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(54) **Title**: DEPLOYMENT SLEEVE SHORTENING MECHANISM

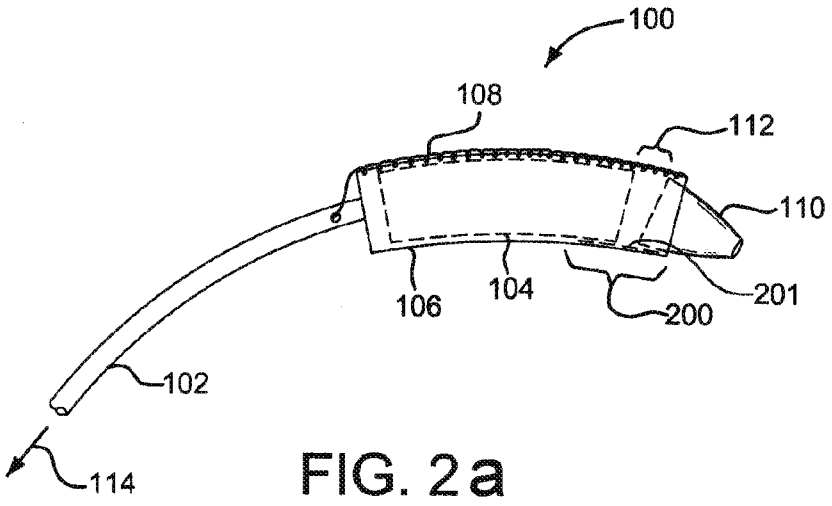

FIG. 2a

(57) **Abstract**: A medical device constraint includes an elastic element having proximal and distal ends, a continuous lumen extending between the proximal and distal ends of the tubular elastic element; and a medical device disposed at least partially within the continuous lumen, wherein the generally tubular element has a first state in which the tubular element is longitudinally held in tension to conceal a gap between the medical device and a distal tip and a second state in which the tubular element is longitudinally relaxed and spaced apart from the gap.

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DEPLOYMENT SLEEVE SHORTENING MECHANISM

BACKGROUND

Cross Reference to Related Applications

[0001] This application is a non-provisional of, and claims priority to, U.S. Provisional Patent Application No. 61/412,621, entitled "Deployment Sleeve Shortening Mechanism" filed November 11, 2010, the content of which is hereby incorporated by reference in its entirety.

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 The device can then be released from the catheter allowing the catheter to be withdrawn from the vasculature.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 torturous 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] To minimize this gap between a semi-rigid compacted device and a soft flexible leading tip various gap fillers and covers have been suggested. For example, a rigid catheter can be used to constrain a device into a small profile. The rigid catheter can extend distally beyond the device and over a portion of a leading tip, therefore covering a potential gap. The device can be allowed to expand by retracting the rigid catheter.

[0005] It remains desirable to have a device delivery system incorporating a releasable sleeve constraint along with an effective means to cover any potential undesirable gap between the compacted device and a leading catheter tip.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] In the following drawings:

[0007] Figure 1 is a partial side view of a delivery system showing a medical device in a compacted and constrained delivery state and illustrating a gap between the compacted device and a catheter leading tip or olive.

[0008] Figure 2 is a partial side view of a delivery system showing a medical device in a compacted and constrained delivery state, incorporating a restraining member having a retractable section.

[0009] Figure 2a is a partial side view of a delivery system showing a medical device in a compacted and constrained delivery state, incorporating a restraining member having a retractable section.

[0010] Figures 3a and 3b are partial side views of a delivery system showing a medical device in a compacted and constrained delivery state, wherein the device is constrained by a restraining member having a retractable section.

[0011] Figures 3c and 3d are partial side views of a delivery system showing the release of a constrained medical device

DETAILED DESCRIPTION

[0012] Persons skilled in the art will readily appreciate that various aspects of the present disclosure can be realized by any number of methods and apparatuses configured to perform the intended functions. Stated differently, other methods and

apparatuses can be incorporated herein to perform the intended functions. It should also be noted that the accompanying drawing figures referred to herein are not all drawn to scale, but can be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the drawing figures should not be construed as limiting. Finally, although the present disclosure can be described in connection with various principles and beliefs, the present disclosure should not be bound by theory.

