



(51) International Patent Classification:

A61B 17/12 (2006.01) A61F 2/958 (2006.01)
A61F 2/06 (2013.01) A61M 25/04 (2006.01)
A61F 2/86 (2013.01)

(21) International Application Number:

PCT/US2017/049202

(22) International Filing Date:

29 August 2017 (29.08.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/382,705 01 September 2016 (01.09.2016) US

(71) Applicant: MICROVENTION, INC. [US/US]; 35 Enterprise, Aliso Viejo, California 92656 (US).

(72) Inventors: GREENE, George R., Jr.; 3019 Java Road, Costa Mesa, California 92626 (US). SEPETKA, Ivan; 346 Costello Court, Los Altos, California 94024 (US). LEI, Cathy; 16611 Living Rock Court, Chino Hills, California 91709 (US). NGUYEN, Rupal; 1164 Atlanta Way, Costa Mesa, California 92626 (US).

(74) Agent: FREDERICKS, Charles E.; Inskeep Intellectual Property Group Inc, 2281 W. 190th Street, Suite 200, Torrance, California 90504 (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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, KM, ML, MR, NE, SN, TD, TG).

Published:

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

(54) Title: TEMPORARY AORTIC OCCLUSION DEVICE

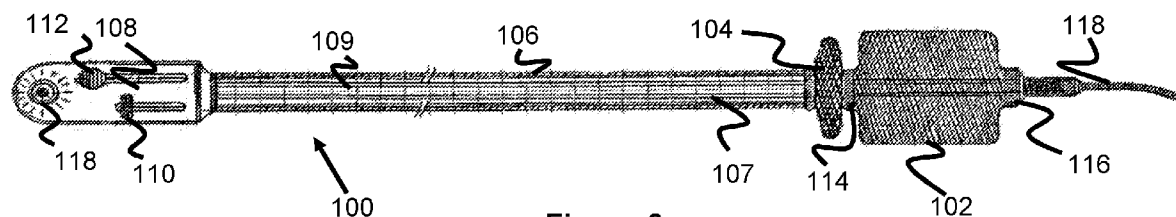


Figure 3

(57) Abstract: A temporary aortic occlusion device is disclosed, having an expandable locator portion and an expandable occlusion portion. The expandable locator portion assists a user in determining whether the distal end of the device has been advanced within a patient's aorta, and the occlusion portion is expanded to occlude the patient's aorta, preferably below the renal arteries.

TEMPORARY AORTIC OCCLUSION DEVICE

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 62/382,705 filed September 1, 2016 entitled *Temporary Aortic Occlusion Device*, which is hereby incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] This application relates to a temporary aortic occlusion device for controlling torso hemorrhage.

[0003] Traumatic hemorrhage, primarily the result of blast injuries, is the leading cause of death in active-duty military service members. Although the widespread use of tourniquets has helped to reduce loss of life from severe lower extremity injury, non-compressible torso hemorrhage remains a challenge with high mortality given the relative anatomic inaccessibility of this region to obtain hemorrhage control.

[0004] Reports have suggested that up to 25% of hemorrhage sustained in the battlefield is potentially survivable with 50% the result of truncal trauma. Pelvic bleeding, in particular, can be severe and difficult to control, requiring advanced, upper echelon hospital-based care, such as angioembolization, for definitive treatment. Because these advanced care methods and specially trained operators are at higher levels of care, mortality remains high. Unfortunately, outside of pelvic binders for pelvic fracture stabilization, which have limited success in hemorrhage control and are of no value in penetrating trauma there, has been little advancement in the control of non-compressible torso bleeding at the lower echelons of care.

[0005] Traditionally, early temporary control for non-compressible torso hemorrhage has been limited to thoracotomy with aortic cross-clamping. This technique has been reserved for moribund patients with absent or lost pulses and has an associated high morbidity and mortality. With growing interest in endovascular techniques for the management of vascular trauma the use of a resuscitative endovascular balloon occlusion of the aorta (REBOA) as an alternative to thoracotomy has been reported. For patients

with massive pelvic or intra-abdominal hemorrhage who survive transport to an advanced care facility, placement of a temporary occlusion balloon in the infra-renal aorta, proximal to the aortic bifurcation, or the within the descending thoracic aorta have been used to provide time for more definitive treatment through surgical or endovascular methods. This in-hospital technique provides a method to stop flow of blood below the level of the balloon until the balloon can be deflated under controlled conditions. Insertion of an occlusive balloon is less invasive than a thoracotomy and can be placed in the unstable patient. Endovascular balloon occlusion has been shown to be lifesaving and superior to thoracotomy with aortic cross-clamping in civilian literature.

[0006] Placement of a temporary occlusion balloon in the aorta is performed under sterile conditions using ultrasound and fluoroscopic guidance, which requires time, skill, and bulky portable x-ray machines. Despite the potentially life-saving nature of aortic balloon occlusion in the setting of massive torso and/or pelvic hemorrhage, current approaches for the placement these devices require fluoroscopic guidance. Fluoroscopy allows for: (i) intra-arterial injection of contrast dye to define the vascular anatomy, (ii) positioning of an aortic occlusion balloon with respect to this defined anatomy, and (iii) precise control of inflation of the device to allow for sufficient occlusion of the aorta while avoiding over-inflation that could result in rupture of the aorta secondary to balloon inflation.

[0007] A technique has been performed utilizing inflation of an aortic occlusion balloon in a trauma bay as a temporary measure for patients with massive pelvic hemorrhage and life-threatening shock, without fluoroscopic guidance. However, this approach requires the expertise of a senior Interventional Radiologist to interpret subtle tactile cues reflecting appropriate balloon placement and inflation. Further, this technique was performed in a “blind” fashion and relied upon the assumption of normal vascular anatomy. In spite of the reported success with balloon occlusion placement, positioning and confirmation has required valuable time, the use of fluoroscopic imaging, and skilled experienced practitioners at higher echelons of care. Additionally, due to the size of the currently available device surgery is required to repair the arteriotomy created by the catheter.

[0008] Any non-fluoroscopic approach for temporary occlusion of the aorta in the setting of hemorrhage should address: (i) positioning of the device with respect to

individual patient anatomy, (ii) controlled inflation of the balloon or other occlusion device to account for varying aorta diameters, particularly in the under-resuscitated patient, (iii) a low profile, allowing for removal of the device without surgical repair, and (iv) must account for considerations related to the need for operator training in how to safely introduce the device into the femoral artery without creation of additional vascular injury.

[0009] Placement of a temporary aortic occlusion device may become an effective technique for hemorrhage control at lower echelons of care if it could be adapted for quicker, easier insertion by non-endovascular specialized providers. For example, Role II facilities such as the Navy Afloat Trauma System (NATS), the Navy/Marine Corps Forward Resuscitative Surgical Systems (FRSS), or Role I settings with Independent Duty Corpsmen and Navy Special Warfare SEAL corpsmen and physicians. Earlier availability of this technique could allow first-responders to stabilize non-compressible torso bleeding until advanced care was available resulting in decreased mortality.

[0010] The present invention addresses the need to improve forward surgical applications and targeted therapy for hemorrhagic injury.

