partially, within the device sheath 20. As illustrated, both the insertion sheath 18

and the device sheath 20 may be retracted a distance from the anchor 10 and/or opening in the vessel wall 32 to provide an area for plug 12 deployment. In the illustrative example, the distance may be about one-quarter the length of the plug 12. However, it is contemplated that any suitable distance may be used, as desired.

Figure 5 shows the plug 12 in a compressed state after the device has been actuated advancing the push rod 22 to slide the knot 16 distally over the filament 14 and compress the plug 12. As discussed previously, the knot 16 may have a friction force on the filament 14, which may be greater than the rebound force of the plug 12. The force exerted by the push rod 22 and plunger compression bead 24 on the knot 16 may be greater than the friction force of the knot 16. As such, the knot 16 can maintain the plug 12 in a compressed state when the device, including the push rod 22, plunger compression bead 24, device sheath 20, and insertion sheath are removed. With the device and insertion sheath 18 removed, the anchor 10, plug 12, filament 14, and knot 16 may remain in the tissue tract 34 and/or vessel wall 32 opening, as shown in Figure 1.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

What is claimed is:

1. A device for sealing an opening in a vessel wall and/or tissue tract, the device comprising:

an anchor member configured to be disposed adjacent to an interior surface of the vessel wall adjacent the opening in the vessel wall;

a filament member having a distal end coupled to the anchor member and configured to extend proximally through the vessel opening and/or tissue tract;

a plug member disposed about at least a portion of the filament member; and

a knot member disposed about the filament member proximal of the plug member, wherein the knot member is configured to move over the filament member and axially compress the plug member against the anchor member, wherein the knot member is independent of the filament member.

2. The device of claim 1 wherein the knot member includes a first suture.

3. The device of claim 2 wherein the filament member includes a second suture.

4. The device of claim 3 wherein the first suture has a diameter that is larger than the second suture.

5. The device of claim 1 wherein the knot member exerts a compressive force on the filament member.

6. The device of claim 5 wherein the compressive force of the knot member on the filament member correlates to a friction force that is greater than a rebound force of the plug member, wherein the rebound force of the plug is a force of the plug trying to expand in the axial direction after compression.

7. The device of claim 5 wherein the knot member has a friction force of at least 0.5 pounds.

8. The device of claim 5 wherein the knot member has a friction force of at least two pounds.

9. A device for sealing an opening in a vessel wall and/or tissue tract, the device comprising:

an anchor member configured to be disposed adjacent to an interior surface of the vessel wall adjacent the opening in the vessel wall;

a first suture member having a distal end coupled to the anchor member and extending proximally through the vessel opening and/or tissue tract;

a plug member disposed about at least a portion of the first suture member adjacent to the anchor member; and

a second suture member includes a first end, a second end, and an intermediate portion having a number of turns defining a lumen, wherein the first end and second end are passed through the lumen, wherein the second suture member is disposed about the first suture member proximal of the plug member, wherein the second suture member exerts a compressive force on the first suture member, wherein the second suture member is independent of the first suture member.

10. The device of claim 9 wherein the second suture member is configured to move over the first suture member and axially compress the plug member against the anchor member.

11. The device of claim 9 wherein the second suture member has a diameter that is larger than the first suture member.

12. The device of claim 9 wherein the compressive force of the second suture member on the first suture member is related to a friction force of the second suture, wherein the friction force of the second suture is greater than a rebound force of the plug member, wherein the rebound force of the plug is a force of the plug trying to expand in the axial direction after compression.

13. The device of claim 12 wherein the second suture member has a friction force of at least two pounds.

14. The device of claim 12 further comprising a push rod configured to exert a force on the second suture member greater than the friction force of the second suture member on the first suture member.

15. A method of sealing and/or closing an opening in a vessel and/or tissue tract with an anchor, a filament, a plug, and a knot, the method comprising:

disposing the anchor against an interior surface of the vessel wall adjacent to the opening in the vessel wall;

disposing the filament at least partially within the tissue tract and coupling a distal end of the filament to the anchor;

disposing the plug about at least a portion of the filament adjacent to the anchor; and

disposing the knot about at least a portion of the filament proximal of the plug, wherein the knot is independent of the filament.

16. The method of claim 15 wherein the knot includes a suture member having a first end, a second end, and an intermediate portion having a number of turns defining a lumen, wherein the first end and second end are passed through the lumen.