[0013] As used herein, the term "elastomer" generally defines a polymer that has the ability to be stretched to at least twice its original length and to retract rapidly to approximately its original length when released. The term "elastomeric" is intended to describe a condition whereby a polymer displays stretch and recovery properties similar to an elastomer, although not necessarily to the same degree of stretch and/or recovery.

[0014] In accordance with various embodiments, a partial side view of a catheter system used to implant a medical device is shown and generally indicated at 100 in Figure 1. The catheter system 100 includes a catheter shaft 102 and an expandable device 104 constrained to a delivery profile or constrained state suitable for endoluminal delivery of the device to a treatment site. The device 104 is held in the constrained state by a flexible, generally tubular constraining sleeve or restraining member 106. The flexible restraining member 106 is held or maintained in a tubular shape by a removable stitch line 108. When the stitch line 108 is actuated by pulling or tensioning in the direction indicated at 114, the restraining member 106 will split open and allow the device 104 to expand. Examples of restraining members and coupling members for releasably maintaining expandable devices in a constrained or collapsed state for endoluminal delivery to a treatment site 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.

[0015] Still referring to Figure 1, as the catheter system 100 is advanced through a curved vessel, a gap 112 can form between the constrained device 104 and a compliant distal catheter tip 110. Described in greater detail below, the restraining member, in accordance with various embodiments, comprises a retractable section that extends over at least a portion of the compacted or constrained device and at least a portion of the catheter tip so as to cover or bridge a gap therebetween. The retractable section can retract away from the catheter tip

sequentially or concurrently with at least a partial actuation or opening of the restraining member.

[0016] Referring to Figure 2, a partial side view of a catheter system, in accordance with various embodiments, used to implant a medical device is shown and generally indicated at 100. The catheter system 100 includes a catheter shaft 102 having opposite proximal and distal ends, and an expandable device 104 (shown in dashed lines) disposed near or at the distal end of the catheter shaft 102. The device 104 is held in a constrained state suitable for endoluminal delivery of the device to a treatment site by a flexible, generally tubular constraining sleeve or restraining member 106. The flexible restraining member 106 is held in the tubular shape by a removable stitch line 108. When the stitch line 108 is actuated by pulling or tensioning in the direction indicated at 114, the restraining member 106 will split open and allow the device 104 to expand. The restraining member 106 at its distal end incorporates a retractable section 200 that extends over at least a portion of both the device 104 and the catheter tip 110. In various embodiments, the retractable section can be a generally tubular element. As the catheter system is advanced through a curved vessel, a gap 112 can form between the constrained device 104 and a compliant distal catheter tip 110. As shown, the retractable section 200 extends over at least a portion of both the device 104 and the catheter tip 110 to bridge the gap 112 therebetween. The retractable section 200 can retract away from the catheter tip 110 sequentially or concurrently with actuation or opening of the restraining member.

[0017] In various embodiments, a retracting element can be operatively coupled to the retractable section to facilitate retraction of the retractable section away from the catheter tip. The retracting element can be an elongated member, such as a tether, wire, string and the like coupled to the retracting section and extending through the catheter for access and selective actuation of the retracting element by the clinician at a proximal end of the catheter.

[0018] In various embodiments, the retracting element, for example as illustrated at 201 in Figure 2a, can be formed from an elastomeric material and operatively coupled to the retractable section 200, such that the retracting element 201 is in a tensioned state while the retractable section 200 is releasably held or maintained over the device 104 and the catheter tip 110 to bridge the gap 112

therebetween. Release or opening of the retractable section 200 allows the retracting element 201 to shorten as it moves toward a relaxed, untensioned state. The retractable section 200 is pulled or displaced away from the catheter tip 110 in response to the shortening of the retracting element 201.

[0019] In various embodiments, the retractable section can be formed from an elastomeric material and tensioned or stretched such that the retractable section can be releasably maintained in a tensioned state while extending over the device and the catheter tip to bridge the gap therebetween, and released to allow movement of the retractable section toward a shortened, relaxed state sequentially or concurrently with opening of the restraining member.