SUMMARY OF THE INVENTION

[0011] The present invention is directed to a temporary aortic occlusion device having an expandable locator portion and an expandable occlusion portion. The expandable locator portion assists a user in determining whether the distal end of the device has been advanced within a patient's aorta, and the occlusion portion is expanded to occlude the patient's aorta, preferably below the renal arteries.

[0012] In one embodiment, the locator portion has a maximum expansion diameter that is smaller than a maximum expansion diameter of the occlusion portion. Additionally, the locator portion preferably has a maximum expansion diameter that is the same size or slightly smaller than the internal diameter of a patient's aorta, providing the user with little or no resistance to expansion when positioned in an aorta.

[0013] In one embodiment, the locator portion and the occlusion portion are each composed of a plurality of braided mesh wires. Both portions can be coated, laminated, or otherwise covered with a polymer.

[0014] In another embodiment, the occlusion portion can include multiple layers of braided wires. These layers can be created from discrete tubular mesh structures or a single, inverted, tubular mesh structure. In another embodiment, the occlusion portion can include an expandable disc structure, woven fabric, and/or spring-biased struts.

[0015] In one embodiment, the locator portion is located distal of the occlusion portion. In another embodiment, the locator portion is located proximal of the occlusion portion.

[0016] In another embodiment, the occlusion portion is a balloon that can be inflated with a fluid from a proximal end of the device.

[0017] The present invention is also directed to a method of temporarily occluding the aorta of a patient by inserting a temporary aortic occlusion device into a femoral sheath and towards the common iliac bifurcation. An actuation mechanism on the handle of the device is actuated to increase a diameter of a locator on a distal end of the device. If resistance is encountered with the locator, the device is advanced further until the locator can be increased in diameter without resistance. Next, an occluder on the distal end of the device is increased in diameter to occlude the patient's aorta.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0019] Fig. 1 is a temporary aortic occlusion device according to one embodiment of the present invention utilizing a proximal locator portion and a distal occlusion portion.

[0020] Fig. 2 is the temporary aortic occlusion device according to Fig. 1 where the proximal locator portion is in a radially expanded configuration.

[0021] Fig. 3 is the temporary aortic occlusion device according to Fig. 1 where both the proximal locator portion and the distal occlusion portion are in radially expanded configurations.

[0022] Fig. 4 is the temporary aortic occlusion device according to Fig. 2 in a blood vessel.

[0023] Fig. 5 is the temporary aortic occlusion device according to Fig. 3 in a blood vessel.

[0024] Fig. 6 is a temporary aortic occlusion device according to another embodiment of the present invention.

[0025] Fig. 7 is a temporary aortic occlusion device occlusion portion according to one embodiment of the present invention.

[0026] Fig. 8 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0027] Fig. 9 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0028] Fig. 10 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0029] Fig. 11 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0030] Fig. 12 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0031] Fig. 13 is a temporary aortic occlusion device occlusion portion according to another embodiment of the present invention.

[0032] Fig. 14 is a temporary aortic occlusion device handle according to one embodiment of the present invention.

[0033] Fig. 15 is a temporary aortic occlusion device handle according to another embodiment of the present invention.

[0034] Fig. 16 is a temporary aortic occlusion device according to one embodiment of the present invention utilizing a distal locator portion and a proximal occlusion portion.

[0035] Fig. 17 is the temporary aortic occlusion device according to Fig. 16 where both the occlusion portion and the locator portion are in radially expanded configurations.

[0036] Fig. 18 is a temporary aortic occlusion device according to one embodiment of the present invention utilizing a proximal balloon and a distal locator portion.

[0037] Fig. 19 is the temporary aortic occlusion device according to Fig. 18 where the locator portion is in a radially expanded configuration.

[0038] Fig. 20 is the temporary aortic occlusion device according to Fig. 18 in a blood vessel, where both the balloon and locator portions are in radially expanded configurations.

DESCRIPTION OF EMBODIMENTS

[0039] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0040] Figures 1-5 are directed to a temporary aortic occlusion device 100 that has a radially expandable mesh locator 104 and a radially expandable mesh occlusion portion 102. The device 100 can be loaded in a femoral sheath (e.g., 6F Sheath) and advanced into the common iliac towards the aortic bifurcation target. Once the distal end of the device 100 is close to the target, the mesh locator 104 can be expanded and, if no resistance to the locator 104 occurs, the mesh occlusion portion 102 can be expanded to occlude the aorta.

[0041] The locator 104 is preferably composed of a wire mesh (e.g., .0005"- .004" Nitinol wires) braided into a generally tubular shape. A proximal end of the locator 104 is fixed to distal end of a kink-resistant catheter tube 106 and a distal end of the locator 104 is fixed to ring 114, which is also connected to control wire 109. The control wire 109 is positioned within the lumen of the catheter tube 106 and its proximal end is fixed to slider 112. Hence, as the slider 112 is moved proximally, the control wire 109 moves the ring 114 proximally towards the catheter tube 106, causing the locator 104 to expand. The fully expanded locator 104 can be one of many different sizes, each of which designed to have a maximum expansion that is equal to or smaller than the target aorta size (e.g., 18 mm to 25 mm). The mesh of the locator 104 also may include an elastic hydrophilic coating to prevent blood flow from entering the catheter tube 106.

[0042] The occlusion portion 102 functions in a similar manner as the locator 104, having a proximal end fixed to ring 114 and a distal end fixed to ring 116. The ring 116 is further connected to control wire 107, which is slidably positioned within the lumen of the catheter tube 106 and has a proximal end connected to slider 110. Hence, as the slider 110 is moved proximally, it causes the occlusion portion 102 to expand.

[0043] The occlusion portion 102 is composed of a wire mesh (e.g., (e.g., .0005"- .004" Nitinol or PET wires) that are laminated, coated (e.g., dip coating), or have a film applied either on its inner surface, outer surface, or both. Coating materials include polyurethane or silicone, and film materials includes polyethylene, linear low-density polyethylene, polyethylene terephthalate, and Nitinol. In one specific example, each of the wires are first coated in a polymer coating (e.g., polyurethane or polyethylene), braided, and then the inner surface of the occlusion portion 102 is completely coated in a thin 10-15 micron film of the same or similar polymer coating. In another specific example, ePTFE is coated on the inner and outer surface of the occlusion portion 102, "sandwiching" its braid. The occlusion portion 102 optionally has a length greater than that of the locator 104, so as to create a sufficient seal with the patient's aorta.

[0044] Preferably, the locator 104 and the occlusion portion 102 are spaced to ensure that the occlusion portion 102 does not occlude the renal arteries leading to the kidneys. A preferred average spacing between the two is about 4.00 cm to about 4.50 cm from each other based on the aortic anatomy of a range of average humans. However, it may

be desirable to increase this distance in some circumstances (e.g., large patients) or decrease this distance (e.g., young/small patients).

