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(54) **Title**: VASCULAR OCCLUSION AND ASPIRATION DEVICE

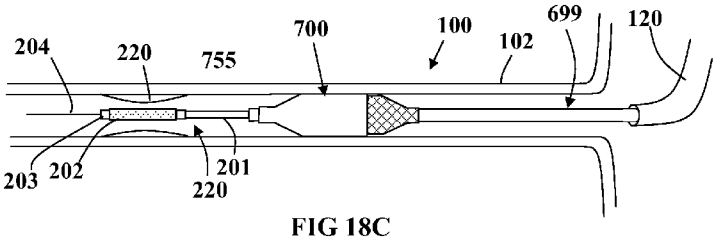


FIG 18C

(57) **Abstract**: Apparatus for aspirating blood from a blood vessel through a catheter located in the blood vessel, the apparatus comprising: a first tube portion having a configuration for which the first portion has an outer diameter substantially equal to an inner diameter of the catheter; and a second tube portion connected to the first tube portion, which second tube portion is expandable to occlude the blood vessel.

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VASCULAR OCCLUSION AND ASPIRATION DEVICE

RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Application 61/486,818 filed on May 17, 2011, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] Embodiments of the invention relate to providing apparatus and methods for performing vascular occlusion.

BACKGROUND

[0003] Minimally invasive procedures for treating a bodily vessel typically involve delivering interventional, diagnostic and/or therapeutical devices to a treatment site in the vessel using tubes, referred to as catheters, that are configured for insertion into the body though a natural or artificial orifice formed in the body. Blood vessels, regions of the gastrointestinal tract, and the urethra, are examples of vessels that are treated using minimally invasive procedures.

[0004] Among well-known minimally invasive procedures mediated with catheters are procedures for deploying stents to alleviate coronary blood vessel blockages, referred to as "stenoses", resulting from thromboses (blood clots) or the buildup of plaque that restrict or completely block blood flow. A stent is a tube whose walls are generally formed from a metal mesh, which is introduced into the body in a collapsed state characterized by a small cross section diameter and positioned in a stenosis blocking blood flow in a blood vessel to be treated. When properly positioned, the stent is expanded to increase its diameter so that it presses open the stenosis and enables enhanced blood flow through the vessel.

[0005] A stent deployment procedure to alleviate blockage of blood flow through an artery compromised by a stenosis typically comprises introducing a guiding catheter into the body through an (artificial) opening formed in a femoral artery or a radial artery in the arm and threading the catheter through the vascular system until a distal end of the catheter is located sufficiently close to the stenosis. A steerable guide wire is introduced through the guiding catheter and steered to and through the region of the stenosis. A stent deployment device (i.e. deployment system SDS) comprising its own "deployment catheter" having a stent mounted at its distal end is threaded along the guide wire until the stent is positioned in the stenosis. Expanding the positioned stent opens the stenosis and returns blood flow though the artery.

[0006] Procedures comprising deploying a stent in an artery often involve additional procedures such as capturing and removing debris, which may be small granular plaque or thrombus deposits or embolisms that are produced and released into the blood during a stent deployment process. If not captured and removed, debris introduced into the blood stream during deployment of a stent to treat a stenosis, can cause dangerous blood flow blockages in blood vessels downstream of the stenosis.

[0007] An embolisc protection device (EPD) introduced into the treated blood vessel is used to capture and remove potentially dangerous debris. Some EPDs, referred to as "proximal EPDs", comprise an occlusion balloon and aspirator that are introduced by a catheter into the artery proximal to the stenosis. Inflating the occlusion balloon, temporarily to block blood flow in the blood vessel during stent deployment, and controlling the aspirator to aspirate the blood, removes debris generated by the deployment. In some EPDs, referred to as "distal EPDs", a filter or occlusion element is positioned distal to the stenosis to trap debris that flows downstream of the stenosis with the blood. Upon completion of the deployment procedure, the debris trapped proximal to the distal occlusion element may be aspirated prior to removal of the occlusion element from the artery. Alternatively or additionally, the distal filter may be removed from the artery with the debris trapped within it.

SUMMARY

[0008] An embodiment of the invention relates to providing a vascular occlusion and aspiration adapter (VOCCA) that adapts a catheter introduced into a blood vessel to perform a medical procedure, to provide and control occlusion of the blood vessel and aspirate blood in the blood vessel distal to the catheter. Optionally, the medical procedure is a procedure for deploying a stent to treat a stenosis in the blood vessel.

[0009] In an embodiment of the invention the VOCCA, comprises a tubular body, hereinafter a "flow tube", having an expandable "flow blocker" at an end of the flow tube. The flow tube and flow blocker are configured to enable the flow tube to readily be threaded through a deployed catheter so that the flow blocker is positioned in the blood vessel outside a distal end of the catheter, with at least a portion of the flow tube remaining inside the catheter.

[00010] When the VOCCA is appropriately positioned in the catheter, an outer surface of the flow tube and an inner surface of the catheter make contact to substantially prevent blood flow between the surfaces, and the flow blocker is selectively expanded to, partially or substantially completely, block antegrade blood flow in the blood vessel. In an embodiment of the invention,

contact between the surfaces of the flow tube and the catheter sufficient to prevent blood flow between the surfaces is made by suitably dimensioning the length and cross section of the flow tube. Optionally, the flow tube is expanded to press the flow tube to the catheter and provide contact between the flow tube and catheter that prevents blood flow between the surfaces. When contact made between the outer surface of the flow tube and the inner surface of the catheter is sufficient to substantially prevent blood flow between the surfaces, the flow tube is said to be "sealed" to catheter.

[00011] As a result of "sealing" the flow tube to the catheter and expanding the flow blocker to block antegrade blood flow, blood may be aspirated from a region of the blood vessel downstream of the flow blocker through the flow tube and through the catheter by reducing pressure in the catheter. "Downstream" and "upstream" refer to a displacement or direction respectively in a direction of, and opposite to a direction of normal blood flow. The VOCCA is said to be deployed when it is positioned in a deployed catheter with a portion of its flow tube sealed to the catheter and its flow blocker expanded to, partially or substantially completely, occlude a blood vessel in which the catheter is deployed.

[00012] In an embodiment of the invention the flow blocker and flow tube are self expanding and are maintained in a pre-stressed collapsed, non-expanded state by a restraining sleeve while being threaded through the catheter. The restraining sleeve is pulled off the flow blocker and flow tube when the VOCCA is suitably positioned in the catheter so that the flow tube self expands to seal to the catheter and the flow blocker self expands to contact an inner surface of the blood vessel and occlude the blood vessel. In an embodiment of the invention, the flow tube is substantially non-expandable and houses pre-stressed elastic wires, which are released to expand out from the flow tube and expand the flow blocker to partially or substantially completely occlude the blood vessel.

[00013] In an embodiment of the invention, the wall of the flow tube is relatively thin and when deployed, the flow tube has an inner diameter that approaches an inner diameter of the catheter. A deployed VOCCA, in accordance with an embodiment of the invention, therefore enables efficient aspiration of blood at relatively large flow rates through the catheter. By way of example, for a catheter having an inner diameter of about 1.78 mm, a flow tube comprised in a VOCCA in accordance with embodiment of the invention, may have an inner diameter equal to about 1.42 mm.

[00014] In an embodiment of the invention is provided a disclosure of a vascular occlusion and aspiration adapter (VOCCA) comprising: a support frame having first and second ends; a

membrane or skin covering at least a portion of the support frame; a first activating member coupled to the first end of the support frame; and a second activating member moveable relative to the first activating member, and coupled to the second end of the support frame wherein, relative motion of the first and second activating members that shorten or lengthen the support frame cause the support frame to radially increase or decrease respectively. The first and second ends may be respectively proximal and distal ends or portions of the support frame.

[00015] In an embodiment, a VOCCA comprises a distal end, and wherein a relative motion of the first and second activating members that shortens the support frame affects the distal end to be at or proximal to a location where it was before the relative motion.

[00016] In an embodiment, the second activating member is an inner tube and the first activating member is an outer tube that is concentric with the inner tube.

[00017] In an embodiment, the support frame has a relaxed state and is formed from material that opposes distortion of the support frame from the relaxed state.

[00018] Optionally, in the relaxed state the support frame has a relatively small length and a relatively large radial extent greater than or about equal to a radius of a blood vessel with which it may be used.

[00019] Further optionally, the support frame can be at a state that is not the relaxed state where it has a relatively large length and a relatively small radial extent that is less than or about equal to an internal radius of a guiding catheter with which the VOCCA is used. The material optionally comprises an elastic material or a shape memory alloy.

[00020] In an embodiment, the inner tube has an inner diameter equal to or greater than about 1.42 mm, and optionally the outer tube has an outer diameter equal to or less than about 1.75 mm.

[00021] Optionally, the inner and outer tubes have a length sufficient to extend from a location inside the body where they are deployed to outside the body via the cardiovascular network.

[00022] Further optionally, the inner tube has a length sufficient to extend to an intermediate point between a location inside the body where the support frame is located and a location outside the body, and the outer tube has a length sufficient to extend away from the support frame at most to the intermediate point.

[00023] In an embodiment, a wall thickness of the outer tube is thinner than a wall thickness of the inner tube, with optionally the wall thickness of the outer tube being between 0.05-0.06 mm and the wall thickness of the inner tube being between 0.08-0.1 mm.

[00024] In an embodiment, the membrane covers a portion but not all of the support frame, and/or extends less than the full length of the support frame from the first end of the support frame, and/or is an integral, unbroken membrane optionally also impermeable to blood.

[00025] In an embodiment, the support frame comprises openings and the membrane seals the openings where it covers the support frame, and at a remaining uncovered portion of the support frame the openings communicate between a radial inner space enclosed by the support frame and the environment outside of the support frame.

[00026] The invention may also be described by means of the following numbered clauses:

[00027] 1. A vascular occlusion and aspiration adapter (VOCCA) comprising a flow tube and a flow blocker located at a distal portion of the flow tube, the flow tube comprising first and second activating members and the flow blocker comprising proximal and distal portions being respectively coupled to the first and second activating members, the flow blocker being adapted to assume an expanded state, a contracted state and an intermediate state from which it can be urged towards either the expanded or contracted states, wherein at least when in the intermediate state, movement of the first activating member in a first direction relative to the second activating member is adapted to urge the flow blocker towards its expanded state and movement of the first activating member in a second direction relative to the second activating member is adapted to urge the flow blocker towards its contracted state.

[00028] 2. A VOCCA as in clause 1 and comprising a distal end, and wherein movement of the first activating member in the first direction relative to the second activating member that urges the flow blocker to expand affects the distal end to be at or proximal to a location where it was before the movement.

[00029] 3. A VOCCA as in clause 2, wherein the first and second activating members are respectively in the form of coaxially extending first and second tubes.

[00030] 4. A VOCCA as in clause 3, wherein the first tube is an outer tube and the second tube is an inner tube that is surrounded by the outer tube, and wherein an inner lumen of the second tube constitutes a through going lumen of the flow tube.

[00031] 5. A VOCCA as in anyone of the preceding clauses, wherein the first direction is in the distal direction and the second direction is in the proximal direction.

[00032] 6. A VOCCA as in clause 4 or 5, wherein a wall thickness of the outer tube is thinner than a wall thickness of the inner tube.

[00033] 7. A VOCCA as in clause 6, wherein the wall thickness of the outer tube is between 0.05-0.06 mm and the wall thickness of the inner tube is between 0.08-0.1 mm.

[00034] 8. A VOCCA as in anyone of clauses 3-7 wherein the second tube extends to the distal end with its lumen opening out of the VOCCA at the distal end.

[00035] 9. A VOCCA as in clause 8 and comprising a proximal end and the first and second tubes extend to the proximal end with the lumen of the second tube opening out of the VOCCA also at the proximal end.

[00036] 10. A VOCCA as in clause 8 and comprising a proximal end and an intermediate point that is located between the distal and proximal ends, and wherein the second tube extend to the intermediate point with its lumen opening out at the intermediate point, and the first tube extends towards the intermediate point and at most up to the intermediate point.

[00037] 11. A VOCCA a as in clause 1, wherein the flow blocker is adapted to apply forces that urge it to self expand back towards its expanded state at least when in the intermediate state.

[00038] 12. A VOCCA as in clause 11, wherein the flow blocker comprises elastic and/or shape memory materials that form at least part of the forces urging it to self expand.

[00039] 13. A VOCCA as in clause 11 or 12, wherein the flow blocker comprises a support frame that extends between its distal and proximal portions and a skin or membrane that is applied to at least a portion of the support frame, and wherein the support frame constitutes at least part of the elastic and/or shape memory materials.

[00040] 14. A VOCCA as in clause 13, wherein the flow blocker comprises a coating that is applied to the support frame and the skin is applied upon the coating.

[00041] 15. A VOCCA as in clause 12, 13 or 14, wherein the skin is applied to a portion of the support frame extending from the distal portion towards the proximal portion of the flow blocker.

[00042] 16. A VOCCA as in clause 15, wherein the first and second activating members are in the form of coaxially extending first and second tubes with the first tube surrounding the second tube, and the flow blocker comprises an annular gap formed between the support frame and the second tube.

[00043] 17. A VOCCA as in clause 16, wherein the support frame comprises openings and the skin seals also the openings at the portion of the support frame where it is applied, and wherein the remaining unsealed openings communicate between the gap and the environment outside of the flow blocker.

[00044] 18. A method of treating a stenosis in a blood vessel that supplies blood to the heart comprising the steps of: providing vascular occlusion and aspiration adapter (VOCCA) comprising a flow tube and a flow blocker located at a distal portion of the flow tube, the flow

blocker comprising proximal and distal portions and being adapted to assume expanded and contracted states, and the flow tube comprising first and second activating members respectively coupled to the proximal and distal portions of the flow blocker for urging the flow blocker between its contracted and expanded states, providing a guiding catheter with its distal end proximal to the ostium of the blood vessel, maintaining a relative position between the first and second activating members that maintains the flow blocker in its contracted state and advancing the VOCCA via the guiding catheter to project a portion of the VOCCA out of the distal end of the guiding catheter and into the blood vessel to a position where the flow blocker is proximal to the stenosis, advancing a stent delivery system (SDS) comprising an expansion balloon through the flow tube of the VOCCA in a distal direction to a position where its expansion balloon is distal to the VOCCA, moving the first activating member relative to the second activating member to urge the flow blocker towards its expanded state to block the blood vessel to antegrade flow of blood prior to deploying the expansion balloon to treat the stenosis, and after completing to treat the stenosis applying suction to incite retrograde flow within the blood vessel in the proximal direction that is evacuated via the flow tube.

[00045] 19. A method as in clause 18, wherein the VOCCA has a distal end, and wherein the movement of the first activating member relative to the second activating member that urges the flow blocker towards its expanded state does not substantiality urge the distal end distally beyond a location where it was before the movement.

[00046] 20. A method as in clause 19, wherein the movement urges the distal end in a proximal direction in relation to the location where it was before the movement.

[00047] 21. A method as in anyone of clauses 18-20, wherein the completion of the treating of the stenosis with the SDS includes completely retreating the SDS back out via the flow tube.

[00048] 22. A method as in anyone of clauses 18-21, wherein the flow blocker comprises a support frame that extends between its distal and proximal portions and a membrane that is applied to the support frame and extends from the distal portion towards the proximal portion and assists in the blocking of the blood vessel when the flow blocker is expanded towards its expanded state to block the blood vessel.

[00049] 23. A method as in clause 22, wherein the support frame comprises openings and the membrane seals also the openings at the portion of the support frame where it is applied.

[00050] 24. A method as in anyone of clauses 18-23, wherein the first and second activating members are in the form of coaxially extending first and second tubes with the first tube surrounding the second tube, and the flow blocker comprises an annular gap formed between

the scaffolding and the second tube, and wherein blood from upstream that entered the gap via the openings is adapted to bear against the skin from within the gap to at least assist in the expansion of the flow blocker that blocks the antegrade flow of blood.

[00051] In the discussion unless otherwise stated, adjectives such as "substantially" and "about" modifying a condition or relationship characteristic of a feature or features of an embodiment of the invention, are understood to mean that the condition or characteristic is defined to within tolerances that are acceptable for operation of the embodiment for an application for which it is intended.

[00052] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter.

BRIEF DESCRIPTION OF FIGURES

[00053] Non-limiting examples of embodiments of the invention are described below with reference to figures attached hereto that are listed following this paragraph. Identical structures, elements or parts that appear in more than one figure are generally labeled with a same numeral in all the figures in which they appear. Dimensions of components and features shown in the figures are chosen for convenience and clarity of presentation and are not necessarily shown to scale.

[00054] Figs. 1A-1C schematically show components of a self expanding VOCCA and illustrate its deployment in a catheter and blood vessel, in accordance with an embodiment of the invention;

[00055] Figs. 2A-2E schematically illustrate operation of the VOCCA shown in Figs. 1A-1C in performance of a stent procedure , in accordance with an embodiment of the invention;

[00056] Figs. 3A and 3B schematically shows a VOCCA having a non-expandable flow tube, in accordance with an embodiment of the invention;

[00057] Fig. 3C schematically shows a VOCCA that is a variation of the VOCCA shown in Figs. 3A and 3B, in accordance with an embodiment of the invention;

[00058] Figs. 4A and 4B schematically show components of another self expanding VOCCA, in accordance with an embodiment of the invention;

[00059] Fig. 4C schematically shows a VOCCA that is a variation of the VOCCA shown in Figs. 4A and 4B, in accordance with an embodiment of the invention;

[00060] Figs. 5A-5C schematically show cross section views illustrating operation of a restraining nose cone in deploying a self expanding VOCCA, in accordance with an embodiment of the invention;

[00061] Figs. 6A, 6B and 7 schematically show a portion of a VOCCA including a flow blocker, in accordance with an embodiment of the invention;

[00062] Figs. 8 and 9 schematically show cross section views of portions of the VOCCA shown in Figs. 6 (either A or B) and 7, respectively, in accordance with an embodiment of the invention;

[00063] Figs. 10 and 11 schematically show regions of the VOCCA shown in Fig. 8 greatly enlarged, in accordance with an embodiment of the invention;

[00064] Figs. 12 and 13 schematically show the flow blocker of Figs. 6 to 11 used in different configurations of VOCCA, in accordance with embodiments of the invention;

[00065] Fig. 14 schematically shows a greatly enlarged portion of the VOCCA shown in Fig. 13, in accordance with an embodiment of the invention;

[00066] Fig. 15 schematically shows one of the VOCCA configurations of Fig. 12 and 13 with an introducer, in accordance with an embodiment of the invention;

[00067] Figs. 16 and 17 schematically shows enlarged cross sections of portions of the VOCCA shown in Fig. 15, in accordance with an embodiment of the invention; and

[00068] Figs. 18A to 18I schematically illustrate operation of a VOCCA in performance of a stent procedure, in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

[00069] In the detailed description below, features of a VOCCA in accordance with an embodiment of the invention are discussed with reference to Figs. 1A-1C. Operation of the VOCCA in a procedure to deploy a stent is schematically illustrated in Figs. 2A-2G and discussed with reference to the figures. A variation of a VOCCA in accordance with an embodiment of the invention is schematically illustrated in Figs. 3A and 3B. Features and operation of another VOCCA in accordance with an embodiment of the invention are schematically illustrated in and discussed with reference to Figs. 4A-4E. Further variations of VOCCA's in accordance with some embodiments of the invention are schematically illustrated in Figs. 6-17, and operation of such VOCCA's in accordance with an embodiment of the invention are schematically illustrated in and discussed with reference to Figs. 18A-18I.

