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(54) **Titre : SYSTEMES ET PROCEDES POUR ACCEDER A DE PETITES ARTERES POUR TRANSPORTER DES CATHETERS VERS DES VAISSEAUX CIBLES**
(54) **Title: SYSTEMS AND METHODS FOR ACCESSING SMALL ARTERIES FOR CONVEYING CATHETERS TO TARGET VESSELS**

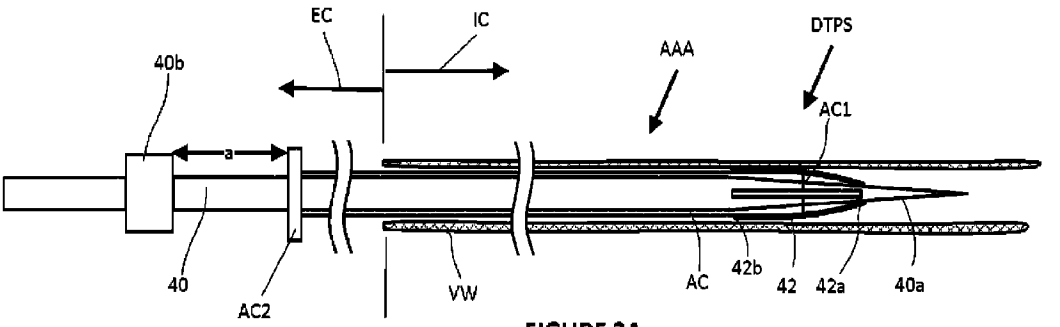

FIGURE 2A

(57) **Abrégé/Abstract:**
Systems and methods for accessing small arteries for conveying catheters to target vessels such as brain vessels are described. In particular, the invention describes systems enabling a catheter to be introduced directly through a vessel opening without an external sheath wherein a distal tip of the catheter is protected by a protective cover. Methods of introducing catheters into vessels and kits are also described.

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Abstract:

Systems and methods for accessing small arteries for conveying catheters to target vessels such as brain vessels are described. In particular, the invention describes systems enabling a catheter to be introduced directly through a vessel opening without an external sheath wherein a distal tip of the catheter is protected by a protective cover. Methods of introducing catheters into vessels and kits are also described.

SYSTEMS AND METHODS FOR ACCESSING SMALL ARTERIES FOR CONVEYING CATHETERS TO TARGET VESSELS

FIELD OF THE INVENTION

[0001] Systems and methods for accessing small arteries for conveying catheters to target vessels such as brain vessels are described. In particular, the invention describes systems enabling a catheter to be introduced directly through a vessel opening without an external sheath wherein a distal tip of the catheter is protected by a protective cover. Methods of introducing catheters into vessels and kits are also described.

BACKGROUND OF THE INVENTION

[0002] Neuro-intervention (NI) procedures utilizing catheter systems to gain access to the cerebral arteries for the treatment of ischemic stroke are varied in terms of approach and the catheter systems utilized. Similarly, other intervention procedures to access other target vessels including the heart or other target areas through the vasculature utilize a range of catheter systems.

[0003] In many cases, and in particular NI and cardiac-intervention (CI) procedures, access to the vasculature is obtained through the femoral artery, mainly due to its size and its proximity to the skin. While the femoral artery is an advantageous access point, there are downsides to its use primarily due to recovery times when NI and CI procedures are conducted through this location. For example, when a procedure is conducted through the femoral artery, a patient must typically be kept in a treatment center for a longer period of time due to the need for more time for the access wound to heal before allowing the patient to walk.

[0004] In comparison, if an NI or CI procedure is conducted through a radial artery, the patient can be discharged more quickly as the healing of the access wound does not prevent the patient becoming ambulatory almost immediately following the procedure. Hence, in an effort to save hospital and other treatment costs, there is a preference, when appropriate to conduct procedures via the arm arteries.

[0005] However, the radial/brachial arteries are smaller and thus generally present limitations and complications for certain procedures. Specifically, there is an upper limit on the size of catheters that be introduced into the arm arteries using conventional artery access equipment.

SUMMARY OF THE INVENTION

[0006] In accordance with the invention, a system for introducing a catheter into the vasculature through a vessel opening (VO) is described, the system including a catheter having an internal diameter and external diameter; an internal guide sized for telescopic movement within the catheter, the internal guide for supporting the catheter and protecting a distal tip of the catheter as the catheter is introduced through a VO, the internal guide having: a tapered distal tip for introducing the system through the VO; and, a protective cover connected to the tapered distal tip extending proximally and expandable for engagement over the distal tip of the catheter, the protective cover moveable between an engaged position over the catheter and a disengaged position; wherein selective movement of the internal guide relative to the catheter causes the protective cover to move from the engaged position to the disengaged position and when in the disengaged position allows the internal support and protective cover to be proximally withdrawn through the catheter.

[0007] In various embodiments,

- The protective cover is a plurality of inwardly biased arms and the internal guide includes corresponding recesses for receiving the arms in a compressed position.
- The protective cover is an elastic sheath circumferentially covering the distal tip of the catheter in the engaged position.
- The elastic sheath seats against the internal guide in the disengaged position.
- The elastic sheath inverts to the disengaged position during withdrawal of the internal guide.
- The catheter has a catheter end stop and the internal guide has an internal guide end stop and wherein when the protective cover is in the engaged position, movement of the internal guide end stop towards the catheter end stop causes the protective cover to move to the disengaged position.

- The catheter is an aspiration catheter having a soft distal tip region and a length sufficient to extend from a radial artery VO to the cerebral vessels for the treatment of ischemic stroke.
- The aspiration catheter is 5-8F.
- The aspiration catheter is 6-8F.
- The internal guide is hollow and the tapered distal tip includes a through bore allowing the internal guide to ride over a wire.
- The system includes an expandable ring, the expandable ring having an internal diameter expandable between an external diameter of the internal support and an external diameter of the catheter, the expandable ring having a distal edge having a thickness to be placed under a proximal edge of the elastic sheath during assembly of the elastic sheath on the catheter.

[0008] In another aspect the invention describes a kit including an internal support within sterilized packaging, the internal guide sized for telescopic movement within a catheter, the internal guide for supporting the catheter and protecting a distal tip of the catheter as the catheter is introduced through a VO, the internal guide having: a tapered distal tip for introducing the system through the VO; and, a protective cover connected to the tapered distal tip extending proximally and expandable for engagement over the distal tip of the catheter, the protective cover moveable between an engaged position over the catheter and a disengaged position; wherein selective movement of the internal guide relative to the catheter causes the protective cover to move from the engaged position to the disengaged position and when in the disengaged position allows the internal support and protective cover to be proximally withdrawn through the catheter.

[0009] In various embodiments,

- The internal support and catheter are packaged within the same sterilized packaging.
- The catheter and the internal support are in separate packages including a catheter package and an internal support package.
- The internal support package, the expandable ring having an internal diameter expandable between an external diameter of the internal support and an external diameter of the catheter, the expandable ring having a distal edge

having a thickness to be placed under a proximal edge of the protective cover during assembly of the protective cover on the catheter.

[0010] In another aspect the invention describes a method of introducing a catheter into a vessel through a vessel opening VO comprising the steps of:

a) puncturing a vessel with a hollow needle to form a VO;

b) introducing a wire through the hollow needle;

c) withdrawing the needle over the wire;

d) introducing an arterial access assembly of an internal guide having a tapered proximal tip and a catheter supported over the internal guide, the catheter having a distal tip operatively engaged with a protective cover configured to the internal guide;

e) advancing the assembly away from the VO;

f) advancing the internal guide proximally relative to the catheter to disengage the protective cover from the distal tip of the catheter; and,

g) withdrawing the internal guide and protective cover through the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Various objects, features and advantages of the invention will be apparent from the following description of particular embodiments of the invention, as illustrated in the accompanying drawings. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of various embodiments of the invention. Similar reference numerals indicate similar components.

Figures 1A-1G are schematic diagrams showing equipment for conducting a typical procedure for gaining access to an artery in accordance with the prior art. Typical steps include needle puncture (Figure 1A), wire insertion (Figure 1B), needle removal (Figure 1C), arterial access system insertion (Figure 1D)

and internal guide removal (Figure 1G). Figures 1E and 1F show an internal guide and external sheath respectively.

Figures 2A-2C are schematic diagrams of an arterial access assembly (AAA) having a distal tip protection system (DTPS) and a method of gaining arterial access in accordance with one embodiment of the invention.

Figures 3A-3D are schematic diagrams of an arterial access assembly (AAA) having a distal tip protection system (DTPS) and a method of gaining arterial access in accordance with another embodiment of the invention.

Figures 4A-4F are schematic diagrams showing a method of assembling an arterial access assembly (AAA) having a distal tip protection system (DTPS) on an aspiration catheter in accordance with one embodiment of the invention. Figure 4F shows an assembly ring in accordance with one embodiment of the invention.

Figure 5 is a flow chart showing the steps for assembling an AAA at a treatment center in accordance with one embodiment of the invention.

DETAILED DESCRIPTION

Rationale

[0012] The inventor who has experience in the treatment of acute ischemic stroke recognized that a problem exists in introducing larger diameter aspiration catheters into smaller arteries, such as the radial artery, utilizing current artery access equipment. The invention as described herein, describes methods for effectively introducing larger diameter catheter systems into smaller arteries at the artery access stage of endovascular/neuro-intervention procedures.

Scope of Language

[0013] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the

presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0014] Spatially relative terms, such as "distal", "proximal", "forward", "rearward", "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a feature in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. A feature may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0015] It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc., another element, it can be directly on, attached to, connected to, coupled with or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with or "directly contacting" another element, there are no intervening elements present.