[0045] One aspect of the device 100 is that it allows a user to sense whether there is resistance to expanding the locator 104 or not. In this respect, the locator 104 preferably has a maximum diameter expansion that is either the same size as or slightly smaller than the patient's aorta diameter (e.g., 18 mm to 25 mm). This expansion limit can be limited by the length of movement of the slider 112, as well as the construction of the braid. In contrast, the occlusion portion 102 is configured to have a slightly larger maximum expansion diameter than the locator 104 and/or patient's aorta. This allows the occlusion portion 102 to properly engage the aorta and occlude blood flow. If the device 100 only included the occlusion portion 102 and not the locator 104, a user would encounter expansion resistance prior to entering the aorta, as well as in the aorta, which could cause user-confusion about the device's position. By including the locator 104 that will not substantially encounter resistance in the aorta, the user can have a much higher degree of confidence that the device has entered the aorta.

[0046] Since the occlusion portion 102 must be capable of expanding within an aorta 1 and applying a reasonably sufficient force against walls of the aorta 1, there is a risk of rupturing or dissecting the smaller vessels connected to the aorta 1 if expanded too soon. In that regard, the locator 104 can be configured to assist expansion only until encountering a predetermined resistance force and/or with a less forceful expansion force. In this regard, the locator 104 can be expanded with less risk of rupturing the smaller, aortic-adjacent vessels.

[0047] One way to achieve this reduced expansion force is to compose the locator 104 of relatively fewer braided wires that, when encountering small amounts of force tend to deform or at least provide less force on the vessels (e.g., 36 .005" wires for the locator 104 vs. 48 .005" wires for the occlusion portion 102). Additionally, as previously mentioned, the locator 104 can be coated or laminated with a polymer material similar to the occlusion portion 102, which can further create resistance to expansion. Providing a relatively thick coating can further disperse force from the wires of the locator 104, thereby further reducing risk of vessel rupture.

[0048] An alternate or additional mechanism includes adding a spring or elastic member between the end of the control wire 109 and the ring 114, such that when resistance is encountered by the locator 104, the spring or elastic expands. Alternately or additionally, the entire control wire 109 can be composed of an elastic material that tends to stretch when resistance is encountered by the locator 104. Optionally, similar mechanisms can be included with regard to the occlusion portion 102, though with the ability to apply somewhat greater force before attenuation.

[0049] The handle 108 of the device 100 may also include an indicator light 120 that illuminates when the locator 104 has fully expanded. The handle 108 may have a contact or switch that is triggered when the slider 112 is slid to its proximal-most position to thereby indicate that the aorta 1 has been reached by the device 100.

[0050] The distal end of the device 100 also includes an atraumatic tip 118 that is fixed to ring 116. In one example, the tip 118 is composed of a helically-wound wire or coil and is sufficiently flexible to avoid injuring the aorta 1 of a patient.

[0051] In operation, the device is loaded directly into a femoral sheath and pushed distally from the femoral artery and into the common iliac towards the common iliac artery bifurcation. Once the catheter tip is close to the target, the slider 112 can be used to slow expand the locator 104. If resistance occurs, the slider 112 can be pushed distally to collapse the locator 104 and the device can be further advanced distally. Once the slider 112 can open fully without resistance, the slider 112 activates the light 120. Finally, the slider 110 can be moved proximally to expand the occlusion portion 102, blocking or occluding the aorta.

[0052] Figure 6 illustrates another embodiment of an occlusion device 130 that is generally similar to the previously described device 100, however, the locator 104 is spaced apart from the occlusion portion 102 by tubular element 132. This embodiment may be useful if occlusion is desired at a higher location in the patient's aorta.

[0053] Figures 7-13 illustrate various alternate embodiments of the occlusion portion. For example, Figure 7 illustrates an occlusion portion 136 braided from a plurality of wires 138 and having a plurality of wire struts 140 disposed within its cavity and connected to the control wire 107. The struts 140 are configured to provide a slight bias or spring-force

to help urge the occlusion portion 136 to its expanded configuration. Specifically, the struts 140 can be metal wires connecting between the proximal and distal end of the occlusion portion 136 and that have a shape-memory configuration of a curve (e.g., a curve shape heat set into a shape memory alloy). In a compressed configuration, the struts 140 are relatively straight, but the shape-memory curve of the struts 140 provides an amount of force on the distal end of the occlusion portion 136 to assist the user in its expansion. Alternately, the struts 140 can be configured to return to a relatively straight configuration, biasing the occlusion portion 136 to its compressed configuration. While not shown, the occlusion portion 136 can be laminated, sealed, or otherwise coated in flexible layer of material, as described for other embodiments in this specification.

[0054] Figure 8 illustrates another embodiment of an occlusion portion 142 that is composed of a plurality of braided wires 144. Within the braided wires 144 is a framework comprised of at least a proximal and distal support wires 148 connected to a circular support wire 143. The support wires 148 are connected to each end of the occlusion portion 142 so that, when expanded, the circular support wire 143 is positioned annularly around an axis of the occlusion portion 142. A polymer film 146 is connected to the circular support wire 143, generally forming a plane perpendicular to the axis of the occlusion portion 142. Since the circular support wire 143 and polymer film 146 is sized to expand to substantially the inner diameter of the inner cavity of the occlusion portion 142, an occlusive barrier is created. The braided wires 144 can be left bare or can include a coating, film, lamination, or other occlusive materials as described elsewhere in this specification.

[0055] Figure 9 illustrates another embodiment of an occlusion portion 150 composed of a plurality of braided wires 152 that have a heat-set or memorized shape that causes the wires 152 to form an outer, cup shape 152A and an inner, inverted cup shape 152B. Put another way, the braided wires 152 invert to create two cylindrical layers. The braided wires 152 can be coated, laminated, covered with a film, or used with other occlusive materials as described elsewhere in this specification.

[0056] Figure 10 illustrates yet another embodiment of an occlusion portion 156 having a generally cylindrical outer mesh layer 158 that surrounds an inner, cylindrical mesh layer 159. In one example, the outer mesh layer 158 is composed of relatively larger wires,

while the inner layer 159 is composed of relatively smaller wires, which allows the inner layer 159 to have a lower porosity than the outer layer 158, since a greater amount of wires can be used (e.g., a higher pic-per-inch) – this would augment the occlusive effect of the occlusion portion by enhancing the resistance to blood flow once the blood permeates the outer layer. The outer and inner mesh layers 158, 159 can be each formed from a braided, mesh, tubular structure, or can alternately be formed from a single braided, tubular structure that is inverted to form the inner tubular layer 159. Either the outer layer 158, the inner layer 159, or both layers can be coated, laminated, covered with a film, or used with other occlusive material as described elsewhere in this specification.

[0057] Figure 11 illustrates another embodiment of an occlusion portion 160 having a plurality of braided wires forming a mesh layer 162, and an inner layer 164 composed of sealing, hydrophobic material such as polyurethane or silicone layer that is disposed within the mesh layer 162. Optionally, the inner layer 164 can be adhered or physically fastened to the outer mesh layer 162. Optionally, the outer surface of the mesh layer 162 can be coated, laminated, covered with a film, or used with other occlusive material as described elsewhere in this specification.