[00070] Fig. 1A schematically shows a perspective view of a self expanding VOCCA 20 comprising a flow tube 30 having at a distal end 31 a flow blocker 40, flow blocker control activating lines 50, and a push tube 60, in accordance with an embodiment of the invention. In the figure the VOCCA is shown in a collapsed state maintained by a restraining sleeve 70 schematically shown in dashed lines. Fig. 1B schematically shows an enlarged view of a portion of VOCCA 20 comprising flow blocker 40.

[00071] Flow tube 30 shown in Fig. 1B comprises a scaffolding 32 having a flow tube portion 33, referred to as a flow tube "rib cage 33", and a portion 34, referred to as an expansion support frame 34 that is included in flow blocker 40. Scaffolding 32 is covered by an elastic skin 35 shown shaded. Optionally, the elastic skin is stretched to fit over scaffolding 32 and is held in place on the scaffolding by tension in the skin. Additionally or alternatively, an adhesive is optionally used to maintain elastic skin 35 in place over scaffolding 32. Optionally, skin 35 is spot welded to regions of scaffolding 32 using ultrasound. Optionally, skin 35 is sprayed to form a film on a scaffolding 32 that was previously coated by a polymer in which the scaffolding was dipped. Any of various materials may be used to produce elastic skin 35, and the skin may for example comprise, silicon, nylon, latex, polyurethane, and/or a polyisoprene.

[00072] Rib cage 33 is pre-stressed and formed so that when restraining sleeve 70 is pulled off flow tube 30 the rib cage expands, stretching elastic skin 35 to seal flow tube 30 to a catheter with which VOCCA 20 is used. Optionally, scaffolding 32 is formed from a shape memory alloy such as nitinol, and comprises a plurality of circular ribs 36 connected by struts 37 and expands towards a remembered diameter when not constrained by restraining sleeve 70. Optionally, circular ribs 36 are formed having indents 38 that function as guide channels for control activating wires 50. Scaffolding 32 may be fabricated from a tube formed from a shape memory alloy by laser cutting the tube in a production process similar to a production process used to produce a self expanding stent.

[00073] Expansion support frame 34 of flow blocker 40 optionally comprises a plurality of prestressed fingers 41 that extend from a collar 42 of rib cage 33. Each control wire 50 is attached to a different finger 41 at a point 44 near a tip 45 of the finger. When restraining sleeve 70 is removed from flow blocker 40, fingers 41 of expansion support frame 34 splay out to stretch skin 35 and press a portion of the skin to a wall of a blood vessel in which the flow blocker is located. Pulling on a control wire 50 after a finger has splayed out, displaces the finger towards its prestressed state and away from contact with the blood vessel wall. Functioning of control wires 50 is discussed below. Whereas in Figs. 1A and 1B VOCCA 20 is

shown having two control wires 50, practice of the invention is not limited to two control wires and a VOCCA in accordance with an embodiment of the invention may have more or less control wires, each optionally attached to a different finger 41.

[00074] Fig. 1C schematically shows VOCCA 20 deployed in a blood vessel 100 having walls 102 with rib cage 33 expanded to seal flow tube 30 to a catheter 120 in the blood vessel and expansion cage fingers 41 splayed out to press a rim region 46 of flow blocker 40 to the blood vessel walls. Optionally, expansion cage fingers 41 are articulated by grooves 47 near tips 45 of the fingers so that when the expansion cage is expanded, the fingers bend inward slightly. The bending aids in preventing trauma to blood vessel 100 and in maintaining skin 35 firmly in place on fingers 41 when the fingers are splayed out. In an embodiment of the invention skin 35 has an apron 135 shown in dashed lines. The apron comprises a distal edge 136 optionally attached to skin 35 near finger tips 45 and a proximal free edge 137. Apron 135 billows out and presses against walls 102 of blood vessel 100 responsive to blood pressure in the blood vessel and aids in sealing flow blocker 40 to the blood vessel when the flow blocker is, as indicated in Fig. 1C, expanded.

[00075] Figs. 2A - 2E illustrate use of VOCCA 20 in a procedure to deploy a stent and treat a stenosis in a blood vessel 100 having walls 102, in accordance with an embodiment of the invention.

[00076] Fig. 2A schematically shows a guide catheter 120 positioned in an aorta of a patient from which blood vessel 100 branches off and VOCCA 20 threaded through the catheter by a medical practitioner (not shown) so that a distal end 22 of the VOCCA is positioned outside of the catheter and in the blood vessel. VOCCA 20 is in a collapsed state and has a restraining sleeve 70 constraining scaffolding 32 (Figs. 1A-1C). The VOCCA has been threaded through the guide catheter and maneuvered into place by pushing a sufficient length of push tube 60 into the blood vessel. Restraining sleeve 70 is long enough and extends through guide catheter 120 towards a proximal end (not shown) of the guide catheter so that a proximal end of the restraining sleeve is outside the patient and available for manipulation by the medical practitioner.

[00077] In Fig. 2B the medical practitioner has pulled restraining sleeve 70 (Fig. 2A) off VOCCA 20 and the VOCCA has self expanded so that a portion of flow tube 30 is sealed to guide catheter 120 and flow blocker 40 has expanded to occlude blood vessel 100.

[00078] In Fig. 2C a stent delivery system (SDS) 200, optionally comprising a stent delivery catheter 201 having a stent 202 overlaying an expansion balloon 203 has been threaded over a

guide wire 204 through guide catheter 120 and VOCCA 20 to position the stent in a stenosis 220 blocking blood vessel 100. To reduce possibility of ischemia downstream of VOCCA 20, the medical practitioner has decided it is prudent to reduce occlusion of blood vessel 100 by flow blocker 40 and allow a modicum of blood flow, optionally between about 60 cc/min (cubic centimeters per minute) and about 70 cc/min, in the blood vessel before proceeding to expand stent 202 and open the stenosis. To reduce occlusion, in accordance with an embodiment of the invention, the practitioner pulls on control wires 50.

[00079] As schematically shown in Fig. 2D, pulling on a control wire 50 bends a finger 41 to which it is attached away from wall 102 of blood vessel 100. The fingers drawn away from blood vessel wall 102 displace a portion of rim region 46 of flow blocker 40 from the wall and open a space 146 between the rim and the blood vessel wall. Opened space 146 enables antegrade blood flow past the flow blocker.

[00080] After allowing antegrade blood flow in blood vessel 100 for a short period of time, the medical practitioner released control wires 50 so that fingers 41 attached to the control wires splay back out to contact blood vessel wall 102 and occlude the blood vessel. The practitioner expands stent 202 to open stenosis 220 and aspirates blood downstream of VOCCA 20 through the VOCCA and guide catheter 120 to remove debris introduced into the blood stream during deployment of the stent. Fig. 2E schematically shows stent 202 after it has been expanded and block arrows 230 indicate aspiration of blood through the VOCCA and guide catheter, in accordance with an embodiment of the invention.

[00081] Following deployment of stent 202 and aspiration of blood, components of stent deployment system 200 (Fig. 2C), VOCCA 20, and optionally guide wire 204 (Fig. 2C) are removed from blood vessel 100. Fig. 2F schematically shows blood vessel 100 after the medical practitioner has removed all the stent deployment components and it remains to remove VOCCA 20. To remove the VOCCA a restraining sleeve 170 is pushed over push tube 60 through guide catheter 120 toward the VOCCA to collapse and constrain the expanded VOCCA so that it may be safely removed from the blood vessel.

[00082] Restraining sleeve 170 is advanced towards VOCCA 20 by locking the proximal end of push tube 60 outside the patient's body so that the VOCCA cannot move along blood vessel 100 and threading the restraining sheath over the push tube towards the VOCCA. Near proximal end 24 of flow tube 30 a draw wire 61 connects the push tube to a region along the circumference of the flow tube substantially opposite a location of the push tube along the circumference of the flow tube. As restraining sleeve 170 is pushed towards flow tube 30 it

encounters draw wire 61 and as the sleeve continues to advance to envelope the flow tube, the draw wire is drawn into the restraining sleeve and collapses proximal end 24 of the flow tube so that the proximal end enters the sleeve. Once the proximal end enters the sleeve, continued advancement of the sleeve engulfs the flow tube and eventually flow blocker 40 until VOCCA 20 is completely collapsed and enveloped in the restraining sleeve. The VOCCA is then pulled into guide catheter 120 by simultaneously pulling restraining sleeve 170 and push tube 60 back into the guide catheter. Fig. 2G schematically shows VOCCA 20 enveloped by restraining sleeve 170 after they have been pulled into guide catheter 120. VOCCA 20 constrained by restraining sleeve 170 may then be removed via guide catheter 120 out of the patient.

[00083] By way of a numerical example, in an embodiment of the invention, VOCCA 20 is configured for use with a catheter having and inner diameter equal to about 1.80 mm. VOCCA flow tube 30 has a length of about 20 cm and in a collapsed state an outer diameter, including elastic skin 35, equal to about 1.5 mm. When expanded, rib cage 33 has an outer diameter equal to about 1.78 mm, a wall thickness including skin 35 of about 180 μm and therefore an inner diameter equal to about 1.42 mm. When flow blocker 40 is positioned outside of a restraining sleeve its rim region 46 may expand to occlude a blood vessel having an inner diameter as large as 5.5 mm. Restraining sleeve may be made from a polymer optionally reinforced with suitable fibers and has an outer diameter equal to about 1.75 mm and a wall thickness equal to about 125 μm.

[00084] Figs. 3A and 3B schematically show a VOCCA 250, in accordance with another embodiment of the invention. In Fig. 3A VOCCA 250 is schematically shown having its flow blocker in a collapsed state. Fig. 3B shows the VOCCA having its flow blocker in an expanded state.

[00085] Referring to Fig. 3A, VOCCA 250 comprises a flexible flow tube 260 comprising a wall 270 having substantially fixed inner and outer diameters and having four through holes 271, 272, 273 and 274 indicated by dashed lines, formed in, and extending the length of the wall. Flow tube 260 is optionally formed in an extrusion process from a suitable polymer, such as a polyether block amide such as Pebax®. VOCCA 250 has a flow blocker 280 comprising prestressed flow blocker activation wires, 281 and 282 optionally formed from a shape memory alloy and an expandable flow blocker sleeve 284 formed from a suitable elastic polymer, such as polyurethane.

[00086] Flow blocker activation wire 281 is threaded through hole 271 in a direction from a proximal end 261 of flow tube 260 to a distal end 262 of the flow tube and back from the distal

end to the proximal end through hole 272. Similarly, flow blocker activation wire 282 is threaded from proximal end 261 to distal end 262 and back to the proximal end through holes 283 and 284. Flow blocker sleeve 284 is fixed to flow tube 260 at its distal end 262. Optionally, expandable flow blocker sleeve 284 is attached to flow tube 260 by bonding the sleeve to the flow tube using a suitable adhesive or by ultrasonic welding the sleeve to the flow tube.

[00087] Flow blocker sleeve 284 is expanded to deploy flow blocker 280 by pushing activation wires 281 and 282 distally relative to flow tube 260 so that they emerge distally out of the flow tube and assume a remembered original forged shape in the form of a support frame upon which blocker sleeve 284 can be disposed. Fig. 2B schematically shows activation wires 281 and 282 pushed out of flow tube 260 to assume a remembered forge support frame shape that expands flow blocker sleeve 284 to a shape suitable for occluding a blood vessel.

[00088] VOCCA 250 may be threaded through a guide catheter and positioned in a blood vessel using a push tube similar to push tube 60 shown in Figs. 1A and 2A. Flow tube 260 is formed having an outer diameter matched to a catheter with which it is to be used so that it can be comfortably threaded through the catheter yet seal to the catheter to prevent blood flow between its outer surface and an inner surface of the catheter. Flow blocker 280 may be collapsed after having functioned to occlude a blood vessel by pulling activation wires in a proximal direction to retract and thereby return the wires into flow tube 260. Occlusion can be controllably relaxed after flow blocker 280 is deployed in a blood vessel to allow a modicum of antegrade blood flow by pulling at least one of activation wires 281 and 282 proximally a suitable distance.

[00089] By way of a numerical example, a VOCCA similar to VOCCA 250 for use with a catheter having an inner diameter equal to about 1.80 mm may comprise a flow tube having a length about equal to 20 cm, and inner and outer diameters equal to about 1.42 mm and 1.76 mm respectively. Activation wires 281 and 282 may have diameters equal to about 360 μm and flow blocker sleeve 284 may have a wall thickness between about 200 μm and about 400 μm.

[00090] A VOCCA in accordance with an embodiment of the invention comprising activation wires that are pushed out of a wall of a flow tube to deploy a flow blocker is not limited to two activation wires. By way of example, Fig. 3C schematically shows a VOCCA 290 having a flow blocker 292 expanded by six activation wires 294 that are pushed out of a flow tube 296 to form a support frame, in accordance with an embodiment of the invention.

[00091] Fig. 4A schematically shows another VOCCA 300 comprising an optionally self expanding scaffolding 310 covered by an elastic skin 340 schematically represented by dotted lines, in accordance with an embodiment of the invention. VOCCA 300 is threaded through a

catheter constrained by a restraining sleeve which is then removed to deploy the VOCCA. Fig. 4A schematically shows VOCCA 300 deployed through a guide catheter 120 positioned in an aorta of a patient and inside a blood vessel 100 that branches off from the aorta. In the figure VOCCA 300 is shown after removal of the restraining sleeve.

[00092] Scaffolding 310 comprises an optionally self expanding rib cage 312 and a flow blocker 320 comprising a plurality of prestressed fingers 321 that form a support frame that splays out to stretch skin 340 and occlude blood vessel 100 upon removal, as shown in Fig. 4A, of the restraining sleeve. Rib cage 312 is connected to an activating push tube 313 which is used to push VOCCA 300 through guide catheter 120 to position the VOCCA at desired locations in the catheter and blood vessel.

[00093] Each finger 321 is cut from its own finger frame 322 and is connected by a finger control wire 323 that passes through a clearance hole 324 at a distal end of the finger frame and extends along rib cage 312 to a control collar 330, to which collar the finger control wire is connected.

[00094] Elastic skin 340 is formed so that it loops over ends of finger frames 322 towards control collar 330. Control collar 330 surrounds push tube 313 and is free to move along the push tube. A collar control activating wire 332 is connected to control collar 330 and extends through catheter 120 to a proximal location outside a patient being treated using VOCCA 300. After deployment of VOCCA 300 an amount of antegrade blood flow in blood vessel 100 may be controlled by pulling on collar control wire 332 so that control collar 330 moves along push tube 313.

[00095] By way of example, Fig. 4B schematically shows VOCCA 300 for which control collar 330 has been displaced in a proximal direction relative to push tube 313 by pulling on collar control wire 332. As a result of the proximal displacement of the control collar 330, finger control wires 323 are pulled proximally and draw support frame fingers 321 and elastic skin 340 away from wall 102 of blood vessel 100 and allow antegrade blood flow, schematically indicted by arrows 350 in blood vessel 100.

[00096] Fig. 4C shows a VOCCA 400, in accordance with an embodiment of the invention, which is a variation of VOCCA 300 shown in Figs. 4A and 4B. VOCCA 400 optionally comprises a scaffolding 410 having prestressed support frame fingers 421 each having a guide loop 422 at its tip. The scaffolding is coupled to a push tube 411. A finger control activating wire 430 extends along scaffolding 410 from a proximal end 412 of the scaffolding towards a distal end 414 of the scaffolding and passes through a clearance hole 424 in a finger frame 426.

From clearance hole 424 finger control wire 430 then passes through loops 422 of all fingers 421. After passing through finger loops 422 control wire 430 optionally passes through clearance hole 424 a second time and extends along the scaffolding back towards proximal end 412 so that, optionally, two ends 432 of control wire 430 are located outside of the body of a patient being treated using VOCCA 400. Simultaneously pulling on portions of control wire 430 near both ends 432 shortens a length of the control wire that passes through loops 422 and draws support frame fingers 421 inwards away from a wall of a blood vessel in which VOCCA 400 is deployed to provide antegrade blood flow in the blood vessel.

[00097] It is noted that whereas in Fig. 4C and the above discussion it is assumed that two ends 432 are located outside the patient's body, practice of the invention is not limited to having two ends of control wire 430 outside the body. In an embodiment of the invention, a first end of control wire 430 may be anchored to scaffolding 410 either before or after control wire 430 passes through clearance hole 424 a second time. A second end of the wire may be located outside the body and pulling on a region of the control wire near the second end shortens a length of the control wire that passes through loops 422 and draws fingers 421 inwards. In addition whereas control wires 30 are shown outside of push tube 411 they may be located in the push tube.

[00098] In some embodiments of the invention a self expanding VOCCA in accordance with an embodiment of the invention is maintained in a collapsed state and threaded through a guide catheter using a restraining nose cone.

[00099] Figs. 5A-5C schematically show cross section views illustrating operation of a restraining nose cone (RNC) 500 used to deploy a self expanding VOCCA 600, in accordance with an embodiment of the invention. In the figures VOCCA 600 is shown in dashed lines and RNC 500 is shown in solid lines.

[000100] VOCCA 600 comprises a self expanding flow tube 602 having a push tube 604 attached at a proximal end 605 of the flow tube and a flow blocker 606 at a distal end 607 of the flow tube, in accordance with an embodiment of the invention. The flow blocker comprises an expansion support frame including pre-stressed fingers 621 covered by a suitable elastic skin (not shown). For convenience of presentation only two fingers 621 of flow blocker 606 are shown in figures 5A-5C. RNC 500 comprises a deployment tube 502 comprising a restraining cowling 510 and a nose cone 520 having restraining flaps 521 at a distal end of the tube. Deployment tube 502 is long enough so that the tube can be threaded over a guide wire (not

shown) in a guide catheter (not shown) deployed in a blood vessel (not shownl) in a patient's body with a proximal end 503 of the deployment tube outside the patient's body.

[000101] To use RNC 500 to thread VOCCA 600 through the catheter, the VOCCA is mounted to the RNC, as shown in Fig. 5A, with fingers 621 tucked under and restrained by restraining flaps 521 and restraining cowling 510 surrounding and restraining flow tube 602. The VOCCA and RNC 500 are then, together without displacement of the nose cone relative to the VOCCA, pushed through the catheter until the VOCCA is in position in the patient's blood vessel. Pushing RNC 500 and VOCCA 600 together through the catheter may be accomplished by pushing only on the VOCCA push tube 604, which keeps fingers 621 snuggly tucked under restraining flaps 521 during pushing the VOCCA and RNC through the catheter. Alternatively, pushing may be accomplished by locking VOCCA push tube 604 to deployment tube 502 of the RNC and pushing on VOCCA push tube 604 and/or deployment tube 502 to thread the VOCCA and RNC through the catheter.

[000102] Once in position in the blood vessel, flow blocker fingers 521 are released to splay out and occlude the blood vessel by pushing RNC 500 forward, that is distally, relative to VOCCA 600. Pushing the RNC forward relative to the VOCCA may be accomplished by pushing deployment tube 502 forward relative to VOCCA push tube 604. Fig. 5B schematically shows RNC 500 pushed forward relative to VOCCA 600 and flow blocker fingers 621 released and splayed out. Upon release of fingers 621, restraining flaps 521 optionally, as shown in Fig. 5B, fold onto nose cone 520.

