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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 November 2014 (06.11.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/177935 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/IB2014/001564

(22) International Filing Date:
13 March 2014 (13.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/784,742 14 March 2013 (14.03.2013) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

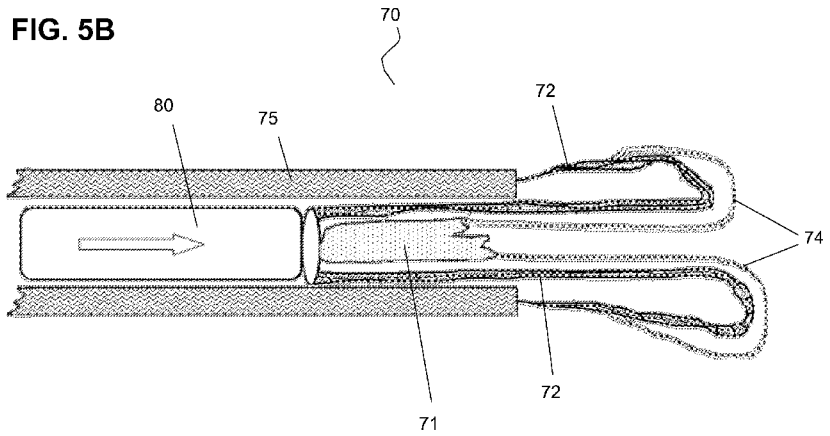
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

[Continued on next page]

(54) **Title**: TEMPORARY VALVE AND VALVE-FILTER

FIG. 5B



(57) **Abstract**: A temporary percutaneous valve-filter device having valve portions non-porous to blood and filter portions non-porous to emboli but at least in part porous to blood. In one embodiment, the device has a substantially flat valve unit and a substantially flat filter unit. In another embodiment, the device has at least one open umbrella deployed configuration. In one aspect, the device has a unitary construction with one umbrella canopy with one or more filter areas with flaps allowing unidirectional blood flow. In another aspect, the device has a valve unit and filter unit, the umbrella canopies oriented in opposite directions, and the valve unit "closes" and opens to allow blood to flow to one direction. Also provided is a temporary valve system, including a core having an inverted delivery configuration and everted deployed configuration, that may be used with or without a filter unit, and a method of deployment.

WO 2014/177935 A2

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

TEMPORARY VALVE AND VALVE-FILTER

FIELD OF INVENTION

[001] The present invention relates to a temporary valve for maintaining normal blood flow and a temporary valve with embolic filter for maintaining normal blood flow while simultaneously trapping emboli during percutaneous cardiovascular procedures. The invention also relates to a system comprising such a valve or valve-filter device and a delivery device, and a method of deploying such a device.

BACKGROUND OF THE INVENTION

[002] Valves are important structures in the human heart because they maintain blood flow in a single direction with minimal pressure loss. However, human heart valves can degenerate for a variety of reasons. A malfunctioning heart valve may be stenotic, where the leaflets of the valve do not open fully, or it may be regurgitant, where the leaflets of the valve do not close properly, or a combination of both. Valve repair and replacement procedures have thus been developed to either restore the function of the native valves or to implant a permanent prosthetic valve with or without removal of the original native valve. The standard surgical procedure involves the opening of the patient's thoracic cavity, which is highly invasive and requires cardiopulmonary bypass and prolonged recovery time.

[003] Percutaneous valve repair and replacement procedures have been developed as cheaper and safer substitutes for the traditional open chest surgeries. Compared to traditional surgery, a percutaneous procedure is minimally invasive and it

eliminates the need for cardiopulmonary bypass. In the absence of cardiopulmonary bypass, the percutaneous procedure must take place quickly to restore normal circulation, because native valve function is interrupted during the repair or the positioning and implantation of the permanent prosthetic valve. A temporary valve is a useful correlate to maintain unidirectional blood flow during the percutaneous procedure and is particularly useful in conjunction with the deployment of modular percutaneous valve devices, which require assembly prior to implantation.

[004] Additionally, the manipulation of the delivery device, repair tools and/or valve device during a percutaneous valve repair or valve replacement procedure may dislodge tissue and/or tissue adherents such as calcium deposits and/or generate thrombi. This debris may form emboli that travel through the circulatory system and block smaller vessels, which can lead to severe complications, such as stroke, tissue ischemia or death. Consequently, it is desirable to have a filtering device to trap the emboli.

[005] Therefore, a need exists for a single device that can simultaneously address both problems in the art, more specifically, a device that can both maintain blood flow in a single direction and contain the movement of emboli during a percutaneous valve repair or replacement procedure is highly desirable.

SUMMARY OF THE INVENTION

[006] The present invention relates to a system and method of deploying a temporary valve having a filter to contain emboli for use during a percutaneous cardiovascular procedure. In particular, the invention provides a percutaneous

prosthetic valve-filter device, a system comprising such device, and a method of percutaneously delivering and deploying the device. The system and method may be especially useful in conjunction with percutaneous heart valve repair and replacement procedures.

[007] It is an object of the invention to provide a temporary percutaneous valve combined with an embolic protection feature – a valve-filter device, as either a unitary construction, where the valve and the embolic filter are integrated into a single unit, or as a multi-component construction, where the valve and the embolic filter functions are not integrated into a single unit, but are performed by two units that may be conjoined, overlapping or separate.

[008] In one embodiment of the single-unit device, the valve-filter device is impermeable to blood except at blood permeable areas, for example perforations. The blood permeable areas may include filter areas which have a porosity that is permeable to blood but impermeable to emboli, and flaps that cover the filter areas. The flaps that cover the blood permeable areas may open to allow blood to flow through the blood permeable areas, for example during systole, and close to prevent backflow of the blood through the blood permeable areas, for example during diastole.

[009] In the multi-unit temporary valve-filter device, the valve and filter functions are effected by two conjoined units, a valve unit and a filter unit. The filter unit may be made of a material permeable to blood but impermeable to emboli. The valve unit may be made of a non-porous pliable material. The valve unit and filter unit may be delivered in a closed or folded state, and after being deployed, both the valve unit and

filter unit may attain an open shape. In one embodiment, the deployed valve unit and filter unit may be substantially flat, and in one aspect disk-shaped, and in another embodiment the deployed valve unit and filter unit may be umbrella-shaped. The valve unit may be supported by a frame comprising a plurality of stiff struts or a ring. In one aspect of either embodiment, the filter unit and valve unit may be separated by a distance along a longitudinal axis. In some embodiments, the valve unit is made of a material sufficiently pliable to fold inwardly, for example in one aspect of one embodiment folding inward between struts, to allow blood flow during systole, and to expand outward to the vessel wall during diastole to prevent backflow. In one embodiment where the valve unit and filter unit are substantially flat, the valve unit – positioned on the distal side of the filter unit – moves away from the filter unit during systole to permit blood flow through a filter area on the filter unit, and overlaps, and thereby covers, the filter area on the filter unit during diastole to prevent backflow. In embodiments where the valve unit and filter unit have an open umbrella shape, each umbrella canopy having a convex surface and concave surface, in one aspect of the embodiment, the convex surfaces of the two canopies may face each other and in another aspect of the embodiment, the convex surfaces of the two canopies may face away from each other.

[010] It is also an object of the invention to provide a temporary percutaneous valve system that may be used with or without a filter unit, which provides a unique method of deploying the valve. In this embodiment the temporary valve system may include a jellyfish-shaped valve and a tubular central core attached to a sheath, for example, an introducer sheath. The valve and central core are folded in an inverted

manner within the sheath in a delivery configuration and are deployed by everting the valve and central core using a pusher. The temporary valve system may be used with or without a filter element. The system is designed to accommodate the use of a catheter for delivering a permanent prosthetic valve when the temporary valve device is used in a valve replacement procedure, or for delivering a repair tool when the temporary valve device is used in a valve repair procedure.

[011] Yet another object of the invention provides a system comprising a temporary valve-filter device mounted on a delivery device. One embodiment of the valve filter system comprises the temporary valve-filter device and a delivery device, such as a catheter, which delivers the device to the target site of a blood vessel. The valve-filter device has a delivery configuration, for example folded or closed, to minimize the delivery diameter. The valve-filter device may be delivered in or on the delivery device in a radially collapsed delivery configuration, and deployed to a radially expanded working configuration. The system is designed to accommodate the use of a catheter for delivering a permanent prosthetic valve when the valve-filter device is used in a valve replacement procedure, or for delivering a repair tool when the valve-filter device is used in a valve repair procedure. When the temporary valve is no longer needed, the valve-filter device may be removed along with the entrapped emboli.

[012] It is a further object of the invention to provide a method of deploying a temporary percutaneous valve-filter device, comprising: introducing into a vessel, a system comprising a valve-filter device mounted on a first delivery device having a lumen, said valve-filter device designed for simultaneously regulating flow of blood and collecting emboli; said valve-filter device having a rim, a center, a closed shape in a

delivery configuration, and an open shape in a deployed working configuration, said first delivery device extending through and attached to said center; advancing said valve-filter device to a target site; deploying said valve-filter device from the delivery device; and expanding radially said valve-filter device to said working configuration. The method may include deploying the valve unit and filter unit together or separately. In one embodiment, the above methods are used to deploy a valve-filter device that is a unitary device, i.e., the valve and the embolic filter functions are integrated into a single unit or structure. In another embodiment, the above methods are used to deploy a valve-filter device, where the valve and the embolic filter functions are not integrated into a single unit, but are distinct units that may be connected, conjoined, overlapping or physically separated, i.e., a multi-unit device.

[013] In yet another embodiment, the above method further includes deploying a second delivery device, which may be extended through the valve-filter device to a vessel region distal of the deployed valve-filter for implantation of a percutaneous prosthetic valve or repair of the native valve: that is, the temporary valve-filter device may be mounted on a first delivery device having a lumen of sufficiently large internal diameter for a second delivery device to pass therethrough. In one aspect, the second delivery device is used to deliver a percutaneous valve device for permanent implantation. The method of deployment includes after said expanding step and before said collapsing step: extending said second delivery device through the center portion of said valve-filter device; deploying and implanting said percutaneous valve device; and retracting said second delivery device. In another aspect, second delivery device is used to deliver a percutaneous valve repair tool, such as, for example, a balloon used

for balloon valvuloplasty. The method of deployment includes after said expanding step and before said collapsing step: extending said second delivery device through the center portion of said valve-filter device; deploying said valve repair tool and repairing a native valve; retracting said repair tool; and retracting said second delivery device.

[014] It is a further object of the invention to provide a method of deploying a percutaneous temporary valve device. In one embodiment, the method includes providing a temporary valve device system comprising a temporary valve, a central core, lines connecting the rim of the temporary valve to the central core, and a sheath, where the temporary valve, lines and central core are folded and contained within the sheath for delivery, in an inverted configuration; pushing the central core out of the sheath using a pusher thereby inverting the central core to a deployed configuration and releasing the valve from the sheath to an open configuration. In one aspect of this embodiment, a filter unit is also deployed for use with the temporary valve device.