17. The method of claim 16 further comprising tightening the suture of the knot to provide a friction force of at least 0.5 pounds.

18. The method of claim 16 further comprising tightening the suture of the knot to provide a friction force greater than a rebound force of the plug.

19. The method of claim 15 further comprising moving the knot in a distal direction relative to the suture to compress the plug, wherein the knot has a friction force that is greater than the rebound force of the plug.

20. The device of claim 16 wherein the suture member of the knot has a diameter that is larger than the filament.

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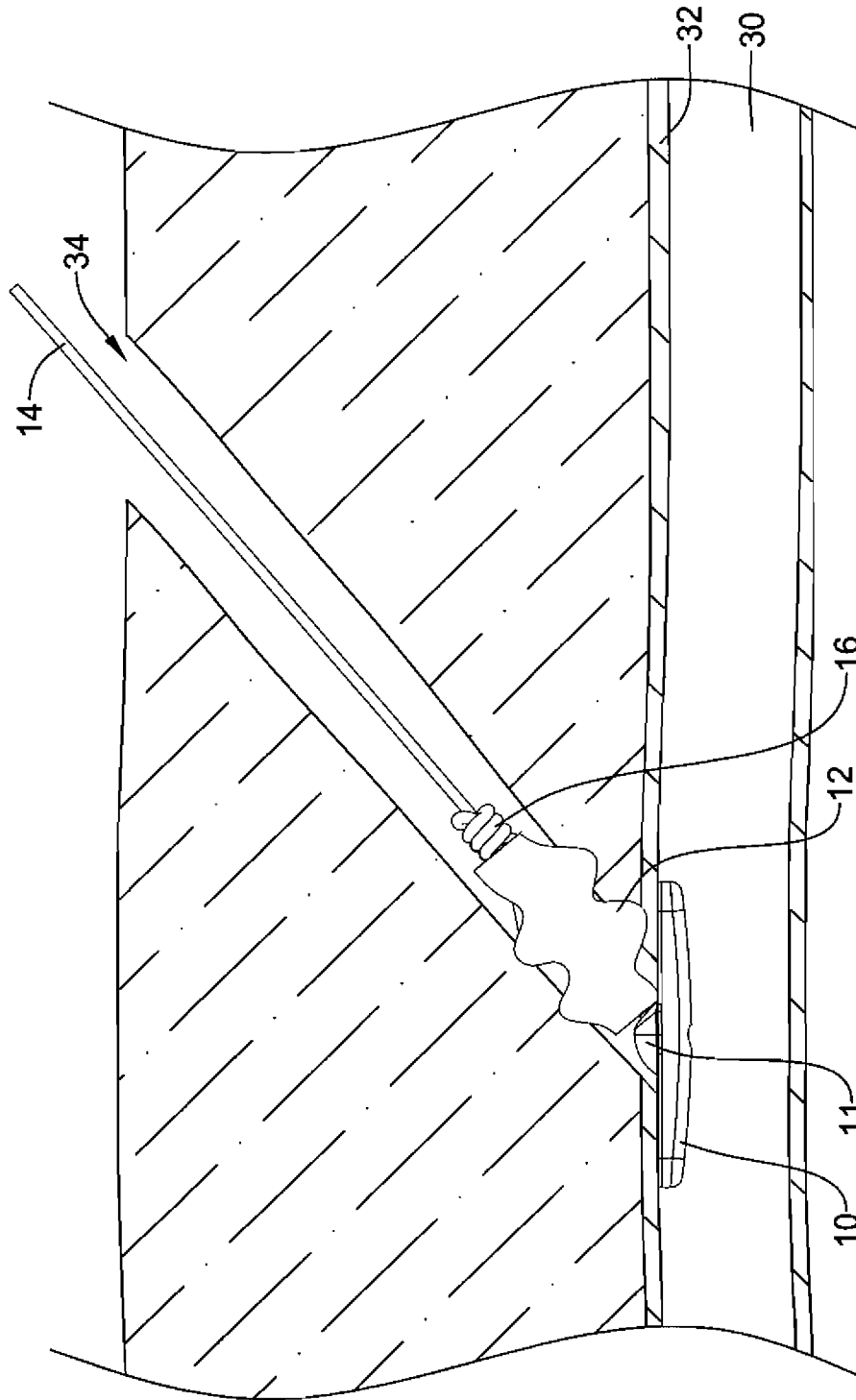