[000103] In the state schematically shown in Fig. 5B flow tube 602 is still restrained by cowling 510. The flow tube is released to expand and seal to the catheter by retracting the RNC from the VOCCA and, optionally, removing the RNC from the catheter. Retracting the RNC is accomplished by pulling on deployment tube 502 so that it displaces proximally relative to push tube 604 of the VOCCA. Fig. 5C schematically shows the RNC being retracted from the VOCCA.

[000104] In the sections below, features of a flow blocker in accordance with some embodiments of the invention and various VOCCA configurations in accordance with further embodiments of the invention that may include such a flow blocker are discussed with reference to Figs. 6-14. Operation of a VOCCA shown in Figs. 6-14 in a procedure to deploy a stent is schematically illustrated in Figs. 15A-15I and discussed with reference to the figures.

[000105] Figs. 6A, 6B and 7 schematically show a side view of a distal segment of a VOCCA 699 in accordance with various embodiments of the invention that includes a flow tube 705 and a

flow blocker 700. In Figs. 6A and 6B flow blocker 700 is in an expanded state and in Fig. 7 flow blocker 700 is in a collapsed state. Fig. 8 schematically shows a cross section of flow blocker 700 shown in Fig. 6A or 6B and Fig. 9 schematically shows a cross section of the flow blocker shown in Fig. 7.

[000106] Flow blocker 700 has a support frame 710 and a skin 720 optionally elastic that is disposed upon the support frame. Skin 720 may be made of materials such as: silicon, nylon, polyurethane (etc.); and may be coated by materials such as Teflon and/or by hydrophilic/hydrophobic materials at its inner and/or outer sides. Flow blocker 700 has in addition distal and proximal portions 730, 740 where it is attached via support frame 710 respectively to inner and outer coaxial tubes 750, 760 of the flow tube of VOCCA 699. A space (not shown) is optionally provided between the tubes to facilitate relative slidable movement between them, and tubes 750 and 760 are used to operate support frame as described below, and advantageously are formed from a material or materials that provide a rigidity compatible with their function. Tubes 750, 760 may for example be a polymer tube, a braided tube optionally reinforced with metal wires, a polyamide tube, a polyimide tube. In addition tubes 750, 760 may be coated on their inner and/or outer surfaces by materials such as Teflon and/or by hydrophilic/hydrophobic materials that e.g. reduce friction. Distal and proximal radiopaque markers (not shown) may be provided respectively adjacent distal and proximal portions 730, 740 to facilitate positioning and manipulation of VOCCA 699 during a procedure for which it is used. For example, VOCCA 699 may be used in interventional cardiology procedures that are typically carried out under fluoroscopy or another x-ray or imaging techniques.

[000107] Referring to Fig. 8, inner tube 750 has a lumen 770 that opens out of inner tube 750 at a distal end 755 of inner tube 750 that constitutes a distal end of VOCCA 699. Outer tube 760 surrounds inner tube 750 and is slidable along the inner tube.

[000108] In the expanded state of flow blocker 700, support frame 710 has an enlarged shape that is expanded in a radial, outward direction away from inner tube 750, and an annular gap 715 that is formed between support frame 710 and inner tube 750 is maximal in the enlarged state of support frame 710.

[000109] Support frame 710 is optionally manufactured in its enlarged state and is made of elastic and/or shape memory materials that may urge support frame 710 back towards its enlarged state if distorted away from this state. Materials from which support frame 710 can be made may include by way of example: Nitinol, Stainless steel, polyester, nylon. Skin 720 that may be

applied onto support frame 710 in its enlarged state, further stiffens support frame 710 in its enlarged state and increases forces that may urge it back towards this state if distorted.

[000110] Any of various methods may be used to form skin 720 and attach the skin to support frame 710. In an embodiment of the invention support frame 710 may initially be coated during manufacture of flow blocker 700 with a polymer coating 780 that aids in binding the skin 720 to the support frame. Optionally, coating 780 is formed by dipping support frame 710 into a polymer that bonds to a material from which skin 720 is formed. After forming coating 780 skin 720 may be sprayed onto support frame 710. Other ways of applying skin 720 to support frame 710 are also considered such as suturing skin 720 to support frame 710.

[000111] Fig. 11 shows a section of support frame 710 with a coating 780 to which skin 720 is attached by spraying a suitable material, such as Polyurethane, onto the coated support frame. The coating may assist to better bond the skin to the support frame and in addition may serve as an additional means for stiffening support frame 710 in its enlarged state and thereby increasing the forces that may act to urge support frame 710 back towards its enlarged state if distorted. Support frame 710 preferably includes openings that are formed therein so that at portions where it is not covered by skin 720, communication between gap 715 and the environment outside of flow blocker 700 can be provided. Optionally, support frame 710 may be in the form of a braid and the openings may thus be provided by spaces formed between the strands of the braid.

[000112] In VOCCA 699, inner and outer tubes 750 and 760 of flow tube 705 function as activating members of the VOCCA. Urging a relative movement between the inner and outer tubes that distances distal end 755 of inner tube 750 from outer tube 760 distorts flow blocker 700 away from its expanded state towards its contracted state and thus support frame 710 away from its enlarged state. Similarly, urging movement between the inner and outer tubes that brings distal end 755 of inner tube 750 closer to outer tube 760 urges or allows flow blocker 700 to move back towards its expanded state and thus support frame 710 back towards its enlarged state. Flow blocker 700 (as will be described in more detail below) is in its contracted state shown in Fig. 7 when first inserted via a guide catheter (not shown in this figure) into a blood vessel to be treated. Once in the blood vessel, distal end 755 is typically maneuvered by a physician using VOCCA 699 to an operative location proximal to a stenosis to be treated. When this operative location has been assumed, distal movement of portions of VOCCA 699 passed the operative location may preferably be avoided or limited while flow blocker 700 is manipulated towards its expanded state in order to avoid any unintentional collision between

VOCCA 699 and the stenosis that might dislodge debris from the stenosis. This operative location is marked by dashed line 757 that passes to the left of Figs. 6A, 6B and 7. From the contracted state shown in Fig. 7, urging or allowing outer tube 760 to slide in a distal direction while keeping inner tube 750 fixed in place will allow flow blocker 700 to be urged away from its contracted state and towards its expanded state as seen in Fig. 6B. Alternatively, in some embodiments flow blocker 700 may be urged towards its expanded state also by urging inner tube 750 to slide in a proximal direction while keeping outer tube 760 fixed in place as seen in Fig. 6A. In both cases, it is seen that during the expansion of flow blocker 700 (which is characterized by axial shortening of the flow blocker) distal movement of portions of the VOCCA passed the operative location 757 may be avoided or limited. In the option shown in Fig. 6B, distal end 755 is kept substantially at the operative location, and at the option shown in Fig. 6A distal end 755 is moved in a proximal direction away from the operative location. It is also noted that the expansion of flow blocker 700 (shown in Figs. 6A, 6B) may be assisted by the elastic and/or shape memory properties of flow blocker 700. In the example shown in Fig. 6B, this may allow outer tube 760 to simply slide in the distal direction without applying any forces that urge it in this direction in order to allow the expansion. However if frictional forces between e.g. the inner and outer tubes are relatively large it may be required to also urge the outer tube to slide in the distal direction relative to the inner tube to facilitate this expansion.

[000113] In Figs. 8 and 9, walls 102 of a blood vessel are also indicated, and as illustrated VOCCA 699, in its expanded state or when urged towards its expanded state (Fig. 8), may be used to block antegrade blood flow within such a blood vessel while unblocking the blood flow in its collapsed state (Fig. 9). Preferably, skin 720 extends upon support frame 710 from distal portion 730 of flow blocker 700 in a proximal direction while leaving an area of support frame 710 towards its proximal portion 740 uncovered. Via this uncovered area, blood may enter gap 715 via the openings of the support frame and bear against skin 720 from within the gap to urge it against the walls 102 of the blood vessel and assist in the expansion of flow blocker 700. This may assist in the sealing of the blood vessel to antegrade blood flow when flow blocker 700 is in its expanded state.

[000114] In an embodiment, flow blocker 700 is designed to be "over sized" to have an expanded state with a diameter that is larger than the diameter of the blood vessel that it is designed to block. For example, flow blocker 700 may be designed to have an outer diameter of about 4.5 mm at its expanded state for blocking blood vessels having a diameter between 2 to 4mm. As a result, when flow blocker 700 is urged towards its expanded state it may engage and bear

against wall 102 before it is fully expanded and thereby apply a radial force per unit area, that is pressure, on the vessel wall. The pressure exerted by flow blocker 700 on the vessel wall is may be designed to be less than about 1 atmosphere which has been found to be atraumatic to the vessel wall. Optionally, the pressure that flow blocker 700 applies to a blood vessel wall and also the rate of expansion of flow blocker 700 can be controlled by controlling rate of motion of outer tube relative to inner tube. Furthermore, a physician controlling the expansion of flow blocker 700 may gradually expand flow blocker 700 while injecting small amounts of contrast media into the blood vessel in which flow blocker 700 is deployed. By monitoring the contrast media while expanding flow blocker 700 and identifying the moment when it is not washed downstream and remains static within the vessel, the physician can identify that flow blocker 700 has been expanded to a sufficient size and then avoid further expansion that may otherwise traumatize the blood vessel. In a similar manner, a physician controlling the expansion of flow blocker 700 may also monitor signals of blood pressure measured at the distal end of the VOCCA. Once flow blocker 700 is expanded to a sufficient size to block the flow of blood through the blood vessel, blood pressure fluctuations will not be transmitted from the aorta downstream into the coronary being treated, and the disappearance of the pressure waveform can therefore be used to identify the moment at which the flow blocker 700 is sufficiently expanded thereby avoiding further expansion that may otherwise traumatize the blood vessel.

[000115] VOCCA 699 is preferably sized to fit within a guiding catheter for its insertion into a blood vessel, while maintaining a path for a SDS to be inserted therethough for treating the blood vessel at a location distally downstream of the VOCCA. As already noted above, when being inserted into the blood vessel via the guiding catheter, flow blocker 700 is maintained in its collapsed state in which support frame 710 and skin 720 tightly surround the inner tube. Thus the outer profile of a VOCCA including flow blocker 700 in its collapsed state is determined by the outer diameter (OD) of outer tube 760 which should be sized to fit within the lumen of the guiding catheter. The path for a SDS through at least the flow tube of the VOCCA is provided on the other hand via inner lumen 770 and therefore the inner diameter (ID) of inner tube 750 which defines inner lumen 770 should be sized to allow a passage of a SDS. The inner and outer diameters ID, OD of respectively the inner and outer tubes 750, 760 are indicated in Fig. 10.

[000116] Guiding catheters for performing intravascular procedures typically range in size from larger diameter catheters such as 8F catheters to smaller diameter catheters such as 6F catheters. Therefore the diameters of such guiding catheters should be taken into account when adapting a

VOCCA including flow blocker 700 for such procedures, and in particular when adapting such a VOCCA for use with smaller diameter catheters such as 6F catheters. In order to minimize the OD on the one hand and maximize the ID on the other hand, while still maintaining a VOCCA structure that can support functionality during intravascular procedures, an embodiment of a VOCCA including flow blocker 700 may be configured to have at its outer tube 760 a wall thickness W1 that is thinner than a wall thickness W2 at its inner tube 750.

[000117] The relatively large wall thickness W2 of the inner tube provides a supporting structure against collapse of the VOCCA during use. During use in a therapeutic procedure within a blood vessel, the thinner walled outer tube 760 in this embodiment is kept slidably supported at its inner side by inner tube 750 during manipulation of the flow blocker between its expanded and collapsed states, and is provided with additional structural support at its outer side by the guiding catheter at portions of the VOCCA that are within the guiding catheter.

[000118] In embodiments for which flow blocker 700 is optionally configured to be made of elastic and/or shape memory materials that urge it back towards its expanded state, outer tube 760 may be used for transmitting tensional forces by pulling it proximally to urge flow blocker 700 towards its collapsed state. For urging flow blocker 700 back towards its expanded state smaller (or no) forces may be required due to the self expansion of flow blocker 700. This may aid in limiting thickness of outer tube 760 in these embodiments.

[000119] More detailed embodiments of VOCCA 699 will now be described with reference to Figs. 12-14. In an embodiment of a VOCCA 790 including flow blocker 700 shown in Fig. 12, the inner and outer tubes 750 and 760 of flow tube 705 of the VOCCA extend in a proximal direction from flow blocker 700 to a proximal end 800 of the VOCCA. During use in an intravascular therapeutic procedure, VOCCA 790 is threaded along a guide wire 204 that extends through lumen 770 (Figs. 8, 9) of inner tube 750 between the distal and proximal ends 755, 800 of the VOCCA.

[000120] In another embodiment of a VOCCA 840 including flow blocker 700 shown in Fig. 13, the inner and outer tubes of flow tube 705 of the VOCCA extend in a proximal direction from flow blocker 700 to an intermediate point 830 of the VOCCA. From intermediate point 830 (which is preferably closer to the distal end of VOCCA 840 than to the proximal end of VOCCA 840), a thinner hollow push tube 850 in the form of a hypotube that is attached to inner tube 750 (Fig. 14) extends in the proximal direction to the proximal end of the VOCCA. During use in an intravascular therapeutic procedure, VOCCA 840 is threaded along a guide wire 204 that extends through its lumen 770 between distal end 755 and intermediate point 830

of the VOCCA. An activating wire 860 extending through push tube 850 is attached at distal end of the wire at a join 867 to outer tube 760. From join 867 the activating wire extends proximally through push tube 850 and then out of push tube 850 at the proximal end of VOCCA 840 so that activating wire 860 is made available for manipulation by a physician handling VOCCA 840 at its proximal end. Activating wire 860, when pulled in the proximal direction urges outer tube 760 to move in the proximal direction relative to inner tube 750 to lengthen support frame 710 and contract the support frame and thereby flow blocker 700 radially inwards. Flow blocker 700 in this embodiment is preferably made of the elastic and/or shape memory materials. As a result, releasing activating wire 860 to move back in the distal direction from this position allows flow blocker 700 to self shorten and radially self expand outwards towards its expanded state. In the expanded state flow blocker 840 blocks retrograde blood flow in a blood vessel in which VOCCA.

[000121] In some embodiments of VOCCA 840, outer tube 760 may extend along shorter distances than up to the intermediate point. In fact, the axial extension of outer tube 760 may be shortened to an extent that the outer tube forms a shape of a ring (not shown). Such a ring shaped outer tube 760 preferably has an axial extension that is at least equal to twice its outer diameter (OD) in order to avoid getting wedged while sliding along inner tube 750. Such shortening of the outer tube in some embodiments may also be accompanied by a formation of a path (optionally along the inner tube) through which activating wire 860 may extend between the location where it exits push tube 850 and the location where it connects to the outer tube at the join.

[000122] Attention is now drawn to Figs. 15 to 17 showing an embodiment of an introducer (or obturator) that may be used for guiding a VOCCA, such as VOCCA 790, 840 during insertion into a blood vessel to be treated. In Figs. 15 to 17 the VOCCA shown is VOCCA 790 however it is evident that same is applicable to VOCCA 840 or any other VOCCA including flow blocker 700. An introducer 845 for inserting VOCCA 790 into a blood vessel to be treated includes a distal nose cone 855 and a shaft 865 that extends in a proximal direction from nose cone 855 to a proximal end 875 of the shaft. A pushing rod 885 of the introducer extends proximally from proximal end 875 of shaft 865.

[000123] For insertion of VOCCA 790 into a blood vessel to be treated, introducer 845 is first placed over a guide wire (not shown) that passes through shaft 865. Introducer 845 is then inserted into flow tube 705 to position nose cone 855 protruding out at the distal end of VOCCA 790. Shaft 865 in this position extends along a distal portion of flow tube 705 and

pushing rod 885 extends the remainder of flow tube 705 to protrude out of VOCCA 790 at its proximal end 800. These two coaxial members (VOCCA 790 and introducer 845) may then be advanced through a guide catheter (not shown) towards a blood vessel to be treated. Introducer 845 provides an inner support member for proper translation over the guide wire and once VOCCA 790 is in place introducer 845 may be removed by pulling it proximally out of the patient.

[000124] Figs. 18A – 18I illustrate use of a VOCCA 699 such as VOCCA 790 or 840 in a procedure to deploy a stent and treat a stenosis in a blood vessel 100 having walls 102, in accordance with an embodiment of the invention.

[000125] Fig. 18A schematically shows a guide catheter 120 positioned in an aorta of a patient from which blood vessel 100 branches off and VOCCA 699 threaded through the catheter by a medical practitioner (not shown) so that a distal end 755 of the VOCCA is positioned outside of the catheter and in the blood vessel at the operative location (discussed above with respect to Figs. 6A, 6B and 7). Flow blocker 700 of VOCCA 699 is in a collapsed state and VOCCA 699 has been threaded through the guide catheter and maneuvered into place by pushing either a sufficient length of tubes 750, 760 in VOCCA 790 into the blood vessel or a sufficient length of push tube 850 (Fig. 14) in VOCCA 840 into the blood vessel.

[000126] In Fig. 18B a stent delivery system (SDS) 200 comprising a stent delivery catheter 201 having a stent 202 optionally overlaying an expansion balloon 203 has been threaded over a guide wire 204 through guide catheter 120 and VOCCA 699 to position the stent in a stenosis 220 blocking blood vessel 100.

[000127] In Fig. 18C before expanding stent 202 to open stenosis 220, the medical practitioner expands flow blocker 700 by either directly allowing (or urging), e.g., outer tube 760 to move distally relative to inner tube 750 in VOCCA 790 or by releasing activating wire 860 so that outer tube 760 of VOCCA 840 is allowed to move distally relative to inner tube 750 to facilitate the expansion of flow blocker 700.

[000128] In Fig. 18D the practitioner expands stent 202 to open stenosis 220 and then deflates the balloon of SDS 200 (Fig. 18E) and removes SDS back through VOCCA 699 and out of the patient (Fig. 18F). In Fig. 18G the practitioner then aspirates blood downstream of VOCCA 699 through the VOCCA and guide catheter 120 to remove debris introduced into the blood stream during deployment of the stent. It is noted that in VOCCA 790 the aspirated blood flows through inner lumen 770 of flow tube 705 all the way to the proximal end 800 of the VOCCA, while in VOCCA 840 the aspirated blood flows through inner lumen 770 of flow tube 705 up to

intermediate point 830 (Fig. 13) and from there along the guiding catheter 120 to outside of the patient. Block arrows 230 in Fig. 18G indicate aspiration of blood, in accordance with an embodiment of the invention.

[000129] Following aspiration of blood, the flow blocker of VOCCA 699 is contracted (Fig. 18H) and then VOCCA 699 may be removed from blood vessel 100 (Fig. 18I).