[015] In yet another embodiment, the above method further include deploying a delivery device, which may be extended through the central core and valve device to a vessel region distal of the deployed valve for implantation of a percutaneous prosthetic valve or repair of the native valve: that is, the temporary valve device and central core may be mounted on a sheath having a lumen of sufficiently large internal diameter for a delivery device such as a catheter to pass therethrough. In one aspect, the delivery device is used to deliver a percutaneous valve device for permanent implantation. The method of deployment includes after said expanding step and before said collapsing step: extending said delivery device through the center portion of said valve and central core; deploying and implanting said percutaneous valve device; and retracting said

delivery device. In another aspect, the delivery device is used to deliver a percutaneous valve repair tool, such as, for example, a balloon used for balloon valvuloplasty. The method of deployment includes after said expanding step and before said collapsing step: extending said second delivery device through the center portion of said valve and central core; deploying said valve repair tool and repairing a native valve; retracting said repair tool; and retracting said delivery device.

[016] Advantages that may be achieved by the present invention include combined maintenance of blood flow and minimization of emboli in the blood stream requiring deployment of a single device. The installation of the percutaneous temporary valve-filter before commencing percutaneous vascular procedures, such as implanting a permanent percutaneous prosthetic device or repairing a native valve, may alleviate the time pressure for such further procedures by preventing wide open regurgitation of blood. In other words, the temporary valve or temporary valve-filter device of the invention permits stabilization of the system during a valve replacement or valve repair procedure. For example, when used during replacement with a modular percutaneous valve device, the temporary valve provides sufficient time to deploy and dock the valve modules into the modular frame. The embolic filter function of the temporary valve-filter of the invention minimizes the escape of emboli that may be generated during a percutaneous procedure thereby avoiding embolic blockage of the blood vessels. As such, the valve-filter device of the invention may improve the safety and outcome of percutaneous cardiovascular procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

[017] FIG. 1 illustrates an embodiment of the temporary valve-filter device having unitary construction after deployment at the target site of a blood vessel.

[018] FIG. 1A is an enlarged view of the circled area of FIG. 1, which depicts a filter area.

[019] FIG. 2 illustrates a multi-unit embodiment of the valve-filter device with convex-facing valve unit and filter unit canopies, deployed at a target site of a blood vessel, and one aspect of a valve unit of this embodiment.

[020] FIG. 2A illustrates another aspect of a valve unit of the multi-unit convex-facing embodiment of FIG. 2.

[021] FIG. 3 illustrates a multi-unit embodiment of the valve-filter device with concave-facing valve unit and filter unit canopies, deployed at the target site of a blood vessel.

[022] FIG. 4A illustrates one embodiment of the percutaneous substantially flat valve-filter device during diastole.

[023] FIG. 4B illustrates the embodiment of FIG. 4A during systole.

[024] FIG. 4C illustrates another embodiment of the percutaneous substantially flat valve filter device of the invention during diastole.

[025] FIG. 4D illustrates another embodiment of the percutaneous substantially flat valve filter device of the invention during systole.

[026] FIGS. 5A-C illustrate an embodiment of the percutaneous temporary valve system of the invention and a method of deploying the valve in cut-away views. FIG. 5A depicts the folded state; FIG. 5B depicts deployment; FIG. 5C depicts the deployed state.

[027] FIG. 6 illustrates the percutaneous temporary valve of FIGS. 5A-C fully deployed with an optional filter unit in a cut-away view.

DETAILED DESCRIPTION OF THE INVENTION

[028] The present invention provides a percutaneous temporary valve-filter device and systems and methods for deploying the valve-filter device, for example in a blood vessel. The invention also provides a percutaneous temporary valve system and a method of deploying the temporary valve. The temporary valve system may be used with or without a filter unit.

[029] The percutaneous temporary valve-filter device may be an integrated, or unitary, device – a device comprising one unit providing both valve and filtering functions, or it may be a multi-unit device comprising a valve unit and a filter unit that are separated or conjoined. In accordance with the invention, the percutaneous temporary valve filter device may have a variety of shapes from, for example, umbrella shaped to substantially flat. A substantially flat valve filter device may be, for example, disk shaped. The portion of the device that serves as valve is not porous to blood. The portion of the device that serves as a filter is not porous to emboli but is at least in part porous to blood. A suitable pore size for the blood-porous part of the filter portion may

be in a range of, for example, 10-200 microns, 50-500 microns, 80-250 microns, 80-200 microns, or 100-200 microns.

[030] In one embodiment of the invention the valve-filter device includes a substantially flat valve unit and a substantially flat filter unit. Each of the valve unit and filter unit may be shaped, for example, like disks – a first disk and second disk. In one aspect of the embodiment, the first and second disks are adjacent to one another, for example, overlapping. In one aspect, the first and second disks are connected at a center point, which may be a location where the first and second disks are attached to a delivery device. In another aspect of the embodiment, the first disk and second disk are separated by a distance along a longitudinal axis, which may be defined by the delivery device to which the first and second disks may be attached. In one embodiment, the second disk – the filter unit – is proximal of the first disk – the valve unit, i.e., the second disk is located at a point on the delivery device distal of the first disk.

[031] In another embodiment, the single unit valve-filter device has the shape of an open umbrella after being deployed at the target site, with a canopy having a concave surface and a convex surface. The concave surface of the umbrella canopy faces the heart, i.e., with respect to blood flow, the concave surface faces upstream. The concave shape may provide a collection field to trap and contain emboli. The valve-filter device is made from material non-porous to blood, with the exception of one or more filter areas. The filter areas comprise areas having a pore size large enough to allow blood flow but small enough to block emboli. To prevent backflow of blood during diastole, each filter area has a corresponding flap on the convex surface of the canopy, *i.e.*, the downstream side of the device when deployed. The flaps open during systole,

when the heart pumps blood to the aorta, so that blood can pass through the filter areas, and they close during diastole, between pulses to prevent backflow of blood through the filter areas. The flaps may be attached in any number of ways that are within the skill in the art, for example by a hinge on one side, by connection at the center of a membrane covering the hole, or by being an integral piece the canopy partially cut away to reveal a layer of membrane as described in more detail below.

[032] In yet another embodiment of the invention, the valve-filter device is a multi-unit device that has a valve unit and a filter unit which are joined. Each of the valve unit and filter unit has the shape of an umbrella, each umbrella having a canopy with a concave surface and a convex surface. The valve unit and the filter unit may be comparable in size, however their canopies are oriented in opposite directions. The canopy of the deployed filter unit is oriented so that the concave surface of the canopy faces upstream, e.g., towards the heart. The filter unit canopy comprises a filter area which may include a permeable membrane or a woven structure that allows blood to flow through but blocks emboli. The rim of the filter unit canopy preferably may form an emboli-excluding seal against the vessel wall when deployed. The canopy of the deployed valve unit is oriented so that the convex surface faces upstream, at least during diastole. The canopy of the valve unit is made of pliable material and it may be supported by a plurality of stiff struts, for example three struts. Alternatively, the canopy of the valve unit may have no struts, and operate in a manner similar to a jellyfish, as described below for the temporary valve system. During diastole, the pliable canopy of the valve unit expands to an open umbrella shape to prevent backflow. During systole, the valve unit canopy folds inward, for example between the struts, to allow blood to

flow through. In one aspect of this embodiment, the concave surface of the valve unit canopy and that of the filter unit face away from each other (convex-facing). In another aspect of this embodiment, the concave surface of the valve unit canopy and that of the filter unit canopy face each other (concave-facing).

[033] The percutaneous temporary valve system includes a valve, a valve backbone – for example, a central core, a plurality of lines connecting the valve to the backbone – for example, connecting the rim of the valve to the central core, and a sheath which may constrain the central core, the valve and the plurality of lines for delivery. The central core is folded back upon itself so as to be inverted, and may be deployed by pushing with a pusher to evert the central core to its deployed configuration.

[034] The percutaneous temporary valve preferably is flexible and jellyfish-shaped, attached by lines to the tubular central core which likewise is flexible but stiffer than the valve. The central core may serve to hold the center of the jellyfish valve in a steady proximal – i.e., upstream – position during systole and diastole, while the body of the valve opens during diastole and closes during systole, the lines restrain the body of the valve to prevent it from inverting during diastole. The central core may be a braid or a mesh, for example made of metal or fabric, or any biocompatible material that is highly flexible so that it can invert on itself. The valve and central core have an inverted delivery configuration, and are housed for delivery in a sheath, for example, an introducer sheath. The valve and central core have an everted deployed configuration, and the components may be deployed using a pusher contained within the sheath and proximal of the valve device; pushing the pusher causes the components to be everted

and ejected from the sheath in which they are delivered. The percutaneous temporary valve system of the invention may be used with or without a filter unit. The percutaneous temporary valve system of the invention is particularly useful in conjunction with percutaneous valve replacements, especially with percutaneous modular valves which require assembly in situ, as described in detail in pending US published application nos. 2010/0185275 and 2011/0172784.

[035] The aforementioned embodiments, as well as other embodiments, are discussed and explained below with reference to the accompanying drawings. Note that the drawings are provided as an exemplary understanding of the present invention and to schematically illustrate particular embodiments of the present invention. The skilled artisan will readily recognize other similar examples equally within the scope of the invention. The drawings are not intended to limit the scope of the present invention as defined in the appended claims.

[036] **FIG. 1** schematically illustrates an embodiment of a single-unit percutaneous temporary valve-filter device of the invention, where the device comprises an integrated valve-filter **30** having a canopy **31** with a concave surface, a convex surface and one or more filter areas **32**. Valve-filter **30** is shown in its expanded working configuration in **FIG. 1**, in which it has the shape of an open umbrella and the concave surface of the canopy **31** faces the heart. In one aspect of this embodiment, the rim of the canopy **31** includes a ring **33**. Ring **33** may be radially compressed into a roughly round structure with a small diameter for delivery thereby maintaining valve-filter **30** in a delivery configuration. Upon placement at the target site, ring **33** may be made to fully expand so that the valve-filter **30** assumes a working configuration. Ring **33** may

be made of materials commonly used for the foldable scaffold of percutaneous prosthetic devices, for example Nitinol, stainless steel, cobalt chromium, or other biocompatible materials, for example a plastic. Ring **33** may contain flex points or kink points to assist folding or radial compression. Alternatively, ring **33** may be made of shape memory material that has radially compressed configuration for delivery, and a pre-set expanded configuration. The pre-set configuration may be thermo-mechanically set to permit body temperature trigger reversion to the pre-set configuration. In one aspect, when fully expanded, the ring **33** may achieve a diameter that allows close contact with the aorta wall **16** without applying undue pressure, thereby "sealing" the rim of valve-filter **30** against aorta wall **16** so as not to allow debris to pass around valve-filter **30**. In another aspect of this embodiment the canopy rim has no ring, and the canopy material itself maintains the shape of the canopy.

[037] Canopy **31** is made of a material non-porous to blood, with the exception of a plurality of filter areas **32**, discussed below. The material for canopy **31** is substantially stiff to keep valve-filter **30** in the umbrella shape, but it is also pliable enough to conform with the bending of the aortic arch and to be folded into the delivery configuration. Material for canopy **31** may be a fabric, polymer, tissue, or other material. Non-limiting examples of suitable fabrics include polyethylene terephthalate (PET), polytetrafluorethylene (PTFE), and polypropylene. Non-limiting examples of suitable polymers include polyether block amides such as PEBAX (Arkema S.A.), silicone polycarbonate urethane, polyurethane, silicone, nylon, and PET. Non-limiting examples of suitable tissues include bovine pericardium, porcine pericardium, and comparable

minimally immunogenic tissues. Canopy **31** may further contain ribs or struts (not shown) to support the umbrella shape.