[0016] It will be understood that, although the terms "first", "second", etc may be used herein to describe various elements, components, etc., these elements, components, etc. should not be limited by these terms. These terms are only used to distinguish one element, component, etc. from another element, component. Thus, a "first" element, or component discussed herein could also be termed a "second" element or component without departing from the teachings of the present invention. In addition, the sequence of operations (or steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise.

[0017] Other than described herein, or unless otherwise expressly specified, all of the numerical ranges, amounts, values and percentages, such as those for amounts of materials, elemental contents, times and temperatures, ratios of amounts, and others, in the following portion of the specification and attached claims may be read as if prefaced by the word "about" even though the term "about" may not expressly appear with the value, amount, or range. Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

[0018] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0019] Various aspects of the invention will now be described with reference to the figures. For the purposes of illustration, components depicted in the figures are not necessarily drawn to scale. In particular, directions of width and length may be distorted with respect to one another in that widths generally reflect the internal diameters of arteries (typically mm scale) whereas lengths reflect the lengths of arteries (typically a cm+ scale). Thus, for clarity, the "length" scale is generally (but not necessarily) compressed with respect to the width scale and/or shows breaks in the length of components. As such, emphasis is placed on highlighting the various contributions of the components to the functionality of various aspects of the invention. A number of possible alternative features are introduced during the course of this description. It is to be understood that, according to the knowledge and judgment of persons skilled in the art, such alternative features may be substituted in various combinations to arrive at different embodiments of the present invention.

[0020] With reference to the figures, systems and methods for introducing catheters into smaller arteries are described. Figures 1A-1G illustrate known steps of gaining access to an artery and are provided for background.

[0021] In a first step, as shown in Figure 1A a hollow bore needle N is used to puncture an artery. The needle has a typical outer diameter of about 1mm and internal diameter of about 0.5 mm.

[0022] As shown in Figure 1B, a wire W is introduced into the needle such that it feeds through the needle and out of the distal tip N1 of the needle. The wire will have a diameter that allows its passage through the needle.

[0023] As shown in Figure 1C, the needle is then withdrawn over the wire leaving the wire in place in the vessel and protruding through the vessel opening VO.

[0024] An arterial access system (AAS) as shown in Figures 1D, 1E and 1F, is guided over the wire and into the vessel through the VO. In accordance with the prior art, the AAS typically includes an internal guide/introducer 20 having a pointed distal tip 22 and an external sheath 30. Both the internal guide and the external sheath have known extracorporeal connectors 24, 32 that during insertion into the BV are connected at junction 25 allowing the assembled AAS to be inserted together. The overall length of an internal guide 20 is typically in the range of 15cm and the external sheath 30 typically has an overall length of about 12 cm.

[0025] After the AAS has been introduced as shown in Figure 1D, the internal guide 20 and wire W are removed (Figure 1G) thus providing a conduit into the vessel through the external sheath 30 that allows fluids and/or instruments to be introduced into the vessel through the AAS.

[0026] In accordance with the invention, the inventor recognized that the introduction of a larger bore catheter such as an aspiration catheter (AC) suitable for aspirating a clot from the cerebral arteries would be too large to be introduced into smaller vessels (such as the radial or brachial arteries) within an external sheath 30. That is, the external sheath of a radial artery AAS has a practical maximum internal diameter of about 6F (OD of about 7.2F) to allow the passage of a 6F AC through the external sheath whereas it is desirable to introduce ACs into the cerebral vessels that have outside diameters greater than 6F (eg. about 6-8F).

[0027] Hence, there has been need for arterial access assemblies (AAAs) that enable the introduction of larger catheters such as an aspiration catheter (AC) into the radial arteries. AAAs are described herein with reference to ACs and cerebral access

procedures, although it is understood that different types of catheters for different procedures are contemplated.

[0028] As described in Applicant's co-pending applications, US provisional application 62/878,652 filed July 25, 2019, US provisional application 63/029,401 filed May 23, 2020 and International patent application PCT/CA2020/051026 filed July 24, 2020, all incorporated herein by reference, the design of an aspiration catheter that can be maneuvered from the arterial access point (e.g. groin or radial artery) is characterized by a soft distal tip section that is both sufficiently soft to be atraumatic as it navigates through the cerebral arteries, flexible enough to pass through tight curves and also allow effective suction to be applied to a blood clot. Also, the tip is radio-opaque to allow visualization during navigation through neck and intracranial vessels.

[0029] Importantly, in order to ensure that the AC is suitable for aspiration, the AC tip generally cannot have a taper at its distal tip (i.e. a narrower wall thickness at the distal tip tapering to a wider wall thickness in the proximal direction) as an AC requires a certain radial stiffness to prevent the distal tip from collapsing when suction is being applied to a clot.

[0030] It is also important that when an AAS is being deployed through a VO that the risk of damaging the vessel wall is minimized. Thus, while equipment being pushed into a vessel can tightly engage the vessel, AASs have generally been designed such that the external sheath has an internal taper that enables a smooth transition between the internal guide and external sheath without a significant edge at point 27 (see Figure 1D). The absence of a significant edge at the boundary between the internal guide and external sheath allows the external sheath to be pushed through the VO while engaged with the vessel wall without damaging the vessel wall.

[0031] The inventor also realized it would be desirable to be able to introduce an AC into a radial artery with the AC being supported internally by an internal guide 20 with the tapered tip 22 of the internal guide protruding from the end of the AC. However, the inventor recognized that the transition between the internal guide 20 and AC is problematic due to the oblique shape of the distal tip of an AC, the softness/flexibility of the distal tip of the AC, the presence of a radio-opaque marker and the lack of distal taper. In other words, without a substantially equivalent stiffness as a comparable external sheath (as shown in Figure 1F), the distal tip of an AC supported by an internal guide alone has a tendency to crumple and/or buckle with respect to the internal guide

when the two are combined as an internal guide and AC. In particular, this problem occurs when such an assembly is being pushed through the vessel opening VO and for a number of centimeters upstream of the VO.

[0032] The inventor recognized that in order for the soft distal tip of an AC to pass through and past the VO, a portion of the distal tip of the AC must be protected for its passage through the first 0-15+ cm (approximately) of the vessel as the surgeon is pushing the AC upstream, for example, towards the aortic arch. Generally, internal support in the form of an introducer is not needed after the initial approximate 15 cm as the arteries become sufficiently large that the AC tip will not be tightly engaged against the VW and will be able to be pushed forward without internal support and without crumpling.

[0033] Accordingly, in a first embodiment of the invention as shown in Figures 2A-2C, a system (referred herein as an arterial access assembly (AAA)) for advancing an AC through a VO and into such smaller arteries is described.

[0034] In Figure 2A, an assembled AC and internal guide 40 having an AC distal tip protection system (DTPS) is shown (AAA). The internal guide 40 is similar in design to prior art internal guides 20 insomuch as it has a tapered distal tip 40a and an internal bore allowing a wire to pass through its center. In contrast to past internal guides, the length is sufficient to extend the full length of an AC (or equivalent) and protrude beyond the proximal end of the AC. Figures 2A-2C show an assembled AC/internal guide assembly (AAA) pushed through a VO and a short distance into an intracorporeal zone (IC) of a vessel as well as extracorporeal zone (EC) where the AAA can be manipulated.

[0035] In greater detail, the internal guide 40 is sufficiently long to extend beyond the proximal end of the AC and be capable of manipulation from the proximal end of the AC. In addition, the internal guide 40 includes the DTPS that is formed as part of the internal guide to protect and prevent buckling of the AC tip as it is being inserted through the VO and into the artery.

[0036] As shown in Figures 2A and 3A, in various embodiments, the DTPS includes a plurality of biased or elastic arms (Figure 2A) or sheath (Figure 3A) 42 configured to the internal guide 40 adjacent and/or forming part of its tapered surface 40a that function as a protective sheath for the distal tip AC1 of the AC during the critical steps

of passing the distal tip AC1 of the AC through the skin (i.e. VO) and pushing it forward through the narrowest portions of a vessel. The elastic arms/sheath 42 provide partial or full circumferential cover to the distal tip AC1 of the AC whether a single body or multiple arms.

[0037] The DTPS has a distal end 42a secured to the internal guide 40 and a proximal end 42b that covers the distal tip AC1 of the AC. The DTPS extends proximally a sufficient distance to frictionally engage over a sufficient length of the AC so as to prevent separation/buckling of the AC1 with respect to the internal guide 40.

[0038] As shown schematically, the proximal end of the AC includes a stop AC3 that defines a proximal end of the AC. Similarly, the internal guide 40 includes a proximal end stop 40b. The end stop 40b and AC2 are separated a short distance shown as "a" in Figures 2A and 3A. As can be understood, by manipulating both the end stop 40b and AC2 with respect to one another, the AC and internal guide 40 can telescopically move with respect to one another.

[0039] As shown in Figure 2B, the end stop 40b and AC2 have been moved towards one another to a distance "b". As can be seen, this has moved the internal guide 40 distally with respect to the AC such that the proximal edges 42b of the elastic arms 42 are distal to AC1. Distance "b" can be zero where the end stop 40b and AC2 abut one another.

[0040] The internal guide 40 can be provided with one or more recesses 42d within the internal guide 40 such that as the elastic arm ends 42b of DTPS move past AC1, they will be drawn into the recess(es) 42d (dotted line) and thus become flush (or recessed) with respect to the external surface of the internal guide 40.

[0041] Thereafter, the end stop 40b can be moved proximally to a length greater than "a" (shown as "c") and relative to AC2 such that the internal guide 40 can be withdrawn from the AC with the DTPS being able to pass into AC through AC1 (Figure 2C).

[0042] The internal guide 40 can then be fully removed from the AC thus having introduced the AC into the vessel and allowing further steps of the procedure to be completed.

[0043] Typically, the AC/internal guide assembly (AAA) would be pushed forward a distance up to about 15cm from the VO before conducting the steps as described above.

