

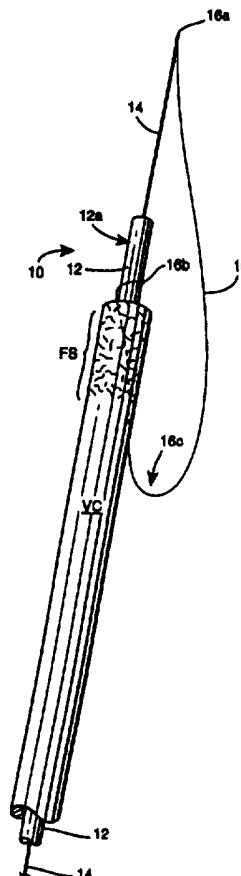


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(21) International Application Number: PCT/US96/04799 (22) International Filing Date: 5 April 1996 (05.04.96) (30) Priority Data: 08/417,018 5 April 1995 (05.04.95) US (71) Applicant: DUKE UNIVERSITY [US/US]; 230 North Building, Research Drive, P.O. Box 90083, Durham, NC 27708-0083 (US). (72) Inventors: RIDINGER, Mark, T.; Duke University Medical Center, P.O. Box 3808, Durham, NC 27710 (US). SUHOCKI, Paul, V.; Duke University Medical Center, P.O. Box 3808, Durham, NC 27710 (US). (74) Agent: DAVIDSON, Bryan, H.; Nixon & Vanderhye P.C., 8th floor, 1100 North Glebe Road, Arlington, VA 22201-4714 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: IMPROVED DEVICES FOR REMOVING FIBRIN SHEATHS FROM CATHETERS**(57) Abstract**

A medical device (10) adapted especially to remove biological material (e.g., fibrin sheath) from the distal end of a patient internal catheter that includes a tubular element (12), a central wire (14) positioned within the tubular element, a snare wire (16) attached at one end (16a) to the central wire so as to form an acute angle therewith, and at its other end (16b) to the tubular member. The snare wire includes a proximally extending segment which follows a course of about 360 degrees about the distal end (12a) of the tubular member, and thus may be positioned adjacent the catheter's distal end. By effecting relative rotation between the central wire and the tubular member (for example, by rotating the central wire about its longitudinal axis while maintaining the tubular member stationary) will cause the snare wire segment to wrap around the catheter's distal end. Thereafter, manipulation of the device so as to advance the wrapped snare wire segment in a distal direction will strip the biological material from the distal end of the catheter.



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IMPROVED DEVICES FOR REMOVING FIBRIN SHEATHS FROM CATHETERS

RELATED APPLICATIONS

5 This application may be deemed to be related to U.S. Patent Application Serial No. ---,--- (Atty. Dkt. 1579-79) filed even date herewith in the name of the same inventors as the present application, the entire content of which is expressly incorporated hereinto by reference.

10

FIELD OF INVENTION

 The present invention relates generally to the field of medical devices. More particularly, the present invention relates to the field of snares used during medical procedures to remove material from a patient. In its preferred embodiments, the present invention is especially adapted to remove fibrin sheaths from the distal ends of intravascular catheters.

15

BACKGROUND AND SUMMARY OF THE INVENTION

20 Catheters formed of a biocompatible plastics material are sometimes implanted in patients to relieve various symptoms and/or to assist in medical procedures. For example, central venous catheters have been implanted into a patient's vein during vascular surgery. One problem associated with such implanted catheters, however, is that a fibrin sheath (which is a deposit of fibrin and platelets) may form on the implanted catheter, initially at the entrance site into the vein and then along the length of the catheter.

25

While it usually takes weeks to months for the fibrin sheath to form, it has been reported to form in as little as 24-48 hours following implant.

5 The fibrin sheath can cause catheter dysfunction, usually being manifested by the physician being able to infuse through, but not to aspirate from, the catheter. Intraluminal urokinase may then be administered several times to exclude the possibility of intraluminal clotting. If intraluminal urokinase treatment is ineffective,
10 fluoroscopy may then be performed to allow the physician to evaluate catheter tip location and to obtain evidence of fibrin sheath formation.