[038] Filter areas **32** are blood permeable regions of the canopy **31**, i.e., they have a porosity or pore size large enough to allow blood flow but small enough to block emboli. For example, a pore size of between 10-200 microns, 50-500 microns, 80-250 microns, 80-200 microns, or 100-200 microns may be suitable. Filter areas **32** may vary in number, shape and size to achieve the most effective passage of blood. Filter areas **32** may have any geometric shape, for example, oval as depicted schematically in **FIGS. 1** and **1A**, or round or rectangular. The number of filter areas **32** in canopy **31** may vary depending on the embodiment. For example, the canopy **31** may have 1-30 filter areas, or 1-10 filter areas, or 1-5 filter areas, in particular, 1 or 2 or 3 filter areas. A filter area **32** may comprise a permeable membrane. Filter areas **32** may include flaps **35**, hingedly attached to the canopy **31**. Flaps **35** may be in the same shape as filter areas **32** or they may have a different shape. Preferably, each flap **35** has about the same or slightly bigger area as the corresponding filter area **32**, so as to cover the filter area when it closes.

[039] The filter areas **32** may be manufactured from the same material as the canopy **31**, but modified to be porous. Alternatively, the filter areas may be made a material different than that of the canopy. To manufacture filter areas **32**, perforations can be made in canopy **31** by a mechanical method, for example by laser drilling or hole-punching, or by chemical reaction, depending on the material of canopy **31**. In one embodiment, a filter areas **32** may be a modified regions of the canopy **31** where micropores are created, and then flaps **35** are attached. In another embodiment, a

blood permeable membranes may be attached to canopy **31** to cover holes in the canopy to form the filter areas **32**. Permeable membrane may be attached to the canopy **31** by methods known in the art appropriate for the materials used, for example, with adhesives, by thermal bonding, or through conventional mechanical fixtures. The flaps **35** may be hingedly attached to the canopy **31**. In one embodiment, the attachment point for the flap **35** may be a hinge **36** that is a physical structure made of metal or plastic. Hinges **36** together with flaps **35** may be attached to the convex surface of canopy **31** by methods within the skill in the art, for example using adhesives, by thermal bonding, or through conventional physical fixtures. In an alternative embodiment, filter areas **32** may be made by partially cutting out shapes of the material of the canopy **31**, creating flaps **35** made of the canopy material, with the portion of the flap **35** material remaining attached to the canopy **31**, forming the hinge **36**, and permeable membrane may be attached to the canopy **31** at the filter areas **32**. By "hinge" or "hingedly" is meant, for example, a jointed or flexible attachment, serving as a pivot or fulcrum, such that the flap 35 may move about a transverse axis, like a swinging door or a bivalve shell. Permeable membrane material may be attached to the concave surface of the canopy **31** to cover the cut away portion of the canopy **31** thereby forming the filter area **32**.

[040] With reference to the particular embodiment depicted in **FIG. 1**, canopy **31** of valve-filter **30** may include a plurality of filter areas **32**. On the convex surface of the canopy **31**, *i.e.*, the downstream side of the deployed device, each filter area **32** has a corresponding flap **35** connected to the filter area **32** by a hinge **36**. During systole the pulse of blood (shown in **FIG. 1** by arrows) permits the flaps **35** to open allowing blood

but not emboli to pass through the filter area **32**. During diastole, the flaps **35** close preventing back flow of the blood through the filter areas **32**, e.g., towards the heart. **Fig. 1** depicts a high density of filter areas **32**, however it is contemplated that 2 or 3 such filter areas **32** with hinged flaps **35**, or one large filter area, may also be suitable. The flaps **35** may be made of a pliable material that is not permeable to emboli. Non-limiting examples of the material for these pliable flaps may include fabric, polymer, tissue, or other material.

[041] **FIG. 1A** schematically illustrates a close-up view of one embodiment of a filter area **32** of the embodiment of **FIG. 1**. As noted above, each filter area **32** may include a membrane that is porous to blood but substantially blocks emboli. Non-limiting examples of suitable membrane material include materials similar to those useful for the canopy **31** but made porous, weaves, and meshes including metallic mesh. The permeable membranes may have a pore size of, for example, about 10 μm to about 2000 μm diameter, or from about 50 μm to about 500 μm diameter, or from about 80 μm to about 200 μm diameter. Each filter area **32** has a corresponding flap **35** on the convex surface of canopy **31** and flap **35** is connected to the canopy surface via a hinge **36**. Flap **35** may be made of the same material as canopy **31**; or it may be made of other suitable material non-porous to blood. Flap **35** opens during systole to allow blood flow through filter area **32** in the direction away from the heart, and closes during diastole to prevent blood from flowing through filter area **32** in the reverse direction. Hinge **36** may be a passive structure, located on the convex side of the canopy **31**, i.e., the side facing away from the heart, or downstream along the artery. In this way, flap **35** serves the valve function of the device. Backflow of blood during

diastole closes the flaps **35** thereby limiting blood flow to a direction away from the heart.

[042] **FIG. 1** further shows a catheter **20** extending through the apex **38** of canopy **31**, with the distal end of the catheter extending distal of ring **33**. With respect to the catheter, the term "distal" refers to the direction closer to the heart, or upstream along the artery. Catheter **20** may deliver a permanent valve or a valve repair tool to the site distal of valve-filter **30**. The apex **38** of canopy **31** is preferably attached to the catheter **20**. The canopy may be attached to the catheter or delivery device **20** by means known in the art, for example, by gluing or bonding, e.g., thermal bonding.

[043] Percutaneous temporary valve-filter **30** preferably is deployed in the aorta **10** between the sinotubular junction **11** and branching point of the right brachial artery **12**, which is close to the aortic valve to be replaced, as illustrated in **FIG. 1**, so that debris generated by the replacement or repair can be effectively caught before entering arteries in the brachial arch. Alternatively, the temporary valve-filter device may be placed between the right brachial artery **12** and the left common carotid artery **13**, or between the left common carotid artery **13** and the left subclavian artery **14**, or further "down-stream". The more distal the position of the device relative to the sinotubular junction **11** – specifically beyond right brachial artery **12** – the greater the sacrifice of function, i.e., progressively decreasing effectiveness of trapping emboli before they enter one or more arteries.

[044] **FIGS. 2** , **2A**, and **3** illustrate two embodiments of a multi-unit valve-filter device **130**, **131** having a valve unit **140, 240** and a filter unit **150**, **250**, which are joined.

Each valve unit **140, 240** has a valve canopy **141**, **241**, and each filter unit **150**, **250** has a filter canopy **151**, **251**. When the valve-filter device **130**, **230** is deployed, the valve unit **140, 240** adopts a working configuration in which the valve unit valve canopy **141**, **241** has concave surface facing away from the heart and the filter unit **150**, **250** adopts a working configuration in which the filter canopy **151**, **251** has a concave surface facing toward the heart. The valve canopy **141**, **241** is made of a pliable material that is not porous to blood, which material expands into an open umbrella shape during diastole to prevent backflow of blood towards the heart. For example, the valve canopy **141**, **241** is sufficiently flexible such that during systole (not depicted), the flow of blood causes at least a portion of the valve canopy **141**, **241** to bend radially inward to permit blood to flow downstream away from the heart. Non-limiting examples of materials for valve canopy **141**, **241** include fabric, polymer, tissue, or other material as discussed above for canopy **31** of **FIG. 1**.

[045] In one aspect of this embodiment the valve unit and filter unit are adjacent (as shown), in another aspect of this embodiment the valve unit and filter unit are separated by some distance along a longitudinal axis (not shown). In an alternative embodiment, the valve unit **140, 240** and filter unit **150, 250** are not joined and are separated by some distance along a longitudinal axis (not shown). Like the single unit embodiment of the valve-filter device **30**, the multi-unit valve-filter device **130**, **230** or the filter unit **150, 250** of the device, may be deployed in the aorta **15** between the sino-tubular junction **11** and branching point of the right brachial artery **12**, or further downstream. When deployed, filter unit **150**, **250** has the shape of an open umbrella, with the concave surface of filter canopy **151**, **251** facing the heart. The rim of the filter

canopy **151**, **251** is a ring **153**, **253**. Similar to ring **33** of valve-filter **30** in **FIG. 1**, ring **153**, **253** is radially compressed and folded when filter unit **150**, **250** is in a delivery configuration, and it is expanded when filter unit **150**, **250** is in a working configuration. Ring **153**, **253** may be made similarly to ring **33**, and the fully expanded ring **153**, **253** makes close contact with aorta wall **16** without applying undue pressure, to provide a seal that limits debris from passing around filter unit **150**, **250**. Filter unit **150**, **250** may be made of a material permeable to blood flow but impermeable to emboli. It preferably has a porosity of 80 to 200 μm; or, the pore size may be, for example, in the range of from 50 to 500 μm, or from 10 to 2000 μm. Any material with such porosity may potentially be suitable for filter unit **150**, **250**, provided that the material is pliable to fold, for example, the same material as the valve canopy **31**, **141**, **241**, but modified to be porous or a material different than that of the canopy, as described above for the filter areas **32** and membranes. The porosity of the filter unit **150**, **250** may also be fabricated from fibers. The fibers may be knitted, woven, or braided to achieve the desired porosity. As with the filter areas of FIGS 1 and 1A, the filter unit of the multi-unit device may have a pore size of, for example, between 10-200 microns, 50-500 microns, 80-250 microns, 80-200 microns, or 100-200 microns.

[046] In the embodiment illustrated in **FIG. 2**, the concave surfaces of the valve canopy **141** and the filter canopy **151**, face away from each other (convex-facing). In one aspect of this embodiment, illustrated in **FIG. 2**, valve unit **140** may comprise a plurality of lines **144**, which connect the rim **143** of valve canopy **141** to band **142** attached to catheter **20** proximal of the valve-filter device. Lines **144** may be wires, strings, or may be made of the same material as the valve canopy **141**, and in one

aspect may be a unitary construction with the valve canopy **141**. In combination, lines **144** and band **142** help maintain the working configuration of valve **140**. As shown in **FIG. 2**, in this embodiment, the pulse of blood flow during systole causes the portion of the valve canopy **141** between the points on the rim **143** where the lines **144** are connected (to bend radially inward to permit the blood to flow downstream). During diastole, backflow causes the portion of the canopy between the points on the rim **143** at which the lines **144** are connected to bend radially outward to the vessel wall so that the canopy **141** is fully open, thereby limiting blood flow downstream. In one aspect of the embodiment, the band **142** may slide back and forth along the catheter **20** moving the catheter rim via the lines **144** to allow blood to flow during systole and to prevent backflow during diastole. In another aspect of the embodiment, the band **142** may be used to control the diameter of the open valve canopy **141**. Thus the device may be adjusted to the diameter of the aorta **15**; in a larger aorta, the band **142** can be slid distally towards the valve canopy **141** and in a smaller aorta the band **142** could be slid proximally away from the valve canopy **141**.

[047] As illustrated in **FIG. 2**, a catheter **20** for delivering a permanent valve or repair tool extends through both valve unit **140** and filter unit **150**, with the distal end extending to the space distal of ring **153**. The apex **148** of the valve unit **140** and apex **158** of the filter unit **150**, respectively, may be attached to the catheter **20**.