[0044] Figures 3A-3D show a different embodiment of the DTPS. In this embodiment, the DTPS is a resiliently flexible "umbrella" 42 that is attached to the tapered surface 40a of the internal guide 40 at point 44. Initially, at the start of the procedures, umbrella 42 extends over AC1 and a distance X sufficient to frictionally retain the umbrella 30 over AC1. The umbrella may be an elastic material.

[0045] In this embodiment, after the AC/internal guide assembly has been inserted into the vessel, the internal guide 40is removed following similar steps to those described above. That is, the internal guide is initially pushed distally to push the umbrella past AC1 (Figure 3B) such that AC1 is uncovered. Depending on the design of the umbrella, the umbrella may elastically contract (as shown by opposing arrows in Figure 3B) over the internal guide and within an appropriate recess 40e on the internal guide 40 to become flush with the internal guide 40 as shown in Figure 3B.

[0046] In another embodiment, the umbrella 30 may "invert" with respect the internal guide 40 when subsequently withdrawn as shown in Figures 3C and 3D. Figure 3C shows the umbrella beginning to invert and Figure 3D shows the umbrella inverted and being withdrawn into the AC. Inverting the umbrella may occur by pushing the internal support forward to disengage the umbrella from the AC or by simply pulling back on the AC.

[0047] Accordingly, as above, the internal guide can then be fully withdrawn.

Assembly

[0048] The arterial access assemblies described above may be assembled at a factory or at a treatment center immediately prior to use.

[0049] In the case of factory assembly, kits including various catheters and internal guides may be packaged together. Typically, after manufacture of the internal guide with a DTPS and the catheter, both having appropriate internal and external diameters for engagement with one another, the two components would be assembled such that the DTPS is properly engaged with the distal end of the catheter. After assembly and

sterilization, the AAA would be packaged in a single package for delivery and subsequent use at a treatment facility.

[0050] As understood by those skilled in the art, various combinations of catheters and internal guides may be assembled based on the properties of specific catheters and their diameters.

[0051] For example, a factory assembled kit may include any one of a 6-8F AC having particular functional properties for cerebral endovascular procedures configured to an appropriately sized internal guide.

[0052] Practically, as physicians may desire to use particularly brands of catheters, it may not be commercially feasible for the manufacturer of internal guides to assemble internal guides for a wider range of catheters. As a result, assembly of internal guides with physician selected catheters at a treatment center is desirable.

[0053] As shown in Figures 4A-4F and Figure 5, systems and methods for assembly of an internal guide 40 with an AC are described.

[0054] In accordance with one embodiment, the following steps may be followed to assemble an internal support 40 manufactured and packaged (referred to as Package A) within sterilized packaging with a catheter (AC) from another manufacturer, packaged and sterilized within separate packaging (referred to as Package B).

[0055] Package A containing an internal support 40 and a ring 50 from one supplier/manufacturer is selected. The internal support 40 has a displayed outside diameter (OD) and length. The ring 50 has an inside diameter (ID) substantially corresponding to the internal support OD and able to slide over the internal support.

[0056] Package B containing a catheter having a known OD, ID and length is selected. The catheter may be from a different supplier/manufacturer.

[0057] The internal support 40 of package A has a length longer than the length of the catheter in package B. Package A may also include a wire.

[0058] Both packages are opened and the distal end of the internal support 40 is inserted into the proximal end of the catheter through the proximal end of the catheter until it extends from the distal end of the catheter. The DTPS 42 of the internal support

40 is pushed past the distal end of the catheter AC1, a distance sufficient to allow the ring to be placed over and proximal to the DTPS.

[0059] The ring 50 is slid over the distal tip of the internal support 40 and placed proximal to the DTPS as shown in Figure 4A and then moved distally such that the distal edge 50a of the ring is worked under the proximal edge 42b of the DTPS. A separate edge lifting device (eg. a non-traumatic spatula; not shown) may be utilized to assist in lifting the DTPS away from the internal support 40 such that the proximal edge 42b fully surrounds the distal edge 50a of the ring as shown in Figure 4B.

[0060] As shown in Figures 4C, 4D and 4F, ring 50 is elastically expandable or openable having at least a portion of the ring with a flexible portion or openable junction 50b enabling expansion or opening of the OD of the ring. Ring 50 is preferably provided with flange 50c enabling a user to hold and/or apply pressure to the ring.

[0061] As shown in Figure 4C, catheter AC is pushed forward and flange 50c manipulated to open the ring 50 to enable the AC to insert within the ring 50 thus causing the DTPS to expand over the AC. The AC is pushed forward a sufficient distance for the DTPS to overlap the AC and frictionally engage with the distal tip region of the DTPS. As shown in Figure 4D, the ring is then pulled back from the DTPS such that the DTPS engages over the AC and disengages with the DTPS.

[0062] As shown in Figure 4F, the ring is then opened and pushed forward over the AC and DTPS to remove the ring from the assembly. Alternatively, the ring may be opened at one or more junctions 50b to allow the ring to be removed.

[0063] The combined AC and internal support can then be introduced into an artery via the procedures described above.

[0064] Sterilization of the internal support and DTPS is an important consideration. Hence, it is desirable that the DTPS is manufactured from materials allowing appropriate sterilization to be conducted prior to packaging. Expanded poly tetrafluoroethylene (EPTFE) can have sufficient porosity to enable sterilizing gases such as ethylene oxide to fully and properly penetrate the structures for sterilization.

[0065] Although the present invention has been described and illustrated with respect to preferred embodiments and preferred uses thereof, it is not to be so limited since

modifications and changes can be made therein which are within the full, intended scope of the invention as understood by those skilled in the art.

CLAIMS

1. A system for introducing a catheter into the vasculature through a vessel opening (VO) comprising:

   a catheter having an internal diameter and external diameter;

   an internal guide sized for telescopic movement within the catheter, the internal guide for supporting the catheter and protecting a distal tip of the catheter as the catheter is introduced through a VO, the internal guide having:

      a tapered distal tip for introducing the system through the VO; and,

      a protective cover connected to the tapered distal tip extending proximally and expandable for engagement over the distal tip of the catheter, the protective cover moveable between an engaged position over the catheter and a disengaged position;

      wherein selective movement of the internal guide relative to the catheter causes the protective cover to move from the engaged position to the disengaged position and when in the disengaged position allows the internal support and protective cover to be proximally withdrawn through the catheter.

2. The system as in claim 1 wherein the protective cover is a plurality of inwardly biased arms and the internal guide includes corresponding recesses for receiving the arms in a compressed position.

3. The system as in claim 1 wherein the protective cover is an elastic sheath circumferentially covering the distal tip of the catheter in the engaged position.

4. The system as in claim 3 wherein the elastic sheath seats against the internal guide in the disengaged position.

5. The system as in claim 3 wherein the elastic sheath inverts to the disengaged position during withdrawal of the internal guide.

6. The system as in any one of claims 1-5 wherein the catheter has a catheter end stop and the internal guide has an internal guide end stop and wherein when the protective cover is in the engaged position, movement of the internal guide end stop towards the catheter end stop causes the protective cover to move to the disengaged position.

7. The system as in any one of claims 1- 6 where the catheter is an aspiration catheter having a soft distal tip region and a length sufficient to extend from a radial artery VO to the cerebral vessels for the treatment of ischemic stroke.

8. The system as in claim 7 where the aspiration catheter is 5-8F.

9. The system as in claim 7 where the aspiration catheter is 6-8F.

10. The system as in any one of claims 1-9 where the internal guide is hollow, and the tapered distal tip includes a through bore allowing the internal guide to ride over a wire.

11. The system as in any one of claims 3-10 further comprising an expandable ring, the expandable ring having an internal diameter expandable between an external diameter of the internal support and an external diameter of the catheter, the expandable ring having a distal edge having a thickness to be placed under a proximal edge of the elastic sheath during assembly of the elastic sheath on the catheter.

12. The system as in claim 11 where the expandable ring is openable.

13. A kit comprising:

an internal support within sterilized packaging, the internal guide sized for telescopic movement within a catheter, the internal guide for supporting the catheter and protecting a distal tip of the catheter as the catheter is introduced through a VO, the internal guide having:

a tapered distal tip for introducing the system through the VO; and,

a protective cover connected to the tapered distal tip extending proximally and expandable for engagement over the distal tip of the catheter, the protective cover moveable between an engaged position over the catheter and a disengaged position;

wherein selective movement of the internal guide relative to the catheter causes the protective cover to move from the engaged position to the disengaged position and when in the disengaged position allows the internal support and protective cover to be proximally withdrawn through the catheter.

14. The kit as in claim 13 further comprising the catheter and wherein the internal support and catheter are packaged within the same sterilized packaging.

15. The kit as in claim 13 further comprising the catheter and wherein the catheter and the internal support are in separate packages including a catheter package and an internal support package.

16. The kit as in claim 15 further comprising an expandable ring within the internal support package, the expandable ring having an internal diameter expandable between an external diameter of the internal support and an external diameter of the catheter, the expandable ring having a distal edge having a thickness to be placed under a proximal edge of the protective cover during assembly of the protective cover on the catheter.

17. A method of introducing a catheter into a vessel through a vessel opening VO comprising the steps of:

a) puncturing a vessel with a hollow needle to form a VO;

b) introducing a wire through the hollow needle;

c) withdrawing the needle over the wire;

d) introducing an arterial access assembly of an internal guide having a tapered proximal tip and a catheter supported over the internal guide, the catheter having

a distal tip operatively engaged with a protective cover configured to the internal guide;

e) advancing the assembly away from the VO;

f) advancing the internal guide proximally relative to the catheter to disengage the protective cover from the distal tip of the catheter; and,

g) withdrawing the internal guide and protective cover through the catheter.