 Once the presence and extent of the fibrin sheath have been
15 identified, the physician must take the necessary steps to remove the sheath from the implanted catheter. While it is conceivable that the implanted catheter may be removed and replaced surgically, it is more desirable for the fibrin sheath to be removed without surgical removal of the implanted catheter.

20 Presently, there are basically two approaches which may be employed without removal of the implanted catheter. The first approach involves introducing percutaneously a goose-neck snare (e.g., a snare device generally disclosed in U.S. Patent No. 5,171,233
25 to Amplatz et al, the entire content of which is incorporated expressly hereinto by reference) into the patient's groin area. The snare is then advanced through the patient's femoral vein to the catheter implant

site, at which time it is manipulated so that the snare encircles the distal end of the implanted catheter so that the fibrin sheath may be stripped therefrom. While the fibrin sheath which is stripped from the distal end of the implanted catheter travels to the patient's lung, surgical removal has been shown to result in embolization as well.

Another technique that has been employed to strip fibrin sheaths from the distal ends of implanted catheters is to introduce a J-tipped wire intraluminally through the implanted catheter. Rotation of the J-tipped wire about the distal end of the implanted catheter will thus strip a portion of the fibrin sheath therefrom. While this technique is advantageous since the implanted catheter serves as a guide passageway (i.e., separate incisions to access the femoral vein are unnecessary), the J-tipped wire is typically only capable of removing less than all of the fibrin sheath from the implanted catheter due to its size limitations.

What has been needed in this art, therefore, is a medical device which is capable of being guided intraluminally through an implanted catheter, but which is capable of removing substantially all of the fibrin sheath that may have formed at the catheter's distal end. It is towards fulfilling such a need that the present invention is directed.

Broadly, the present invention is embodied in medical devices having a snare loop for removing patient-internal biological material from an implanted catheter (e.g., a fibrin sheath which may form at

the distal end of a venous catheter) which may be inserted intraluminally through the catheter during a medical procedure. The tubular member has a length sufficient to allow its distal end portion extend beyond the distal end of the patient-internal catheter. A
5 central wire element is movably positioned within the elongate tubular member and has a sufficient length so that its terminal end portion extends distally beyond said distal end of said tubular member.

10 Importantly, a snare wire is provided such that one of its ends is attached to the central wire with the other end attached to the distal end of said tubular member after completing approximately 360° wrap around the tubular member between the ends. The snare wire, between its attached ends, will include a segment which
15 extends proximally at an acute angle and may therefore be located upon manipulation of the device adjacent the distal end of the patient-internal catheter. Relative rotation between the central wire and the tubular member (e.g., by rotating the central wire about its longitudinal axis while maintaining the tubular member stationary
20 or vice versa) causes said snare wire segment to be wrapped around said distal end of the patient-internal catheter. Distal advancement of this wrapped snare wire segment relative to said distal end of the patient-internal catheter will therefore strip the biological material therefrom.

25

Further aspects and advantages of this invention will become more clear after careful consideration is given to the following detailed description of the preferred exemplary embodiment thereof.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Reference will hereinafter be made to the accompanying drawings wherein like reference numerals throughout the various FIGURES denote like structural elements, and wherein;

10

FIGURE 1 is a schematic perspective view of a preferred medical snare device embodying the present invention; and

15

FIGURES 2A-2C are schematic elevational views showing a sequence of the device depicted in FIGURE 1 during use.

DETAILED DESCRIPTION OF THE PREFERRED EXEMPLARY EMBODIMENTS

20

One preferred embodiment of a medical snare device 10 according to the present invention is shown in accompanying FIGURE 1. The snare device 10 is depicted schematically as being positioned intraluminally within a venous catheter VC, it being understood that the distal end region of venous catheter VC will in use be implanted within a patient's vein. The distal end section of the venous catheter VC is depicted in accompanying FIGURE 1 as

25

having a fibrin sheath FS extending proximally along the catheter's exterior surface.