[048] In another aspect of this embodiment, illustrated in **FIG. 2A**, the valve unit **140a** includes a plurality of stiff struts **145**, which are connected to the apex **148** of valve unit **140a** by a strut hinge **146**. The stiff struts **145** help maintain the working configuration of the valve unit **140**. As shown in **FIG. 2A**, in this embodiment, the pulse

of blood flow during systole causes the portion of the valve canopy **141** between the stiff struts **145** to bend radially inward to permit the blood to flow downstream. During diastole, backflow causes the portion of the valve canopy **141** between the stiff struts **145** to bend radially outward to the vessel wall so that the valve canopy **141** is fully open, thereby limiting blood flow downstream. The strut hinges **146** allow the struts to be opened and closed in a plane perpendicular to the plane of the rim of valve canopy **141** for purposes of delivery of the valve-filter device. When valve unit **140a** is in the delivery configuration, struts **145** close to constrain valve unit **140a** in a small cross-section. Upon deployment, struts **145** may open through the self-expansion mechanism of hinges **146**, and they open to such an angle that the tips of the struts make contact with or are substantially close to aorta wall **16**. Struts **145** may be made of a stiff material such as metal or plastic. Non-limiting examples of such metals include Nitinol, shape memory alloys, metals, e.g., stainless steel or Co-Cr.

[049] In another embodiment of the multi-unit valve-filter device **230**, illustrated in **FIG. 3**, valve-filter device **230** includes a valve unit **240** and a filter unit **250** where the concave surfaces of the valve canopy **241** and the filter canopy **251** face toward each other. The valve unit **240** and the filter unit **250** may be constructed similarly to their counterparts in the embodiment depicted in **FIGS. 2** and **2A** in terms of both structure and materials. In one aspect of this embodiment, the valve filter unit **240** may include a plurality of stiff struts **245**, for example three stiff struts, to form a frame for the valve-filter device. Canopies **241** and **251** may be attached to the frame. Alternatively, the valve filter unit **240** may be frameless, and constructed like the jellyfish embodiment of the temporary valve described below, for example in FIG. 5.

[050] A first delivery system may include a sheath or mechanical constraint structure over catheter **20** and the valve-filter device for radially constraining the valve-filter device in a delivery configuration. Upon reaching the target site, the sheath may be removed and the valve-filter device deployed to its working configuration. In a further alternative, ring **33**, **133** and **233** may be made of a shape memory material to permit the ring to adopt a compressed and folded delivery configuration – e.g., at a lower temperature. Cold saline solution may be infused into the blood vessel to trigger the compression and folding. A permanent valve or valve repair tool may be delivered via a second delivery device that extends through the lumen of the first delivery device.

[051] The valve-filter system of the invention comprises a temporary valve-filter device and a first delivery device for delivering the temporary valve-filter device to the target site of the blood vessel. The valve filter device may be delivered mounted on the catheter **20** that extends through the apices of the canopy **41** or canopies **141**, **151**, **241**, **251**. The valve-filter device is preferably attached to the delivery device at all times during use. The first delivery device may further include a catheter that houses the valve-filter device within it for delivery. The valve-filter device may be deployed with pull wires and/or push rods at the target site.

[052] As shown in **FIG. 3** the concave-facing multi-unit valve-filter device **230** may also include a second delivery device, i.e., a catheter **20** for delivering a permanent valve or repair tool extending through both the apex **248** of the valve unit **240** and the apex **258** of filter unit **250**, with the distal portion of the catheter **20** extending distal of apex **248** of valve unit **240**. As with the valve filter-device of **FIGS. 2** and **2A**, during diastole, the portion of valve canopy **241** of valve unit **240** between the struts expands

radially to an open umbrella shape to prevent backflow. During systole (not depicted), the same portion of valve canopy **241** folds radially inward between struts to allow blood flow through the vessel. The blood then passes through filter unit **250** so that any emboli are collected and retained in the space between valve unit **240** and filter unit **250**.

[053] In another embodiment, the valve-filter device **60** has substantially flat components, as illustrated in **FIGS. 4A-4D**, that may be disk-shaped, for example circular, elliptical, or the like. The device of this embodiment comprises a first substantially flat portion or disk **61, 161** and a second substantially flat portion or disk **62, 162**, said first and second portions concentrically aligned. In this embodiment, the first disk **61, 161** is impermeable to blood and functions as the valve and the second disk **62, 162** is permeable to blood but impermeable to emboli and functions as an embolic filter. The second disk **62, 162** may comprise a permeable membrane, constructed of the materials described above for the embodiments of FIGS. 1-3, and having a porosity, for example, of between 10-200 microns, 50-500 microns, 80-250 microns, 80-200 microns, or 100-200 microns. The valve filter-device of **FIGS. 4A-4C** is designed so that blood may flow around the first disk **61, 161** which preferably is sufficiently flexible to fold downstream at least in part during systole and sufficiently stiff and elastic to regain its substantially flat configuration during diastole to minimize blood backflow. Arrows indicate direction of blood flow, and in **FIGS. 4A** and **4C** illustrate how the valve may prevent back-flow during diastole.

[054] In one aspect of this embodiment, the first and second disk **61, 62** may have similar diameter and lie adjacent one another as illustrated in **FIG. 4A**. For

example, the first disk **61** may lie on top of the second disk **62**, overlapping during diastole. In **FIG. 4A**, a small space is shown between the first and second disks **61, 62** for clarity of illustration. The first and second disks **61, 62** may be attached to each other in the center where they are connected to the delivery device **20**, at points along the periphery (rims), or both. As illustrated in **FIG. 4A**, the first disk **61**, which functions as the valve, may be fully open so that its rim contacts the vessel wall **16** during diastole to prevent backflow of blood. During systole, the first disk **61** may fold toward the center, for example toward the delivery device **20** sufficiently to allow blood flow through the vessel, as illustrated in **FIG. 4B**. The percutaneous valve-filter device may be placed between the sino-tubular junction **11** and branch point of the right brachial artery **12** as shown in **FIGS. 4A** and **4B**. Alternatively, the valve filter device may be placed between the right brachial artery **12** and the left common carotid artery **13**, or between the left common carotid artery **13** and the left subclavian artery **14**, or further "downstream."

[055] In another aspect of this embodiment, the first and second disk may be separated but located along a common longitudinal axis, as illustrated in **FIG. 4C**. To maximize filtering of emboli into the arteries, the second disk **62** having the filtering function is located between the sino-tubular junction **11** and the right brachial artery **12**. However, the second disk alternatively may be placed between the right brachial artery **12** and left common carotid artery **13**, or between the left common carotid artery **13** and the left subclavian artery **14**.

[056] In yet another aspect of this embodiment, illustrated in **FIG. 4D**, the second disk **162** may have a radial inner portion **162a** that is permeable to blood but

impermeable to emboli and a radial outer portion **162b** that is impermeable to blood. The first disk **161**, impermeable to blood, may lie adjacent to and overlap the radial inner portion **162a** of the second disk **162** during diastole, closing the permeable radial inner portion **162a** to limit backflow of blood (not shown), but slide distally along the delivery device **20** to open the valve-filter device, so that the blood may flow through the radial inner portion of the second disk, as illustrated in **FIG. 4D**. Arrows indicate direction of blood flow. Preferably, the valve-filter device of this aspect of the embodiment includes a "stop" (not shown) on the delivery device, or lines (not shown) connecting the first disk **161** to the second disk **162**, or comparable structure to limit the distance the first disk **161** slides along the delivery device **20** during systole. In an alternative version of the embodiment of **FIG. 4D**, the first disk is attached at the center to the second disk, e.g., around the catheter, so that the first disk may flex during the systolic phase to allow blood to flow through the inner radial portion of the second disk. The embodiment of **FIG. 4D** may be positioned in the blood vessel similarly to the embodiment of **FIGS. 4A** and **4B**. The size of the inner radial portion **162a** is as large as the smallest radius required to permit blood flow through the vessel. The remainder of the second disk **162**, i.e., the outer radial portion **162b**, is flexible as to sizing, so as to allow the filter portion of the valve-filter device, i.e., the second disk **162** to fit in the blood vessel. It is well within the skill in the art to determine the appropriate percent cross-sectional area for a particular application.

[057] Suitable materials for the first and second disks of the embodiment of **FIGS. 4A-4D** are as discussed above for other embodiments of the invention. The inner and outer radial portions **162a, 162b** of the second disk **162** could be made of the same

material (with the inner portion made permeable by mechanical or chemical means) or they may be made of different materials.

[058] In any of these aspects of the embodiment of **FIGS. 4A-4D**, the valve-filter device has a delivery configuration, in which the first (valve) disk **61, 161** and second (filter) disk **62, 162** are folded or wrapped around the delivery device **20**.

[059] In any of the above embodiments, the valve-filter device may be self-expandable. For example, in the embodiment of **FIG. 4A-4D**, the second disk may be self-expandable. The ring **142** and wires **144** of the embodiment of **FIG. 2** control the diameter of the valve unit, which is also capable of reducing to near zero diameter. Alternatively, the valve and filter units or single unit valve-filter unit may be manually opened.

[060] A percutaneous temporary valve system **70** and a method of deploying the temporary valve according to the invention is illustrated in **FIGS. 5A-C**. The temporary valve system includes a temporary valve **71**, central core **72**, a plurality of lines **74**, a sheath **75**, and a pusher **80**. The central core **72** is tubular with an open proximal end, for example with a cuff to provide a pushing surface for the pusher **80**, and an open distal end facing (adjacent or non-adjacent) or attached to the valve **71**. The valve **71** has an open center region large enough to accommodate a delivery device passing therethrough, and the edge of the valve **71** open center region may be attached to the distal end of the central core **72**, or it may have a diameter and stiffness sufficient to allow the distal end of the central core **72** to support and maintain the position of the valve center during systole. The plurality of lines **74** connect the rim of the temporary

valve **71** to the central core **72**. Each of the plurality of lines **74** may be attached to the central core **72** by means known in the art, for example, gluing or bonding. The lines **74** may be attached to the valve **71** by similar means. Preferably, the lines **74** are made of the same material as the valve **71**. More preferably, the valve **71** and lines **74** are a unitary structure, constructed from a single mold with a polymer that includes the entire valve and lines, requiring no attachment.

[061] The temporary valve system **70** has a delivery configuration, in which the valve **71** and central core **72** are inverted, for example folded back on itself like a folded sock (with an open toe), and housed within the sheath **75**, along with the lines **74**, as shown in **FIG. 5A**. The central core **72** is preferably in direct continuity with the pusher **80**, and is made of a material that is sufficiently flexible to allow it to invert on itself and into the sheath **75** when folded. Preferably the pusher **80** has an outer diameter that matches the inner diameter of the sheath **75** so that it can push the components contained within the sheath **75** out of the sheath.

[062] The temporary valve **71** will begin to function once the central core **72** and the temporary valve **71** have been pushed out of the sheath **75**. The central core **72** preferably has a diameter large enough to accommodate a catheter carrying a permanent valve device or valve repair tool to pass through to deliver the permanent valve or repair tool to a site distal of the valve (and filter where used). Thus, in use, the delivery catheter may be inserted through the sheath and out the open distal end of the central core **72** and through the temporary valve (and filter where used).