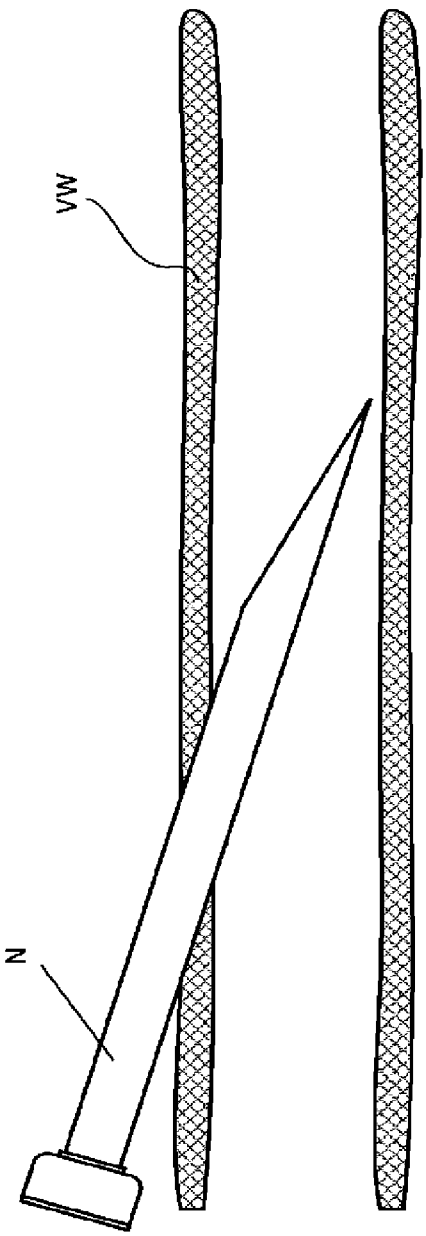

FIGURE 1A
PRIOR ART

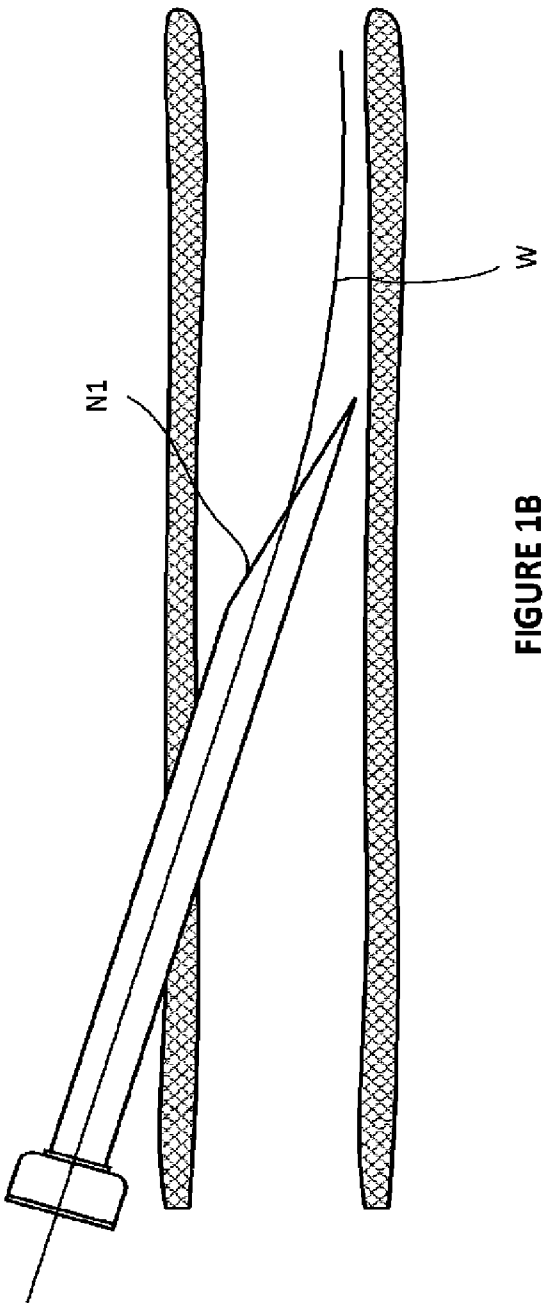

FIGURE 1B
PRIOR ART

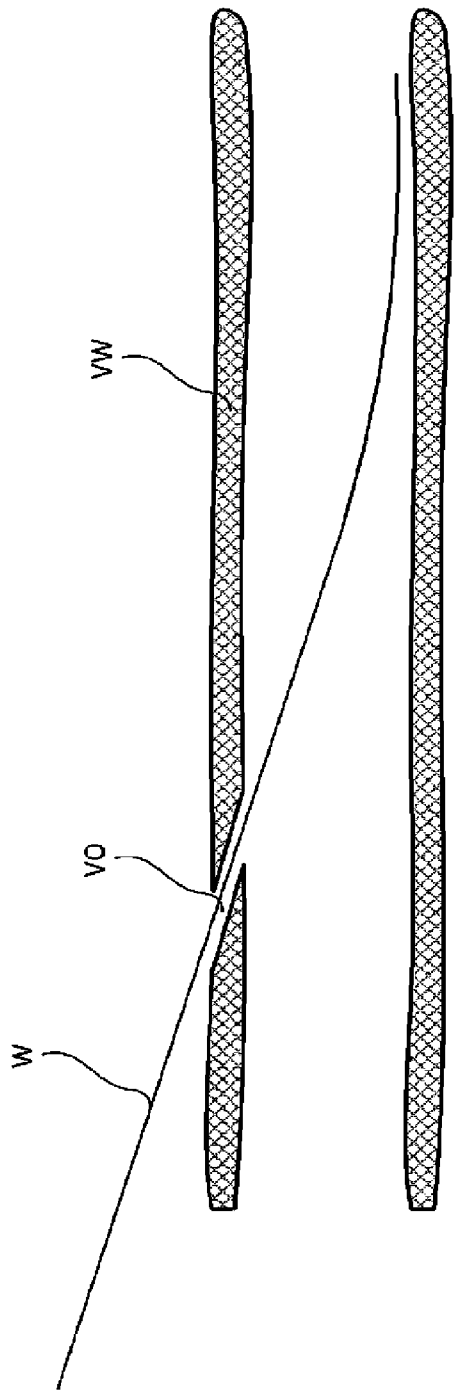

FIGURE 1C
PRIOR ART

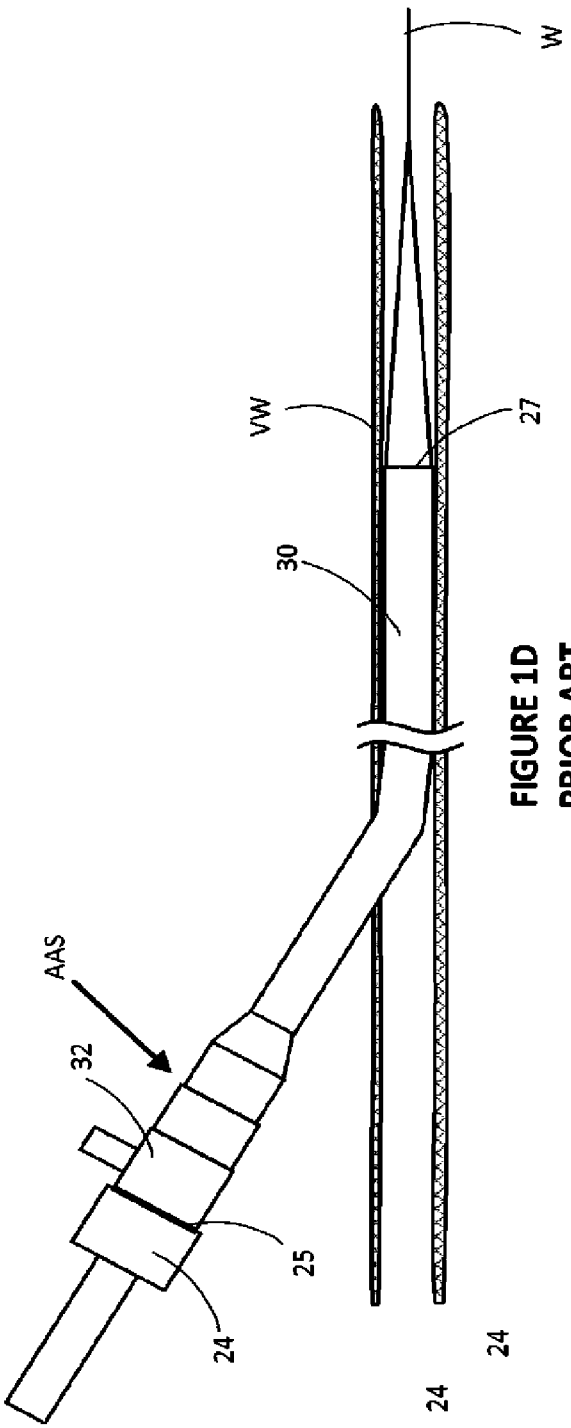

FIGURE 1D
PRIOR ART

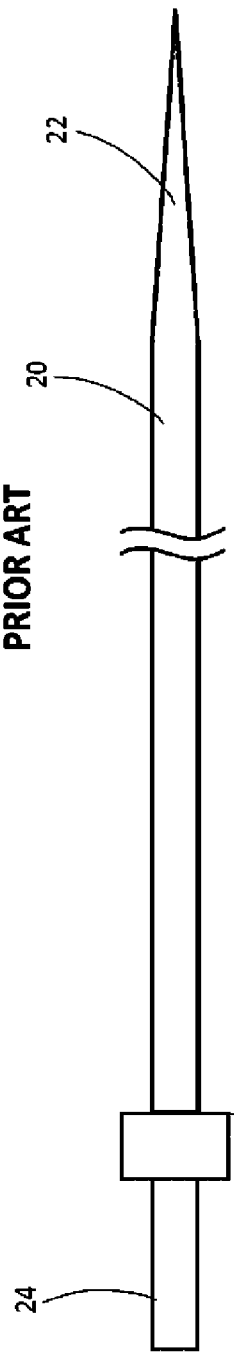

FIGURE 1E
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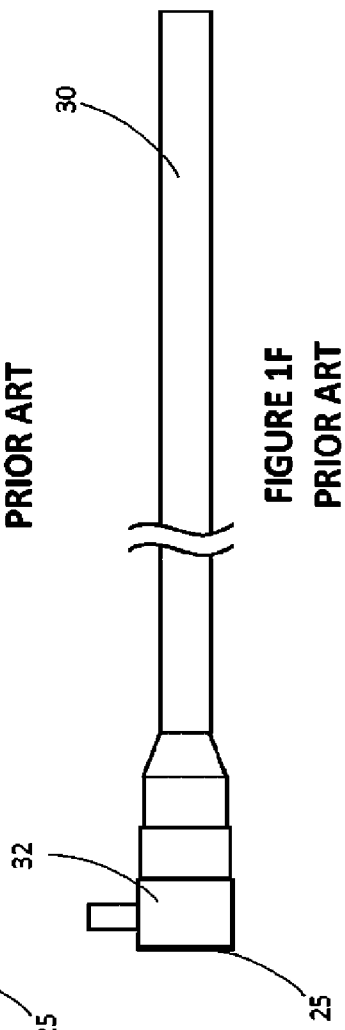

FIGURE 1F
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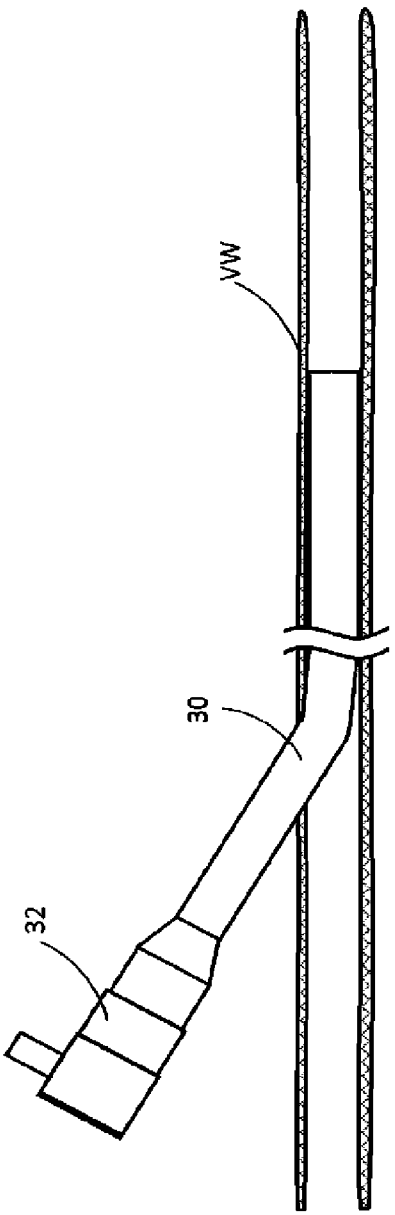


