

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2012/068261 A1

(43) International Publication Date

24 May 2012 (24.05.2012)

(51) International Patent Classification:

A61F 2/84 (2006.01)

(21) International Application Number:

PCT/US2011/061011

(22) International Filing Date:

16 November 2011 (16.11.2011)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/414,270 16 November 2010 (16.11.2010) US  
13/297,036 15 November 2011 (15.11.2011) US

(71) Applicant (for all designated States except US): **GORE ENTERPRISE HOLDINGS, INC** [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **SOKEL, Justin, W.** [US/US]; 2700 N. Nelson Drive, Flagstaff, AZ (US).

(74) Agents: **GABO, Gilbert R** et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (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, QA, RO, RS, RU, RW, 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, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, 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, RS, 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: MEDICAL APPARATUS AND METHOD OF MAKING THE SAME

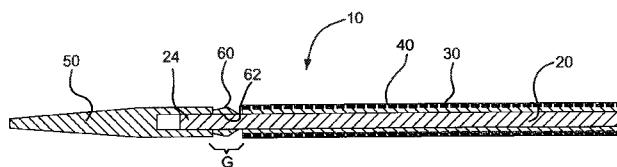


FIG. 1

(57) Abstract: A catheter assembly (10) includes a catheter (20) having a proximal end and a distal end; an expandable device (30) releasably attached to the catheter near the distal end; a generally tubular constraining sleeve (40) extending around and compressing the device to an outer peripheral dimension suitable for endoluminal delivery; a tip (50) fixedly secured to the distal end of the catheter; and a bridge member (60) disposed between the tip and the expandable device so as to fill a gap (G) therebetween as the catheter assembly is bent during endoluminal delivery of the expandable device to a treatment site.

WO 2012/068261 A1

## MEDICAL APPARATUS AND METHOD OF MAKING THE SAME

### Cross Reference to Related Applications

[0001] This application is a non-provisional of, and claims priority to, U.S. Provisional Patent Application No. 61/414,270, entitled "Medical Apparatus and Method of Making The Same," filed November 16, 2010, the content of which is hereby incorporated by reference in its entirety.

### BACKGROUND

#### Field

[0002] The present disclosure relates to catheter-based systems used to deliver medical devices.

#### Discussion of the Related Art

[0003] Various medical devices require catheter based delivery systems. Such medical devices include implantable, diagnostic and therapeutic devices. Common implantable, endovascular devices can include stents, stent grafts, filters, occluders, sensors and other devices. Endovascular devices are commonly advanced through the native vasculature to a treatment site by the use of a flexible catheter. When properly positioned at the treatment site the device (in the case of a stent) can be expanded to appose the vasculature. The device can then be released from the catheter allowing the catheter to be withdrawn from the vasculature. It is desirable to pre-compact endovascular devices into small delivery profiles in order to minimize vascular trauma and enhance maneuverability through tortuous anatomies. A highly compacted device is often relatively stiff and is therefore difficult to bend into a small radius. A soft, flexible "olive" or tip is commonly positioned distal to the compacted device at the leading end of the delivery catheter, again to minimize vascular trauma and to enhance the positioning accuracy. As the device is advanced through a curved vessel, the junction between the relatively stiff compacted device and the soft flexible tip can "open up" presenting a gap.

[0004] It remains desirable to have a device delivery system incorporating a means to cover any potential gap between the compacted device and a leading catheter tip.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0005] In the following drawings:

[0006] Figure 1 is a cross-sectional view of a catheter assembly in accordance with various embodiments with a bridging member shown in an uncompressed state between a distal tip and device of the catheter assembly.

[0007] Figure 2 is a cross-sectional view of the catheter assembly in Figure 1 with the bridging member shown in a compressed state between the distal tip and catheter assembly.

[0008] Figure 3 is a cross-sectional view of the bridging member of Figure 1 in the uncompressed state.

[0009] Figure 4 is a cross-sectional view of the bridging member of Figure 1 in the compressed state.

[0010] Figure 5 is a side view of a catheter assembly in accordance with various embodiments.

[0011] Figure 6 is a perspective view of a bridging member of the catheter assembly shown in Figure 5.

[0012] Figure 7 is side view of a catheter assembly according to various embodiments.