Figure 1

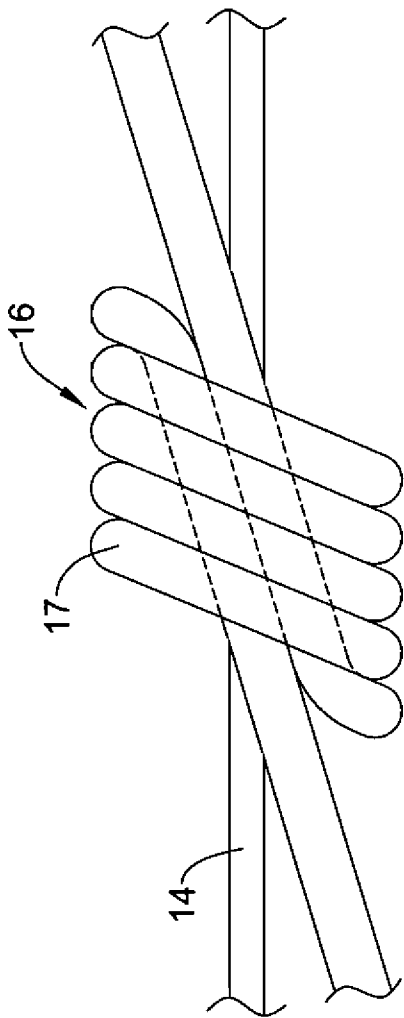


Figure 2

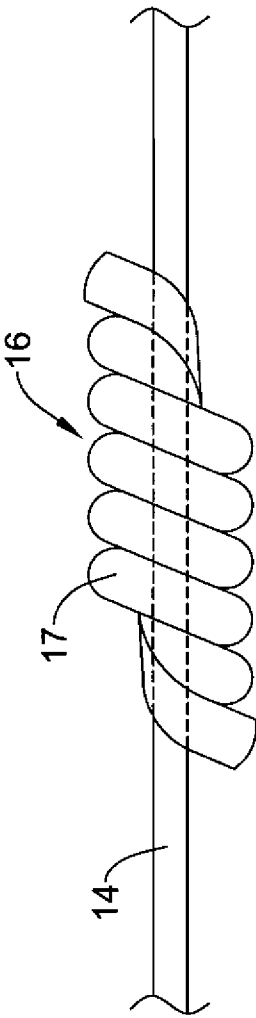


Figure 3

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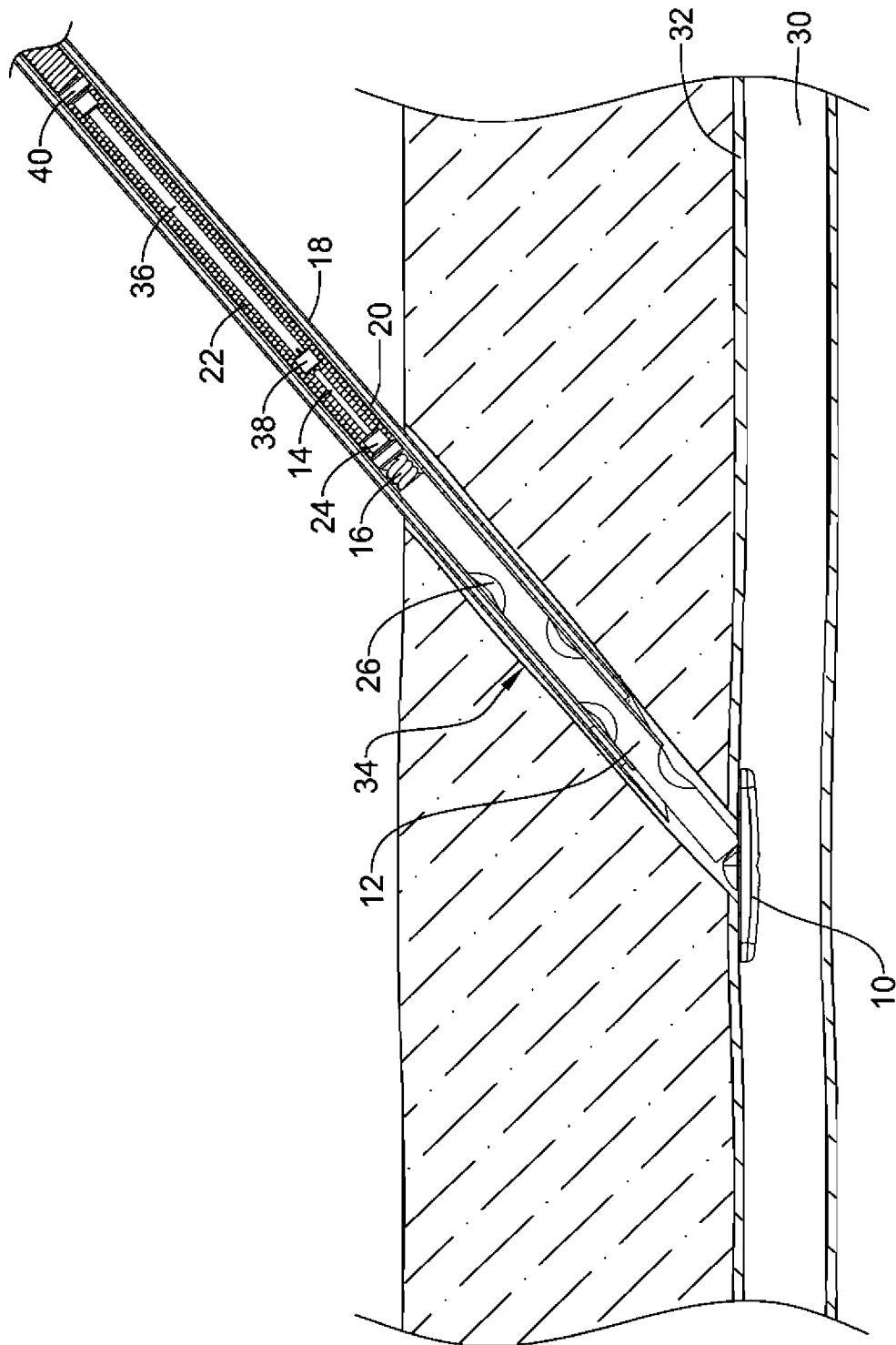