FIGURE 1G
PRIOR ART

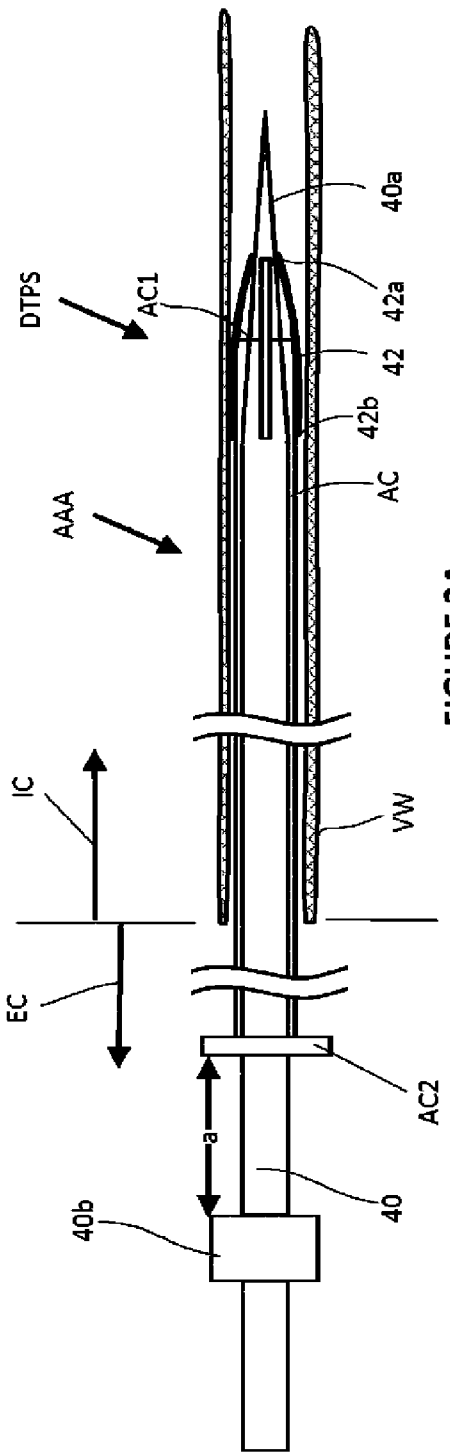


FIGURE 2A

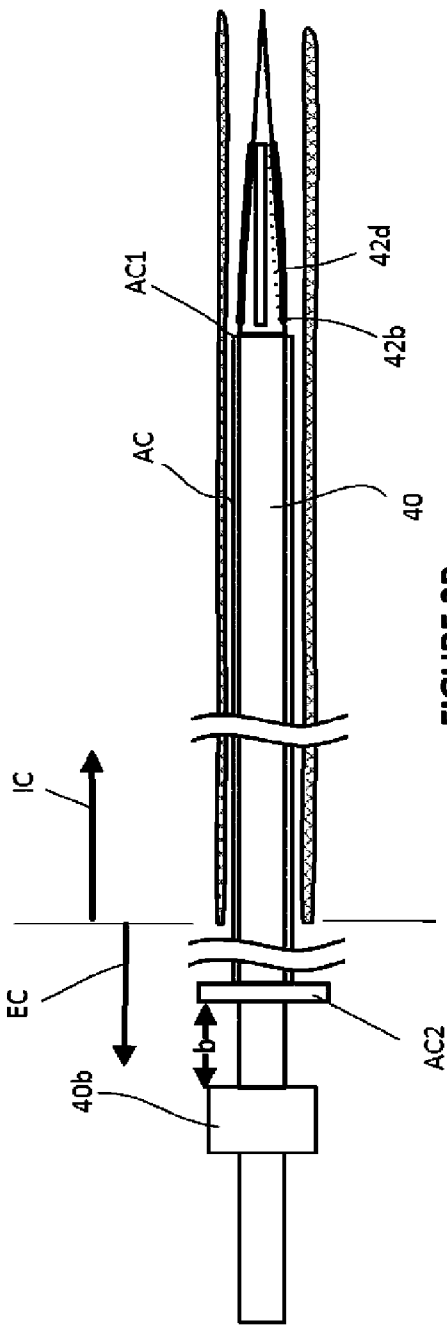


FIGURE 2B

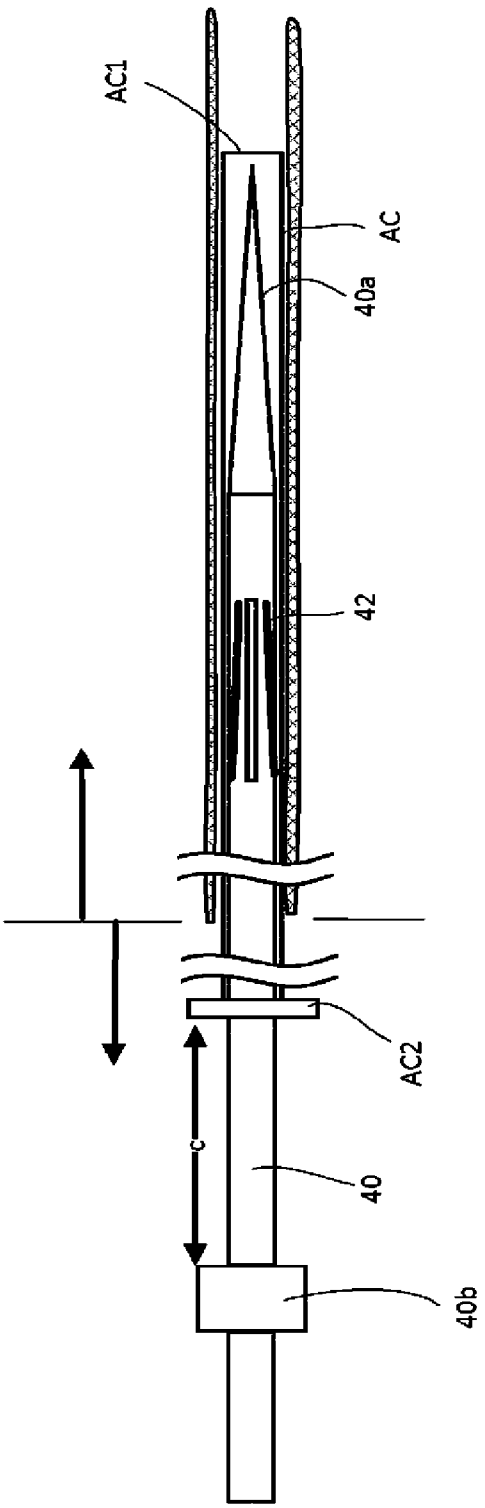


FIGURE 2C

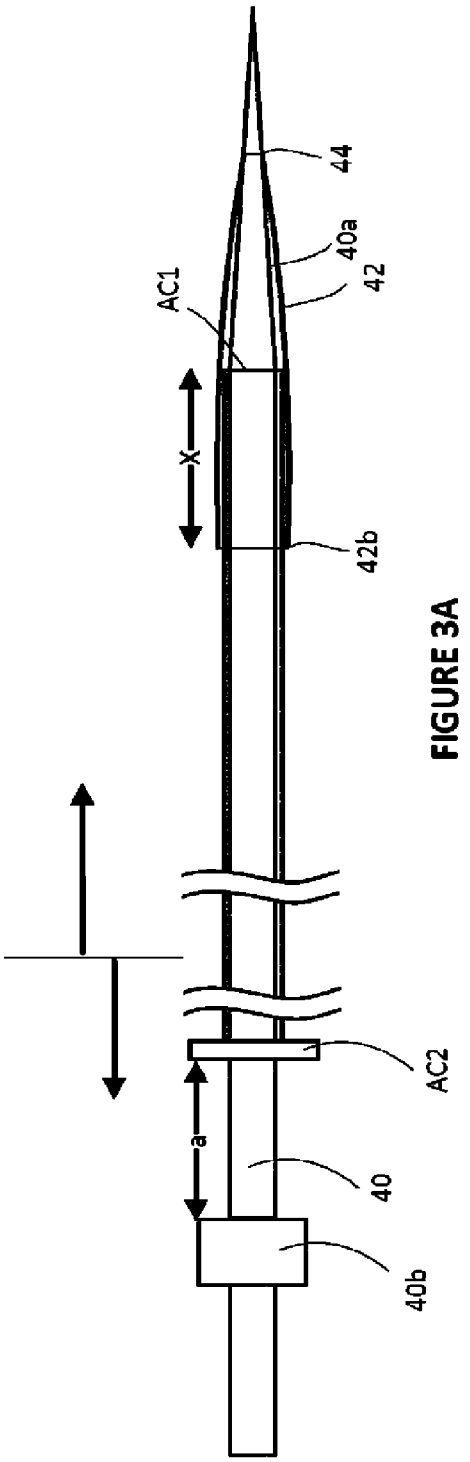