[0020] Upon delivery, the restraining member is released allowing the restraining member to release or "split-open" and permit the compacted device to expand. The device can be expanded by a balloon or can expand due to an outward force applied by a compressed stent wire frame. The restraining member may remain with the device at the treatment site in the vasculature, captured between the device and vascular wall. As the restraining member is released, the retractable section of the restraining member retracts proximally away from the catheter tip. In some cases, the medical device has anchors or barbs that aid in securing the device to the vascular wall along with a blood sealing cuff. Thus, retraction of the retractable section can further expose such anchors or barbs and/or sealing cuffs for engaging the vascular wall.

[0021] Referring to Figure 3a, a catheter system 100, in accordance with various embodiments, is shown having an expandable device 104 partially covered by a constraining sleeve or restraining member 106. The restraining member 106 has a retractable section 200a extending from a relatively non-elastic portion 300. The retractable section 200a is shown in a non-tensioned state having a relaxed, original longitudinal length. As shown in Figure 3b, the retractable section 200b of the restraining member 106 can be longitudinally tensioned (stretched or elongated) in the direction depicted by arrows 302. The retractable section 200b of the restraining member 106 can be stretched longitudinally to extend over the proximal end of the catheter olive or tip 110 to conceal or bridge a gap between the device 104 and the catheter tip 110. Once longitudinally tensioned to the desired stretched length, the retractable section of the restraining member can be longitudinally

restrained in tension. The retractable section 200b can, for example, be longitudinally tensioned or stretched to at least about 10% longitudinal elongation or at least about 110% of an initial or original (relaxed) length and held (restrained) in this stretched condition to bridge the gap between the device and the catheter tip. As illustrated in Figure 3b, a releasable stitch line 108 maintains the retractable section 200b in the elongated, tensioned state.

[0022] As shown in Figure 3c, the releasable stitch line 108 can be actuated or tensioned to allow the restraining member 106 to split open and release the expandable device 104. As the restraining member 106 opens, the retractable section 200c is free to retract in the direction depicted by arrows 304 toward a relaxed, non-tensioned state. The restraining member therefore shortens longitudinally in length and retracts proximally along the compacted device. In some cases, the medical device has anchors or barbs that aid in securing the device to the vascular wall along with a blood sealing cuff. By shortening in length, the restraining member can retract proximally to expose any optional anchors and/or sealing cuffs for engaging the vascular wall.

[0023] As shown in Figure 3d, the releasable stitch line can be actuated, allowing the device 104 to fully expand. The retractable section 200a of the restraining member 106 is now longitudinally shortened as it moves toward the relaxed, non-tensioned state, as shown. Since the retractable section 200a is relaxed and non-tensioned, the retractable section retracts to a length shorter than a longitudinally tensioned or stretched length (as illustrated in Figure 3b, 200b). The restraining member 106 therefore does not cover or interfere with device sealing cuffs 306 or anchor barbs 308, as shown in Figure 3d.

[0024] In various embodiment, a restraining member and retracting element or retractable section of the restraining member can be retained in an elongated and tensioned state by friction between the constrained device and the inner surface of the restraining member. Opening of the restraining member by actuation of the stitch line as described above relieves the friction and allows the restraining member to longitudinally retract as the elastic element returns to a shorter, untensioned state.

[0025] In various embodiments, a restraining member can include an elastic element that is held in an elongated tensioned state to conceal a gap along the catheter assembly, such as between the expandable device and an adjacent

component of the catheter assembly, and that retracts toward a shortened relaxed state upon release or opening of the restraining member to reveal the gap and/or portions of the expandable device and/or adjacent component.

[0026] In various embodiments, the restraining member can include proximal and distal elastic elements which can be held in elongated tensioned states to conceal proximal and distal gaps on opposite ends of the expandable device, and which retract toward shortened relaxed states upon release or opening of the restraining member to reveal the respective proximal and distal gaps and/or portions of the expandable device and/or adjacent components at opposite proximal and distal ends of the expandable device.