[0013] Figure 8 is a perspective view of the a bridging member of the catheter assembly shown in Figure 7.

[0014] Figure 9 is a perspective view of a bridging member in accordance with various embodiments.

[0015] Figure 10 is an enlarged perspective view of the bridging member in Figure 9.

[0016] Figure 11 is an enlarged perspective view of a catheter assembly incorporating the bridging member in Figure 9 and a protective outer sleeve cutting blade.

### DETAILED DESCRIPTION

[0017] Referring to Figures 1 and 2, a catheter assembly in accordance with various embodiments is shown and generally indicated at 10. The catheter assembly 10 includes a catheter 20, an expandable device 30, a generally tubular restraining member or "constraining sleeve" 40 and a tip 50. The catheter 20 extends longitudinally between opposite proximal 22 and distal 24 ends. The expandable device 30 is releasably attached to the catheter 20 near the distal end 24 of the catheter 20. The constraining sleeve 40 is disposed around and compresses the device 30 to an outer peripheral dimension suitable for endoluminal delivery to a treatment site in a patient. The constraining sleeve 40 has a distal end 42 that faces the distal end 24 of the catheter 20. Examples of restraining members or constraining sleeves for releasably maintaining expandable devices in a collapsed state for endoluminal delivery can be found in U.S. 6,352,561 to Leopold et al, the content of which is incorporated herein by reference in its entirety. Described in greater detail below, the catheter assembly 10 further includes a bridge member 60 disposed generally between the tip 50 and the expandable device 30 to fill a gap therebetween.

[0018] In Figure 1, the bridge member 60 is shown positioned along a gap "G" between the tip 50 and the device 30. The bridge member 60, as shown, is not yet fully assembled to the catheter assembly 10 and is in an uncompressed state (also illustrated in Figure 3). During assembly of the catheter assembly 10, the device 30 is positioned along the catheter 20 and compressed or crushed onto the catheter by the constraining sleeve 40 so as to have an outer peripheral dimension suitable for endoluminal delivery. The bridge member 60 includes a bore 62 through which the distal end 24 of the catheter 20 is inserted. The tip 50 is then placed onto the distal end 24 of the catheter 20. The tip 50 is pressed axially toward the device 30, and the bridge member 60 is compressed generally axially between the tip 50 and the device 30, as shown in Figure 2. The tip 50 is fixedly secured to the distal end 24 of the catheter 20 and thereby retains the bridge member 60 in the compressed state (also illustrated in Figure 4). The tip 50 may be fixedly secured to the distal end 24 of the catheter 20 by a variety of fixing methods, such as by using UV-cured adhesives, ultrasonic welding, reflow bonding, press fits, or other joining methods known in the art.

[0019] In one embodiment, the bridge member 60 is compressed elastically between the tip 50 and the device 30 so that as the catheter assembly 10 is bent, such as during endoluminal delivery, the bridge member 60 continues to fill the gap between the tip 5 and the device 30 as well as maintain a generally continuous, transitional surface 64 therebetween. More specifically, as the catheter assembly 10 is bent, the bridge member 60 is further compressed along an inner curve of the bend and at the same time allowed to expand or relax along an outer curve of the bend.

[0020] In Figures 5 and 6, an alternative embodiment of a catheter assembly is shown and generally indicated at 110. The catheter assembly 110 of this embodiment includes a generally tubular bridge member 160 having a lumen or bore 162 defined by a generally cylindrical side wall 166. The side wall 166 may be constructed of ePTFE, or other materials such as FEP, PET, or other medical grade flexible polymers. The bridge member 160 also includes a wire frame 168. The wire frame 168 may be formed from Nitinol. Alternatively, the wire frame may be formed from L605, 304V, MP35N, 316L, or any other medical grade allow. The wire frame 168 may have a generally sinusoidal shape extending peripherally about the side wall 166. The wire frame may also be formed into other shapes depending on the specific treatment needs.

[0021] Referring specifically to Figure 5, the tip 150 may include a circumferential groove 153 onto which the bridge member 160 can be coupled or secured to the tip 150. For example, a releasable shrink tube may be applied about the bridge member 160 along the groove 153 to secure the bridge member 160 to the tip 150.