FIGURE 3A

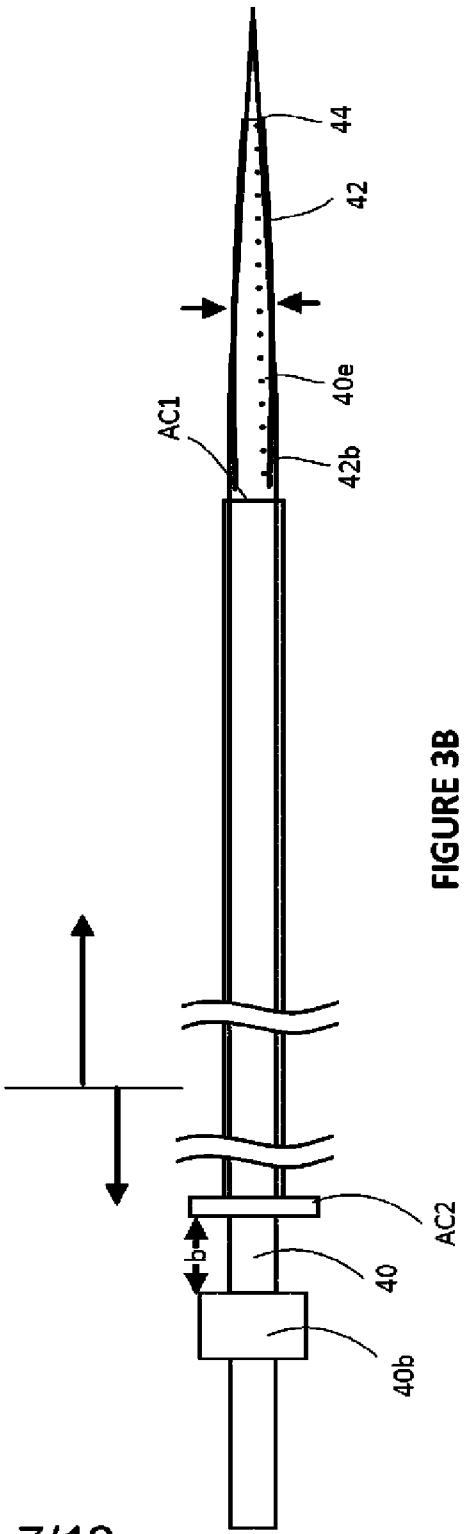


FIGURE 3B

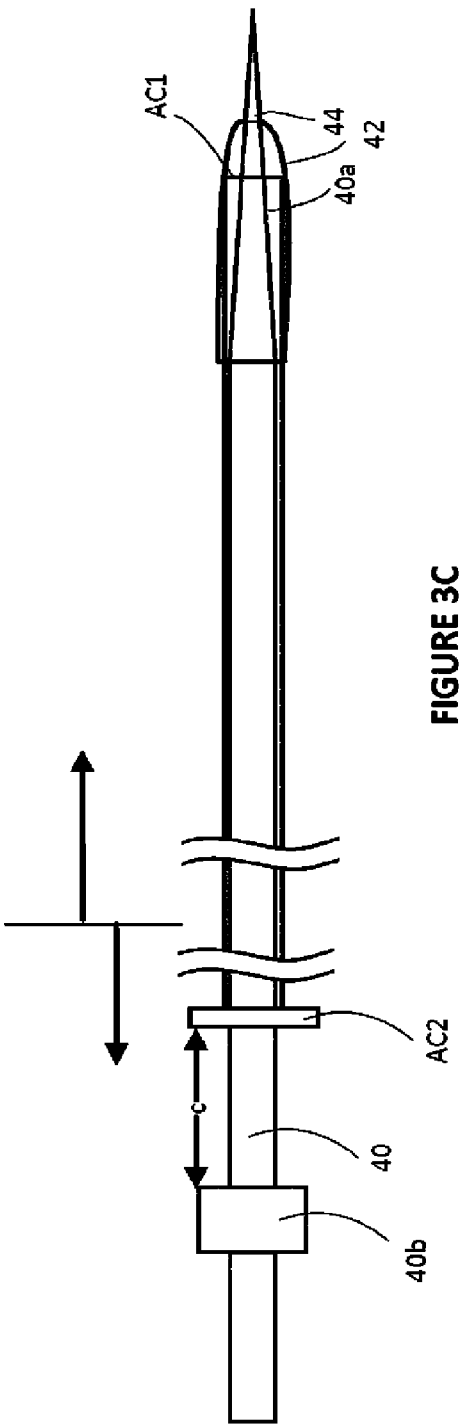


FIGURE 3C

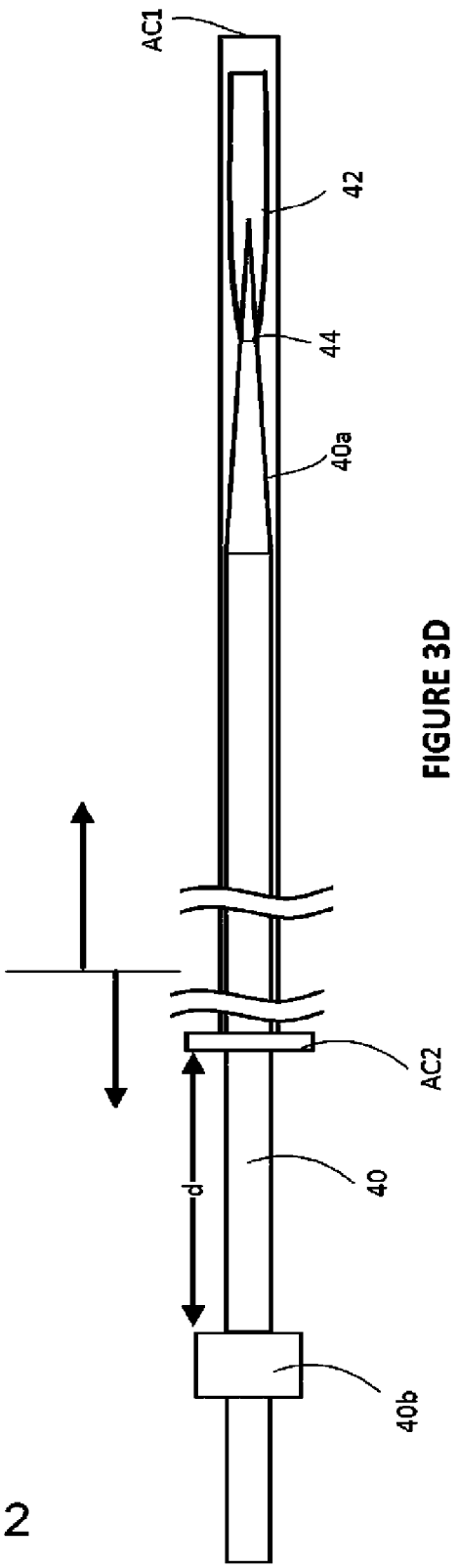
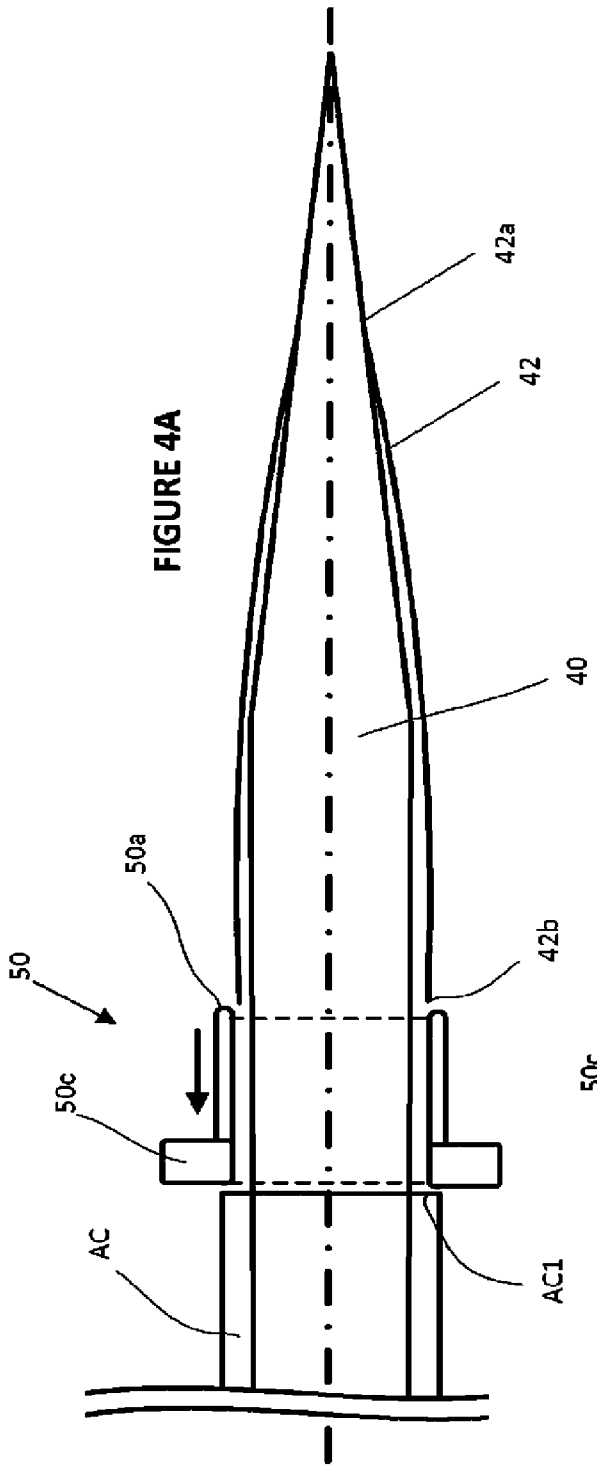