[0027] Elastic restraining members can comprise a variety of polymeric material, such as silicone. Other exemplary biocompatible elastomers can include, but are not limited to, elastomeric copolymers of 6-caprolactone and glycolide (including polyglycolic acid) with a mole ratio of 6-caprolactone to glycolide of from about 35:65 to about 65:35, more preferably from 35:65 to 45:55; elastomeric copolymers of 6-caprolactone and lactide (including L-lactide, D-lactide, blends thereof, and lactic acid polymers and copolymers) where the mole ratio of 6-caprolactone to lactide is from about 35:65 to about 65:35 and more preferably from about 30:70 to 45:55; other preferable blends include a mole ratio of6-caprolactone to lactide from about 85:15 to 95:5; elastomeric copolymers of p-dioxanone (l,4-dioxan-2-one) and lactide (including L-lactide, D-lactide, blends thereof, and lactic acid polymers and copolymers) where the mole ratio of p-dioxanone to lactide is from about 40:60 to about 60:40; elastomeric copolymers of 6-caprolactone and p-dioxanone where the mole ratio of 6-caprolactone to p-dioxanone is from about from 30:70 to about 70:30; elastomeric copolymers of p-dioxanone and trimethylene carbonate where the mole ratio of p-dioxanone to trimethylene carbonate is from about 30:70 to about 70:30; elastomeric copolymers oftrimethylene carbonate and glycolide (including polyglycolic acid) where the mole ratio of trimethylene carbonate to glycolide is from about 30:70 to about 70;30; elastomeric copolymers of trimethylene carbonate and lactide (including L-lactide, D-lactide, blends thereof, and lactic acid polymers and copolymers) where the mole ratio of trimethylene carbonate to lactide is from about 30:70 to about 70;30; and blends thereof.

[0028] Examples of suitable biocompatible elastomers are described in U.S. Pat. Nos. 4,045,418; 4,057,537 and 5,468,253.

[0029] An optional external sleeve, or external sock may be incorporated to cover the retractable section of the restraining member.

[0030] Typical catheters used to deliver medical devices can comprise commonly known materials such as Amorphous Commodity Thermoplastics that include Polymethyl Methacrylate (PMMA or Acrylic), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Modified Polyethylene Terephthalate Glycol (PETG), Cellulose Acetate Butyrate (CAB); Semi-Crystalline Commodity Plastics that include Polyethylene (PE), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE or LLDPE), Polypropylene (PP), Polymethylpentene (PMP); Amorphous Engineering Thermoplastics that include Polycarbonate (PC), Polyphenylene Oxide (PPO), Modified Polyphenylene Oxide (Mod PPO), Polyphenelyne Ether (PPE), Modified Polyphenelyne Ether (Mod PPE),Thermoplastic Polyurethane (TPU); Semi-Crystalline Engineering Thermoplastics that include Polyamide (PA or Nylon), Polyoxymethylene (POM or Acetal), Polyethylene Terephthalate (PET, Thermoplastic Polyester), Polybutylene Terephthalate (PBT, Thermoplastic Polyester), Ultra High Molecular Weight Polyethylene (UHMW-PE); High Performance Thermoplastics that include Polyimide (PI, Imidized Plastic), Polyamide Imide (PAI, Imidized Plastic), Polybenzimidazole (PBI, Imidized Plastic); Amorphous High Performance Thermoplastics that include Polysulfone (PSU), Polyetherimide (PEI), Polyether Sulfone (PES), Polyaryl Sulfone (PAS); Semi-Crystalline High Performance Thermoplastics that include Polyphenylene Sulfide (PPS), Polyetheretherketone (PEEK); and Semi-Crystalline High Performance Thermoplastics, Fluoropolymers that include Fluorinated Ethylene Propylene (FEP), Ethylene Chlorotrifluroethylene (ECTFE), Ethylene, Ethylene Tetrafluoroethylene (ETFE), Polychlortrifluoroethylene (PCTFE), Polytetrafluoroethylene (PTFE), Polyvinylidene Fluoride (PVDF), Perfluoroalkoxy (PFA). Other commonly known medical grade materials include elastomeric organosilicon polymers, polyether block amide or thermoplastic copolyether (PEBAX) and metals such as stainless steel and nickel/titanium alloys. Semi-rigid restraining members can comprise appropriate materials listed above.