[063] In the embodiment of **FIGS. 5A-C**, the valve **71** of the temporary valve system has a jellyfish-like shape in its fully deployed configuration with a plurality of lines **74** that connect the rim of the valve **71** to the central core **72**, for example near the proximal end of the central core **72**, as illustrated in **FIG. 5C**. Alternatively, the lines **74** may be attached to the sheath **75** (not shown). In this embodiment, the lines and valve are manufactured as a single piece, for example by molding polymer material. Alternatively, the lines **74** may be wires or strings attached to the valve **71**, the wires or strings may be made of the same material as the valve **71**. The lines **74** provide tension during diastole to control the diameter of the valve **71**. The lines **74** may be pulled forward or backward to control the diameter of the valve.

[064] As illustrated in **FIG. 5B**, the valve **71** and central core **72** may be deployed by everting the valve and central core using a pusher **80**. The pusher **80** may be, for example, a catheter. Each of the plurality of lines **74** are attached at a first end to the rim of the valve **71** and at a second end to a position on the central core **72**, for example near the distal end **72b** of the central core – distal end **72b** of the central core **72** being the end furthest from the canopy of the temporary valve and the proximal end **72a** of the central core **72** being attached to the canopy of the temporary valve **71**. **FIG. 5C** illustrates a fully deployed temporary valve, with the central core extending down the center of the device. The temporary valve system of **FIGS. 5A-5C** may be used with any of the filter units described above, as illustrated in **FIG. 6**.

[065] In one embodiment, the temporary valve of **FIGS. 5A-5C** is deployed proximal of the left subclavian artery (see, e.g., element 14 of **Fig. 1**). In embodiments such as **FIG. 6**, the filter unit is preferably deployed between the right brachial artery

and sino-tubular junction (e.g., elements 12 and 11 of **Fig. 1**) to maximize trapping of emboli. The temporary valve of the embodiment of **FIG. 6** may be deployed near the filter unit or more proximally, for example proximal of the left subclavian artery (see element 14 of **Fig. 1**). In embodiments where the temporary valve and filter unit are non-adjacent, the filter unit may be delivered and deployed using the delivery device used to deliver a permanent percutaneous valve device or valve repair tools.

[066] The central core **72**, which is the backbone of the temporary valve, may be made of a flexible material, such as a braid or mesh. The central core **72** may be made of a biocompatible metal, such as for example Nitinol or other shape memory material, or it may be made of a biocompatible fabric, such as for example a polymeric material. Non-limiting examples of polymeric materials include, for example, polyesters, such as Dacron and polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), polyurethanes, and nylon. The central core **72** may be constrained by the sheath **75** (or, as shown in **FIG. 6** where an optional filter unit is adjacent the valve body – the delivery device **175**) and the eversion of the central core **72** may take place by unconstraining the central core – pushing it out of the sheath, and allowing it to self-assemble. The valve **71** is attached to the central core **72** by a plurality of lines **74**, and may also be attached at its apex – at the proximal end. For purposes of the temporary valve embodiment of **FIGS. 5A-C** and **6**, "proximal" refers to the end of the component oriented closer to the heart if the device is deployed in the aorta and "distal" refers to the end of the component oriented away from the heart if the device is deployed in the aorta. Use of the temporary valve system of the invention where the central core **72** is tubular with an open end permits placement of the temporary valve anywhere, for

example, along the aortic arch and percutaneously passing a second delivery device through the temporary valve to the native valve where the user may proceed with percutaneous valve replacement or valve repair.

[067] The temporary valve system **70** may be used with or without a filter unit **90**. Filter unit **90** may have an umbrella-shaped canopy, as described in **FIG. 2** (filter unit **150**), or may be substantially flat, as described in **FIGS. 4A-C** (filter unit **62**).

[068] Suitable materials for the temporary valve-filter device and temporary valve of the invention include fabrics, polymers, and tissue or other suitable biocompatible materials known in the art. Fabrics may include, e.g., PET, PTFE, ePTFE, polypropylene, and like materials. Polymers may include, e.g., PEBAX, silicone polycarbonate urethane, silicone, polyurethane, nylon, PET. Tissues may include bovine pericardium, porcine pericardium, or similar minimally immunogenic tissues.

[069] The percutaneous temporary valve-filter system of the present invention may further comprise a permanent prosthetic device, such as a replacement valve device, or a repair tool for the repair of calcified valve. The permanent device or repair tool may be delivered using a different, i.e., second, catheter having a diameter smaller than the diameter of catheter **20**, the first catheter, shown **FIGS. 1, 2, 3, 4A,** and **4B** that permits it to pass through the catheter **20** to deliver the permanent device or repair tool to a site distal of the target site of the valve-filter or valve.

[070] The present invention also relates to a method of deploying a temporary valve-filter device, for example to a target site of a blood vessel. The valve-filter device may be compressed and folded into a delivery configuration, leaving a reduced cross

sectional profile, and housed in a catheter during the navigation in the artery. The valve-filter device may be released from the catheter, for example, by push rods and/or pull wires that are commonly used in percutaneous procedures, for example, upon reaching the target site in the blood vessel,. After being released, the valve-filter device expands into its working configuration. For the single unit embodiment depicted in **FIG. 1**, in one aspect of the invention ring **33** may expand into a circle to contact the aorta wall **16** while the material of canopy **31** renders the valve-filter into an open umbrella shape. Push rods and pull wires may also be used to help maintain the open umbrella shape of the valve-filter. For the multi-unit embodiments depicted in **FIGS. 2, 2A** and **3**, ring **33, 153** and **253** may similarly expand so that the rim of the filter unit **150, 250** presses against the aorta wall **16** effectively sealing the vessel against the passage of emboli. The plurality of struts **145, 245** may open radially by a self-expansion mechanism during deployment, such as through the hinges **146** depicted in **FIG. 2A**, or through expansion to a pre-set, for example thermo-mechanically pre-set curved shape as is depicted in **FIG. 3**, thereby transforming the valve unit **140, 140a, 240** into a working configuration. After the valve-filter device **130, 230** is deployed into a working configuration, a second delivery device having a smaller diameter may be threaded through the delivery device and extended past the valve-filter device to the site of permanent valve placement or valve repair. The device of **FIGS. 4A-4D** may be deployed in a similar manner.

[071] In one embodiment, the temporary valve-filter system may further comprise a permanent percutaneous prosthetic valve, and the method may include deploying the permanent prosthetic device using the second delivery device, for

example, an inner catheter, after deploying the temporary valve-filter. In another embodiment, the system may further include a valve repair tool, and the method includes deploying the repair tool from the second delivery device and repairing a native valve after deploying the temporary valve-filter.

[072] The present invention also relates to a method of deploying a temporary valve. As described above for **FIGS. 5A-5C**, the method comprises providing a sheath containing a folded central core and temporary valve comprising a body and a plurality of lines, wherein said plurality of lines connects a peripheral rim of said temporary valve to said central core, and said central core is attached to the sheath; and pushing said folded central core and temporary valve from the sheath using a pusher, thereby everting the central core and temporary valve into a deployed configuration. Alternatively the lines may be attached to the sheath.

[073] It will be appreciated by persons having ordinary skill in the art that many variations, additions, modifications, and other applications may be made to what has been particularly shown and described herein by way of embodiments, without departing from the spirit or scope of the invention. Therefore it is intended that scope of the invention, as defined by the claims below, includes all foreseeable variations, additions, modifications or applications.

What is claimed is:

1. A percutaneous temporary valve system, comprising a temporary valve, a central core, and a sheath for containing and delivering said temporary valve and central core; said temporary valve comprising a body and a plurality of lines, each of said lines connected at a first end to a rim of said valve body and at a second end to said central core; said central core having an inverted delivery configuration and connected to said sheath.

2. The system of claim 1, further comprising a pusher.

3. The system of claim 1 or 2, wherein said central core includes a pushing surface.

4. The system of any one of claims 1-3, wherein each of said valve and said central core has an open center region.

5. The system of any one of claims 1-4, wherein said sheath includes a filter unit.

6. A method of deploying a temporary valve comprising: providing a sheath containing a central core and temporary valve, said temporary valve comprising a body and plurality of lines, wherein said plurality of lines connects a peripheral rim of said valve body to said central core, and said central core has a folded delivery configuration wherein said central core is inverted within said sheath and connected to said sheath; pushing said folded central core and temporary valve from said sheath using a pusher; and everting said central core into a deployed configuration, said temporary valve thereby assuming a deployed configuration.

7. The method of claim 6, wherein said central core comprises a shape memory material and said sheath constrains said central core in said delivery configuration.

8. The method of claim 6, wherein said sheath further contains a filter unit, said method including pushing said filter unit from said sheath to a deployed configuration, said filter unit located adjacent said valve body.

9. A percutaneous temporary valve-filter device, comprising a valve structure impermeable to blood and a filter structure permeable to blood but impermeable to emboli, said valve-filter device designed for simultaneously regulating flow of blood and collecting emboli.

10. The device according to claim 9, wherein said valve structure comprises a first substantially flat portion and said filter structure comprises a second substantially flat portion, said first substantially flat portion comprising a material impermeable to blood, said second substantially flat portion comprising a material permeable to blood but impermeable to emboli.

11. The device according to claim 10, wherein said second substantially flat portion includes an inner radial portion and an outer radial portion, said inner radial portion comprising said material permeable to blood but impermeable to emboli, and said outer radial portion comprising a material impermeable to blood.

12. The device according to claim 9, wherein said valve filter device has at least one umbrella canopy; said at least one umbrella-shaped canopy having an apex, a

base, an open shape in a deployed working configuration, and a closed shape in a delivery configuration, said base comprising a rim, said at least one umbrella-shaped canopy having a convex surface and a concave surface in said deployed working configuration.

13. The device according to claim 12, wherein said device has a unitary construction comprising one umbrella-shaped canopy that provides both valve and filter functions, said canopy base having a rim designed to form close contact with a vessel wall into which said valve filter device is deployed, wherein said concave surface faces upstream when said valve-filter device is deployed in a blood vessel, wherein said canopy comprises a material impermeable to blood and a plurality of filter areas permeable to blood but impermeable to emboli, each filter area hingedly connected to a flap that is impermeable to blood, said flap located on said convex surface, whereby said flap opens during systole and closes during diastole.

14. The device according to claim 12, wherein said valve-filter device comprises a valve unit and a filter unit, each of said valve unit and filter unit including one of said at least one umbrella-shaped canopies;

wherein said valve unit canopy comprises a material impermeable to blood, and

a portion of said valve unit canopy folds radially inward on systole sufficiently to permit blood flow downstream and expands radially outward sufficiently on diastole to prevent blood backflow;

wherein said filter unit canopy comprises a material impermeable to emboli but permeable to blood, said filter unit canopy base having a rim that forms close contact with a wall of said blood vessel; and

wherein said filter unit is joined to said valve unit, and said concave surface of said filter unit canopy faces in an opposite direction from the concave surface of the valve unit.

15. The device according to claim 14, wherein said concave surface of said valve unit faces said concave surface of said filter unit.

16. The device according to claim 14, wherein said convex surface of said valve unit faces said convex surface of said filter unit.

17. The device according to any one of claims 14-16, further comprising a frame attached to said valve unit, wherein said frame comprises a plurality of stiff struts spaced at intervals around said valve unit canopy, each strut extending from said apex to said rim and attached to said apex via a strut hinge.

18. The device according to claim 17, wherein, when said valve-filter device is deployed in said blood vessel, said material of said valve unit canopy folds radially inward between said plurality of struts during systole and expands radially outward between said plurality of struts during diastole.

19. The device according to any one of claims 9-18, wherein said blood permeable filter structure has a porosity in a range of 10-2000 μm diameter.