[000130] By way of a numerical example, in an embodiment of the invention, VOCCA 699 may be configured as aforementioned for use with a 6F guide catheter having an inner diameter equal to about 1.80 mm. In VOCCA 840 the inner and outer tubes of flow tube 705 have an axial length of about 20 cm and in a collapsed state the axial extension of flow blocker 700 may be about 2 centimeters and its outer diameter including skin 720 may be equal to between 1.75 mm - 1.73 mm, and preferably 1.73 mm. In this example, at proximal portion 740 where flow blocker 700 is bonded to outer tube 760 a larger diameter of e.g. up to 1.78 mm may exist, however this is only along a short segment of ~2 mm that will not affect the possibility of such a sized VOCCA 699 fitting within a 6F guide catheter. In order to fit through a 6F guide catheter the OD of outer tube 760 has a diameter equal to between 1.75 mm - 1.73 mm and preferably 1.73 mm, and a reduced wall thickness W1 in the range of 0.05-0.06 mm and preferably 0.05mm. Inner tube 750 has a wall thickness W2 in the range of 0.08-0.1 mm and preferably 0.08mm. In the case of: OD=1.75mm, W1=0.05mm, W2=0.08mm, and a space of 0.035mm (between the inner and outer tubes to facilitate relative movement or play between them); the inner diameter ID of inner tube 750 will be 1.42mm (i.e. 1.75 -0.05x2 - 0.08x2 - 0.035x2) which is sufficient for providing passage for SDS catheters. Flow blocker 700 in its expanded state may expand to occlude a blood vessel having an inner diameter of up to 7mm or even more.

[000131] In the description and claims of the present application, each of the verbs, "comprise" "include" and "have", and conjugates thereof, are used to indicate that the object or objects of the verb are not necessarily a complete listing of components, elements or parts of the subject or subjects of the verb.

[000132] Descriptions of embodiments of the invention in the present application are provided by way of example and are not intended to limit the scope of the invention. The described embodiments comprise different features, not all of which are required in all embodiments of the invention. Some embodiments utilize only some of the features or possible combinations of the features. Variations of embodiments of the invention that are described, and embodiments of the invention comprising different combinations of features noted in the described

embodiments, will occur to persons of the art. The scope of the invention is limited only by the claims.

CLAIMS

1. A vascular occlusion and aspiration adapter (VOCCA) comprising:

a support frame having first and second ends;

a membrane covering at least a portion of the support frame;

a first activating member coupled to the first end of the support frame; and

a second activating member moveable relative to the first activating member, and coupled to the second end of the support frame

wherein, relative motion of the first and second activating members that shorten or lengthen the support frame cause the support frame to radially increase or decrease respectively.

2. A VOCCA in accordance with claim 1 and comprising a distal end, and wherein a relative motion of the first and second activating members that shortens the support frame affects the distal end to be at or proximal to a location where it was before the relative motion.

3. A VOCCA in accordance with claims 1 or 2 wherein the second activating member is an inner tube and the first activating member is an outer tube that is concentric with the inner tube.

4. A VOCCA in accordance with anyone of the preceding claims wherein the support frame has a relaxed state and is formed from material that opposes distortion of the support frame from the relaxed state.

5. A VOCCA in accordance with claim 4 wherein in the relaxed state the support frame has a relatively small length and a relatively large radial extent greater than or about equal to a radius of a blood vessel with which it may be used.

6. A VOCCA in accordance with claims 4 or 5 wherein the support frame can be at a state that is not the relaxed state where it has a relatively large length and a relatively small radial extent that is less than or about equal to an internal radius of a guiding catheter with which the VOCCA is used

7. A VOCCA in accordance with any of claims 4-6 wherein the material comprises an elastic material.

8. A VOCCA in accordance with any of claims 4-6 wherein the material comprises a shape memory alloy.

9. A VOCCA in accordance with any one of claims 3-8 wherein the inner tube has an inner diameter equal to or greater than about 1.42 mm

10. A VOCCA in accordance with any one of claims 3-9 wherein the outer tube has an outer diameter equal to or less than about 1.75 mm.

11. A VOCCA in accordance with any one of claims 3-10 wherein the inner and outer tubes have a length sufficient to extend from a location inside the body where they are deployed to outside the body via the cardiovascular network.

12. A VOCCA in accordance with any one of claims 3-10 wherein the inner tube has a length sufficient to extend to an intermediate point between a location inside the body where the support frame is located and a location outside the body, and the outer tube has a length sufficient to extend away from the support frame at most to the intermediate point.

13. A VOCCA in accordance with any one of claims 3-12 wherein a wall thickness of the outer tube is thinner than a wall thickness of the inner tube.

14. A VOCCA in accordance with claim 13, wherein the wall thickness of the outer tube is between 0.05-0.06 mm and the wall thickness of the inner tube is between 0.08-0.1 mm.

15. A VOCCA in accordance with any of the preceding claims wherein the membrane covers a portion but not all of the support frame.

16. A VOCCA in accordance with claims 1 or 15 wherein the membrane extends less than the full length of the support frame from the first end of the support frame.

17. A VOCCA in accordance with any one of claims 1 or 15 to 16 wherein the membrane is an integral, unbroken membrane

18. A VOCCA in accordance with anyone of claims 1, 15, 16 or 17 wherein the support frame comprises openings and the membrane seals the openings where it covers the support frame, and at a remaining uncovered portion of the support frame the openings communicate between a radial inner space enclosed by the support frame and the environment outside of the support frame.