[0022] In Figures 7 and 8, another alternative embodiment of a catheter assembly is shown and generally indicated at 210. The catheter assembly 210 of this embodiment includes a generally cylindrical or tube shaped bridge member 260 having an a longitudinally extending slot 268. The bridge member 260 is formed from a metal or metal alloy, such as Nitinol, L605, 304V, MP35N, 316L, or any other medical grade allow. In assembly, the slot 268 allows the bridge member 260 to be expanded radially and elastically to allow insertion of a proximal end of the tip 250 through the bridge member lumen 262. The bridge member 260 is then allowed to return toward its untensioned state and contract toward its untensioned dimension, thereby coupling the bridge member 260 to the tip 250. As in the previous

embodiments, the bridge member 260 fills the gap between the tip 250 and the device 230, even as the catheter assembly 210 is bent during endoluminal delivery. The bridge member 260 includes a generally pointed or narrowing proximal tip 270 that facilitates retraction of the catheter assembly 210 through a sheath (not shown).

[0023] A catheter assembly in accordance with various embodiments is shown illustratively in Figures 9 – 11. Referring to Figure 9, a partial view of a proximal end of a delivery system 900 is shown for positioning a compacted medical device 902. The medical device 902 is constrained by a tubular sleeve 903 and is adjacent to a delivery catheter 906. Covering the compacted device 902 and the tubular sleeve 903 is a protective sleeve 904. The protective sleeve 904 provides a smooth outer surface to the delivery system 900, enhancing device positionability and compatibility with a distal hemostatic valve (not shown). Also shown is a catheter proximal tip 908. Figure 10 is an enlarged view of the proximal end of the delivery system of Figure 9. Shown is a compacted medical device 902, tubular constraining sleeve 903, a proximal catheter tip 908 and a protective outer sleeve 904. The protective outer sleeve 904 is shown releasably attached 909 to the proximal catheter tip 908. A gap 910 is shown between the proximal catheter tip 908 and the compacted medical device 902. A series of semi-rigid bridge straps 912 are shown spanning the gap 910. The bridge straps can be embedded into the protective outer sleeve 904. The bridge straps 912 provide a smooth transition between the proximal catheter tip 908 and the compacted medical device 902. The bridge straps 912 also allow the junction between the proximal catheter tip 908 and the compacted medical device 902 to flex when the delivery system 900 traverses torturous anatomy. Prior to device deployment, the protective outer sleeve 904 can be withdrawn by evertting the sleeve back onto itself. The protective outer sleeve 904 can be everted by applying tension to the sleeve end as shown by direction arrows 914. The tension can be applied by pull lines or other means attached to the proximal end of the protective outer sleeve 904. When adequate tension is applied to the protective outer sleeve 904 the releasable attachment 909 is released allowing the sleeve to evert. The releasable attachment can be an adhesive join, or use other releasable attachment means as commonly known in the art. As further tension 914 is applied, the protective outer sleeve 904 further everts as shown in Figure 11. The semi-rigid bridge straps 912 (embedded into the protective outer sleeve 904) bend and become reversed as shown in Figure 11. The semi-rigid bridge straps 912 can optionally

incorporate pointed or chamfered leading ends 916. The chamfered leading ends 916 will allow an optional cutting blade 918 to self-align to the gaps between the semi-rigid bridge straps 912 allowing the protective outer sleeve 904 to be longitudinally split. The split protective outer sleeve 904 can be subsequently fully removed from the catheter system. Semi-rigid bridge straps 912 can be fabricated from a variety of metallic or polymeric materials as commonly known in the art.