20. The device according to claim 19, wherein said porosity is in a range of 50-500 μm diameter.

21. The device according to claim 19, wherein said porosity is in a range of 80-200 μm diameter.

22. A system comprising the valve-filter device of any one of claims 9-21 and a first delivery device having a lumen, said valve-filter device mounted on said first delivery device.

23. The system according to claim 22, wherein said lumen of said first delivery device has an internal diameter sufficiently large for a second delivery device to pass therethrough.

24. The system according to claim 23, further comprising a second delivery device and a percutaneous valve device for implantation in a blood vessel.

25. The system according to claim 23, further comprising a second delivery device and a valve repair tool for repairing a native valve.

26. A method of deploying a temporary percutaneous valve-filter device, comprising:

introducing into a vessel, a system comprising a valve-filter device mounted on a first delivery device having a lumen, said valve-filter device having a radially collapsed delivery configuration;

advancing said valve-filter device to a target site;

deploying said valve-filter device from the delivery device; and

expanding radially said valve-filter device to a working configuration designed for simultaneously regulating flow of blood and collecting emboli.

27. The method of claim 26, wherein said temporary valve-filter system further comprises a second delivery device and a percutaneous valve device for implantation, said lumen of said first delivery device having an internal diameter sufficiently large for said second delivery device to pass therethrough, said method further comprising after said expanding step and before said collapsing step:

extending said second delivery device through the first delivery device;

deploying and implanting said percutaneous valve device; and

retracting said second delivery device.

28. The method of claim 26, wherein said temporary valve-filter system further comprises a second delivery device and a percutaneous valve repair tool, said lumen of said first delivery device having an internal diameter sufficiently large for said second delivery device to pass therethrough, said method further comprising after said expanding step and before said collapsing step:

extending said second delivery device through the first delivery device;

deploying said valve repair tool and repairing a native valve;

retracting said repair tool; and

retracting said second delivery device.

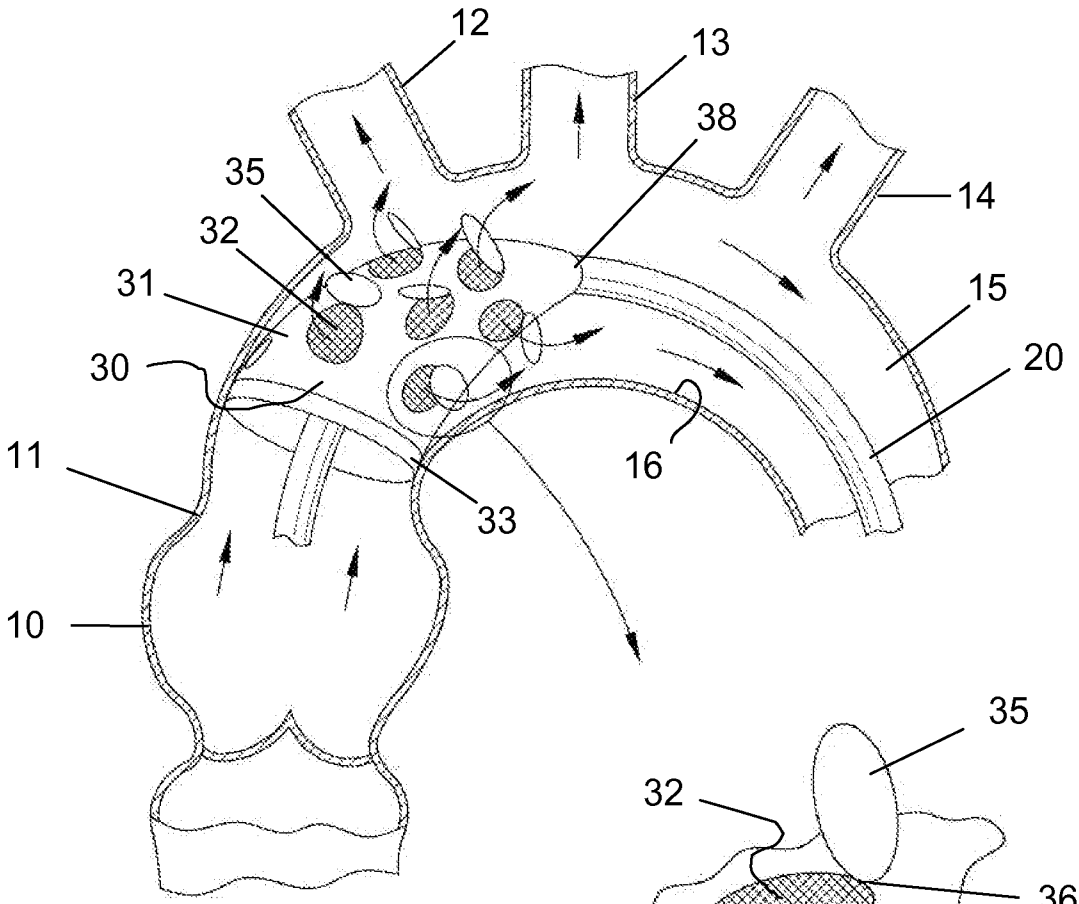


FIG. 1

FIG. 1A

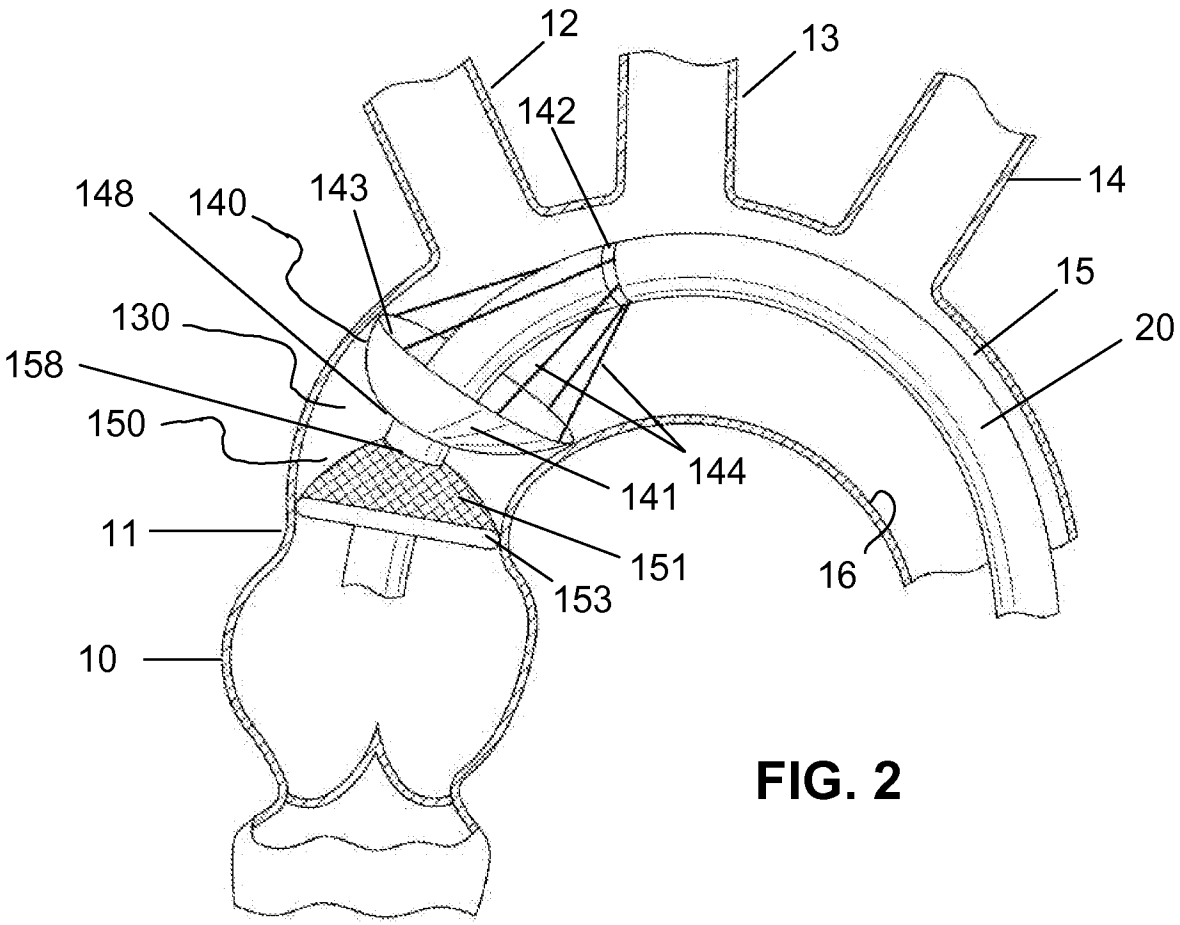

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FIG. 2

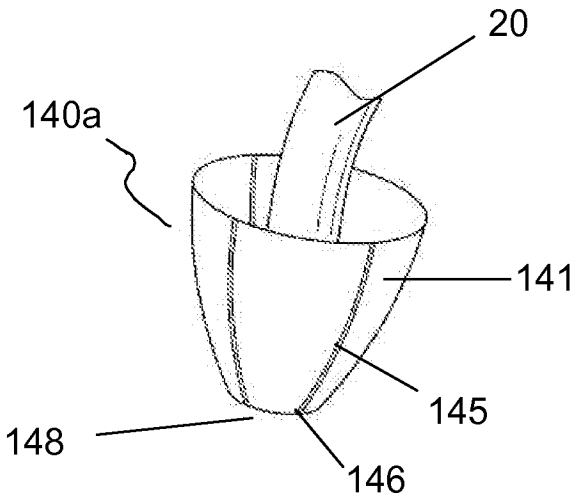
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FIG. 2A