The snare device 10 is generally comprised of an elongate
5 tubular member 12 and a central wire element 14 which is movably
positioned within the lumen of the tubular member 12. Each of the
tubular member 12 and central wire element 14 is of sufficient length
to allow the physician to intraluminally insert them as a unit
through the venous catheter VC so that the distal end 12a of the
10 tubular body 12 is capable of extending distally beyond the distal end
of the venous catheter VC, and so that the terminal end 14a of the
central wire element 14 is capable of being extended beyond the
distal end 12a of the tubular member (e.g., to achieve relative
positioning as shown in FIGURE 1).

15

Important to the present invention, the snare device 10
includes a snare wire 16 formed of a flexible metal or plastics wire,
thread or the like. The snare wire 16 has its distal end 16a
physically attached to the central wire element 14 so as to form an
20 acute angle therewith and its proximal end 16b physically attached
(e.g., via biocompatible epoxy, heat-welding, imbedding or the like) to
the tubular member 12 at or near its distal end 12a. The ends 16a,
16b are thus axially separated from one another along the length of
the device 10 so as to form a snare loop collectively with the terminal
25 end 12a of the tubular member and that length of the central wire
element 14 extending therebeyond. As shown, the snare wire 16,
between the ends 16a and 16b is preferably wrapped approximately

360° around the tubular member 12 so that the end 16b faces distally.

5 The relative diameters of the central wire 14 and the snare wire 16 are dependent in large part upon the particular medical procedure in which the device 10 of this invention is intended to be employed. It is preferred, however, that the diameters of the central wire 14 and the snare wire 16 each be within the range of about 0.001 to about 0.040 inch. Moreover, it is preferred that the snare
10 wire 16 have a lesser diameter as compared to the central wire element 16 so that the former is relatively more flexible, while the latter is relatively more stiff. Therefore, it is preferred that the ratio of the central wire diameter to the snare wire diameter be between about 1.1:1 to about 10.0:1.

15 The snare wire 16 is of sufficient length between its ends 16a, 16b such that a segment 16c thereof may be positioned proximally of the end 16b adjacent the distal end of the venous catheter. With the snare wire segment 16c positioned in such a manner, the physician
20 may rotate the central wire element 14 about its longitudinal axis within the lumen of the tubular member 12 as shown by arrow A₁ in FIGURE 2A. Relative rotation between the central wire element 14 and the tubular member 12 (e.g., rotation of the central wire element 14 while maintaining the tubular member 12 stationary) will thereby
25 cause the snare wire segment 16c to be wrapped or twisted more or less helically about the exterior surface of the venous catheter's distal end as shown in FIGURE 2B. The several turns of the wrapped

snare wire segment 16c will thus be brought into contact with the fibrin sheath FS at the distal end of the venous catheter VC. As such, advancement of the central wire 14 and/or the tubular member 12 in a distal direction (arrow A₂ in FIGURE 2C) will, in turn, cause the wrapped snare wire segment 16c to be moved distally along the exterior surface of the distal end of the venous catheter VC thereby stripping the fibrin sheath FS therefrom.

Although the central wire element 14 has been depicted in the accompanying drawing FIGURES as including an eyelet 14a at its terminal end, it will be appreciated that the eyelet 14a is not critically necessary since the end 16a of the snare wire 16 may be bonded to the central wire's terminal end via biocompatible epoxy, solder, or the like. Furthermore, the central wire 14 and the snare wire 16 may be formed as a single (unitary) monofilament wire, instead of the separate, but connected, wires as shown in the accompanying drawing FIGURES.

Therefore, while the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS:

- 1 1. A medical device comprising:
2 an elongate tubular member;
3 a central wire positioned within said tubular member;
4 a snare wire having one end attached to a terminal end
5 of said central wire to form an acute angle therewith,
6 and another end attached to a distal end of said
7 tubular member, said snare wire between said one
8 and another ends being wrapped about an exterior
9 surface of said distal end of said tubular
10 member, wherein relative rotation between said
11 central wire and said tubular member causes said
12 snare wire to wrap around said distal end of said
13 tubular member.
- 1 2. A medical device as in claim 1, wherein said snare wire is
2 wrapped about 360° about said distal end of said tubular member.
- 1 3. A medical device as in claim 1, wherein said central wire is
2 axially and rotationally moveable within said tubular member.
- 1 4. A medical device as in claim 1, wherein said snare wire has
2 a length sufficient to establish a segment between said one and
3 another ends which extends proximally of said distal end of said
4 tubular member.