[0024] It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

**WHAT IS CLAIMED IS:**

1. A catheter assembly comprising:
  - a catheter having a proximal end and a distal end;
  - an expandable device releasably attached to the catheter near the distal end;
  - a constraining sleeve extending around and compressing the device to an outer peripheral dimension suitable for endoluminal delivery, the constraining sleeve having an end facing the distal end of the catheter;
  - a tip fixedly secured to the distal end of the catheter; and
  - a bridge member disposed between the tip and the expandable device and filling a gap therebetween.
2. A catheter assembly as set forth in claim 1, wherein the bridge member is generally annular and includes a tapered surface radially engaging at least one of the expandable device and constraining sleeve.
3. A catheter assembly as set forth in claim 2, wherein the tapered surface outwardly radially tensions at least one of the expandable device and constraining sleeve.
4. A catheter assembly as set forth in claim 3, wherein the tapered surface is generally frustoconically shaped.
5. A catheter assembly as set forth in claim 1, wherein the catheter includes a lumen extending between the proximal and distal ends, the catheter assembly further comprising a tubular member extending through the lumen and having an end fixedly secured to the tip.
6. A catheter assembly as set forth in claim 5, wherein the tubular member includes a guidewire lumen extending axially therethrough.

7. A catheter assembly as set forth in claim 6, wherein the bridge member generally annular and includes a bore which receives the tubular member therethrough.

8. A catheter assembly as set forth in claim 1, wherein the bridge member fills a gap between the tip and the expandable device and provides a transition therebetween upon bending of the distal end of the catheter during deployment at an angled treatment site.

9. A catheter assembly as set forth in claim 1, wherein the bridge member is elastically deformed upon compression between the tip and the expandable device.

10. A catheter assembly as set forth in claim 9, wherein the bridge member is axially movable with respect to the catheter.

11. A catheter assembly as set forth in claim 10, wherein at least a portion of the bridge member is fixedly secured to the tip or catheter.

12. A catheter assembly as set forth in claim 5, wherein a portion of the bridge member is fixedly secured to the tubular member so that a remaining portion of the bridge member is axially movable with respect to the catheter.

13. A catheter assembly as set forth in claim 1, wherein the tip includes a bore generally axially aligned with the guidewire lumen to allow a guidewire to be fed through the catheter and the tip.

14. A catheter assembly as set forth in claim 1, wherein the bridge member includes a frustoconically shaped leading surface that faces the tip, which upon compression between the expandable device and tip provides a transition between the tip and the constraining sleeve.

15. A catheter assembly as set forth in claim 1, wherein the bridge member includes portions of varying durometer.

16. A catheter assembly as set forth in claim 1, wherein the bridge member includes a generally tubular shaped side wall and includes a wire frame coupled thereto to help the side maintain the gap between the tip and the device as the catheter assembly is bent during endoluminal delivery of the expandable device to a treatment site..

17. A method of manufacturing a catheter assembly including:

- providing a catheter having a distal end and an expandable device fixedly secured thereto;
- providing a bridge member generally coaxial with the catheter and disposed onto an exposed portion of the distal end of the catheter;
- providing a tip generally coaxial with the catheter and disposed onto the exposed portion of the distal end of the catheter;
- axially compressing the bridge member between the expandable device and the tip; and
- fixedly securing the tip to the catheter to retain the bridge member in the compressed state between the expandable device and the tip.

18. The method as set forth in claim 16 including compressing the expandable device with an outer constraining sleeve to an outer dimension suitable for endoluminal delivery.

19. The method as set forth in claim 17 including axially compressing the bridge member toward the device so as to outwardly radially tension the expandable device.

20. The method as set forth in claim 18 including axially compressing the bridge member toward the device to cause outward displacement of the bridge member to a desired outer profile.

21. The method as set forth in claim 18 including axially compressing the bridge member toward the device to cause outward displacement of the bridge member to an outer profile that provides a transition between the tip and the expandable device.