[0058] Figure 12 illustrates another embodiment of an occlusion portion 166 having a plurality of braided wires forming a mesh layer 168, and an inner fabric material 166 fixed at a distal end of the occlusion portion 166. The inner fabric material 166 can be attached to locations around the circumference of the mesh layer 168, or can contain a wire support structure (similar to that formed by the support wires of Figure 8) that expand the fabric material 166 when the occlusion portion 166 is expanded. The fabric material 166 can in only a proximal or distal half of the mesh layer 168, or can expand within the entire interior of the mesh layer 168. The fabric material 166 can form a funnel shape, a generally spherical shape, or similar shapes, depending on the interior shape of the mesh layer 168. The fabric material 166 can be formed from a woven fabric threads composed of a biocompatible material such as PET. Optionally, the outer surface of the mesh layer 168 can be coated, laminated, covered with a film, or used with other occlusive material as described elsewhere in this specification.

[0059] Figure 13 illustrates another embodiment of an occlusion portion 170 which is generally similar to the embodiment of Figure 7 in that it has a braided mesh layer 172

that has a plurality of wire struts 174 (e.g., 4) extending between its proximal and distal ends. The struts 174 are bias into a curved shape, such that they provide additional expansion force to the mesh layer 172. The mesh layer 174 forms a generally diamond shape or a shape of two cones connected together. Optionally, the outer surface of the mesh layer 168 can be coated, laminated, covered with a film, or used with other occlusive material as described elsewhere in this specification.

[0060] Turning to Figures 14 and 15, two different embodiments of handles (180, 182) are illustrated. These embodiments arrange the sliders 110, 112 in line with each other, instead of side-by-side, as in prior embodiments. Additionally, the handle 182 includes a slider 112 that is disposed entirely around the distal portion of the handle 182 and slides in a coaxial manner proximally and distally on the handle 182, the tracks are not shown but in such an embodiment slider 112 would have tracks that it slides on similar to the track that slider 110 slides on. In another embodiment, slider 112 could rotate in order to translate a connected wire – in this embodiment slider 112 would mate over the control wire in a ratcheting-type engagement where rotating slider 112 would translate the control wire which is connected to slider 112.

[0061] Figures 16 and 17 illustrate another embodiment of a temporary occlusion device 190 that is generally similar to the device 100 shown in Figures 1-5. However, the locator 104' is positioned distal of the occlusion portion 102.

[0062] Figures 18-20 illustrate yet another embodiment of a temporary occlusion device 200 that is generally similar to the device 190 of Figures 16 and 17, including the distal location of the locator 104'. However, instead of a mesh-based occluding portion, a balloon 208 is fixed proximal of the locator 104' (alternately, the balloon 208 could be fixed distally of the locator 104). A fluid connection port is connected for a fluid source (e.g., a syringe of fluid) and is open to an interior passage 206 within the catheter tube 106, which ultimately connects to an interior of the balloon 208 to allow for selective inflation.

[0063] Preferably, the balloon 208 is composed of a highly compliant material. In this respect, if the balloon 208 is over inflated, it will elongate rather than continuing to apply radial force on the wall of the aorta, thereby avoiding balloon-induced aortic damage.

[0064] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A temporary aortic occlusion device, comprising:
 - an elongated device body having a distal end and a proximal end;
 - a locator portion fixed near said distal end of said elongated device body; said locator portion being radially expandable from said proximal end of said device to a diameter less than or equal to a diameter of an aorta;
 - an occlusion portion fixed near said distal end of said elongated device body and adjacent to said locator portion; said occlusion portion being radially expandable from said proximal end of said device to a diameter equal to or greater than said diameter of said aorta so as to cause occlusion of said aorta.
2. The temporary aortic occlusion device of claim 1, wherein said locator portion is a first plurality of braided wires.
3. The temporary aortic occlusion device of claim 2, wherein said locator portion further comprises a first polymer coating disposed over said first plurality of braided wires.
4. The temporary aortic occlusion device of claim 2, wherein said occlusion portion further comprises a second plurality of braided wires.
5. The temporary aortic occlusion device of claim 4, wherein said occlusion portion further comprises a second polymer coating disposed over said second plurality of braided wires.
6. The temporary aortic occlusion device of claim 4, wherein said occlusion portion further comprises an inner layer inverted from an outer layer of said second plurality of braided wires.
7. The temporary aortic occlusion device of claim 4, wherein said occlusion portion further comprises a plurality of biased struts within an interior of said occlusion portion.
8. The temporary aortic occlusion device of claim 4, wherein said occlusion portion further comprises an expandable disc located within an interior of said occlusion portion.

9. The temporary aortic occlusion device of claim 4, wherein each of said second plurality of wires is individually coated with a polymer, and wherein an inner surface of said occlusion portion is coated with said polymer to form a film.
10. The temporary aortic occlusion device of claim 1, wherein said locator portion is positioned proximal of said occlusion portion.
11. The temporary aortic occlusion device of claim 1, wherein said locator portion is positioned distal of said occlusion portion.
12. The temporary aortic occlusion device of claim 1, wherein said occlusion portion is a balloon.
13. The temporary aortic occlusion device of claim 4, wherein said proximal end of said elongated device body further comprises a handle with at least a first slider member.
14. The temporary aortic occlusion device of claim 1, wherein said locator portion has a maximum expansion diameter that is smaller than a maximum expansion diameter of said occlusion portion.
15. The temporary aortic occlusion device of claim 1, wherein said locator portion is configured to stop expansion when encountering resistance thereto.
16. A temporary aortic occlusion device, comprising:
an elongated device body having a distal end and a proximal end;
a first mesh portion located at said distal end of said elongated device body; said first mesh portion being radially expandable to a first diameter;
a second mesh portion fixed near said distal end of said elongated device body and adjacent to said first mesh portion; said second mesh portion being radially expandable to a second diameter being larger than said first diameter;
wherein said second diameter is sized to occlude an aorta.

17. The temporary aortic occlusion device of claim 16, wherein said second mesh portion is coated with a polymer so as to seal an interior from an exterior of said second mesh portion.

18. The temporary aortic occlusion device of claim 16, wherein said first mesh portion is positioned proximally of said second mesh portion.