FIGURE 3D

FIGURE 4A



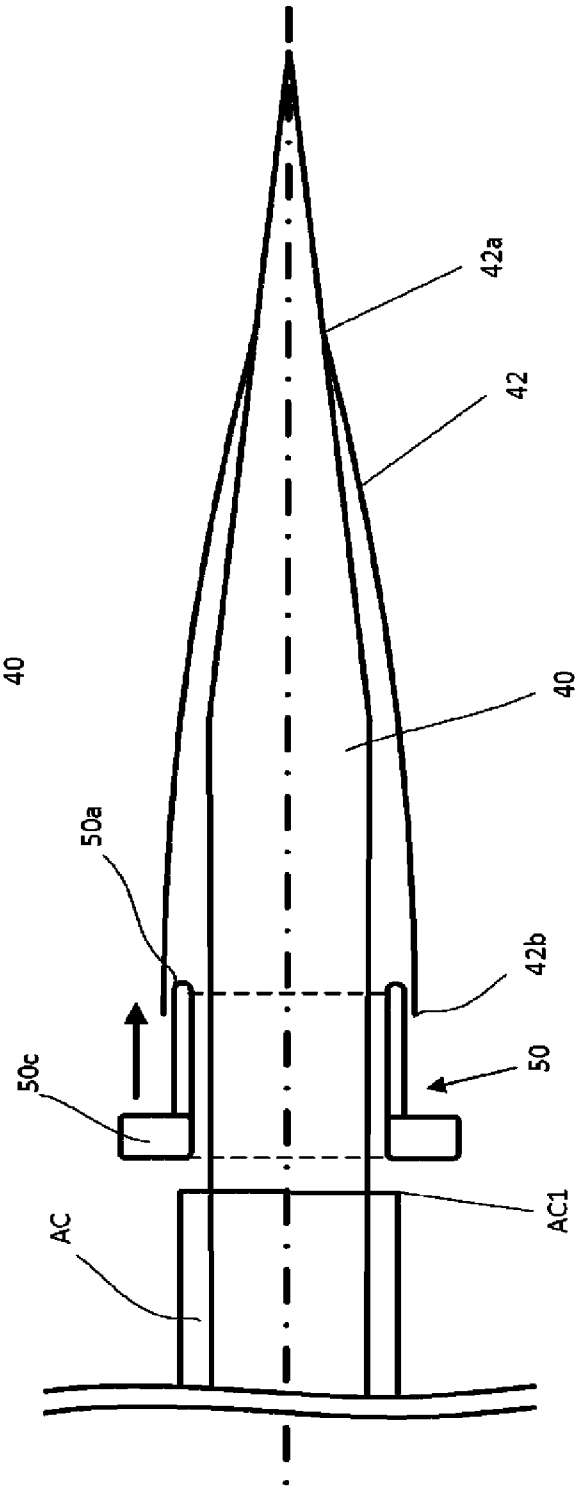


FIGURE 4B

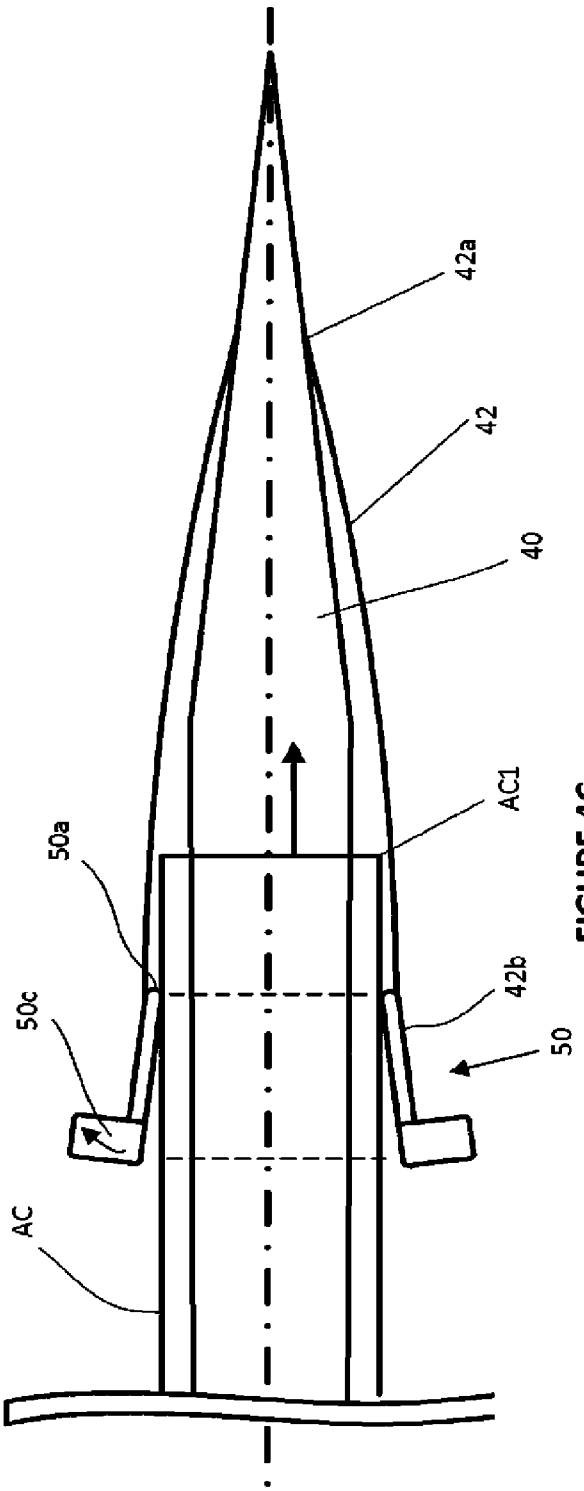


FIGURE 4C

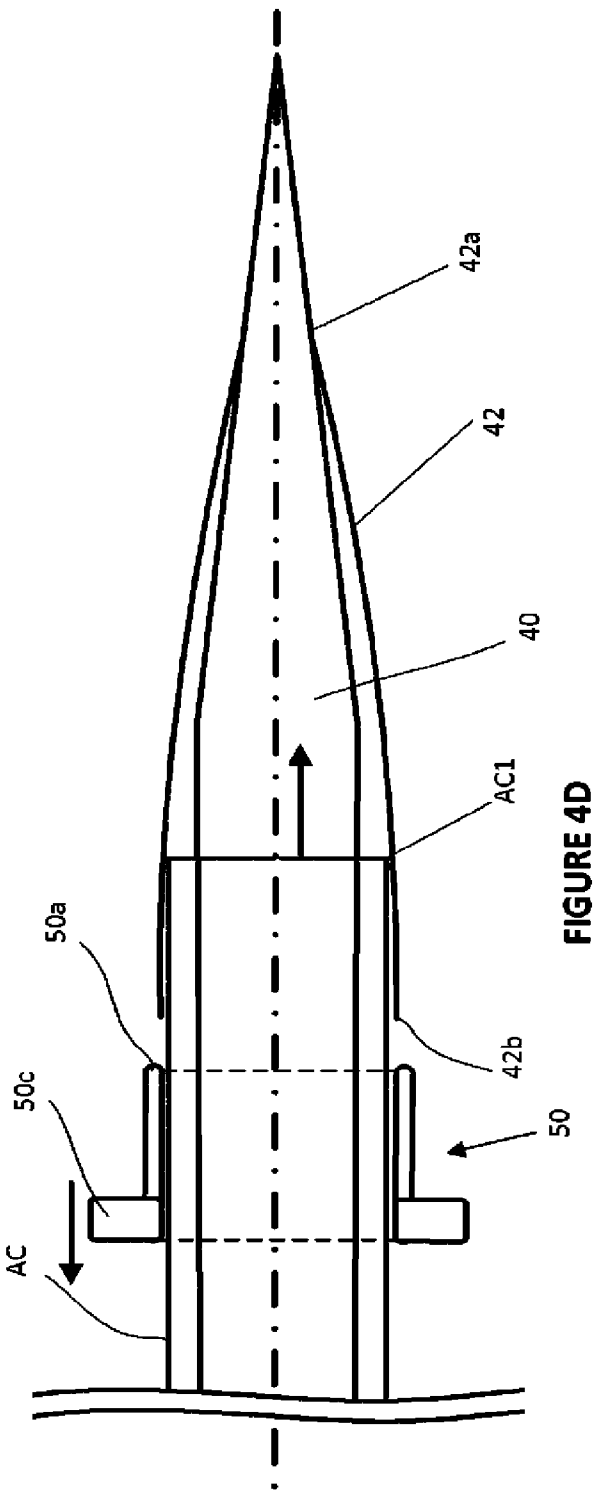


FIGURE 4D