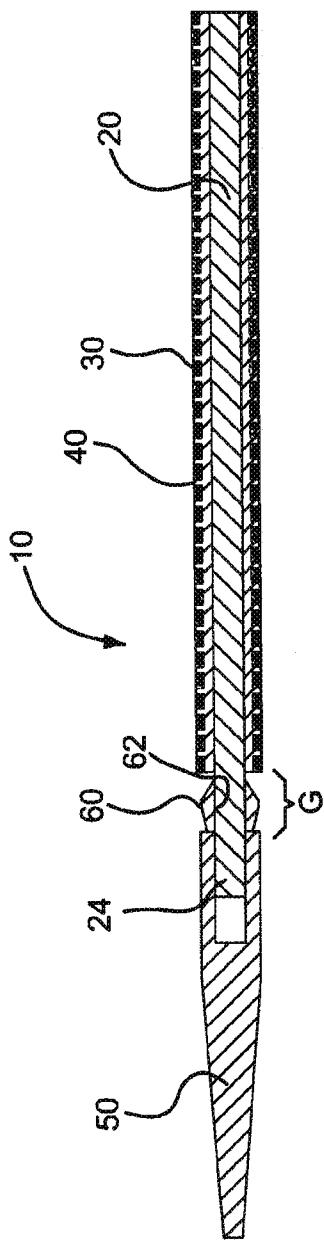


FIG. 1

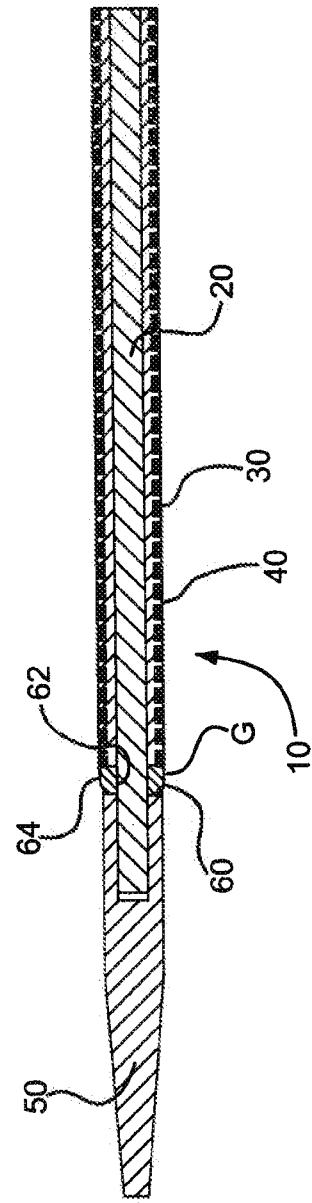


FIG. 2

2/7

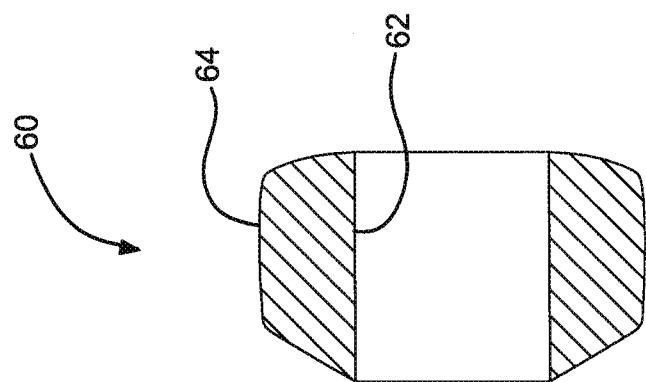


FIG. 4

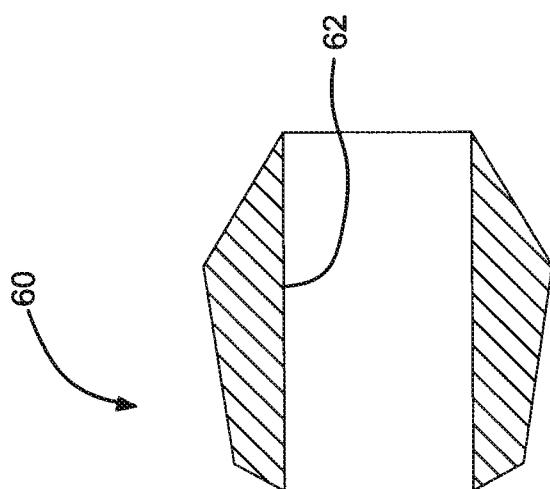