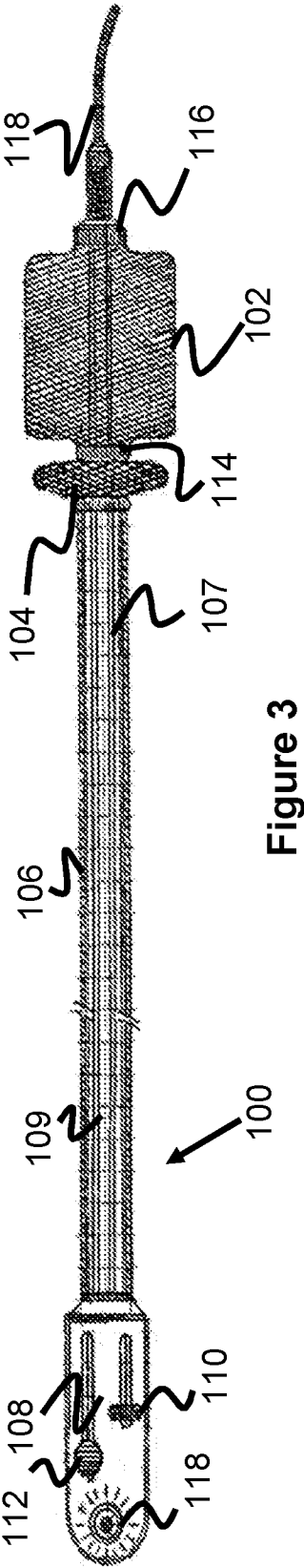
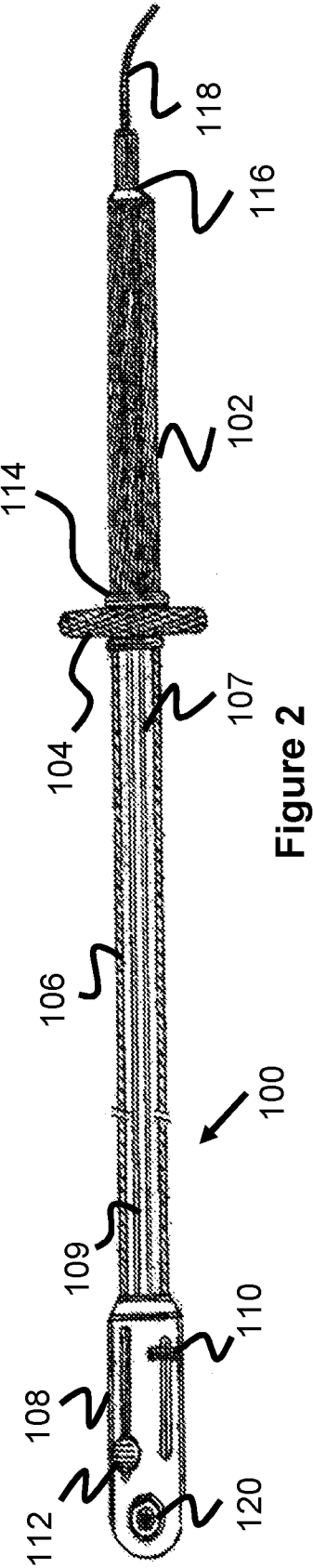
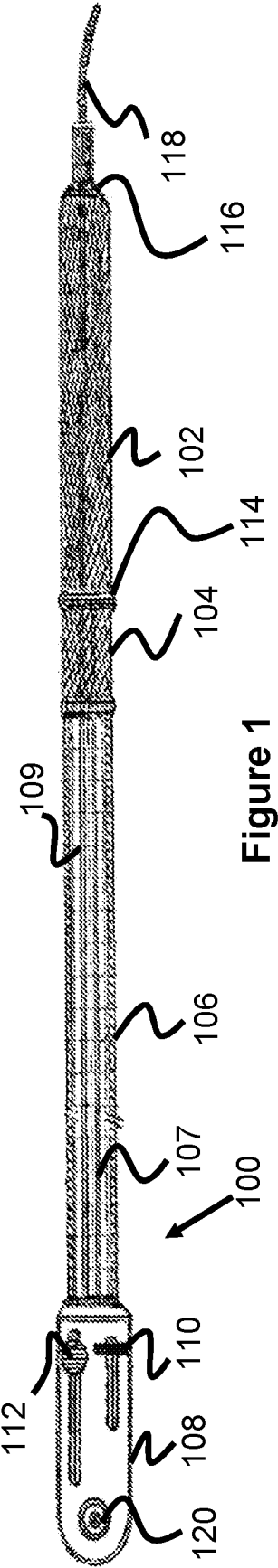
19. A method of temporarily occluding an aorta, comprising:

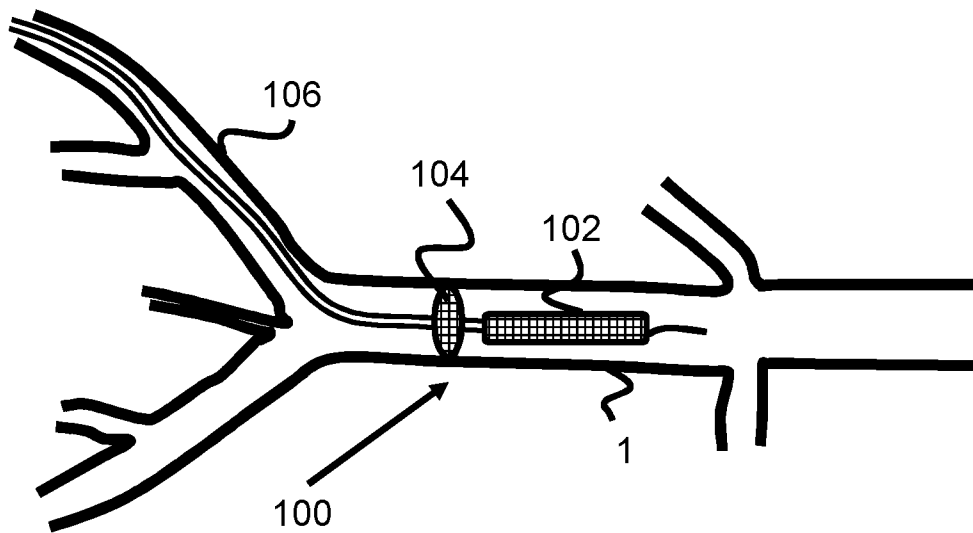
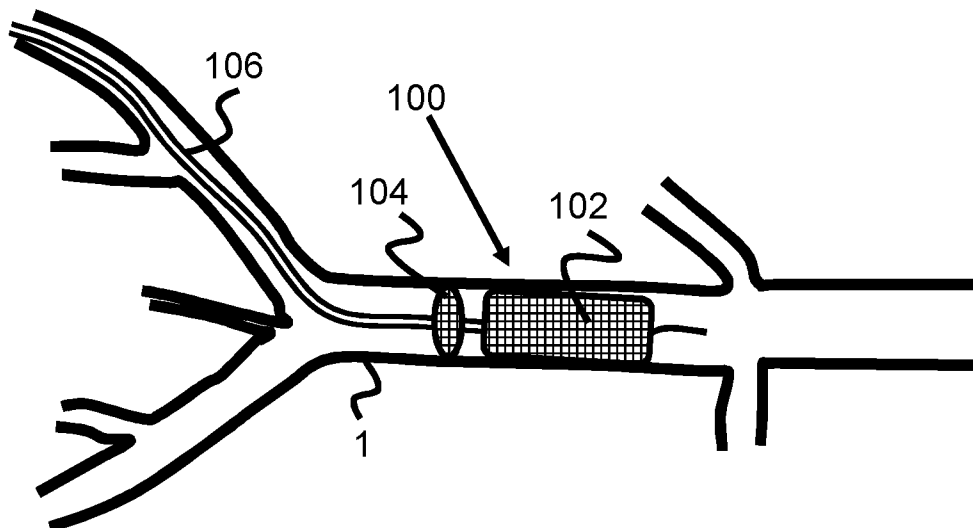
advancing a distal end of a temporary aortic occlusion device within vessels of a patient;