1 5. A medical device as in claim 1 or 4, wherein said one end of
2 said snare wire is bonded to a terminal end of said central wire.

1 6. A medical device as in claim 1 or 4, wherein said terminal
2 end of said central wire includes an eyelet, and wherein said one end
3 of said snare wire is attached to said eyelet.

1 7. A medical device as in claim 6, wherein said one end of said
2 snare wire is bonded to said eyelet.

1 8. A medical device as in claim 1, wherein said central wire
2 and said snare wire are unitary.

1 9. A medical device as in claim 1, wherein said central wire
2 and said snare wire each have a diameter in the range between about
3 0.001 to about 0.040 inch.

1 10. A medical device as in claim 9, wherein a ratio of the
2 central wire diameter to the snare wire diameter is between about
3 1.1:1 to about 10.0:1.

1 11. A medical device for removing biological material from a
2 distal end of a patient-internal catheter comprising:
3 an elongate tubular member for intraluminal insertion
4 within the patient-internal catheter and having a
5 length sufficient to allow a distal end portion of said

6 tubular member to extend beyond the distal end of
7 the patient-internal catheter;
8 a central wire element positioned within said elongate
9 tubular member and having a terminal end portion
10 which extends distally beyond said distal end of said
11 tubular member;
12 a snare wire having one end attached to said central
13 wire to form an acute angle therewith, and another
14 end attached to said distal end of said tubular
15 member at a position proximally of said one end;
16 wherein
17 said snare wire includes a segment thereof between said
18 one and another ends which follows a course which is
19 wrapped about said tubular member and extends in a
20 proximal direction so as to be located adjacent the
21 distal end of the patient-internal catheter; and
22 wherein
23 relative rotation between said central wire and said
24 tubular member causes said snare wire segment to be
25 wrapped around said distal end of the
26 patient-internal catheter such that distal
27 advancement of said wrapped snare wire segment
28 relative to said distal end of the patient-internal
29 catheter strips the biological material therefrom.

1 12. A medical device as in claim 11, wherein said segment of
2 said snare wire follows a course so as to be wrapped about 360° about
3 the tubular member.

1 13. A medical device as in claim 11, wherein said one end of
2 said snare wire is bonded to a terminal end of said central wire.

1 14. A medical device as in claim 11, wherein said central wire
2 includes an eyelet at a terminal end thereof, and wherein said one
3 end of said snare wire is attached to said eyelet.

1 15. A medical device as in claim 14, wherein said one end of
2 said snare wire is bonded to said eyelet.

1 16. A medical device as in claim 11, wherein said central wire
2 and said snare wire are unitary.

1 17. A medical device as in claim 11, wherein said central wire
2 and said snare wire each have a diameter between about 0.001 to
3 about 0.040 inch.

1 18. A medical device as in claim 17, wherein a ratio of the
2 central wire diameter to the snare wire diameter is between about
3 1.1:1 to about 10.0:1.

1 19. A procedure for removing a fibrin sheath from a distal end
2 of a venous catheter comprising:

- 3 (i) intraluminally advancing a medical device having a
4 tubular member, a central wire positioned within
5 said tubular member and a snare wire connected at
6 one end to said central wire and at another end to
7 said tubular member;
- 8 (ii) manipulating said medical device to position a
9 segment of said snare wire proximally of said
10 another end thereof adjacent the fibrin sheath at
11 the distal end of the venous catheter;
- 12 (iii) effecting relative rotation between said central wire
13 and said tubular member to cause said snare wire
14 segment to wrap around the distal end of the
15 venous catheter; and then
- 16 (iv) causing said wrapped snare wire segment to
17 advance in a distal direction relative to the distal
18 end of the venous catheter to thereby strip the
19 fibrin sheath therefrom.

1 20. The procedure as in claim 19, wherein step (iii) is
2 practiced by rotating said central wire about its longitudinal axis
3 while maintaining said tubular member stationary.

1 21. The procedure as in claim 19, wherein step (iv) is practiced
2 by advancing at least one of said central wire and said tubular
3 member in a distal direction.