[0031] Medical devices incorporating stents can have various configurations as known in the art and can be fabricated, for example, from cut tubes, wound wires (or ribbons) or flat patterned sheets rolled into a tubular form. Stents can be formed from metallic, polymeric or natural materials and can comprise conventional medical grade materials such as nylon, polyacrylamide, polycarbonate, polyethylene, polyformaldehyde, polymethylmethacrylate, polypropylene, polytetrafluoroethylene, polytrifluorochlorethylene, polyvinylchloride, polyurethane, elastomeric organosilicon polymers; metals such as stainless steels, cobalt-chromium alloys and nitinol and biologically derived materials such as bovine arteries/veins, pericardium and collagen. Stents can also comprise bioresorbable materials such as poly(amino acids), poly(anhydrides), poly(caprolactones), poly(lactic/glycolic acid) polymers, poly(hydroxybutyrates) and poly(orthoesters).

[0032] 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, said catheter assembly comprising:

a catheter having an end;

a catheter tip disposed at the end of the catheter;

an expandable device positioned near the end of the catheter;

a restraining member extending around at least a portion of the expandable device for releasably maintaining the expandable device in a constrained state suitable for endoluminal delivery of the device, the restraining member having a retractable section that in a first state extends over at least a portion of the device and at least a portion of the catheter tip to bridge a gap therebetween and in a second state is spaced apart from the catheter tip.

2) The catheter assembly as set forth in claim 1, wherein the restraining member is formed from an elastomeric material.

3) The catheter assembly as set forth in claim 2, wherein the restraining member in a tensioned state extends over at least a portion the device and at least a portion of the catheter tip to bridge the gap therebetween.

4) The catheter assembly as set forth in claim 3, wherein the restraining member can be released to allow displacement of the retractable section toward a shortened, relaxed state sequentially or concurrently with opening of the restraining member.

5) The catheter assembly as set forth in claim 4, wherein the restraining member in the tension state is at least about 10% longitudinal elongation.

6) The catheter assembly as set forth in claim 4, wherein the retraining member is releasably held in the constrained state by a releasable stitch.

7) The catheter assembly as set forth in claim 1 including a retracting element operatively coupled to the retractable section to facilitate retraction of the retractable section away from the catheter tip.

8) The catheter assembly set forth in claim 7, wherein the retracting element is an elongated member coupled to the retracting section and extending through the catheter to allow access and selective actuation of the retracting element.

9) The catheter assembly as set forth in claim 7, wherein the retracting element is formed from an elastomeric material and operatively coupled to the retractable section, such that the retracting element is in a tensioned state while the retractable section is releasably held over at least portions of each of the device and the catheter tip to bridge the gap therebetween.

10) The catheter assembly as set forth in claim 9, wherein retracting element relaxes and shortens to cause displacement of the retractable section away from the catheter tip in response to release of the retractable section of the restraining member.

11) The catheter assembly as set forth in claim 9 wherein the retraining member is releasably held in the constrained state by a releasable stitch.

12) The catheter assembly as set forth in claim 11, wherein retracting element relaxes and shortens to cause displacement of the retractable section away from the catheter tip in response to actuation of the releasable stitch.

13) The catheter assembly as set forth in claim 9, wherein the retracting element in the tension state is at least about 10% longitudinal elongation.

14) A medical device constraint, comprising:

an elastic element having proximal and distal ends;

a continuous lumen extending between the tubular element proximal and distal ends;

the generally tubular element having a first state wherein the tubular element is longitudinally restrained in tension;

a medical device having a distal end at least partially contained within the continuous lumen while the tubular element is in the first state;

the generally tubular element having a second state wherein the tubular element is longitudinally relaxed in tension; and

the distal end of the medical device is positioned distal to the distal end of the tubular element when the tubular element is in the second state.