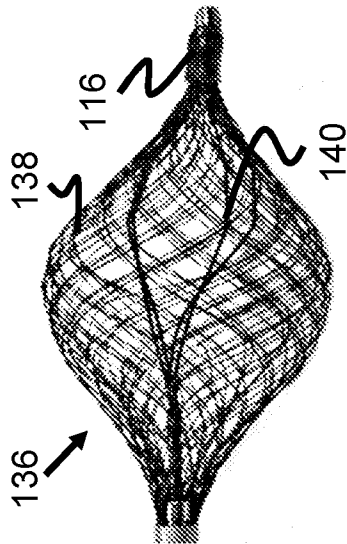
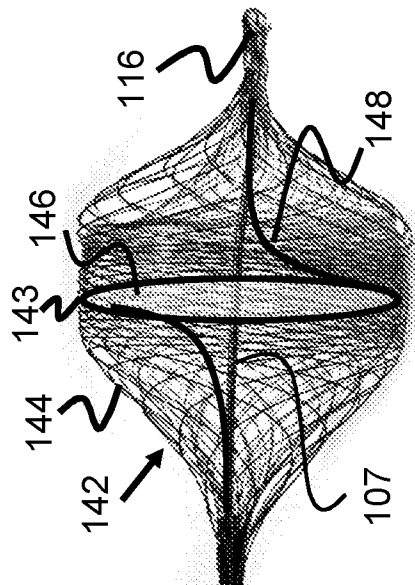
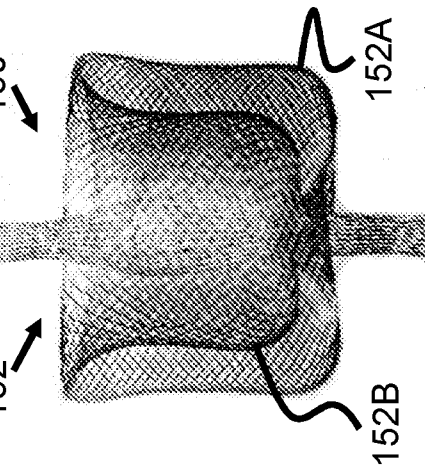
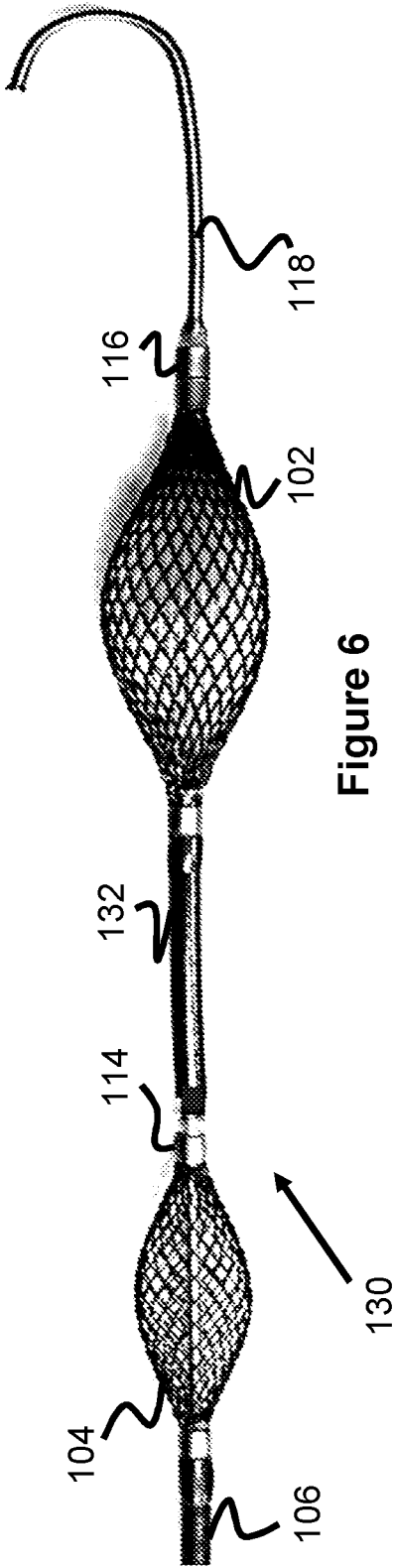
radially expanding a locator portion on a distal end of said temporary aortic occlusion device; and,

expanding an occlusion portion on said distal end of said temporary aortic occlusion device within an aorta if no resistance is encountered by a user when radially expanding said locator portion.

20. The method of claim 19, wherein said locator portion has a maximum expansion diameter less than a diameter of said aorta and wherein said occlusion portion has a maximum expansion diameter that is greater than or equal to said diameter of said aorta.