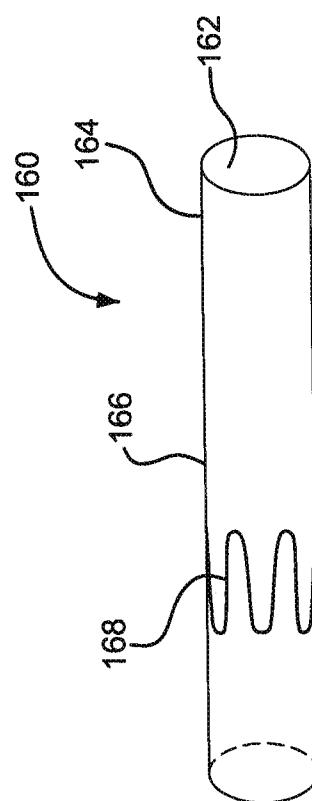
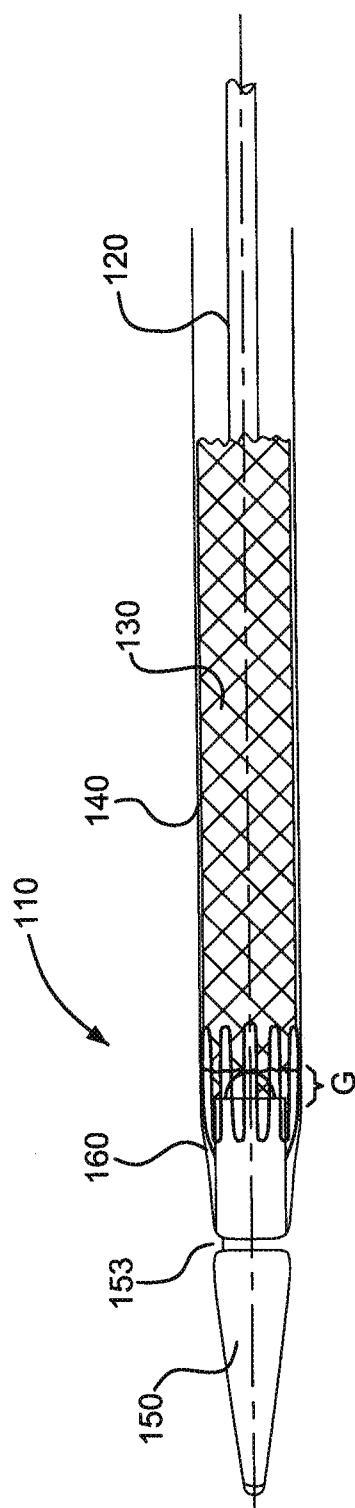


FIG. 3

3/7



4/7

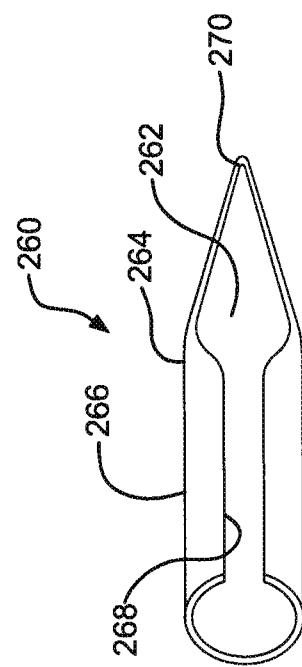
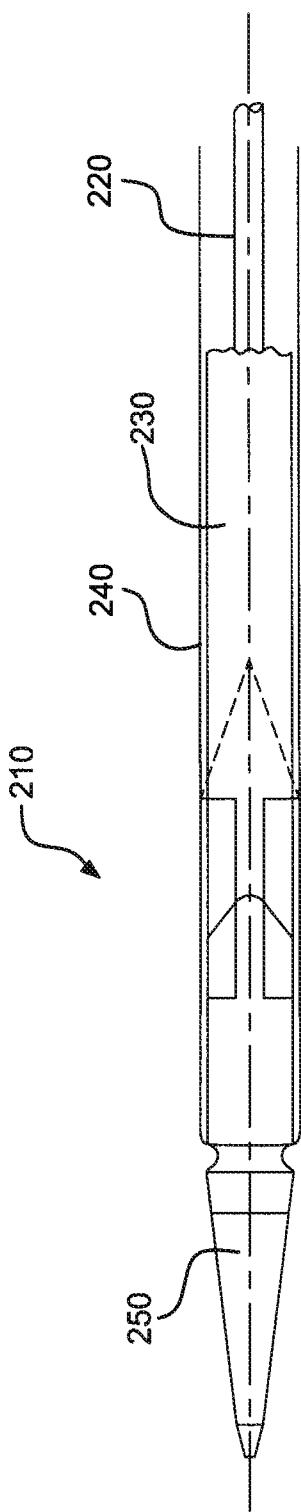