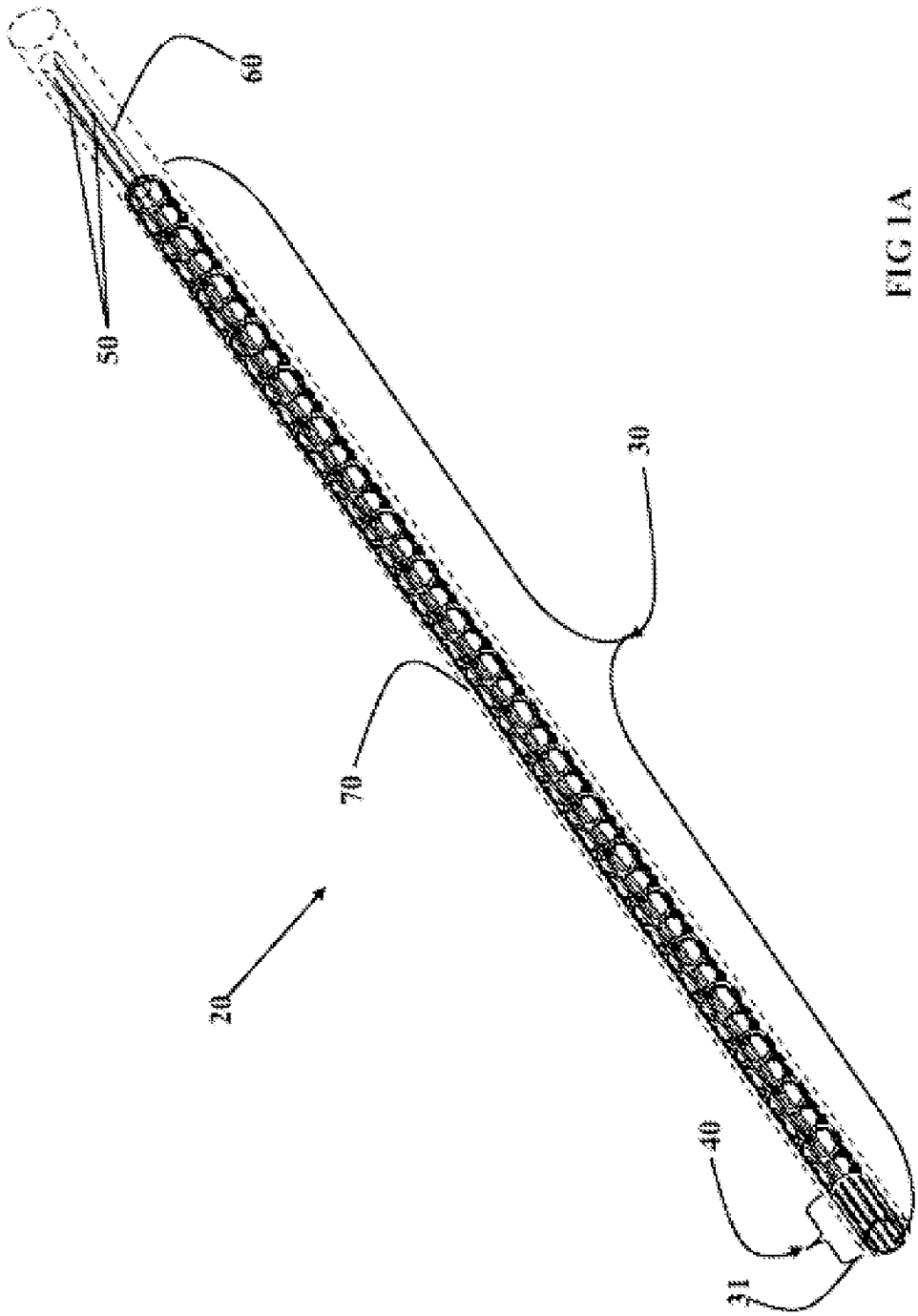


FIG 1A

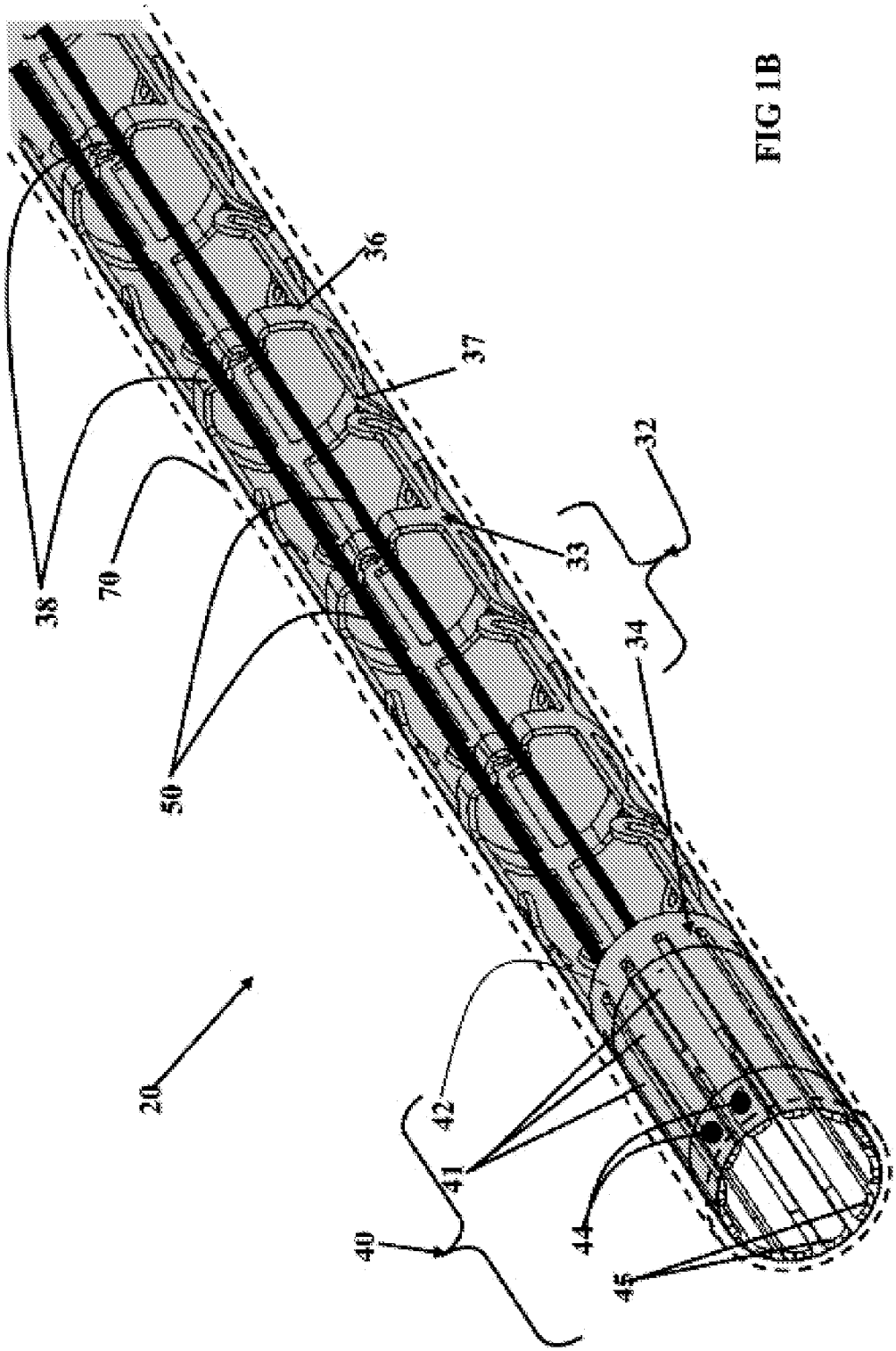


FIG 1B

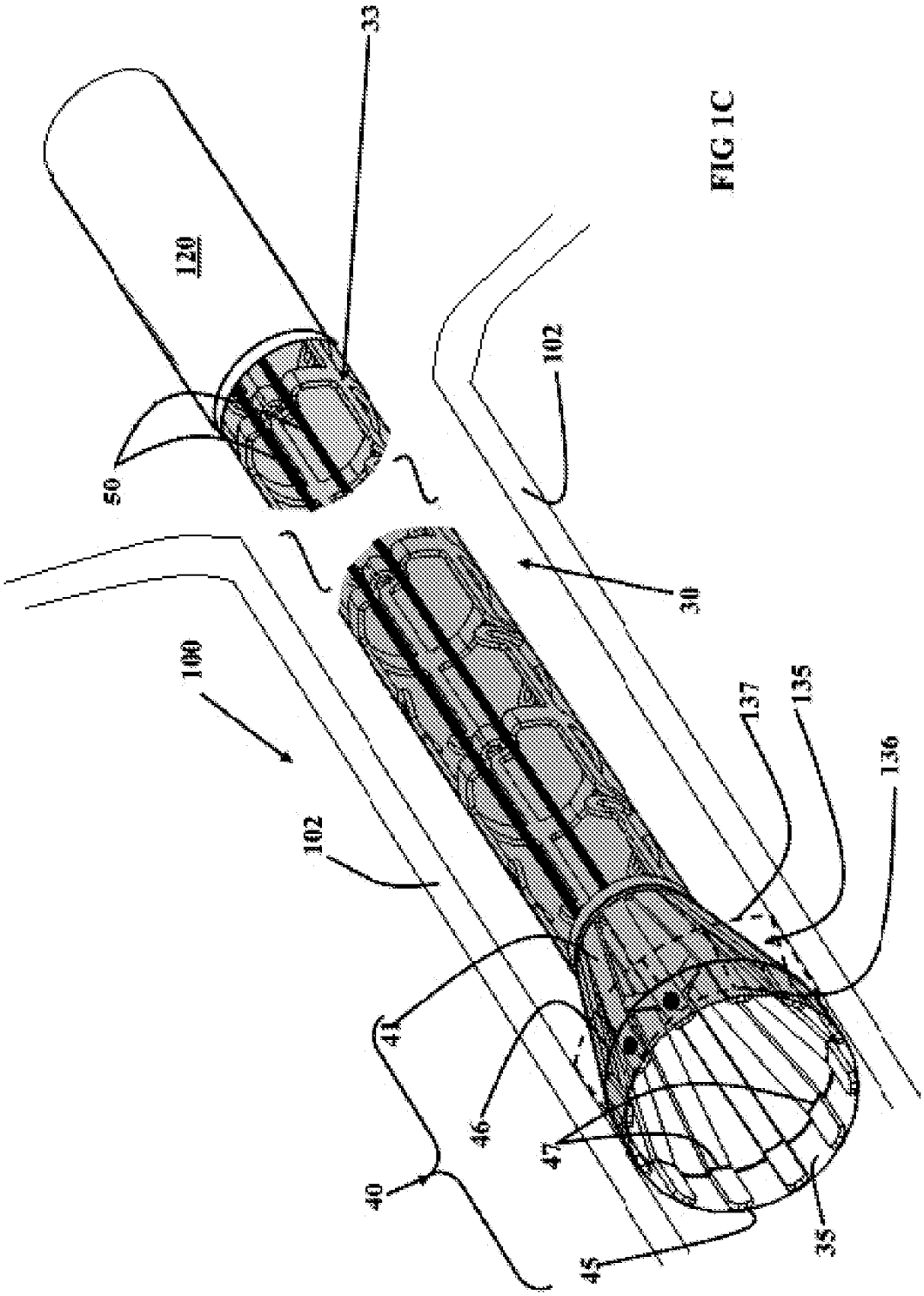


FIG 1C

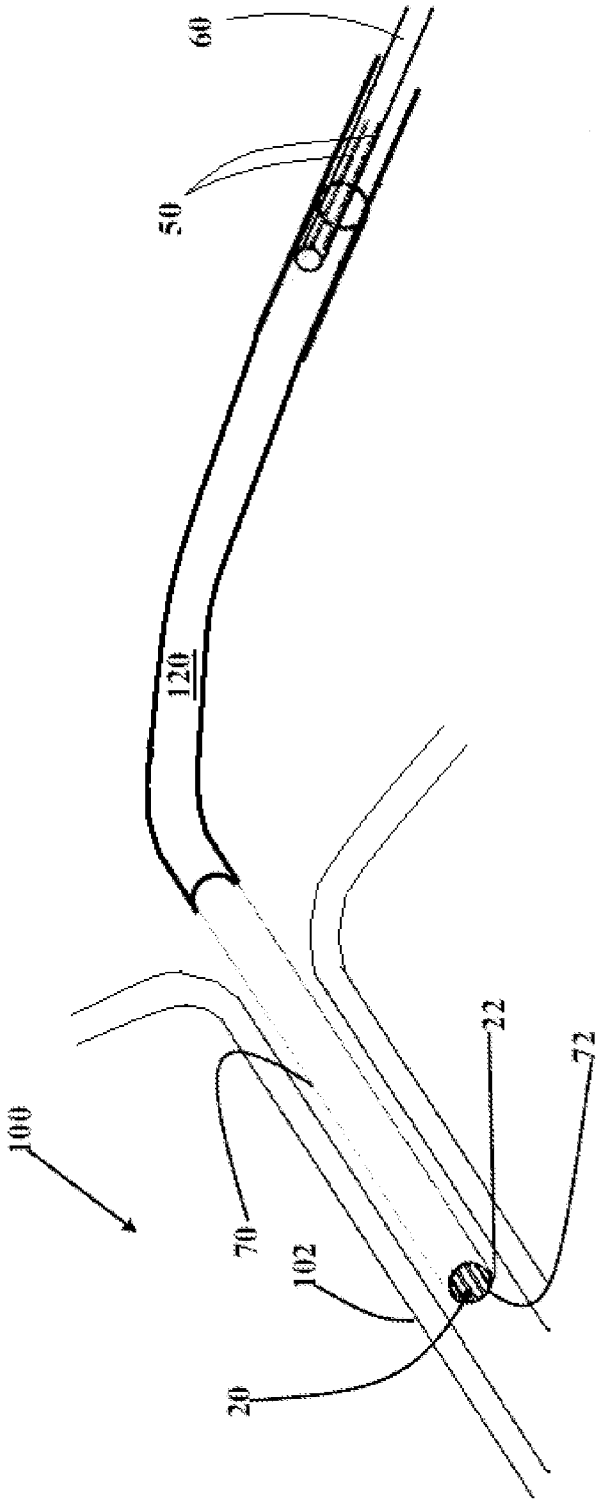


FIG 2A

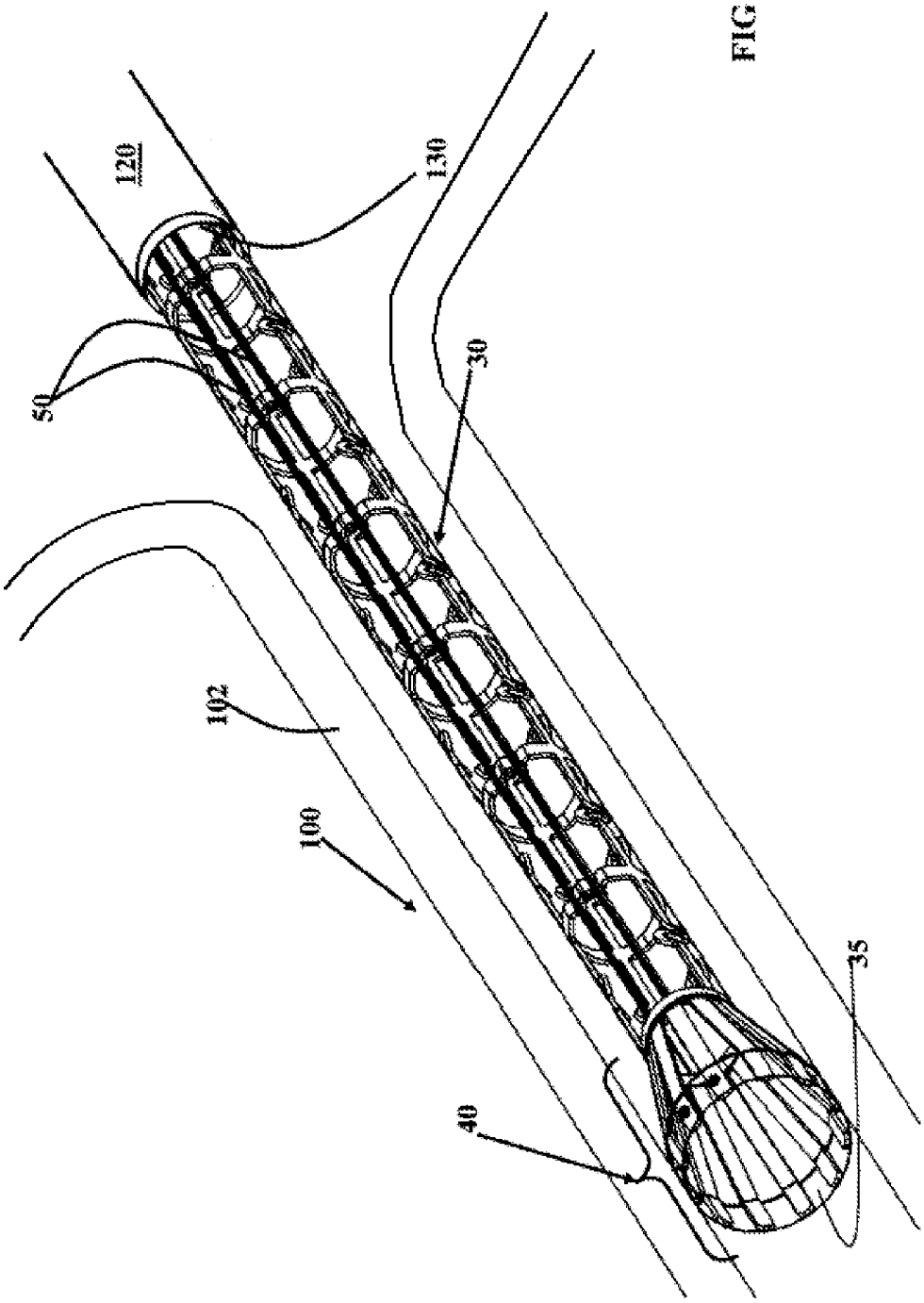


FIG 2B

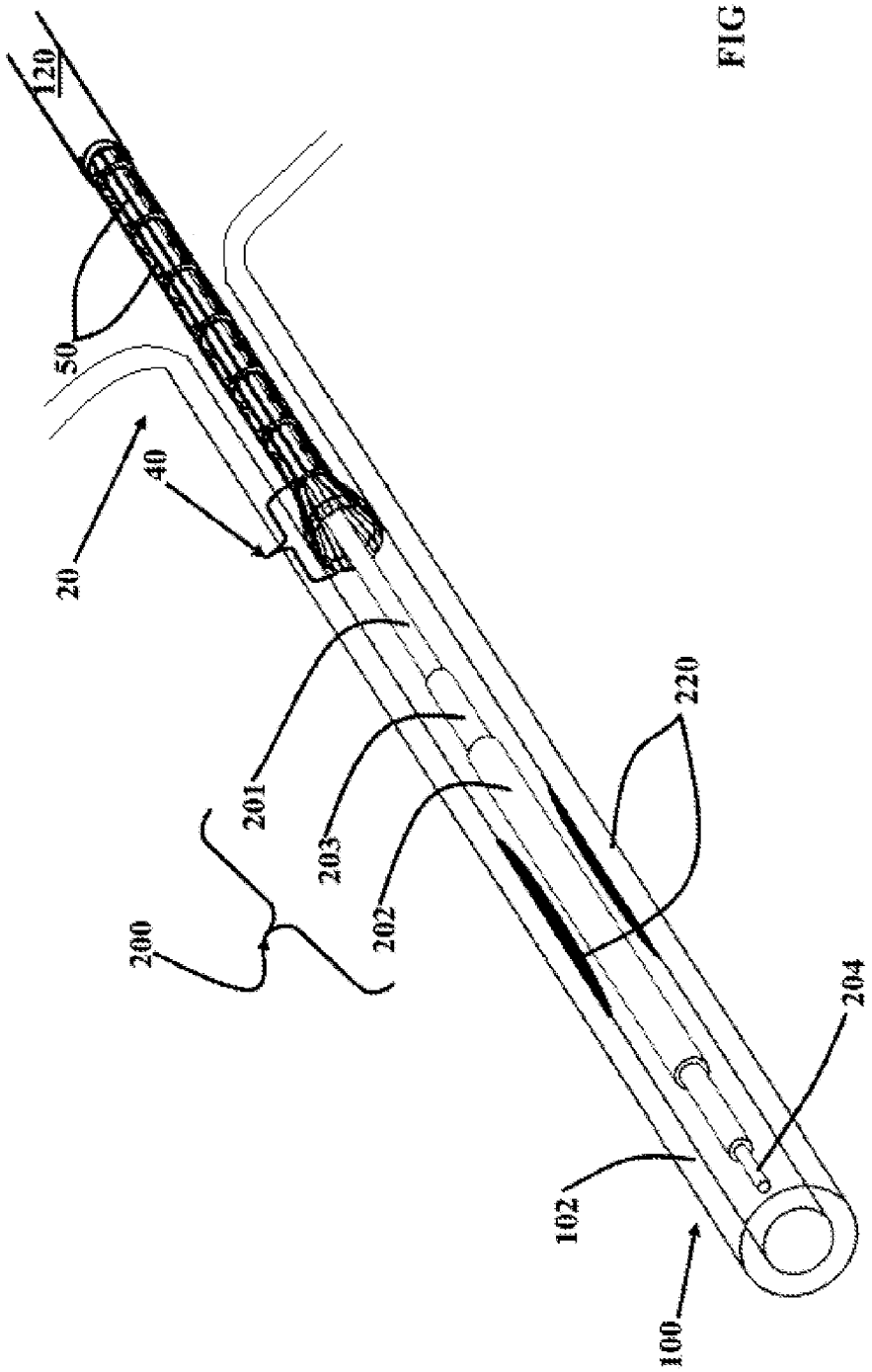


FIG 2C

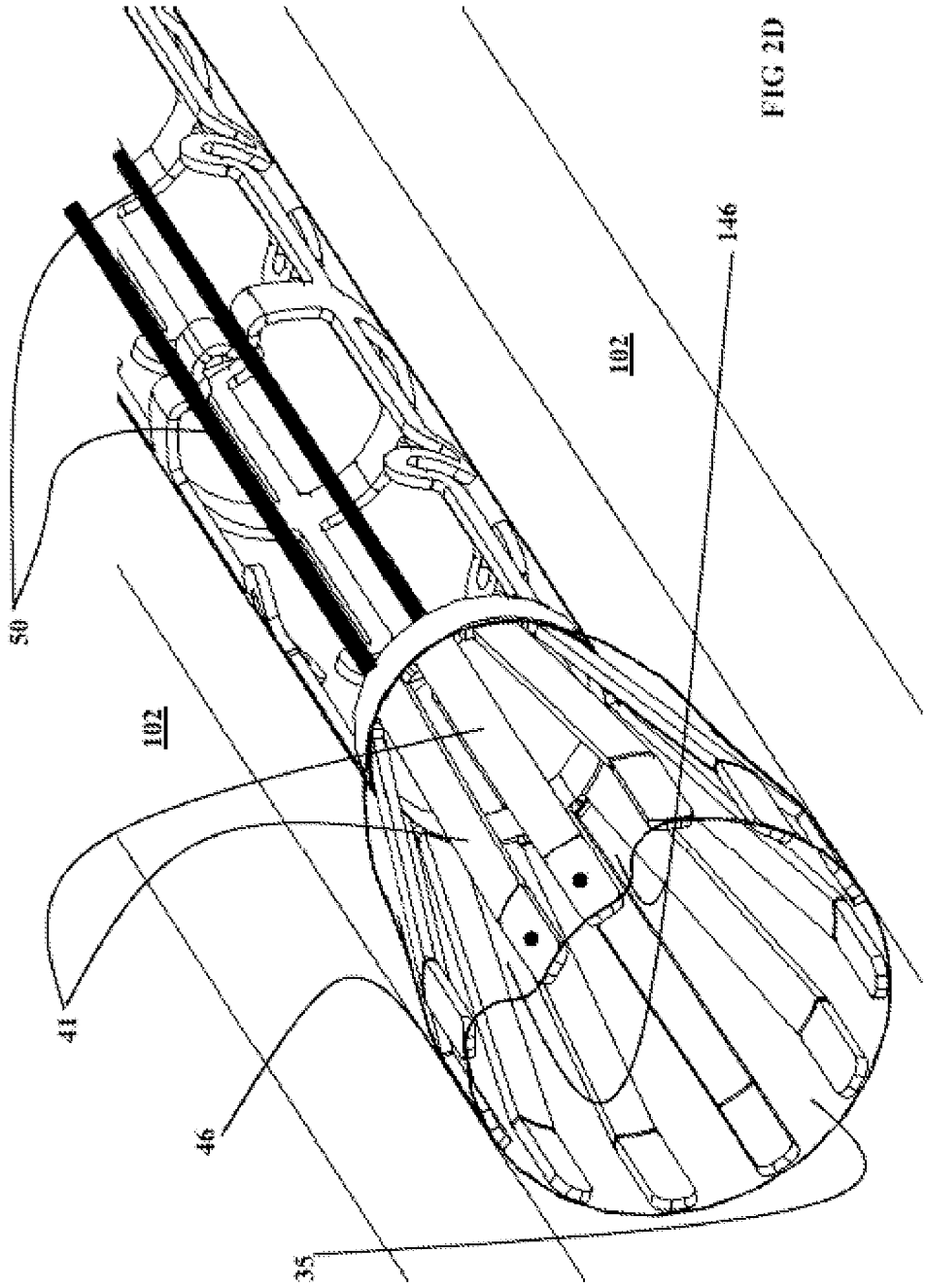
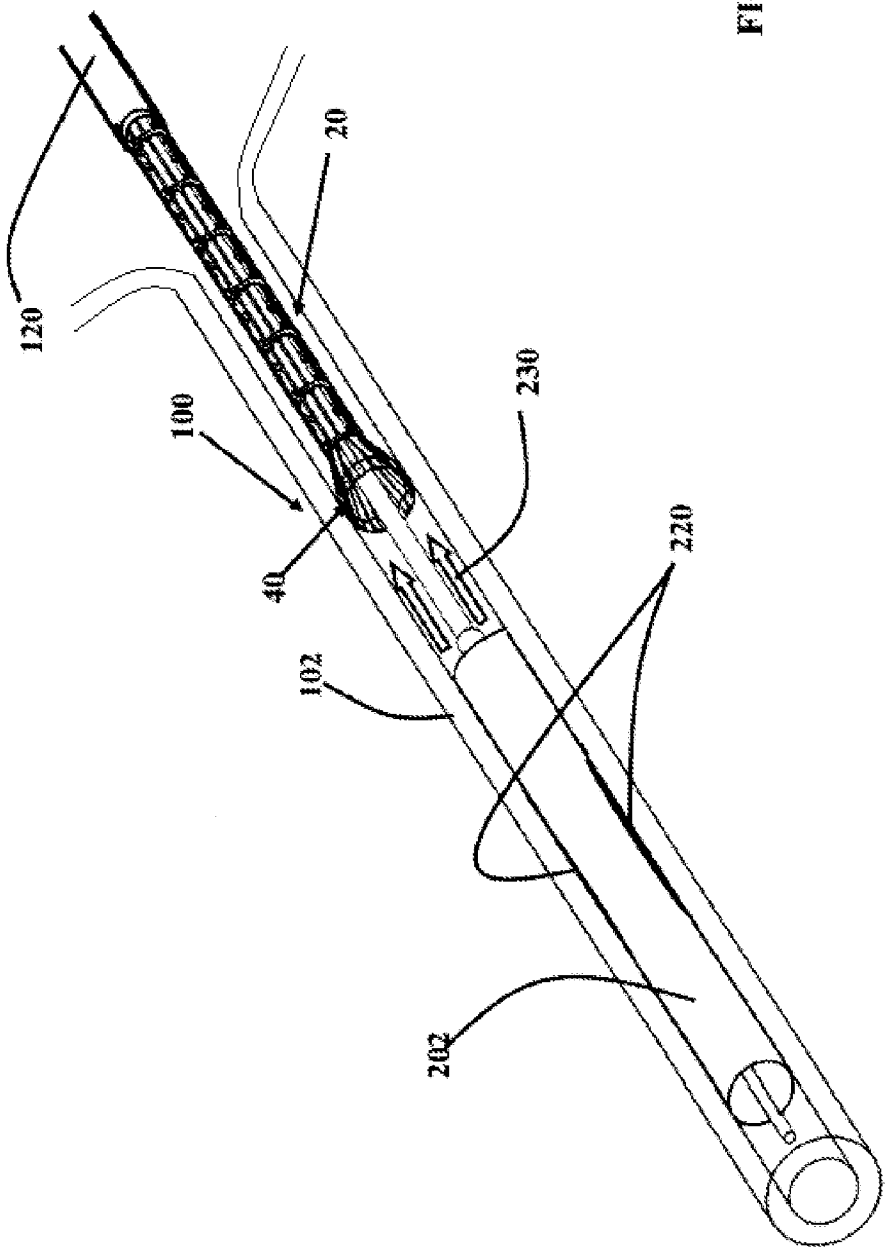