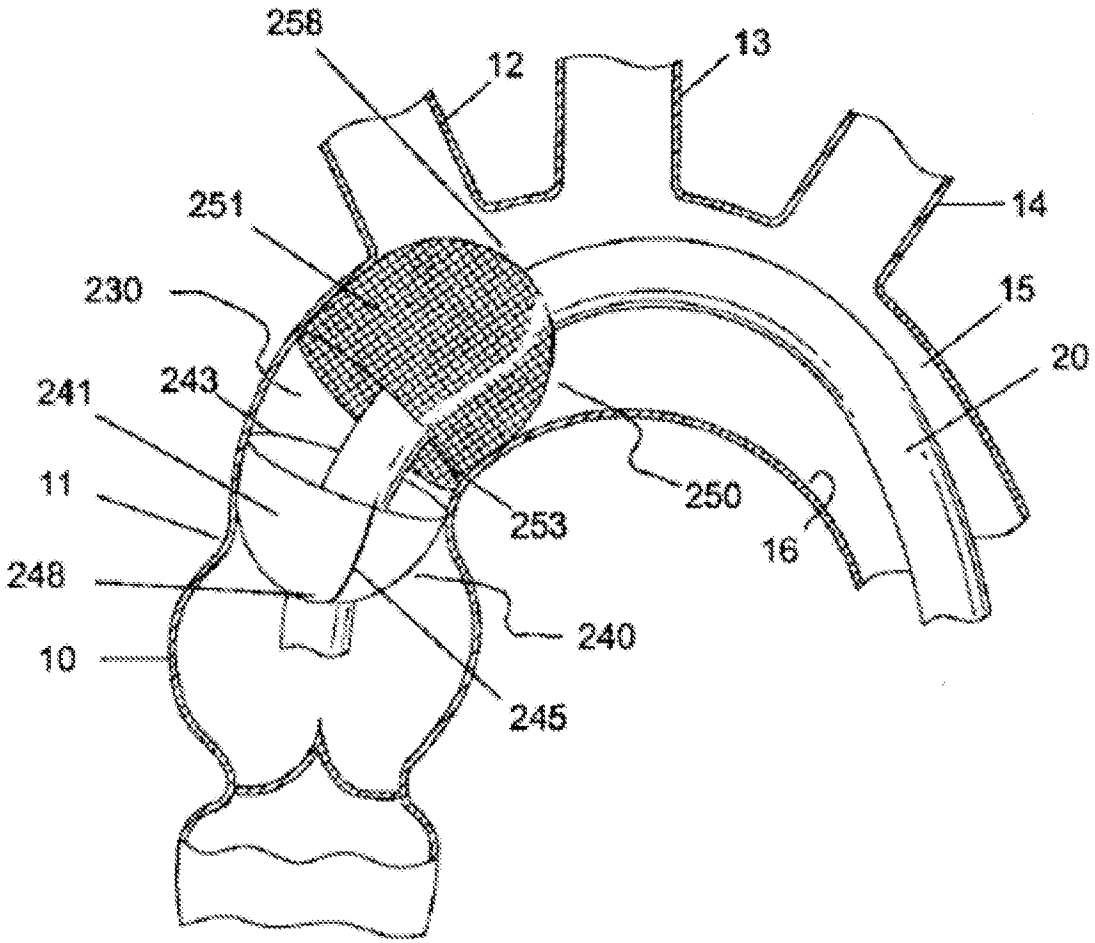

FIG. 3

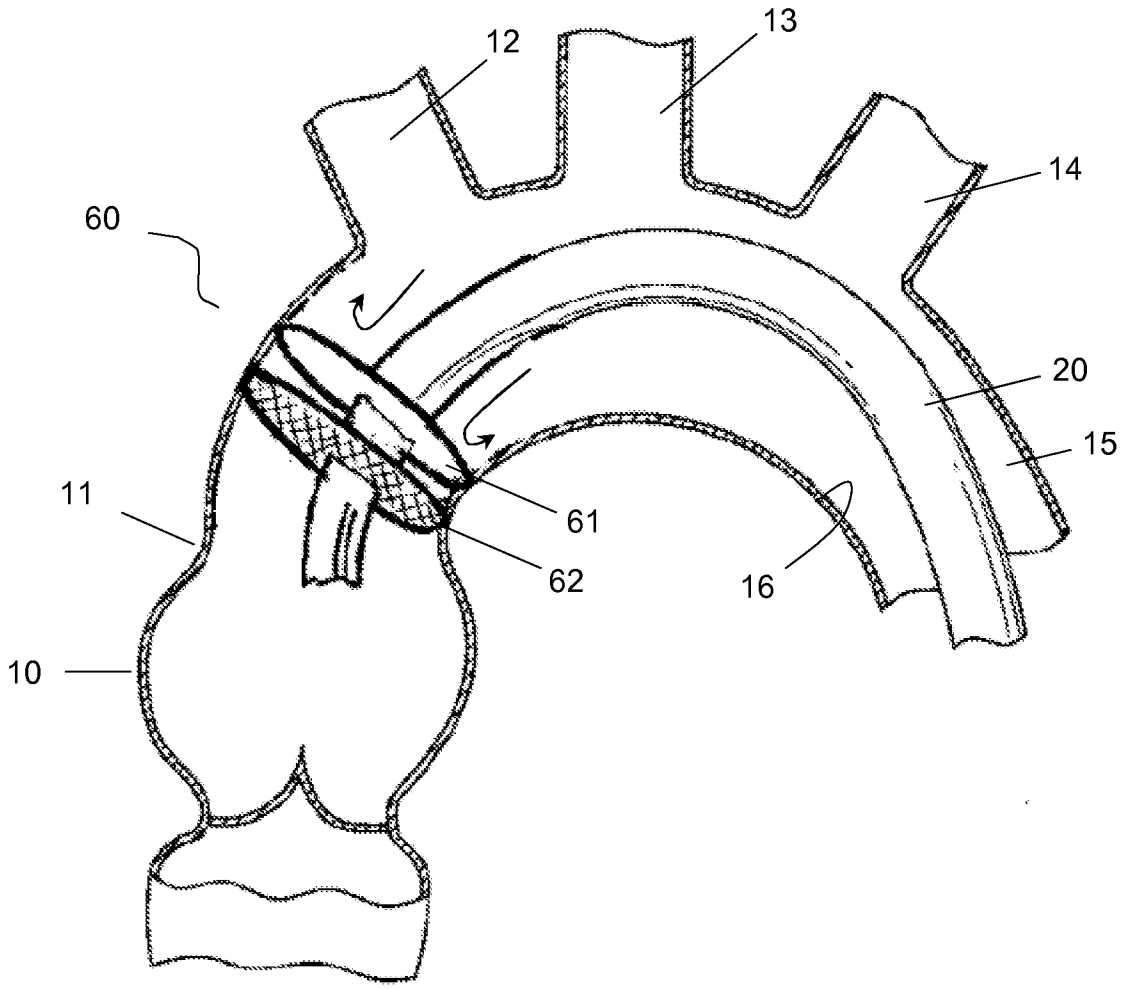

FIG. 4A

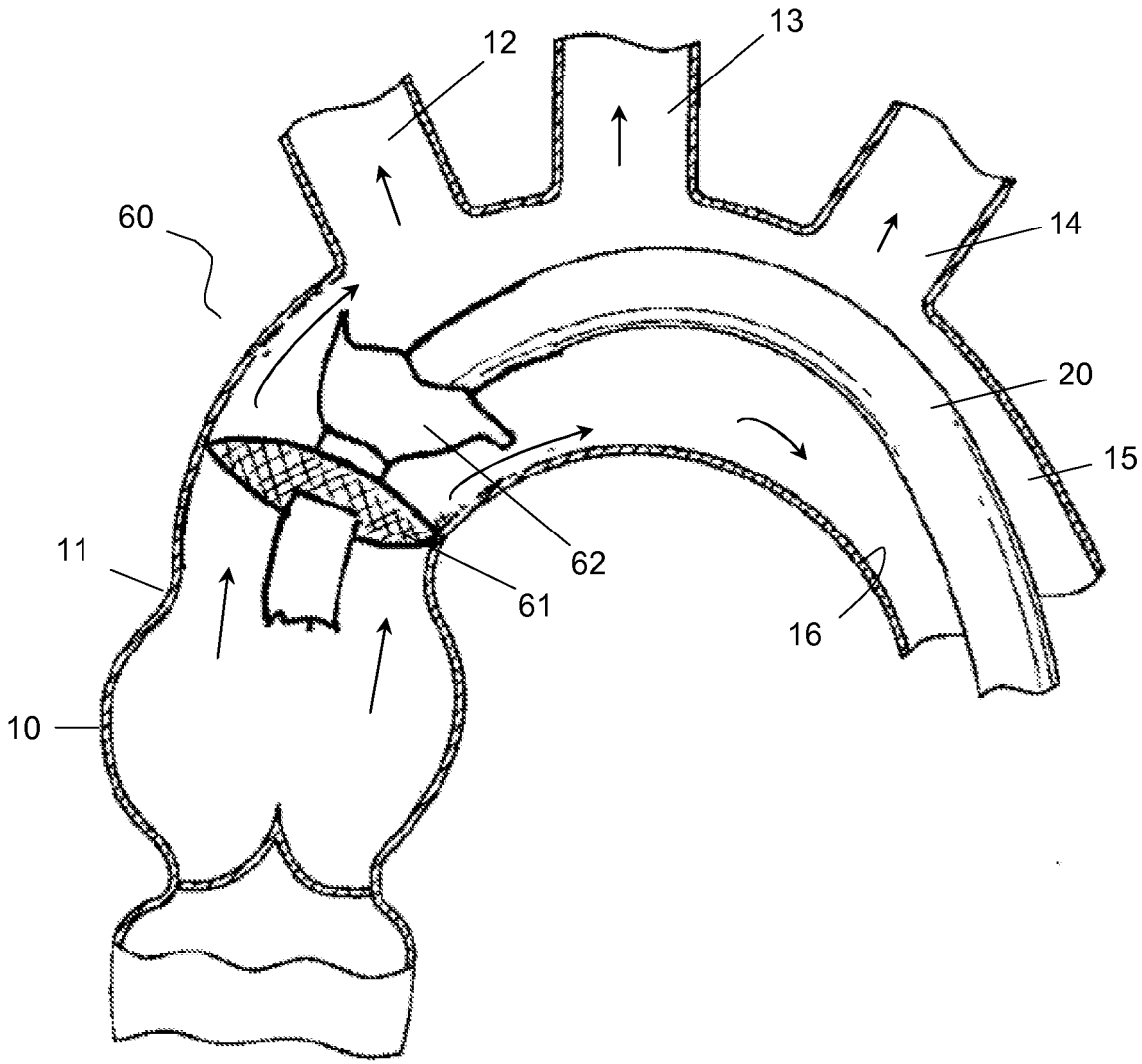

FIG. 4B

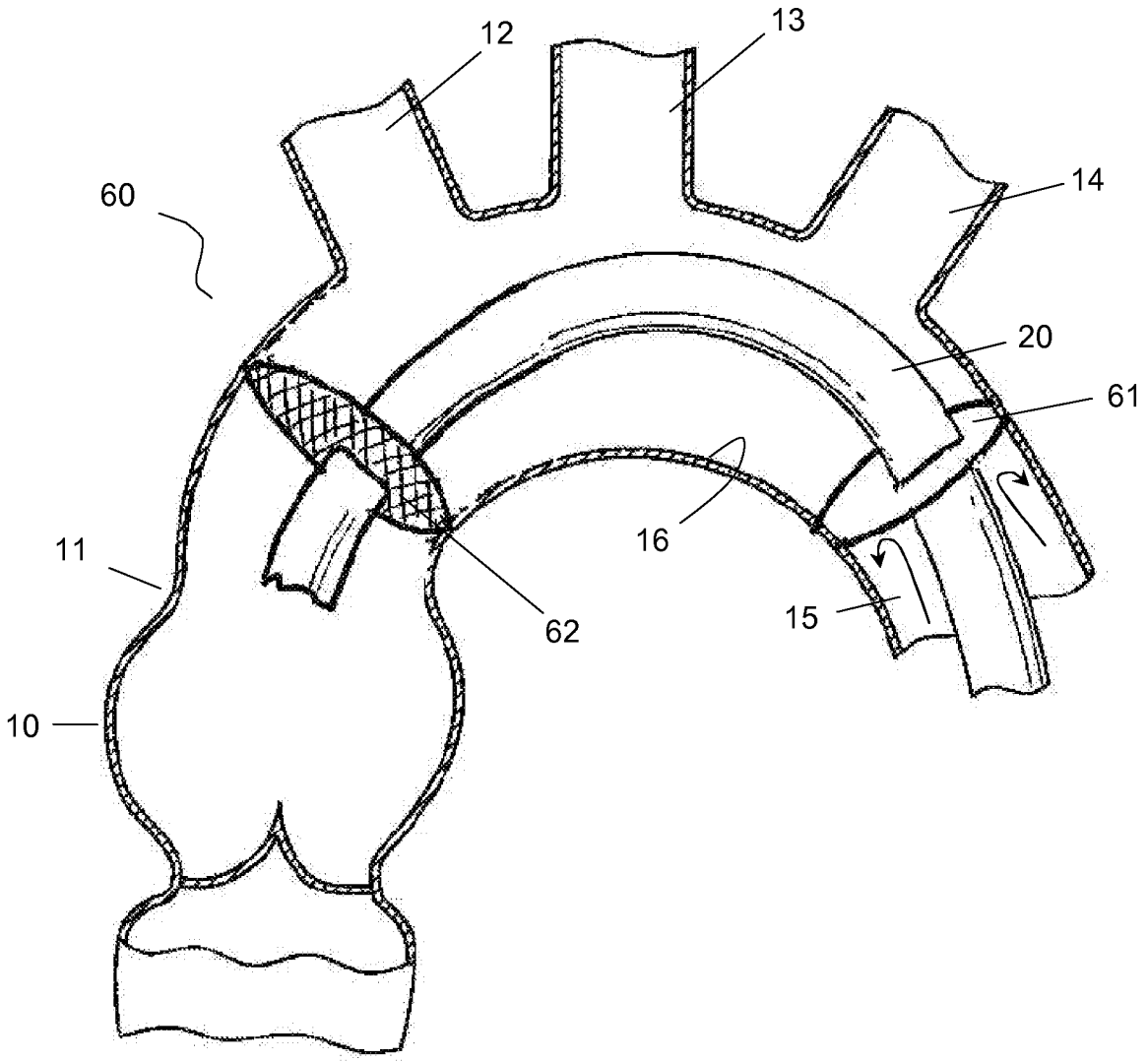