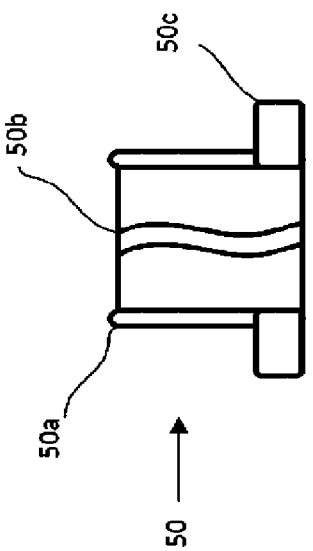


FIGURE 4F

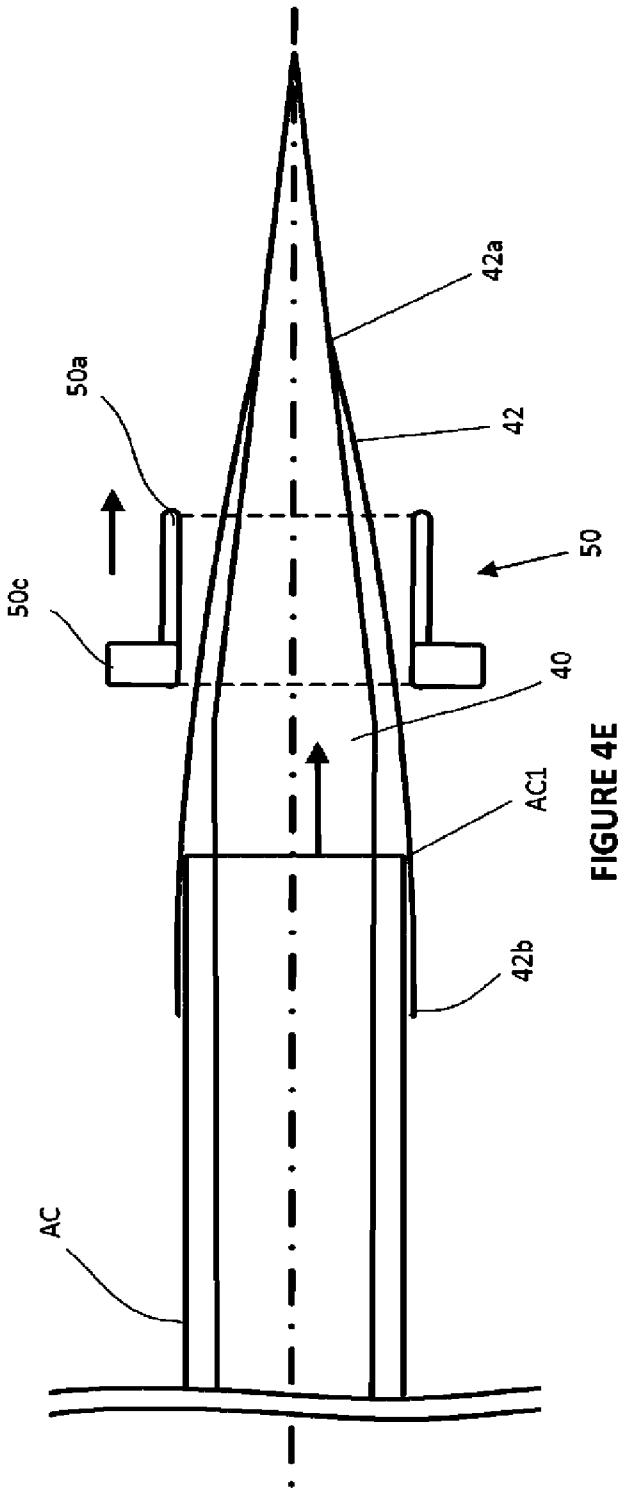


FIGURE 4E

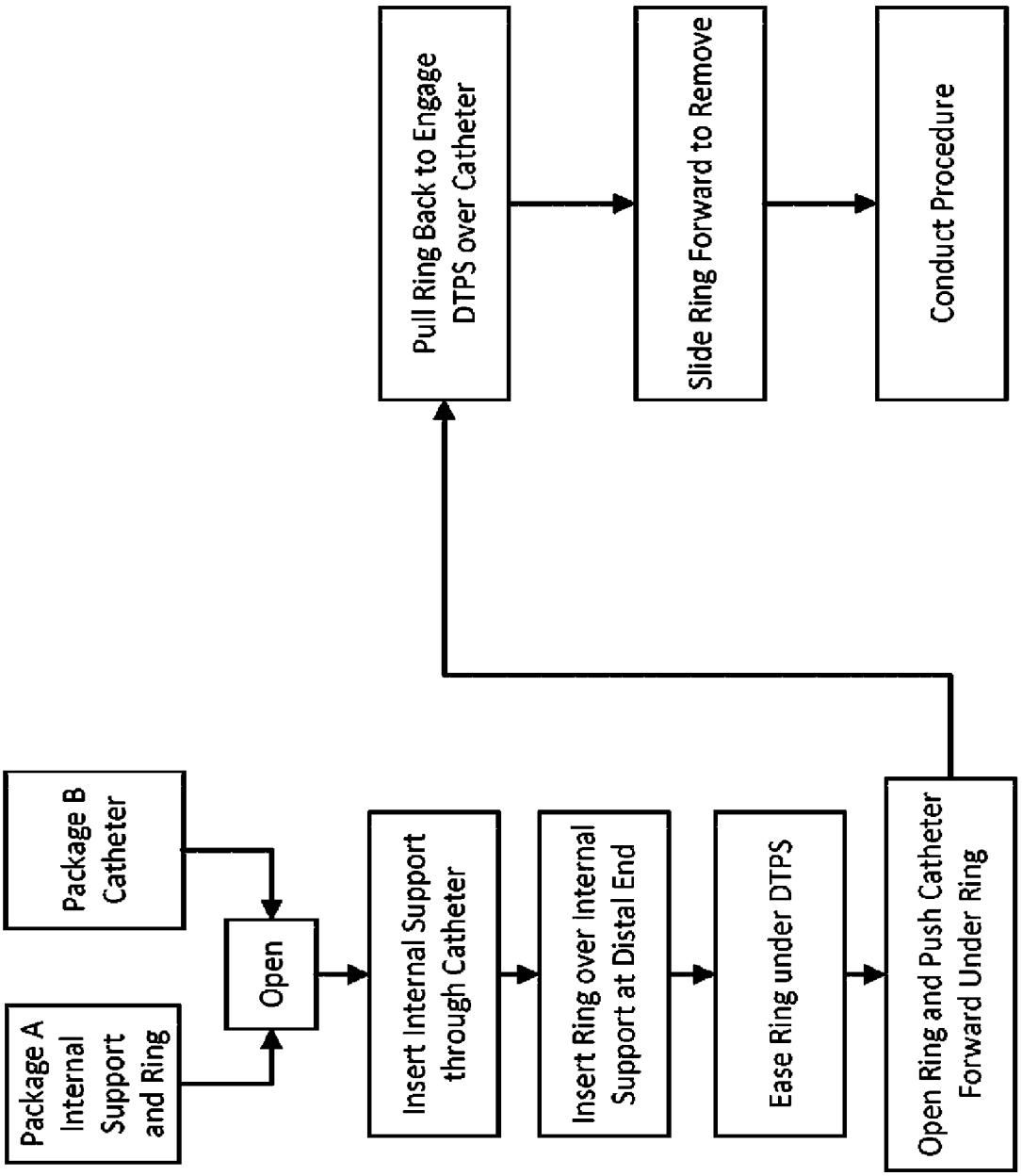


FIGURE 5

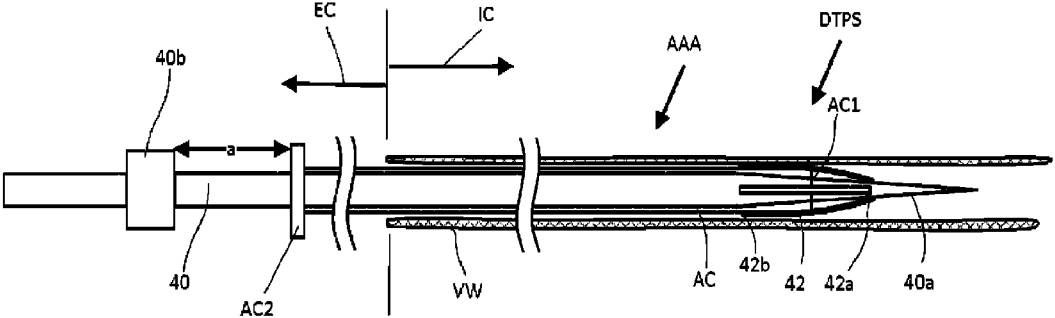


FIGURE 2A