FIG 2D

FIG 2E



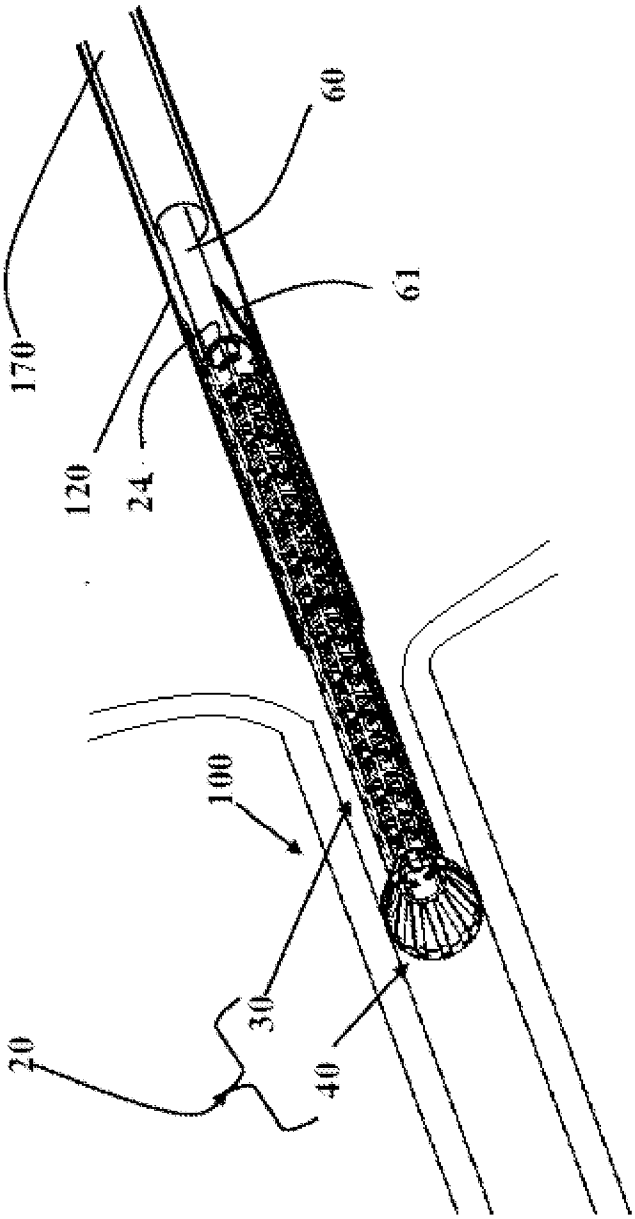


FIG 2F

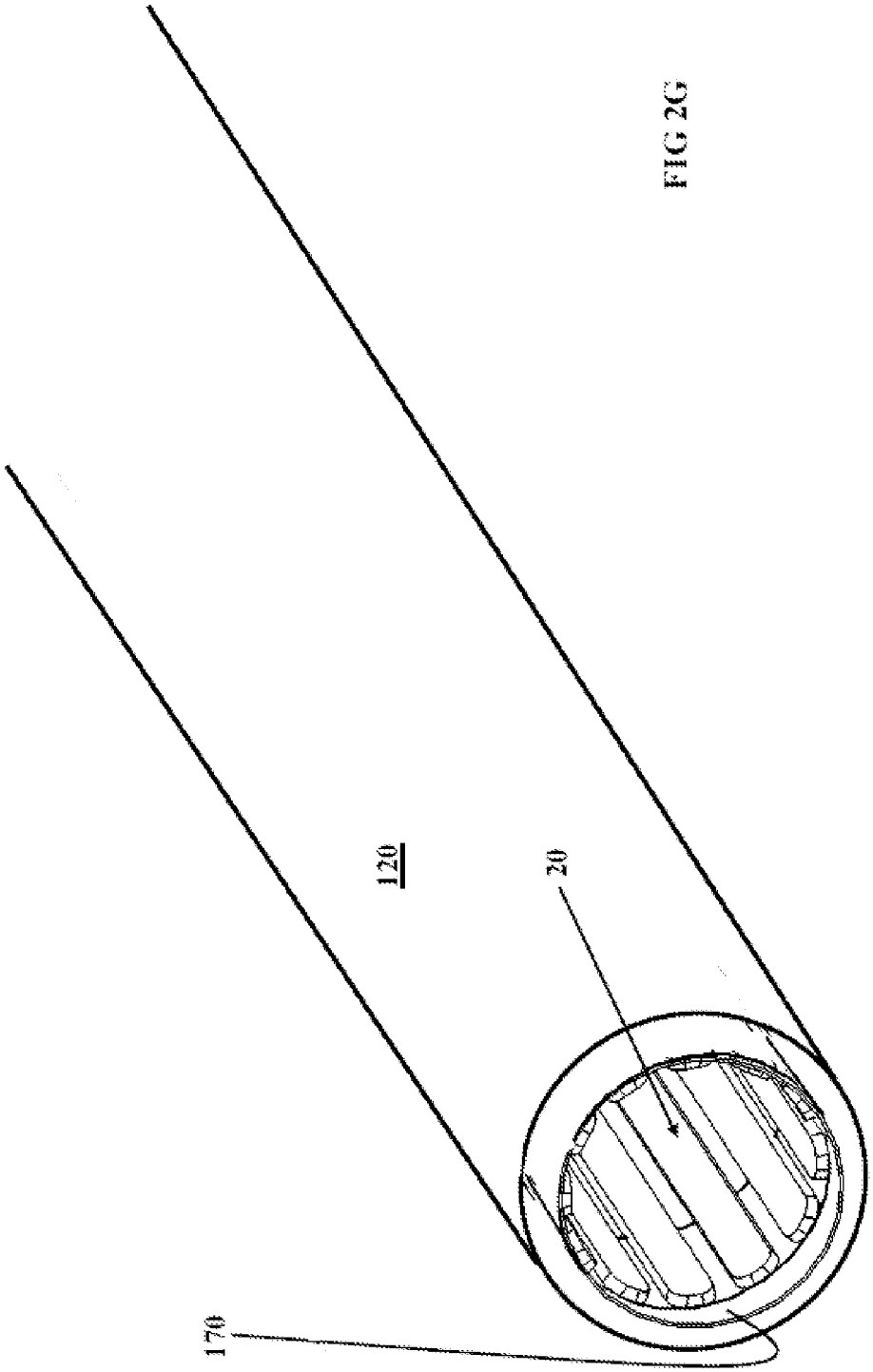


FIG 2G

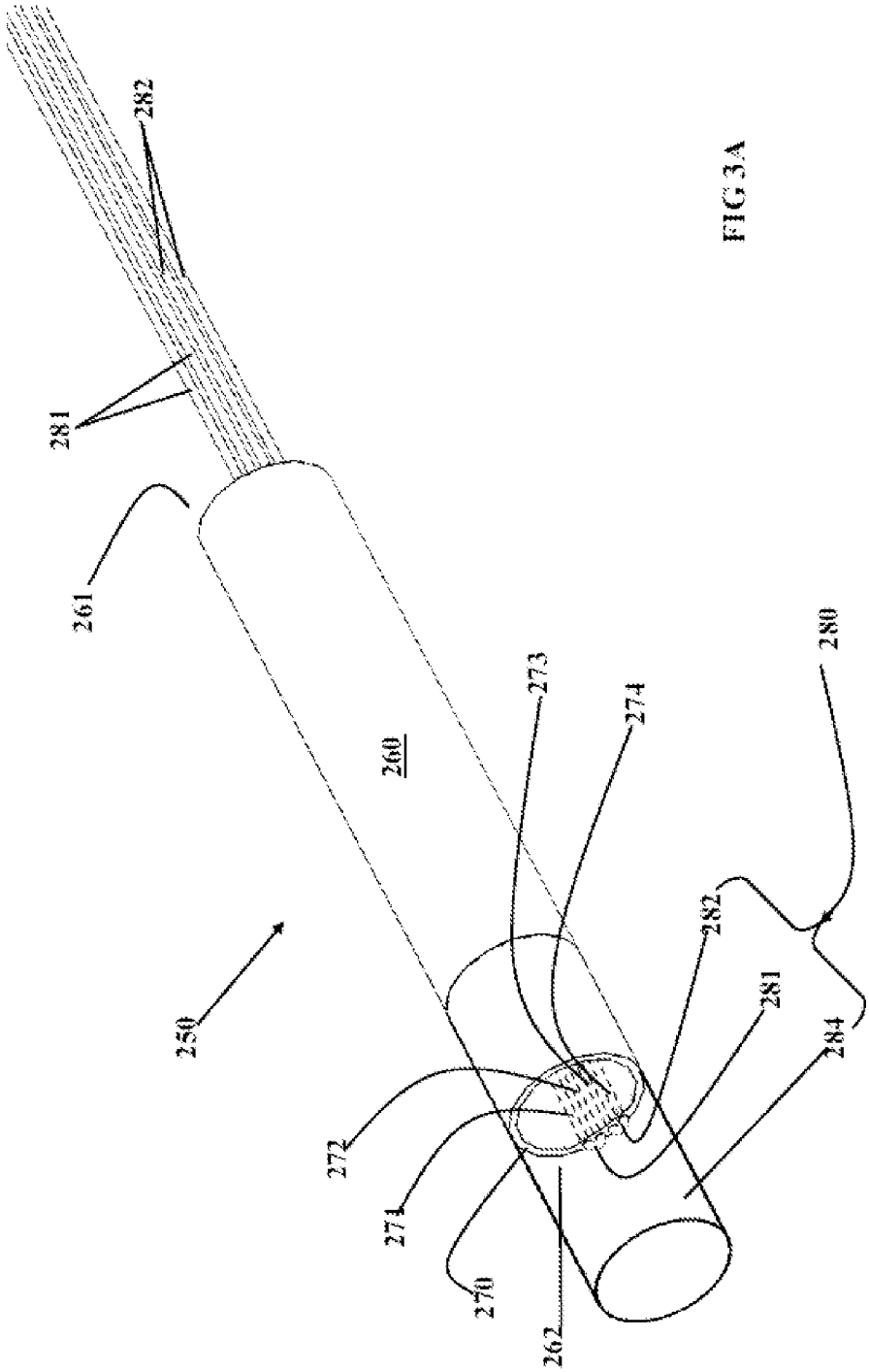


FIG 3A

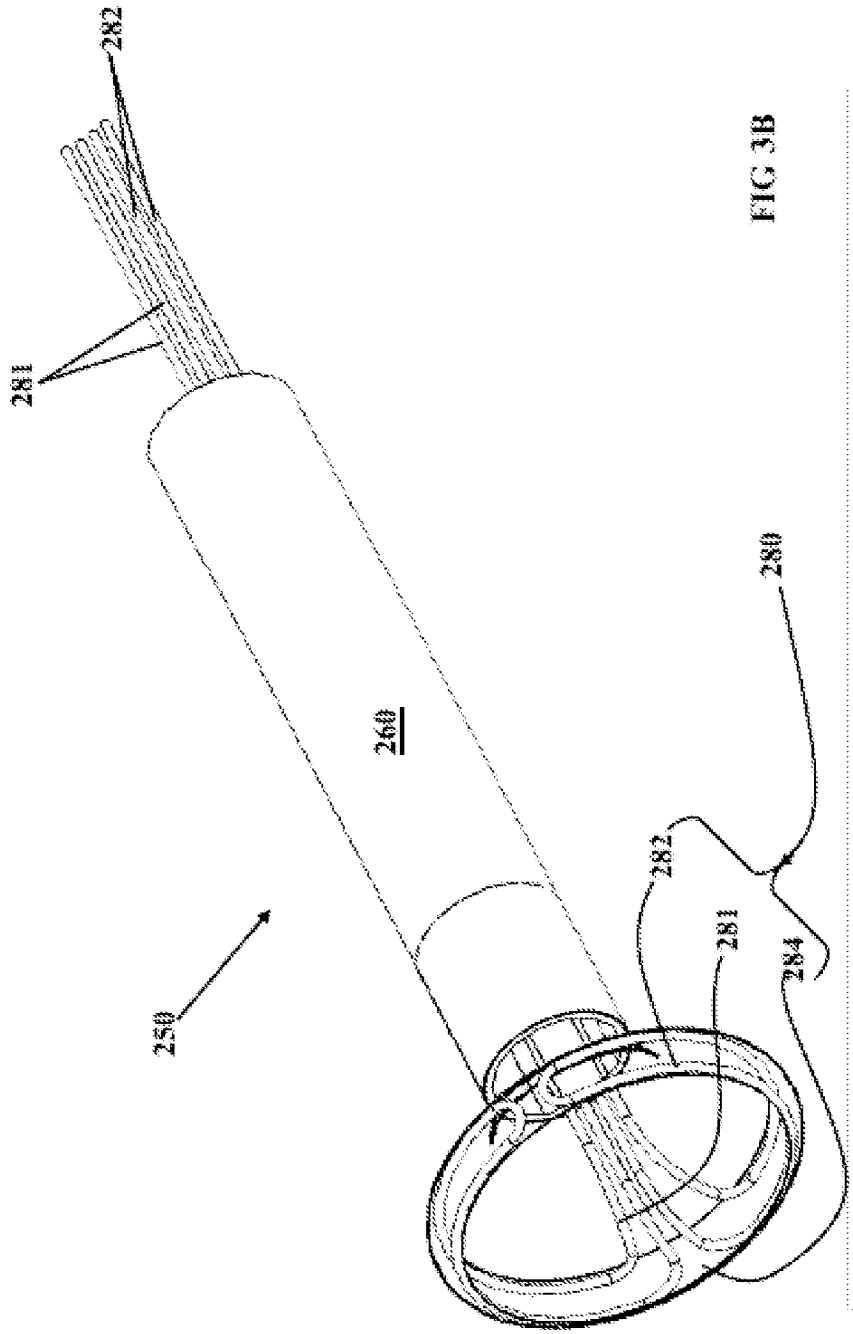


FIG 3B

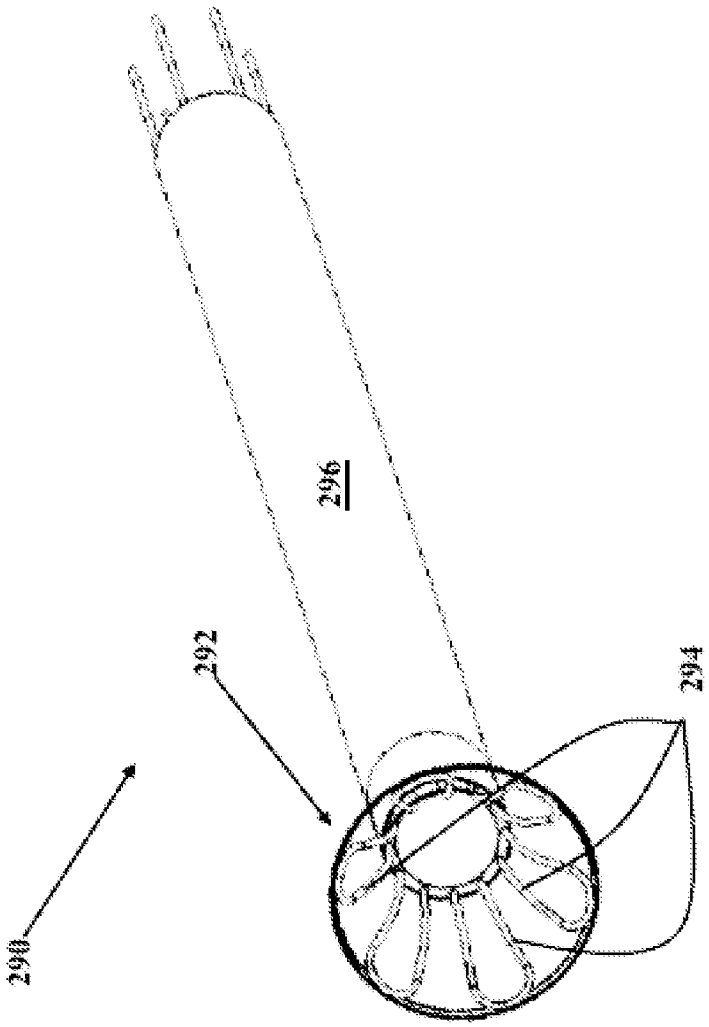


FIG 3C

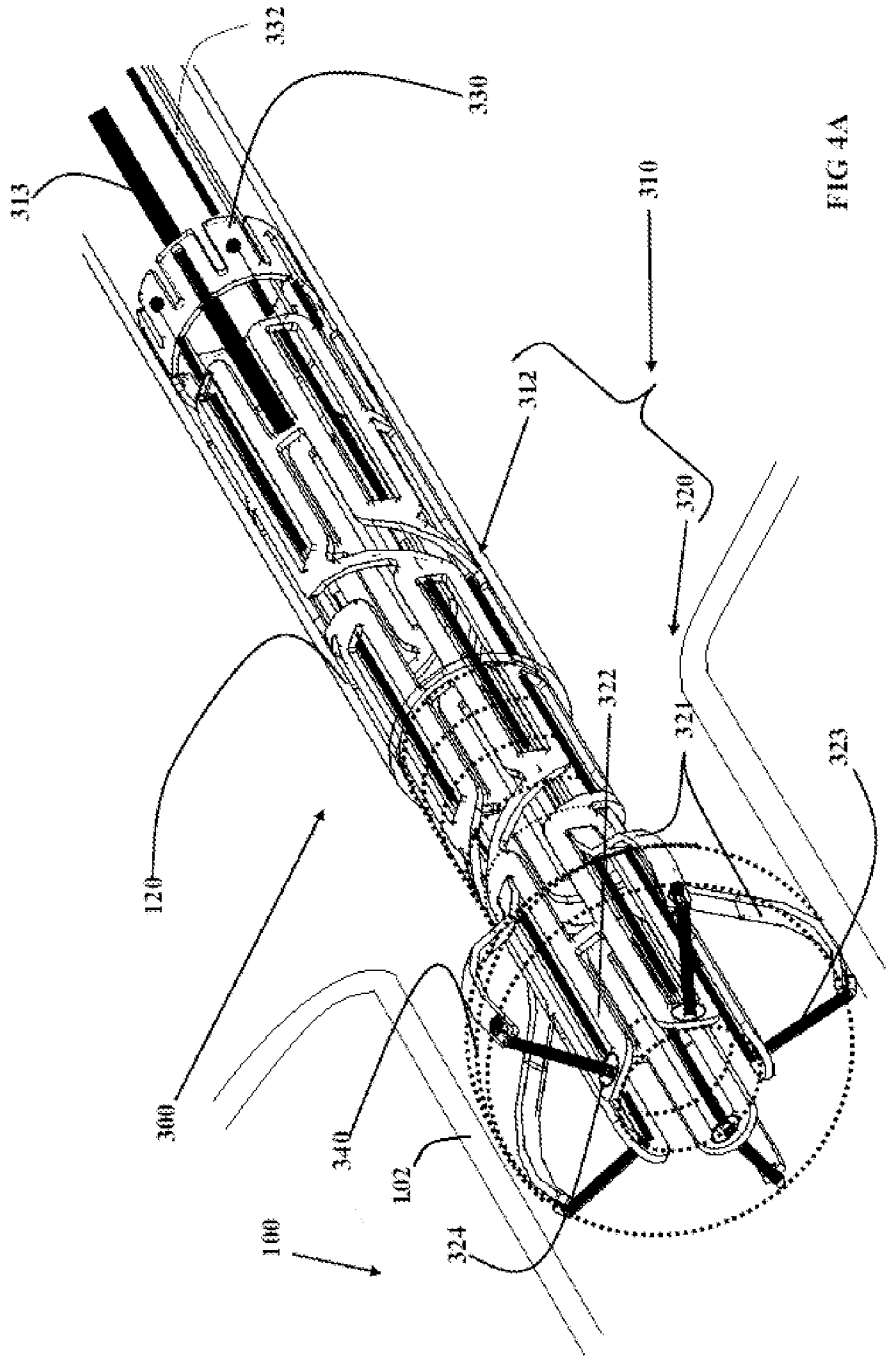


FIG 4A

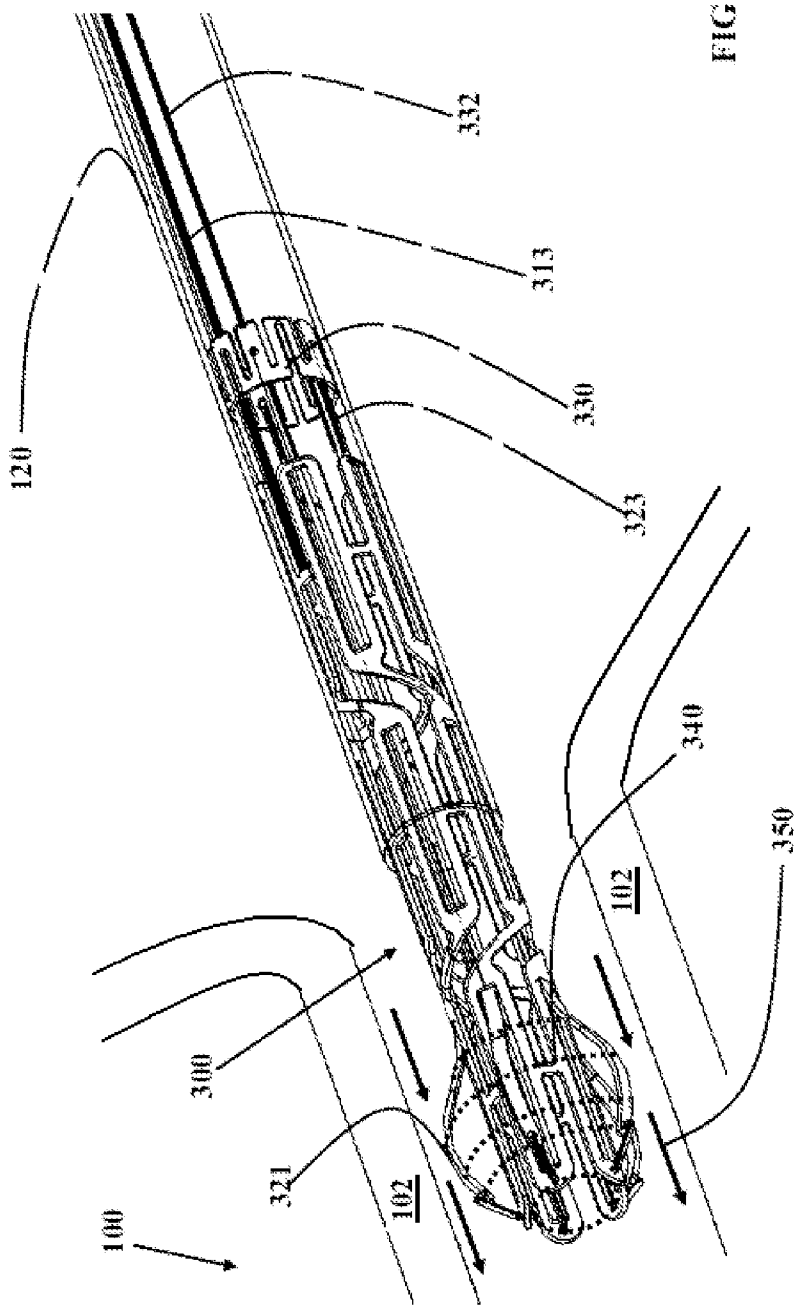


FIG 4B

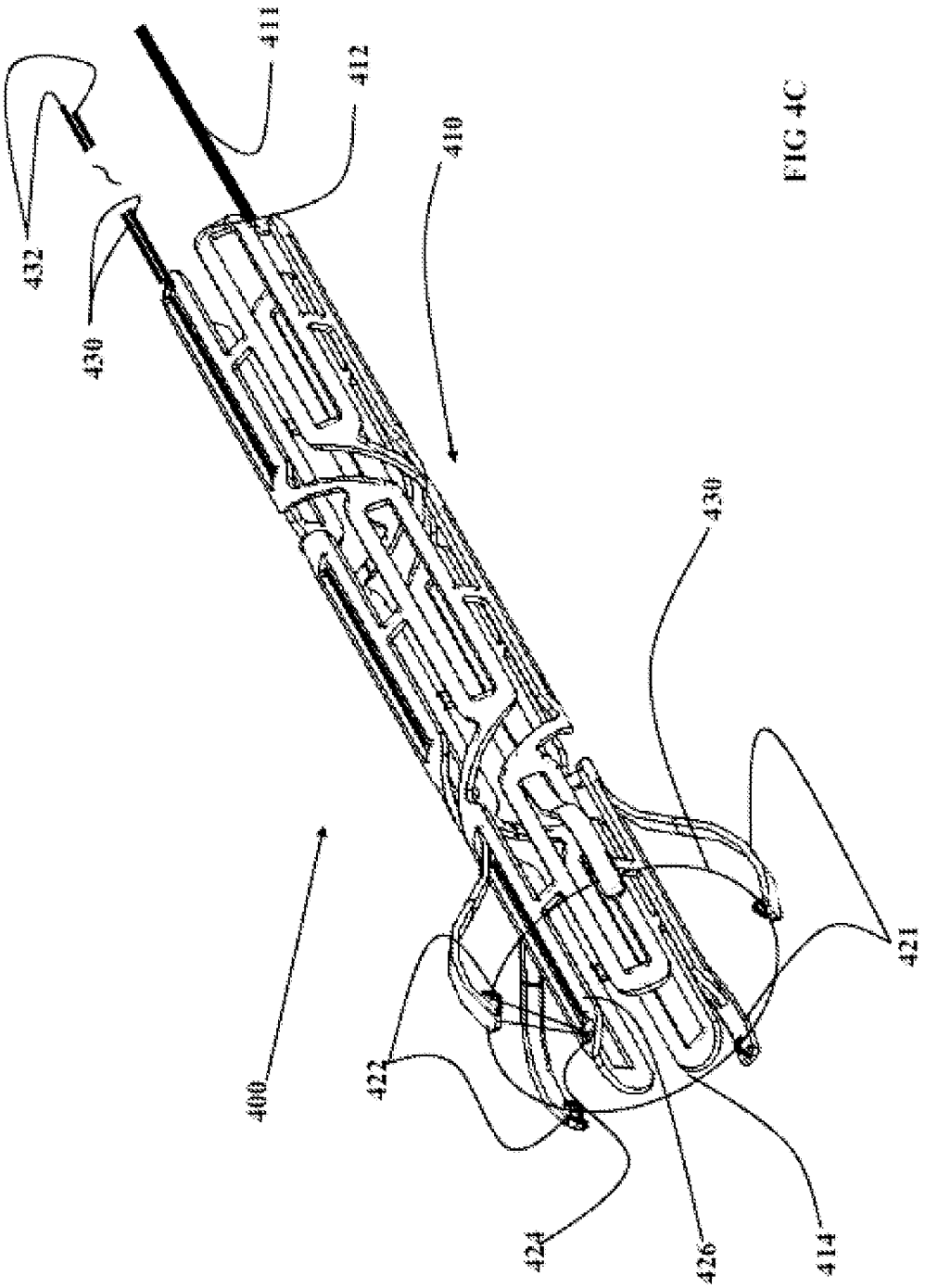


FIG 4C

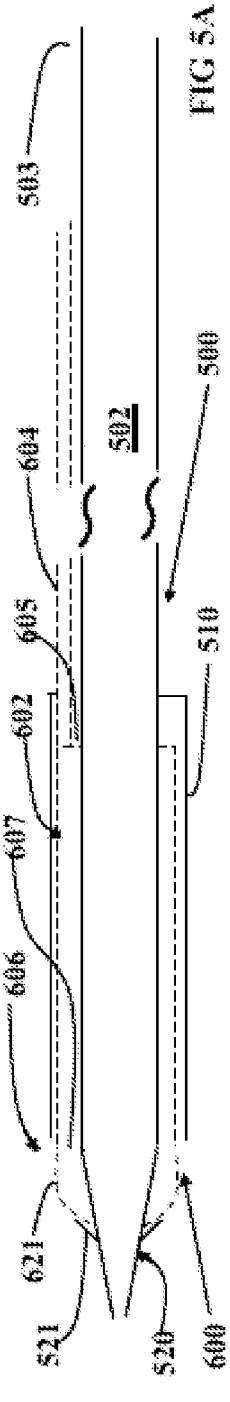


FIG 5A

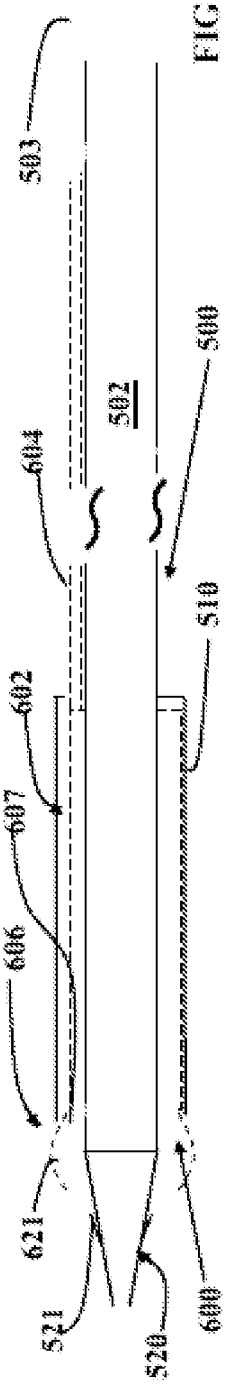


FIG 5B

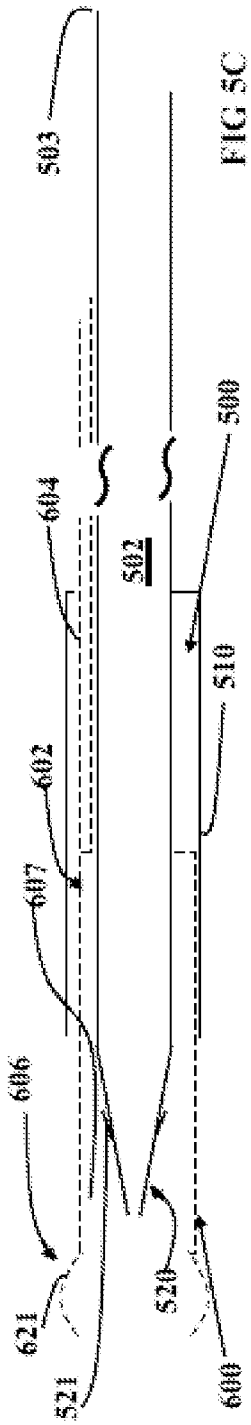


FIG 5C

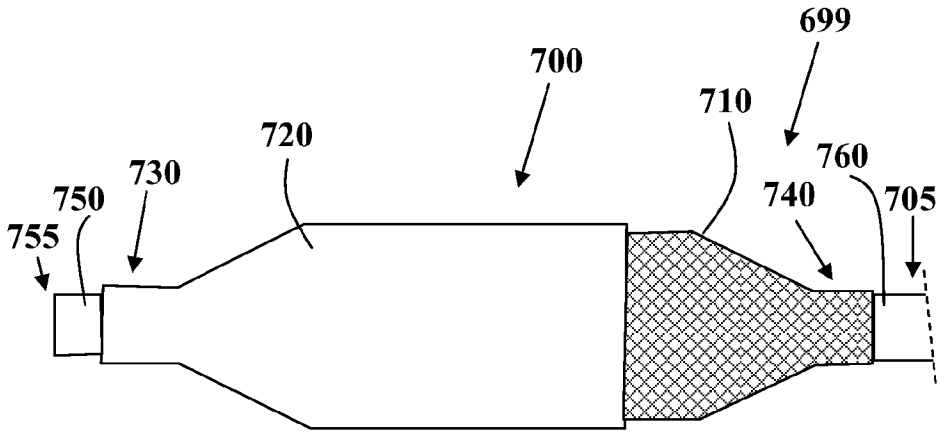


FIG 6A

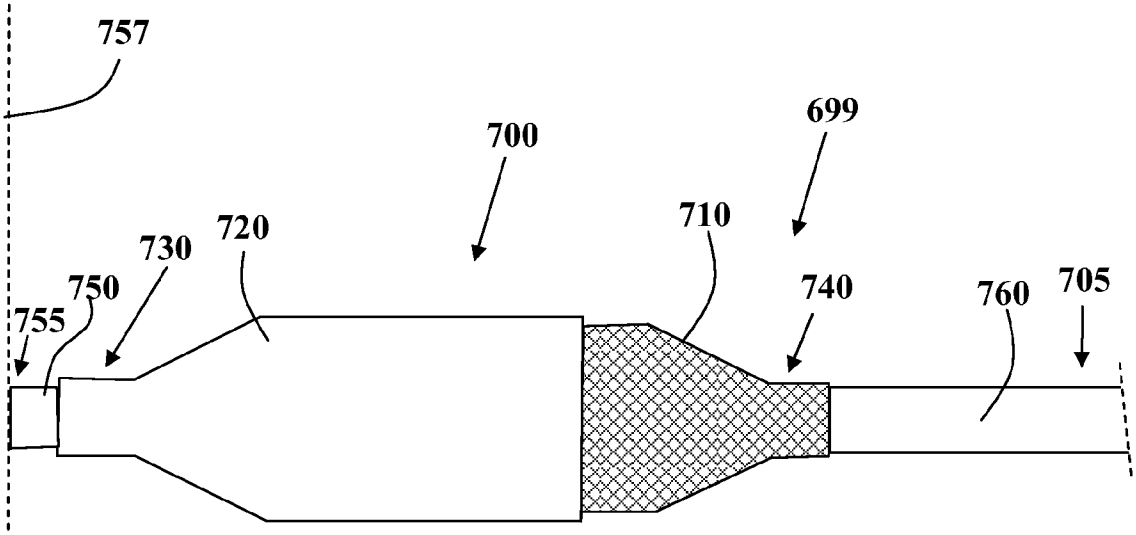


FIG 6B

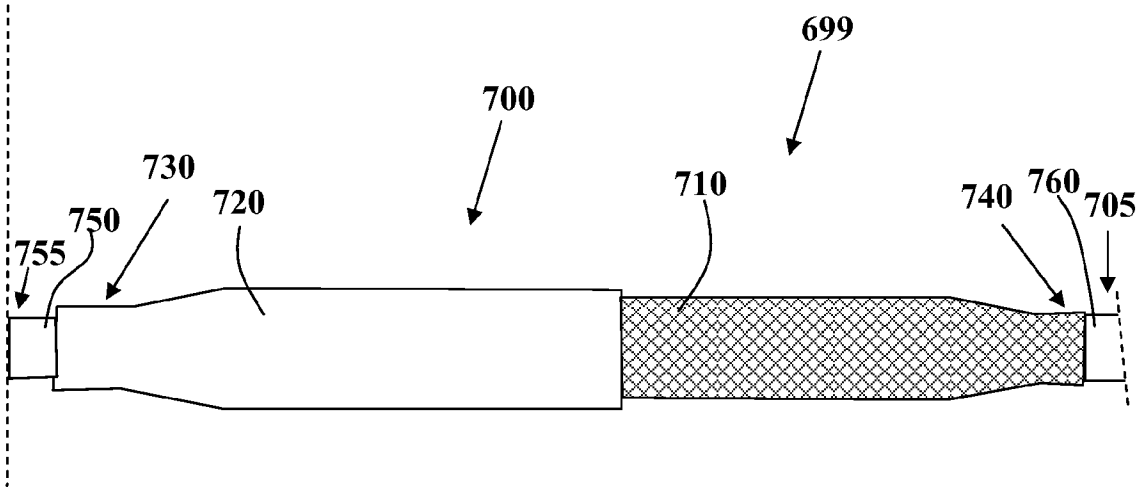


FIG 7

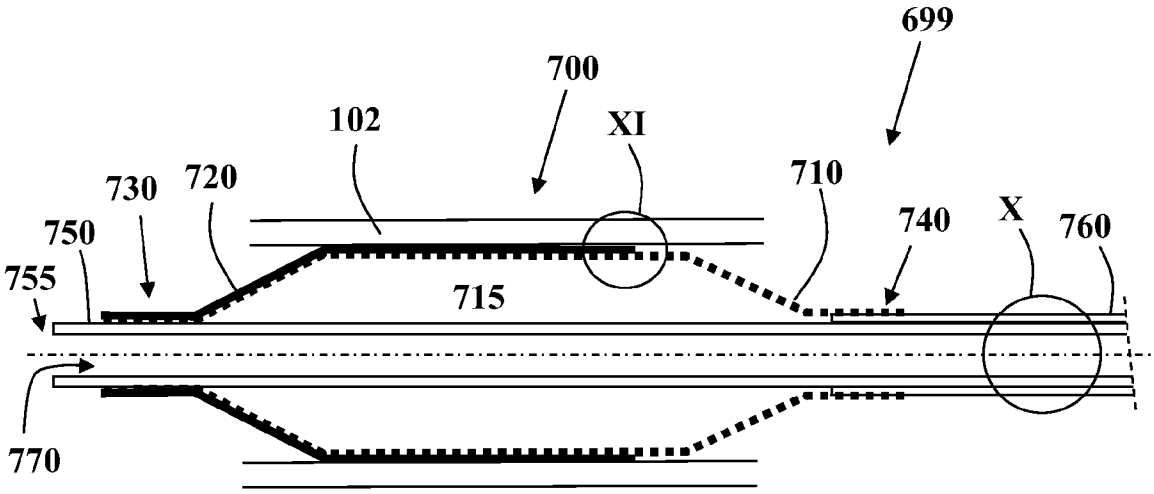


FIG 8

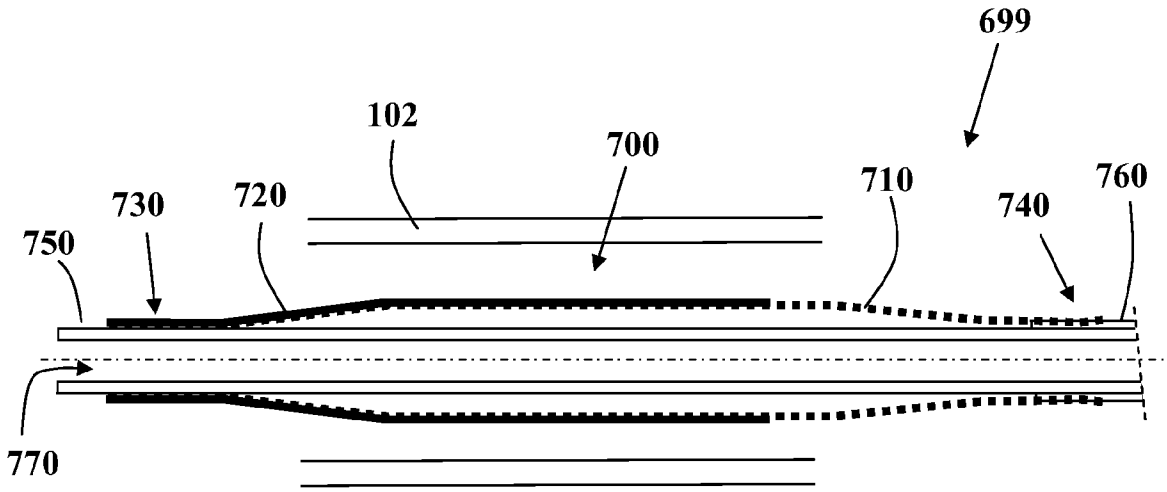


FIG 9

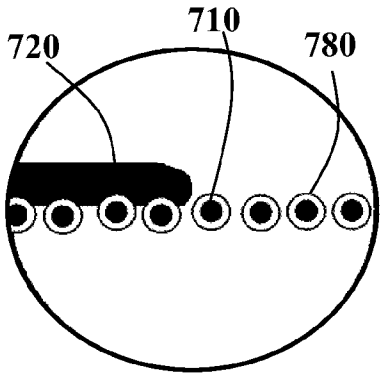


FIG 11

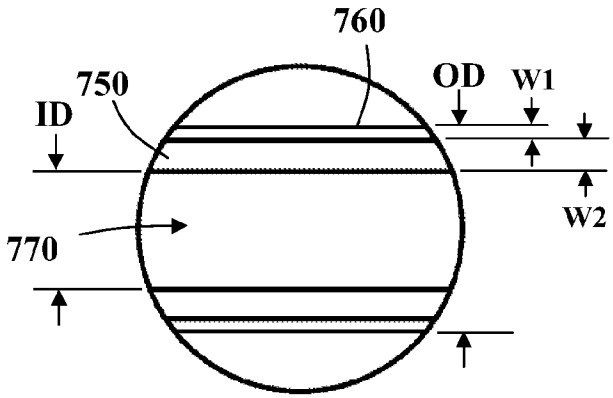


FIG 10

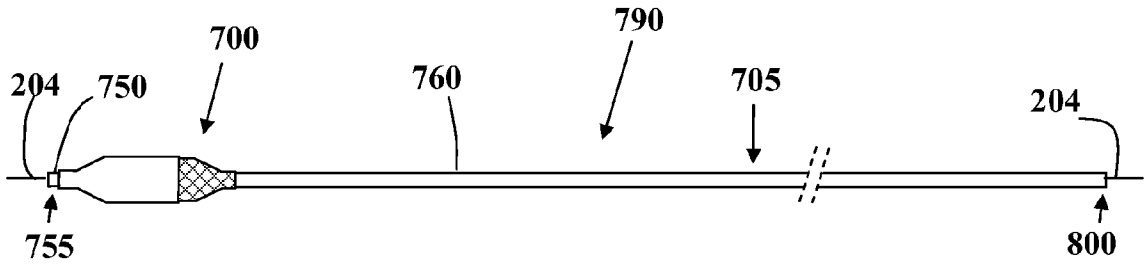


FIG 12

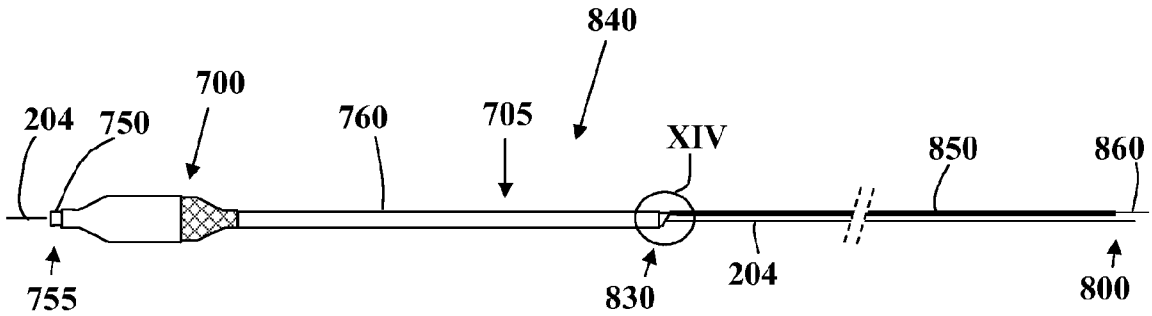


FIG 13

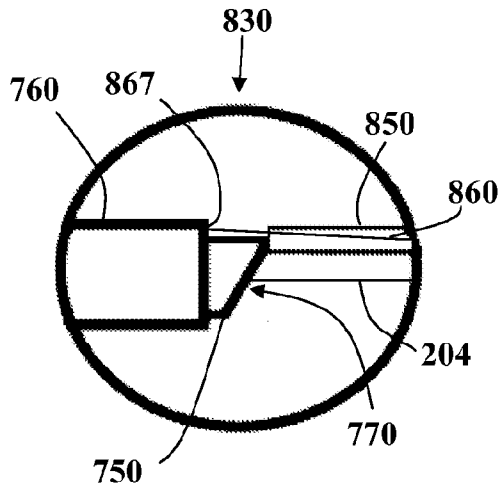


FIG 14

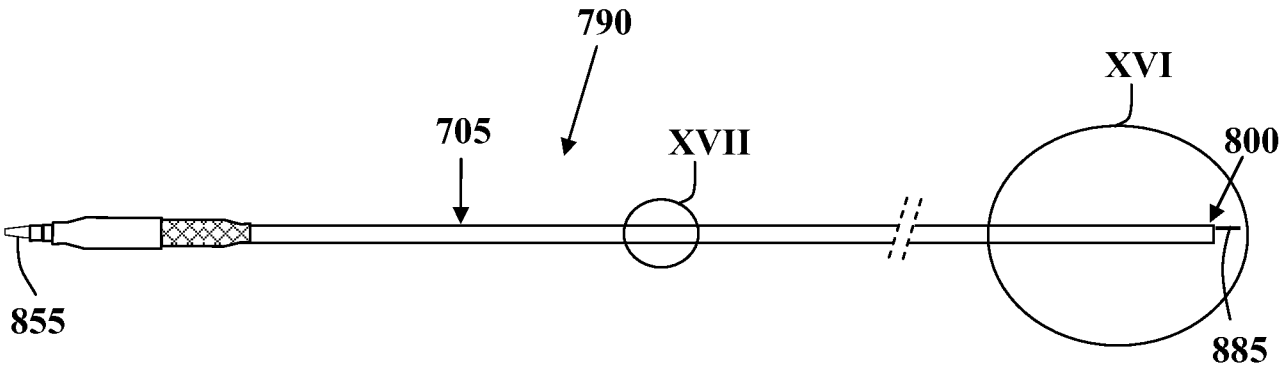


FIG 15

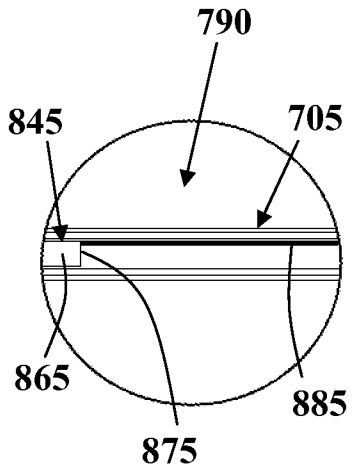


FIG 17

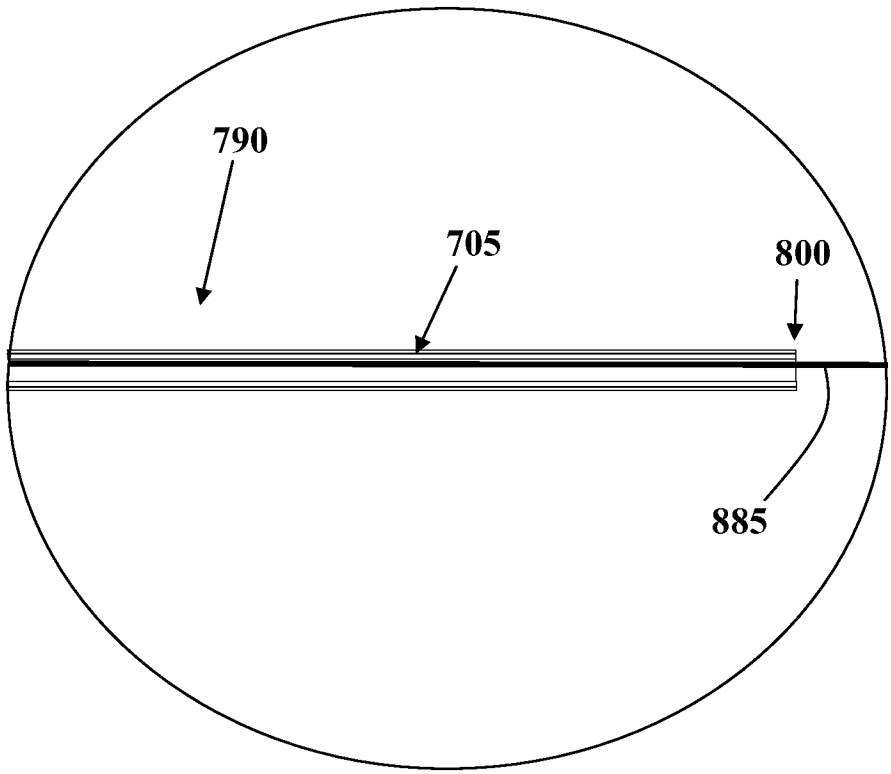