FIG. 8

5/7

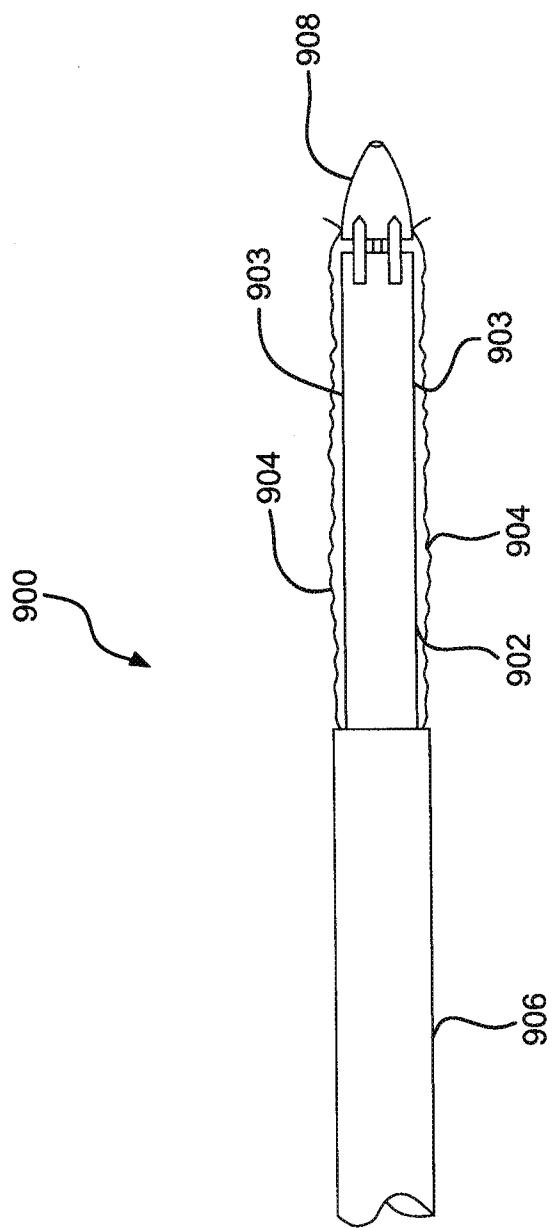


FIG. 9

6/7

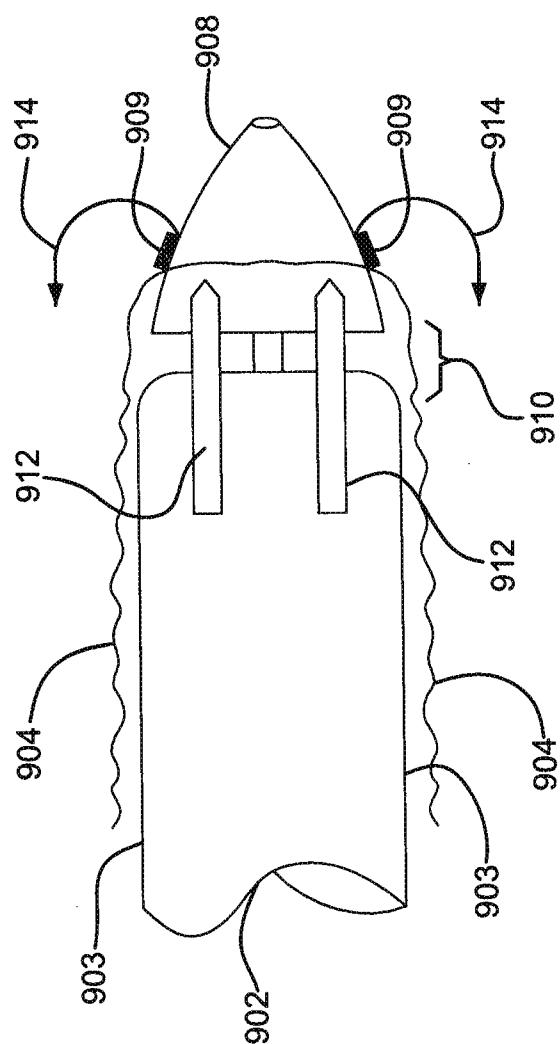


FIG. 10

7/7

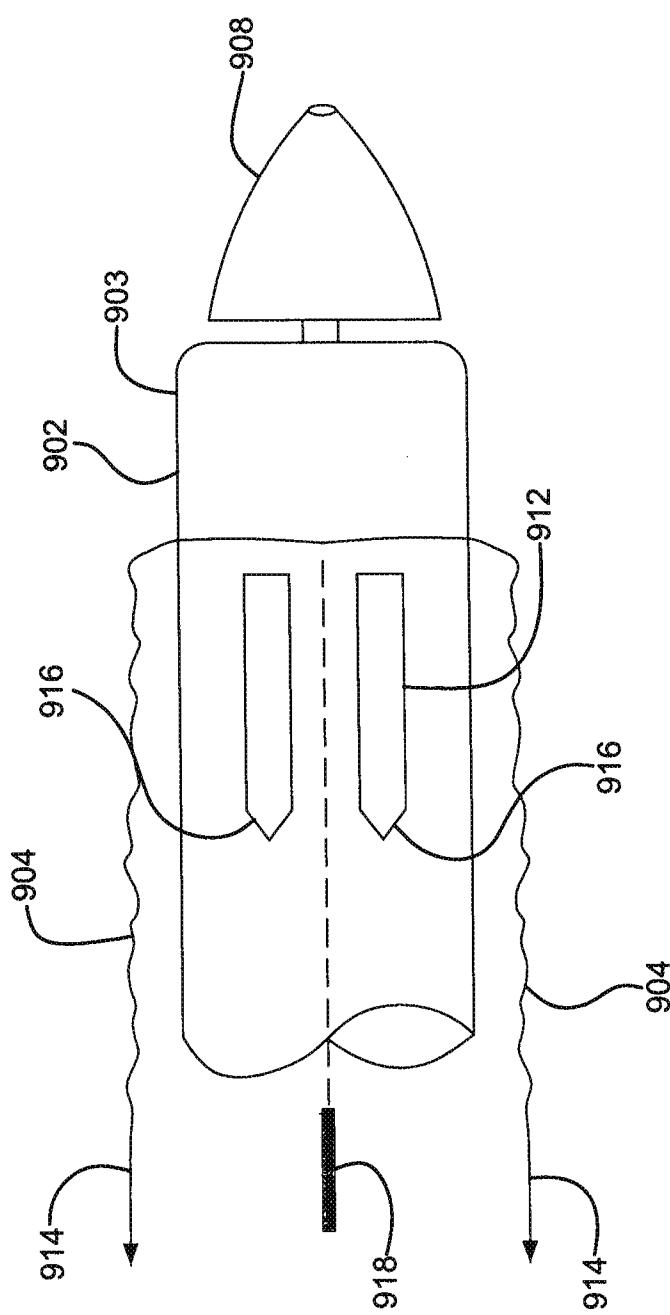


FIG. 11

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2011/061011

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61F2/84  
ADD.

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)  
A61F

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.
X	WO 2009/134801 A2 (MEDTRONIC VASCULAR INC [US]; GLYNN BRIAN [US]) 5 November 2009 (2009-11-05) paragraphs [0035], [0044]; figure 2 -----	1-21
X	WO 94/15549 A1 (SCHNEIDER USA INC [US]) 21 July 1994 (1994-07-21) page 9, line 16 - page 10, line 17; figure 1 -----	1-21



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

Date of mailing of the international search report

28 February 2012

06/03/2012

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

Skorovs, Peteris

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

PCT/US2011/061011

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 2009134801	A2	05-11-2009	CN 102065800 A EP 2280668 A2 JP 2011519608 A US 2009276027 A1 WO 2009134801 A2	18-05-2011 09-02-2011 14-07-2011 05-11-2009 05-11-2009
WO 9415549	A1	21-07-1994	CA 2149887 A1 DE 9321003 U1 EP 0676936 A1 JP H08500757 A WO 9415549 A1	21-07-1994 10-08-1995 18-10-1995 30-01-1996 21-07-1994