**Figure 4****Figure 5**



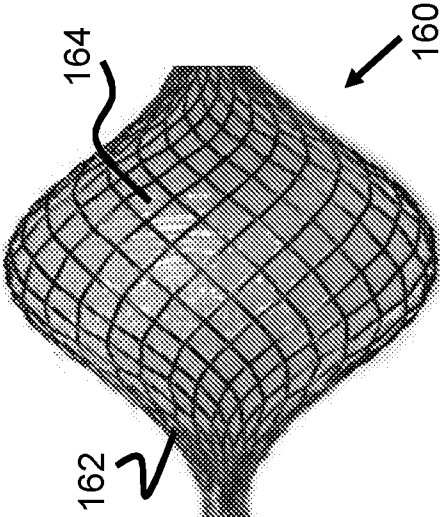


Figure 11

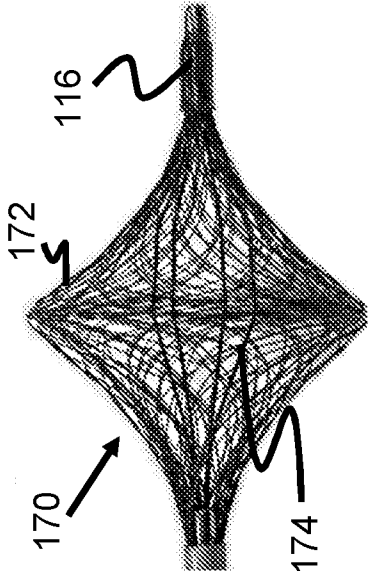


Figure 13

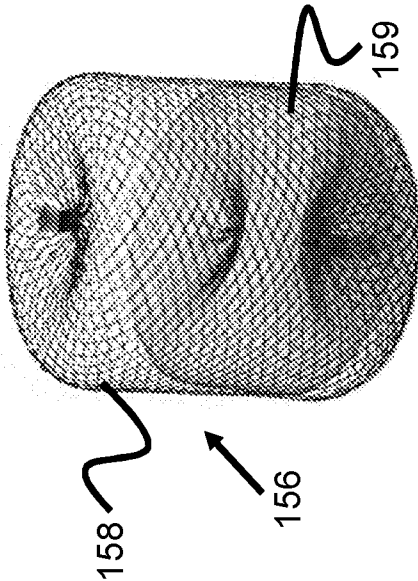


Figure 10

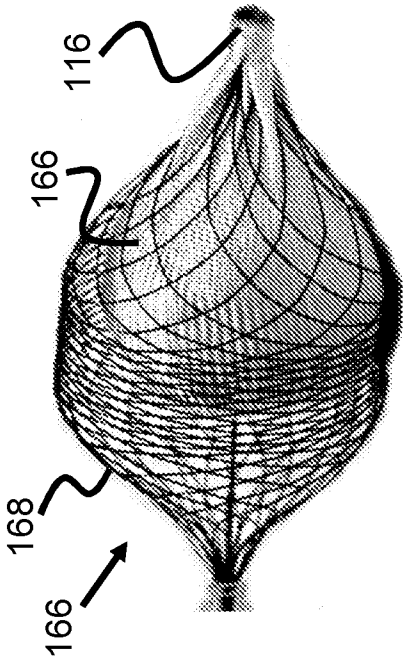


Figure 12

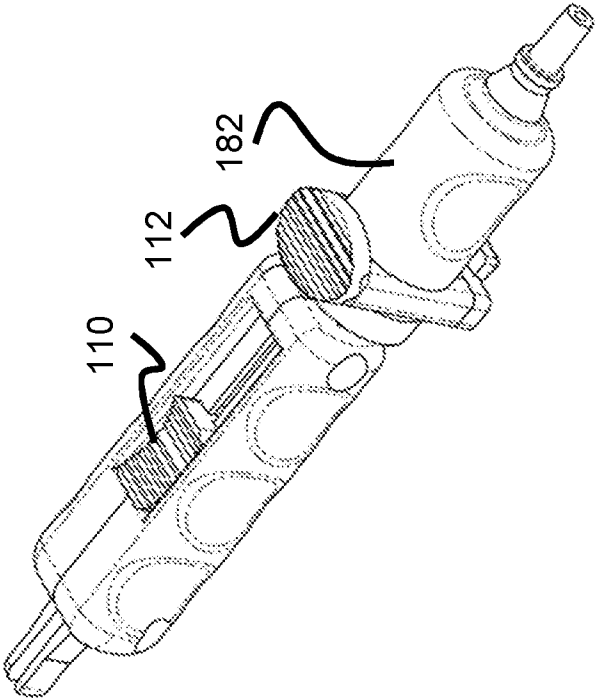


Figure 15

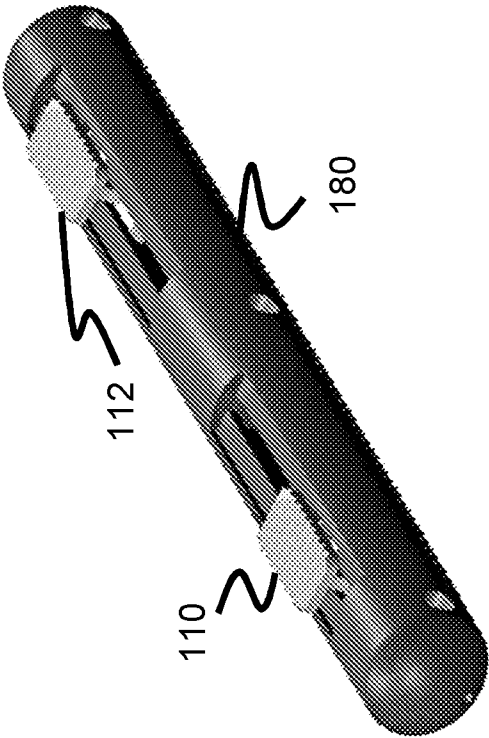


Figure 14

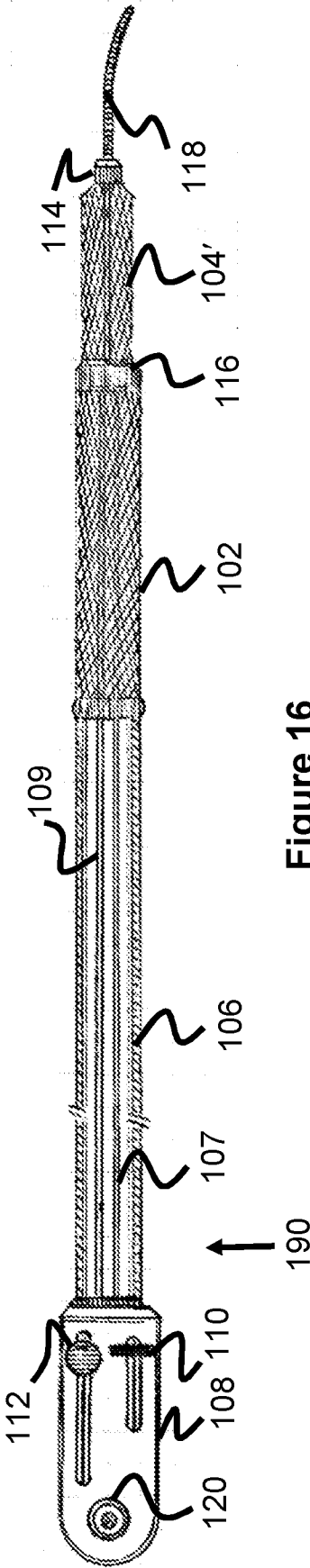


Figure 16

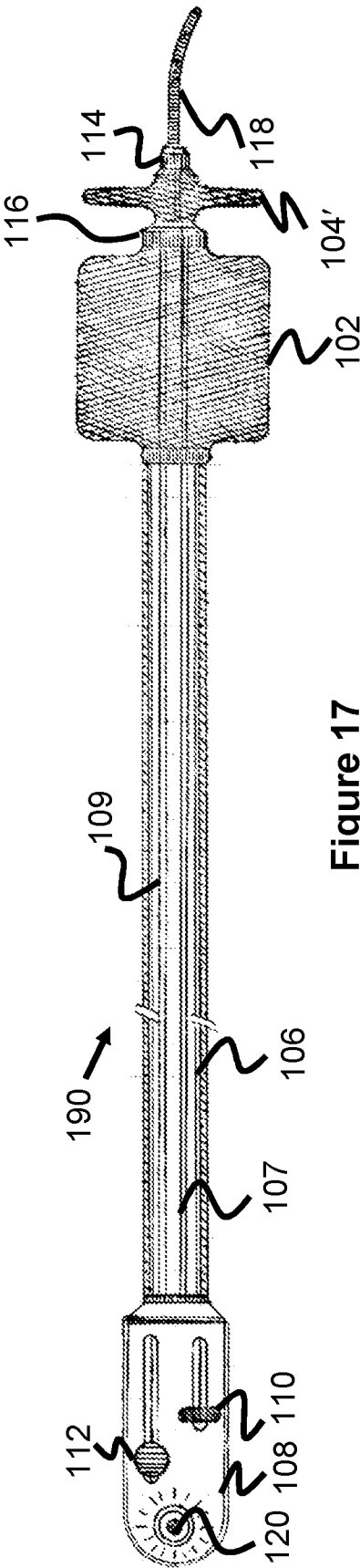


Figure 17

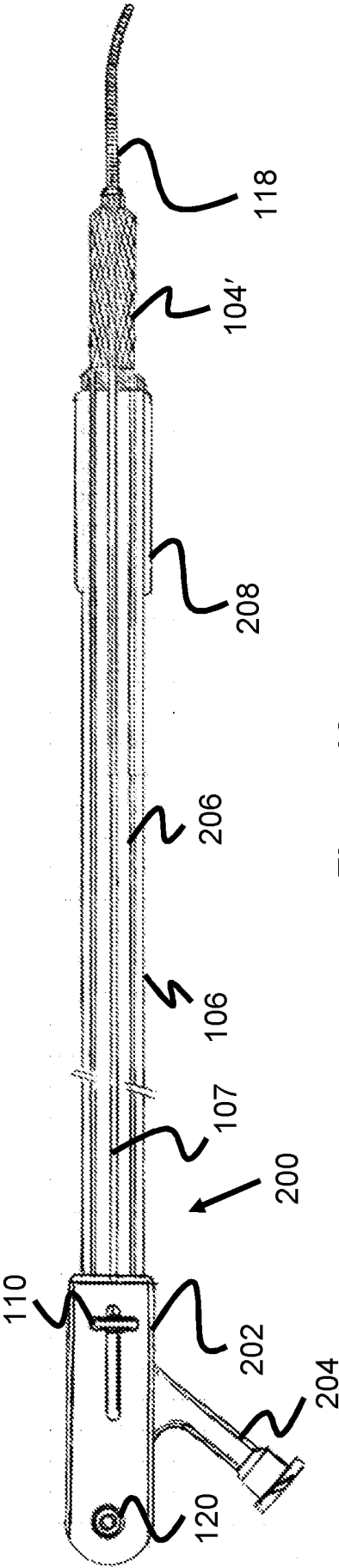


Figure 18

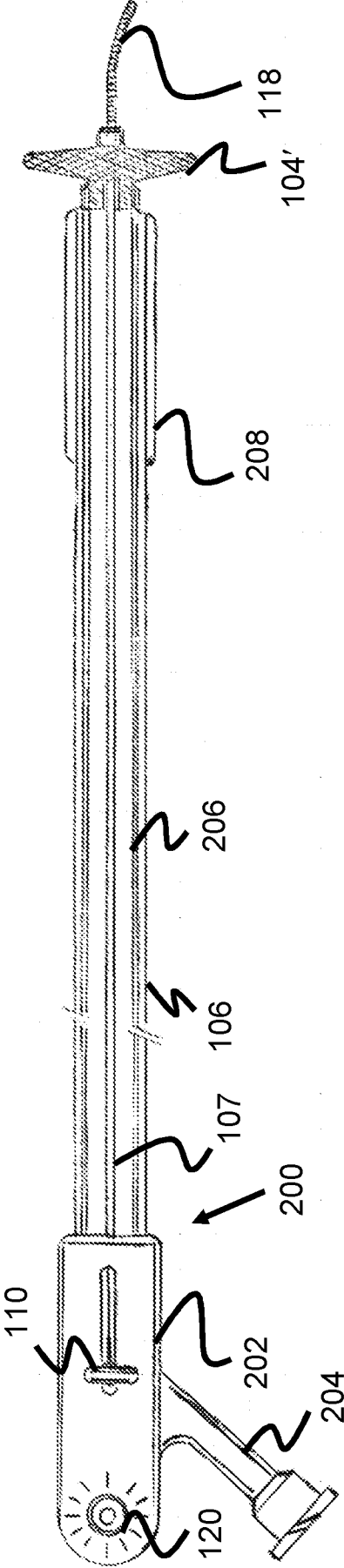


Figure 19

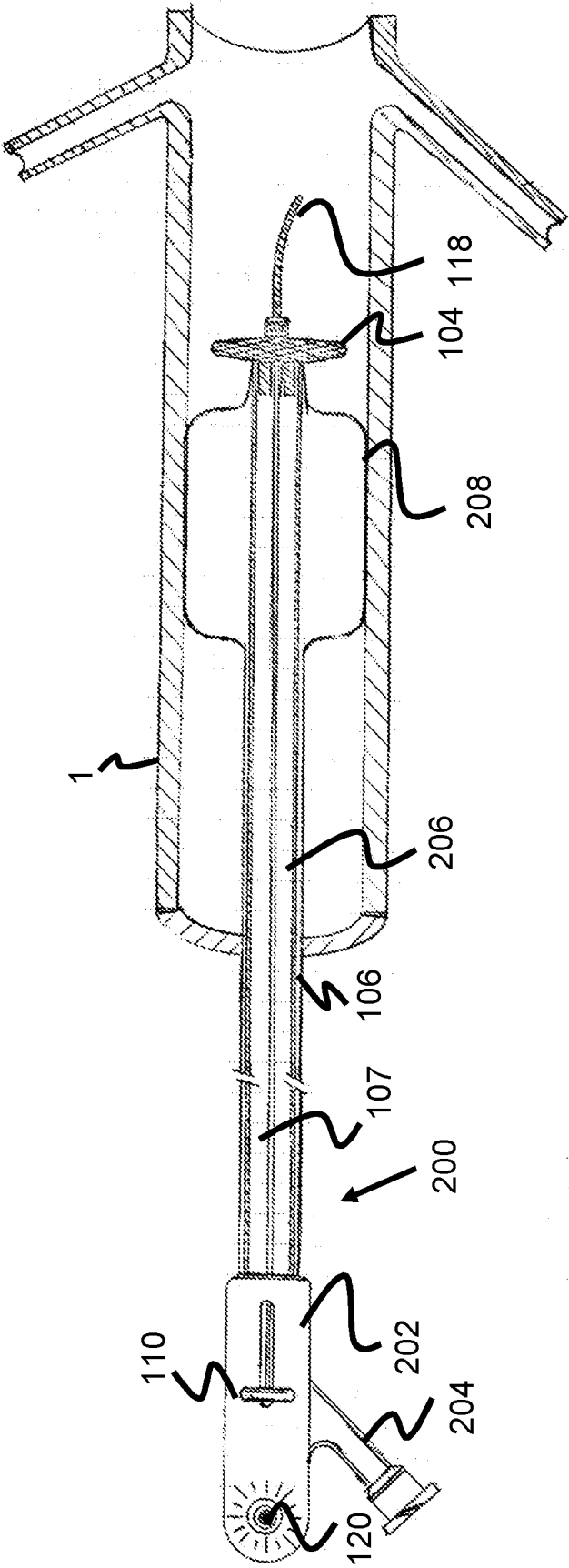


Figure 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/049202

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/12; A61F 2/06; A61F 2/86; A61F 2/958; A61M 25/04 (2017.01)

CPC - A61B 17/12022; A61B 17/12; A61B 17/1204; A61B 17/12109; A61F 2/06; A61F 2/86; A61F 2002/9583 (2017.08)

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)

See Search History document

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

USPC - 604/96.01; 604/103.05; 604/103.08; 604/104; 606/194 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0257361 A1 (AGA MEDICAL CORPORATION) 11 September 2014 (11.09.2014) entire document	1-20
A	US 2015/0005808 A1 (W L GORE & ASSOCIATES INC) 01 January 2015 (01.01.2015) entire document	1-20
A	US 2016/0015397 A1 (OCCLUTECH HOLDING AG) 21 January 2016 (21.01.2016) entire document	1-20

☐ 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 application or patent 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

13 October 2017

Date of mailing of the international search report

03 NOV 2017

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774