FIG 16

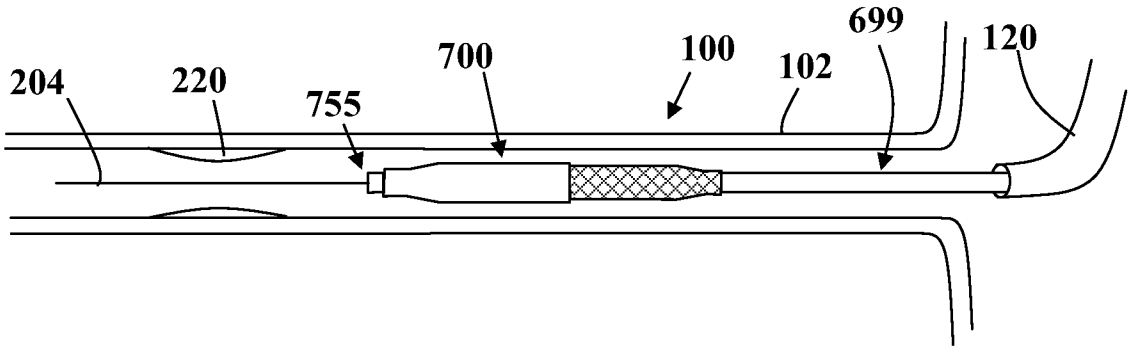


FIG 18A

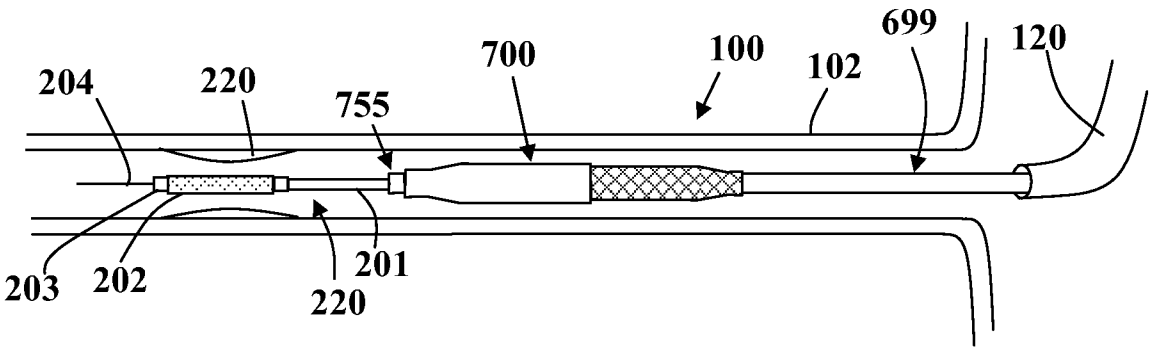


FIG 18B

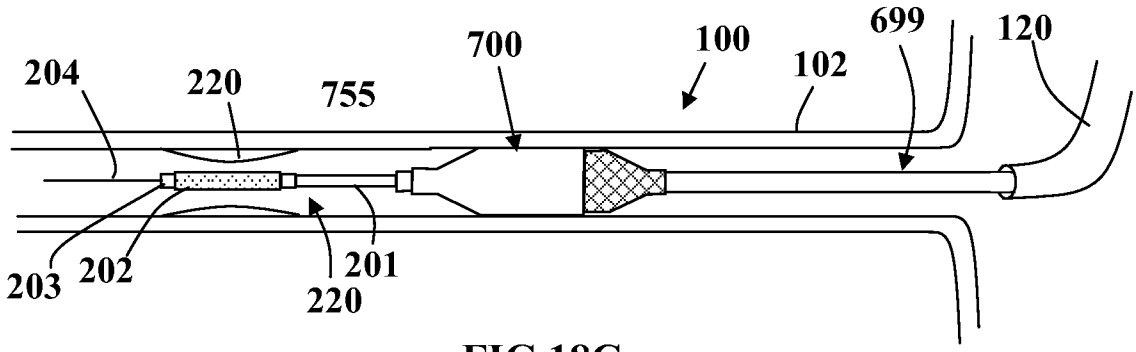


FIG 18C

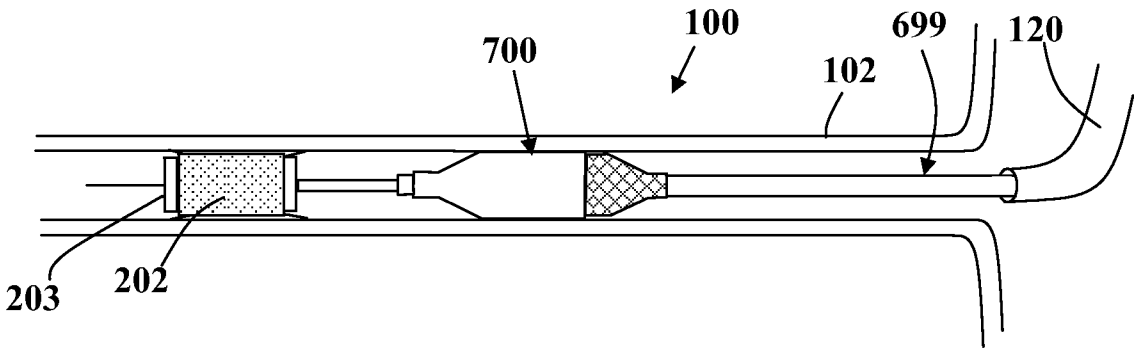


FIG 18D

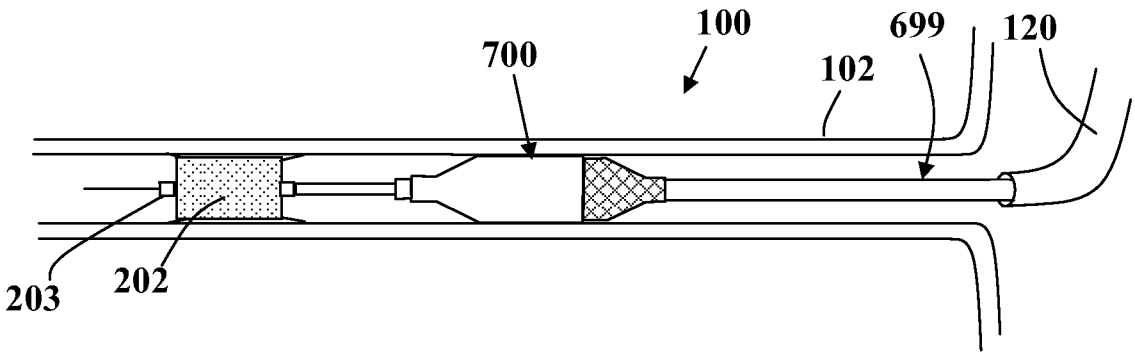


FIG 18E

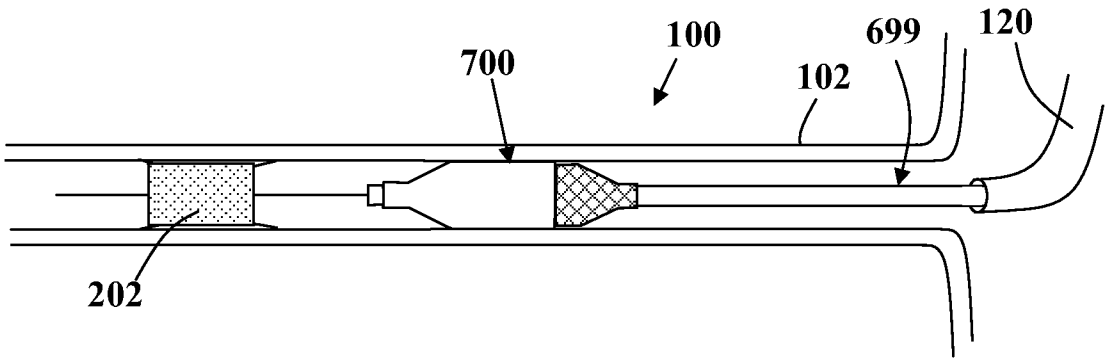


FIG 18F

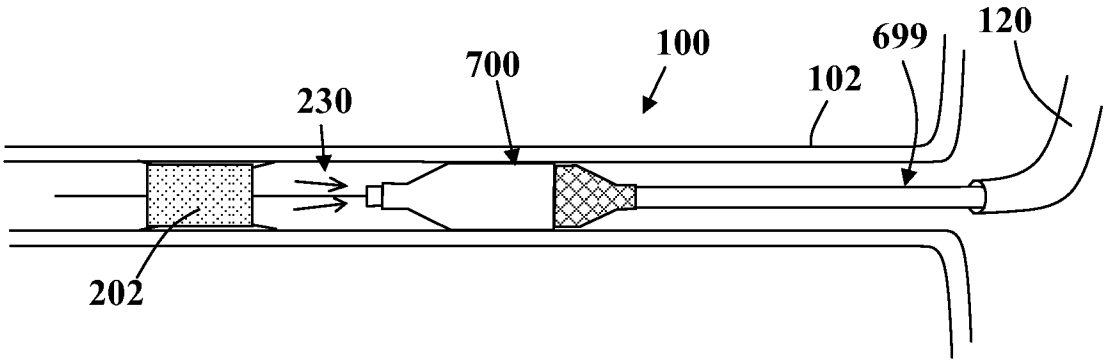


FIG 18G

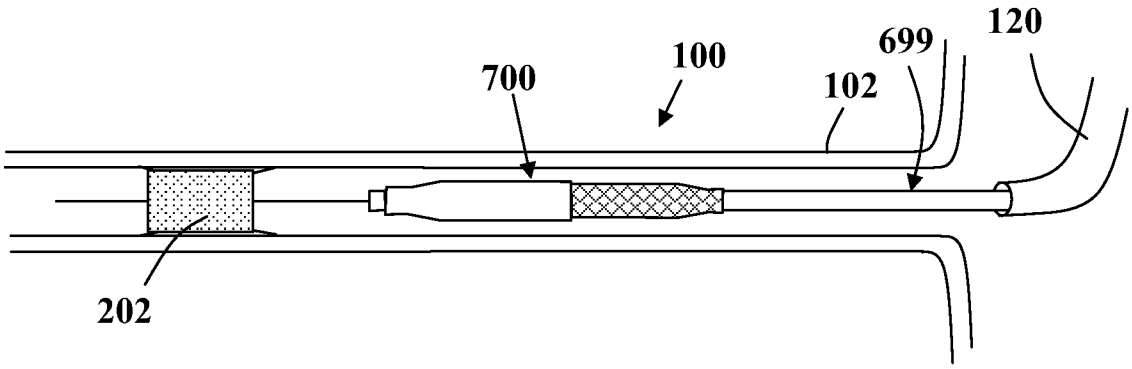


FIG 18H

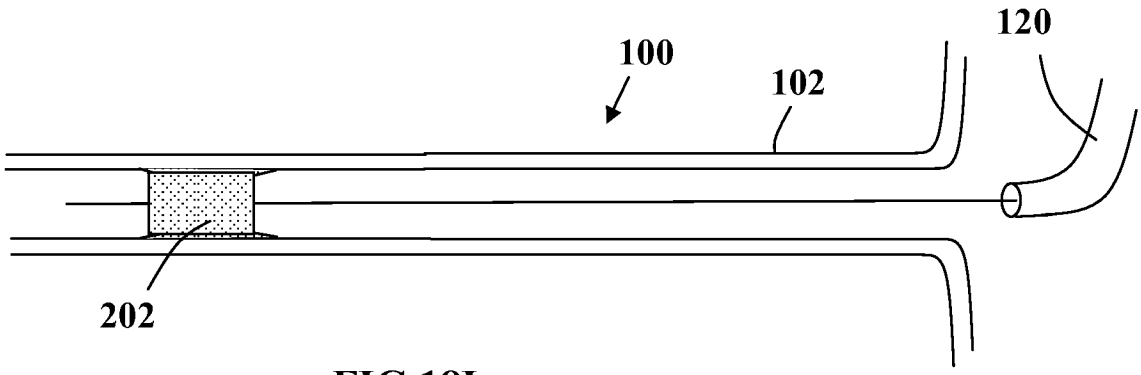


FIG 18I

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/052453

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/12
ADD. A61M1/00 A61M25/00 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M 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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/030256 A1 (DUBRUL WILLIAM R [US] ET AL) 4 February 2010 (2010-02-04) paragraph [0001] - paragraph [0041]; figures 1-62,81-91,98-107,120-122 paragraph [0141] - paragraph [0145] paragraph [0157] - paragraph [0159] paragraph [0172] - paragraph [0202] paragraph [0215] - paragraph [0264] paragraph [0287] - paragraph [0299] -----	1-18