- 1 22. The procedure as in claim 19, wherein step (iv) is practiced
- 2 by advancing said central wire in a distal direction while maintaining
- 3 said tubular member stationary.

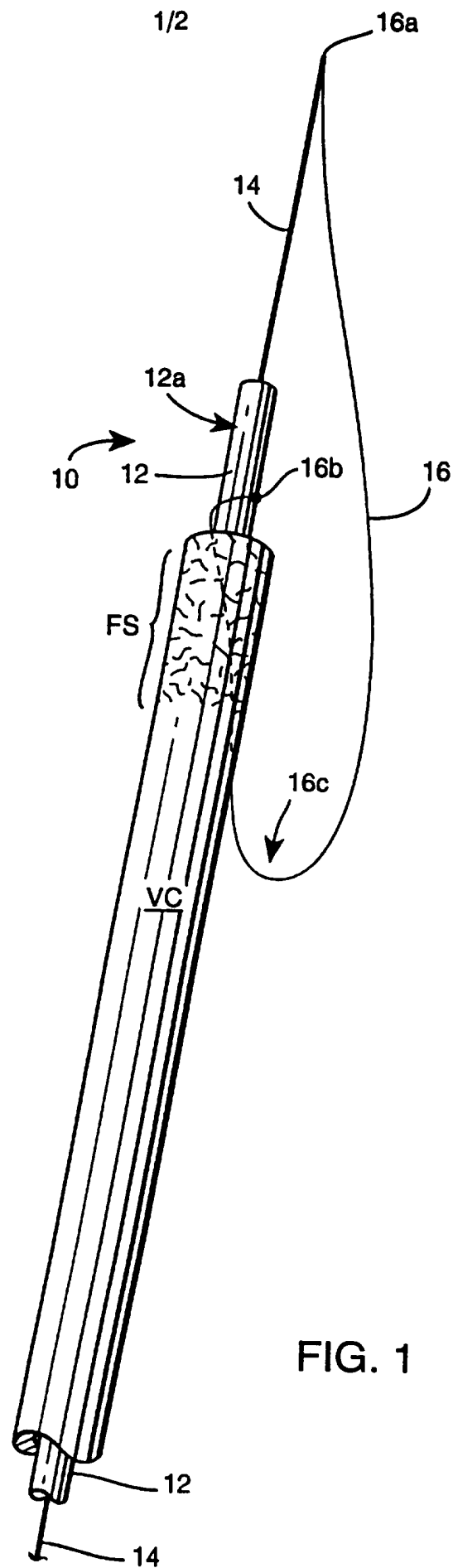


FIG. 1

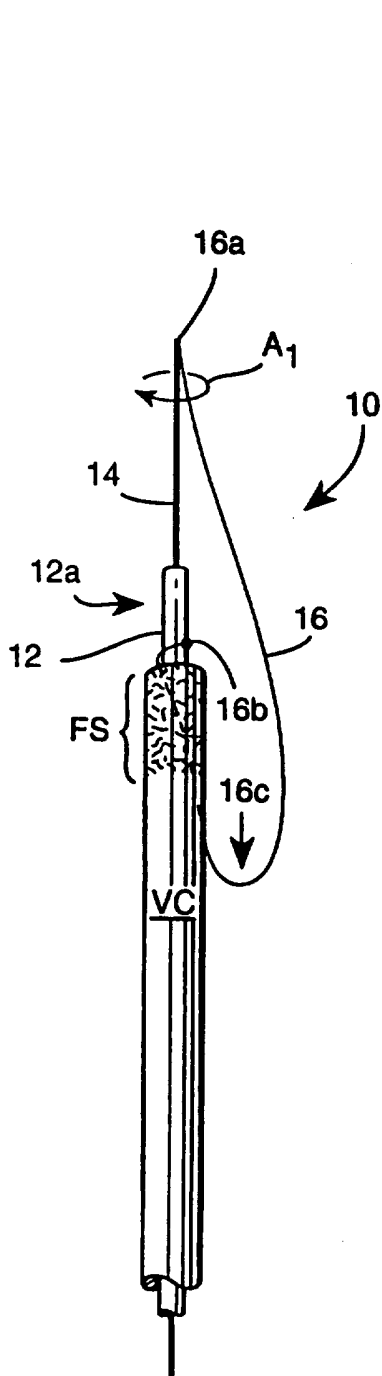


FIG. 2A

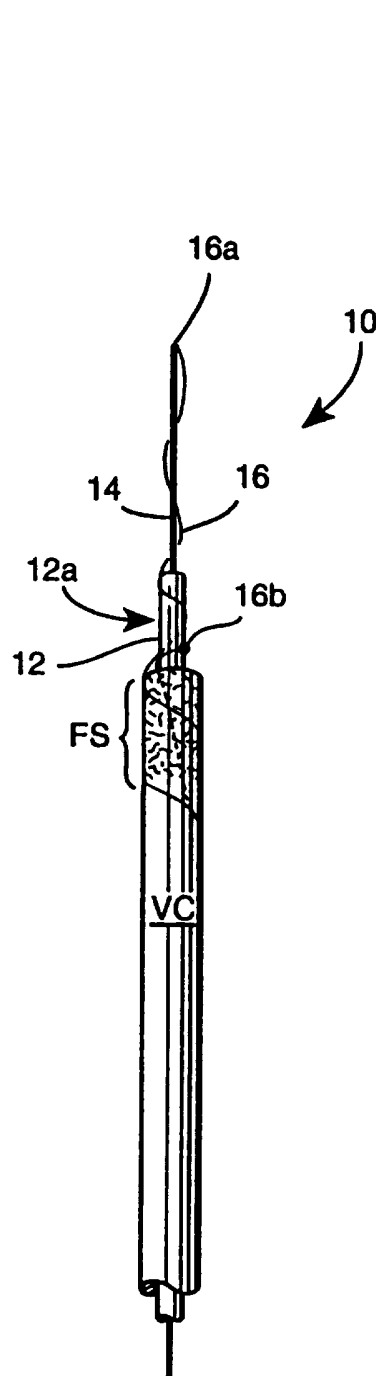


FIG. 2B

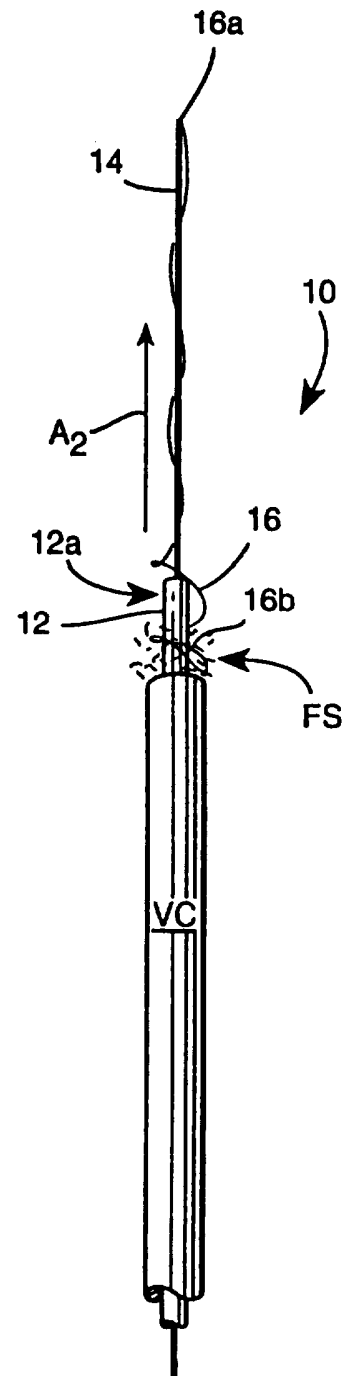


FIG. 2C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/04799

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/24; A61M 25/00; 31/00

US CL : 604/52, 267; 606/113

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)

U.S. : 604/49, 51, 52, 164, 267; 606/113, 114, 194, 195.

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)

APS, STIC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,387,219 (RAPPE) 07 February 1995, note Figs. 1-3D.	1-10.
Y	US, A, 5,342,371 (WELTER ET AL.) 30 August 1994, note Figs. 1-4.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be part of particular relevance	"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
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Date of the actual completion of the international search

24 MAY 1996

Date of mailing of the international search report

21 JUN 1996

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