Figure 4

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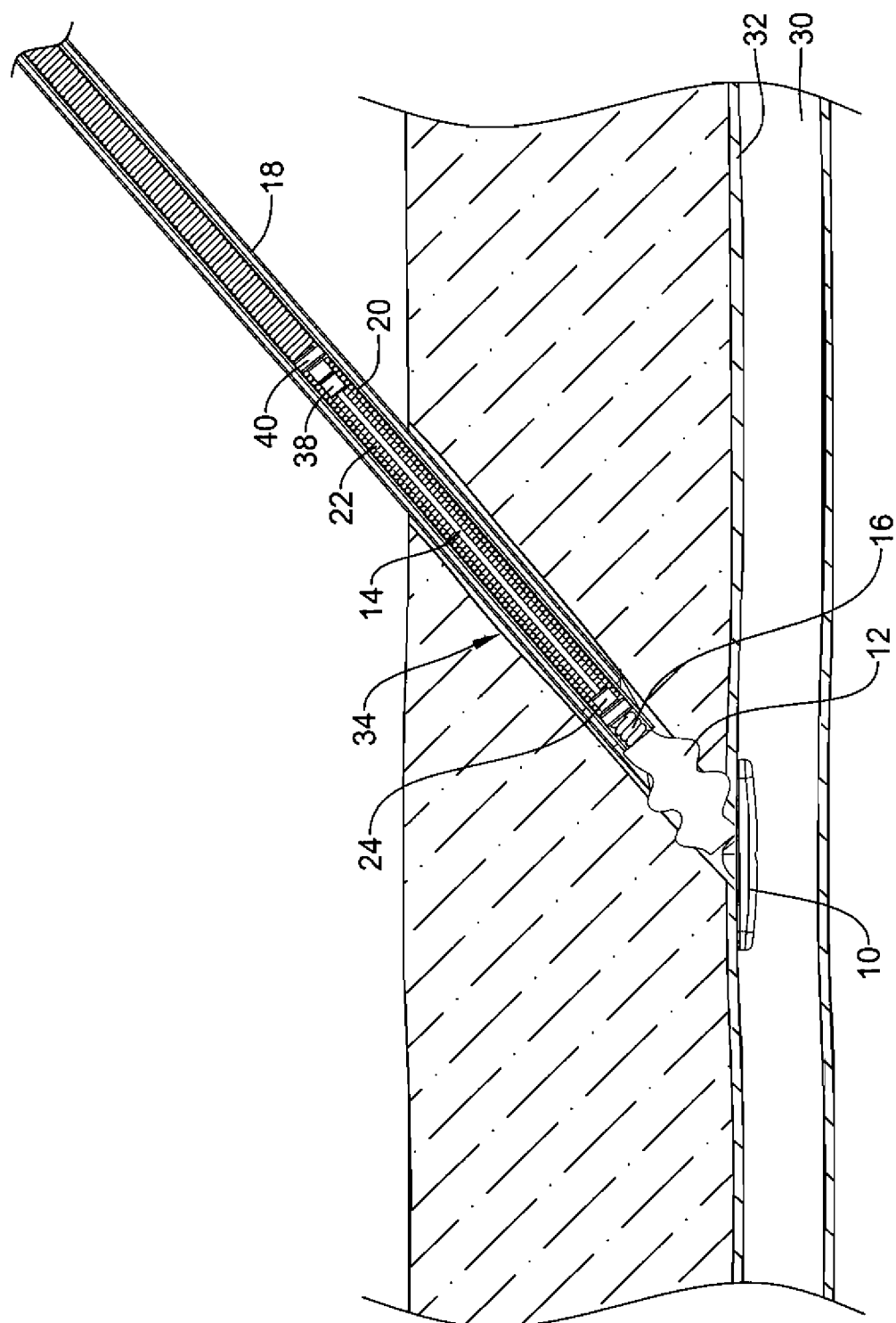