X	US 2004/199202 A1 (DUBRUL WILLIAM [US] ET AL) 7 October 2004 (2004-10-07) paragraph [0031] - paragraph [0045]; figures 1-10,17,23-25 paragraph [0083] - paragraph [0104] paragraph [0139] - paragraph [0151] ----- -/--	1-18

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
30 August 2012	06/09/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Neef, Tatjana

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/052453

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/126747 A1 (REVERSE MEDICAL CORP [US]; BRAUN MICHAEL [DE]; GEIS JOHN S [DE]; STRAU) 15 October 2009 (2009-10-15) paragraph [0003] - paragraph [0016]; figures 1-24 paragraph [0045] paragraph [0098] - paragraph [0112] paragraph [0122] - paragraph [0135]	1-18
X	WO 2009/082513 A1 (VORTEX MEDICAL [US]; AKLOG LISHAN [US]; GLENNON MICHAEL [US]) 2 July 2009 (2009-07-02)	1,2, 4-10, 15-18
A	paragraph [0042] - paragraph [0049]; figures 1-4 paragraph [0082] - paragraph [0084]	3,11-14
X	US 2002/165574 A1 (RESSEMANN THOMAS V [US] ET AL) 7 November 2002 (2002-11-07)	1,2,4-18
A	paragraph [0100] - paragraph [0129]; figures 1-10 paragraph [0180] - paragraph [0199]	3
A	US 2001/044598 A1 (PARODI JUAN CARLOS [AR]) 22 November 2001 (2001-11-22) paragraph [0026] - paragraph [0069]; figures 1-7	1-18
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