15) A catheter assembly comprising:

a catheter extending between a proximal end and an opposite distal end thereof;

an expandable device disposed on the catheter near the distal end;

a restraining member extending over the device and constraining the device to an outer dimension suitable for endoluminal delivery to a treatment site in a patient; and

an elastic element fixedly secured to at least two location on the restraining member,

wherein in a first state, the restraining member extends over a gap between the device and the distal end of the catheter and the elastic element is held in tension due to friction between the expandable device and the restraining member, and in a second state, the restraining member is opened to allow expansion and deployment of the expandable device and further relieve friction to allow longitudinal retraction of the restraining member due to a return of the elastic element to a shorter, untensioned length.

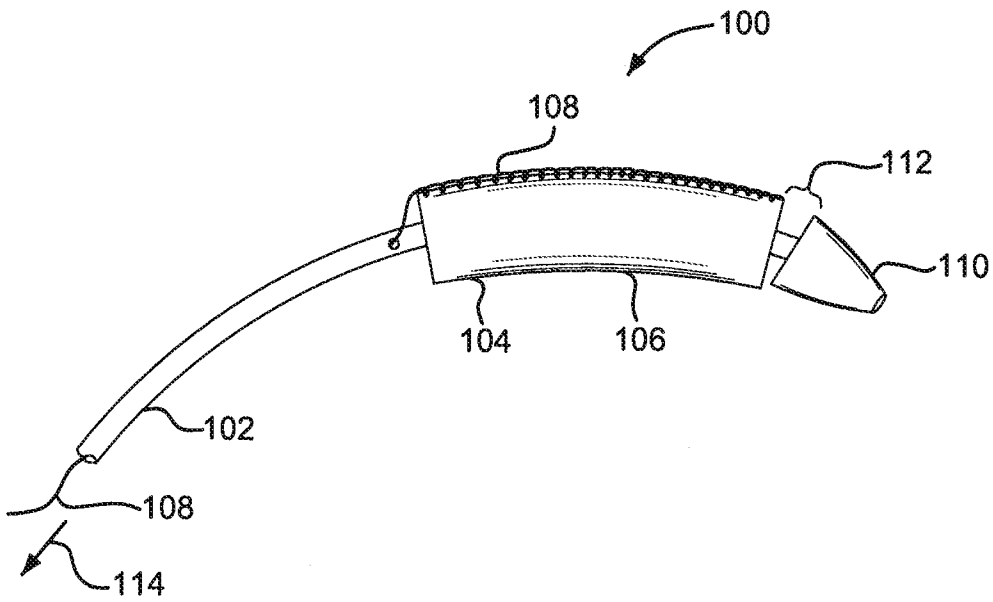

FIG. 1

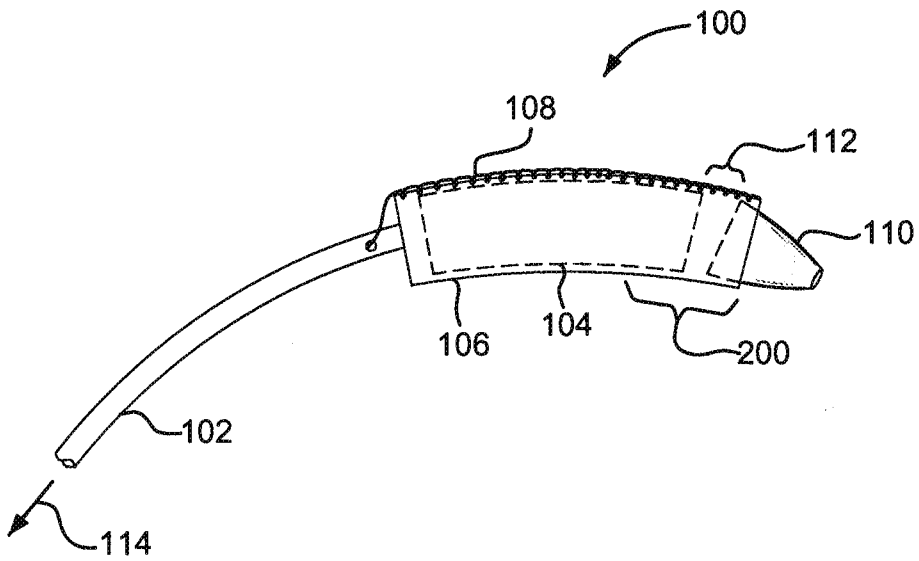

FIG. 2

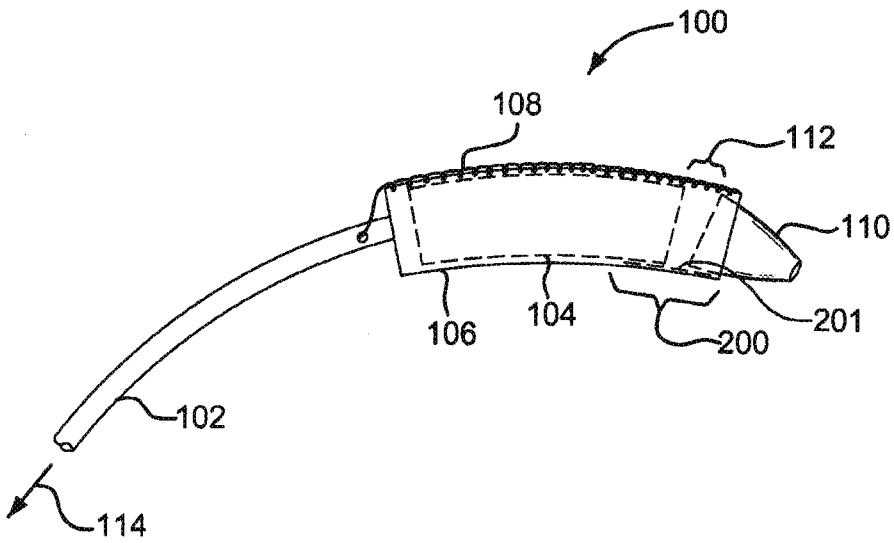

FIG. 2a

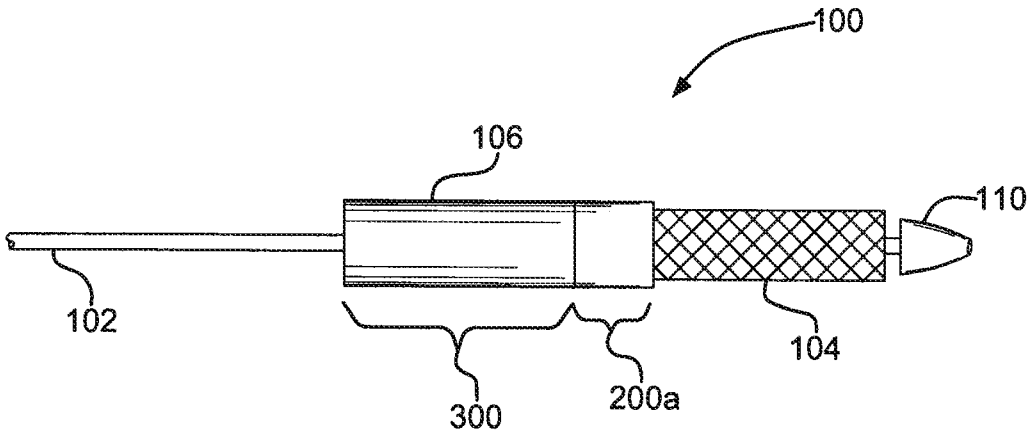

FIG. 3a

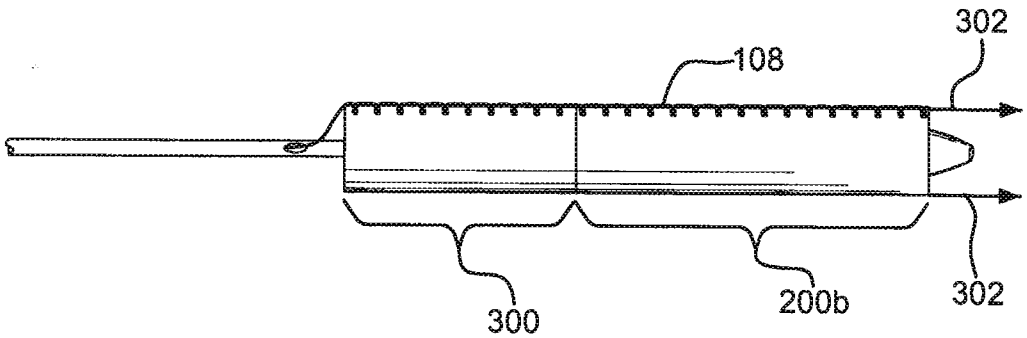

FIG. 3b

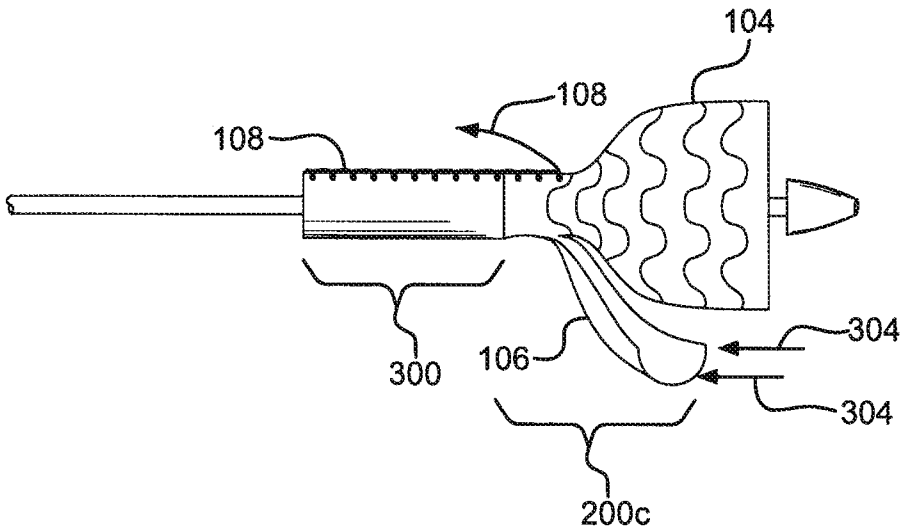

FIG. 3c

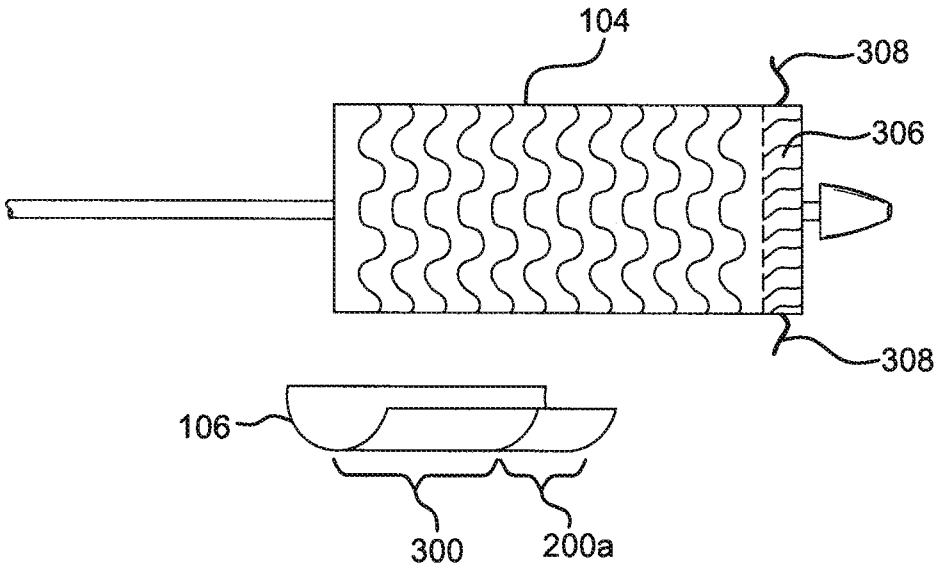

FIG. 3d