Figure 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/024472

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/00

ADD. 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.
A	US 2008/065121 A1 (KAWAURA MASAKATSU [JP] ET AL) 13 March 2008 (2008-03-13) figures 1-3, 17	1-14
A	EP 1 568 326 A1 (DEPUY MITEK INC [US]) 31 August 2005 (2005-08-31) figure 5	1,9
A	US 2008/071311 A1 (WHITE JOHN [US] ET AL) 20 March 2008 (2008-03-20) paragraph [0035]; figures 1,3,4,13 paragraph [0039] paragraph [0046]	1-14
A	EP 1 671 591 A1 (TERUMO CORP [JP]) 21 June 2006 (2006-06-21) figure 2	1-14
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☒ 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 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

5 May 2010

Date of mailing of the international search report

19/05/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Herberhold, C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/024472

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 2005/107827 A1 (PAPROCKI LORAN [US]) 19 May 2005 (2005-05-19) paragraph [0029]; figures 3A-3D -----	1-14
A	US 2005/125031 A1 (PIPENHAGEN CATHERINE A [US] ET AL PIPENHAGEN CATHERINE A [US] ET AL) 9 June 2005 (2005-06-09) figure 6a -----	1-14

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 15-20

Claims 15-20 relate to a method of sealing and/ or closing an opening in a vessel and/or tissue comprising the steps of: - disposing the anchor against an interior surface of the vessel wall adjacent to the opening in the vessel wall - disposing the filament at least partially within the tissue tract At least these steps are clearly of surgical nature. The method of sealing is also therapeutic in that it is therapeutic for the pathologic condition of a hole in the vessel or tissue tract. The method defined in claims 15-20 is therefore a method of treatment of the human or animal body by surgery as well as a method of treatment of the human or animal body by therapy. No international search and no preliminary examination are required for such methods (Art. 17(2)(a)i, Rule 39.1(iv); Art. 34(4)(a)I, Rule 67.1(iv), PCTGL 9.08-9.10)

Continuation of Box II.2

Claims Nos.: 1-14(partially)

Claims 1 and 9 define the knot member / the second suture member to be independent of the filament member / the first suture member. According to the Merriam-Webster dictionary, the term "independent" means "not requiring or relying on something else", which is clearly not the case in the invention: The knot as well as the second suture (which also does form a knot) is connected to the filament / first suture member and is configured to "move over the filament and axially compress the plug member". Thus it is clearly not independent of the filament / first suture member. Furthermore, without the filament / first suture, the knot will easily open, thus it is relying on the filament / suture member. Thus the wording of the claims is severely unclear, because the claim wording is in contradiction to the description and the drawings. However, the applicant gives on p.6, last para, an alternative interpretation of the term "independent", i.e. the "suture of the knot is separate and distinct from the filament". The search has thus been performed assuming that the unclear term "independent" has been clarified using said wording.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/024472

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.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☒ Claims Nos.: 1-14(partially)
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:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/024472

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