FIG. 4C

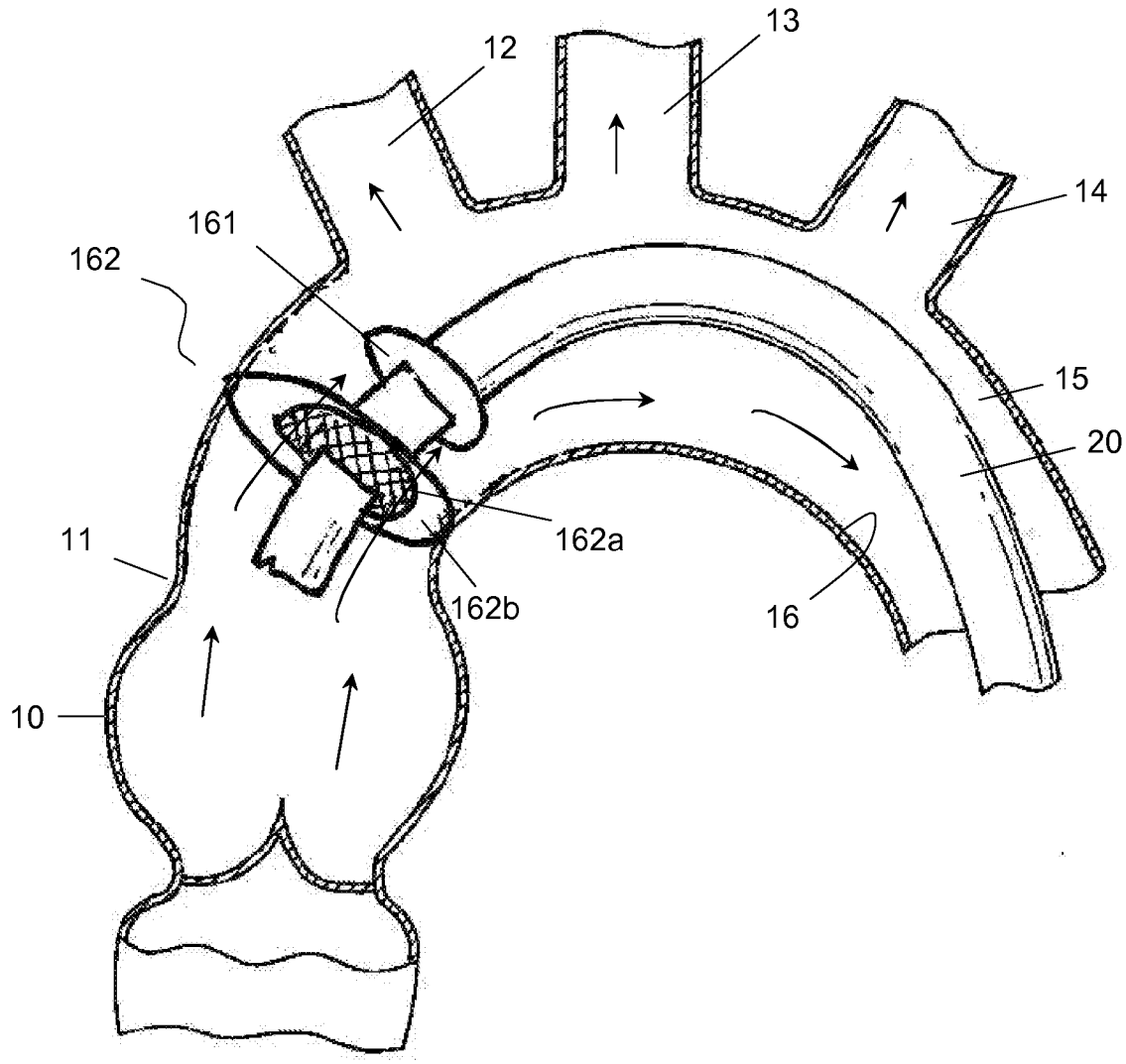

FIG. 4D

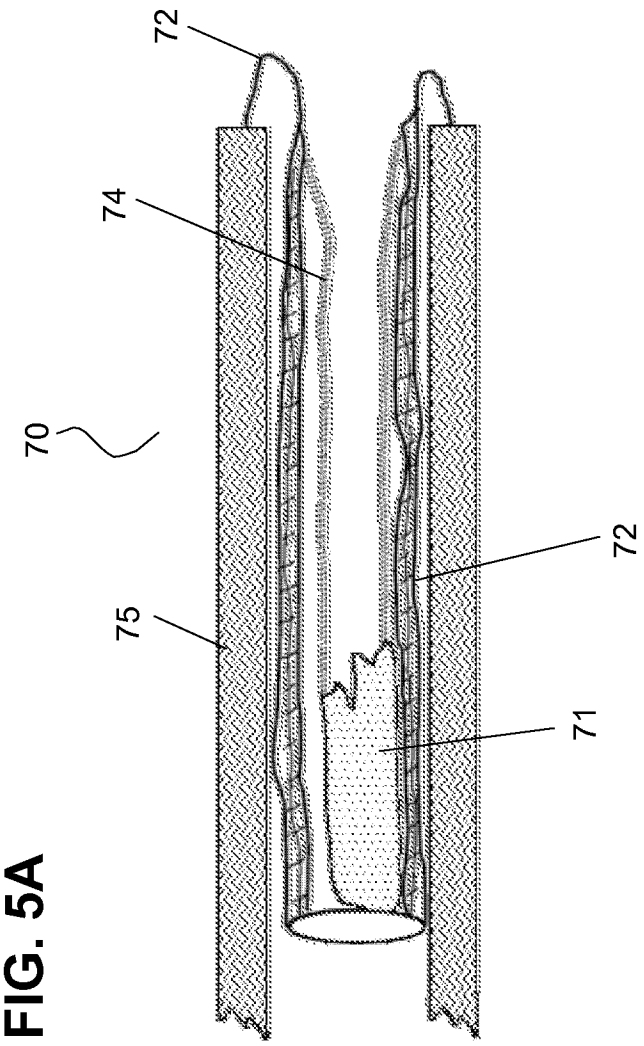

FIG. 5A

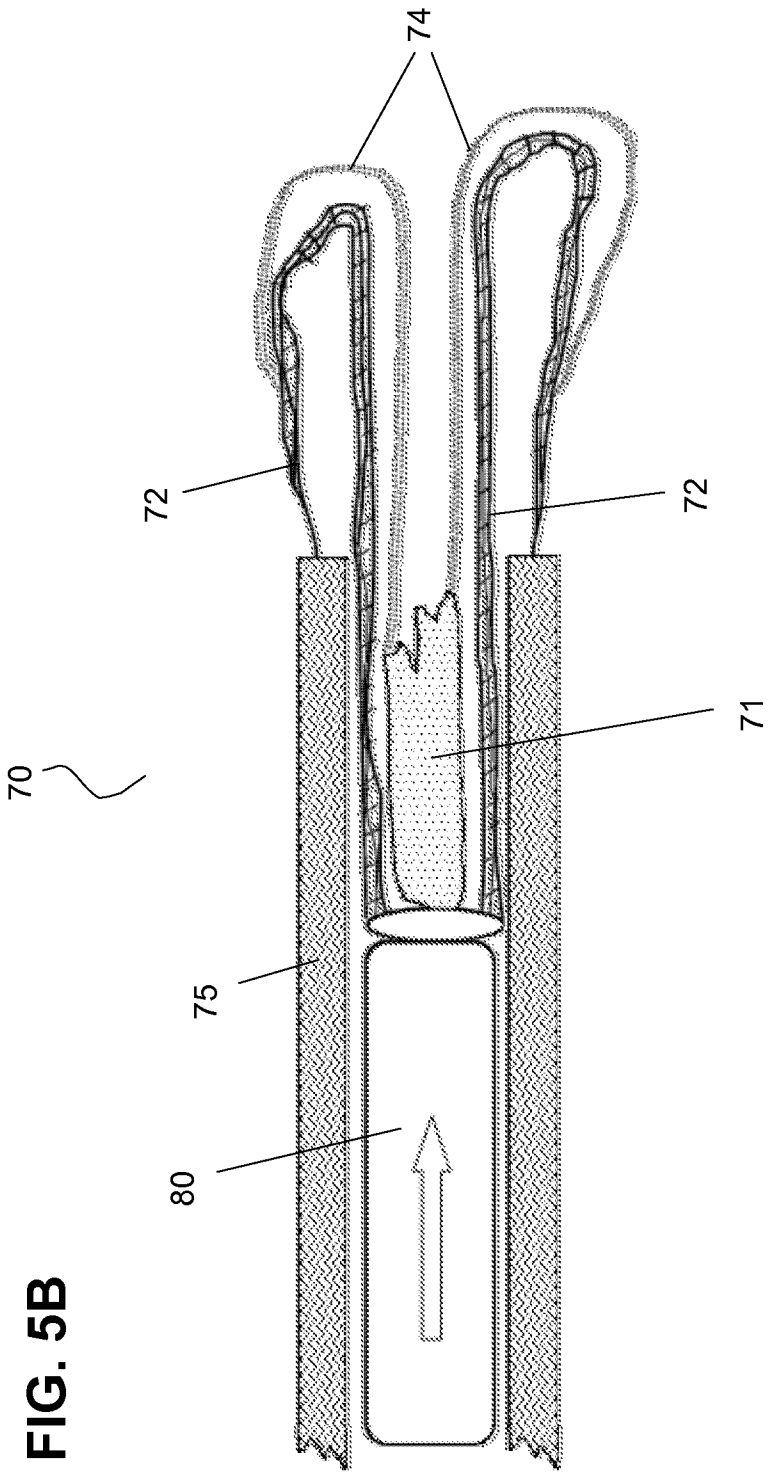

FIG. 5B

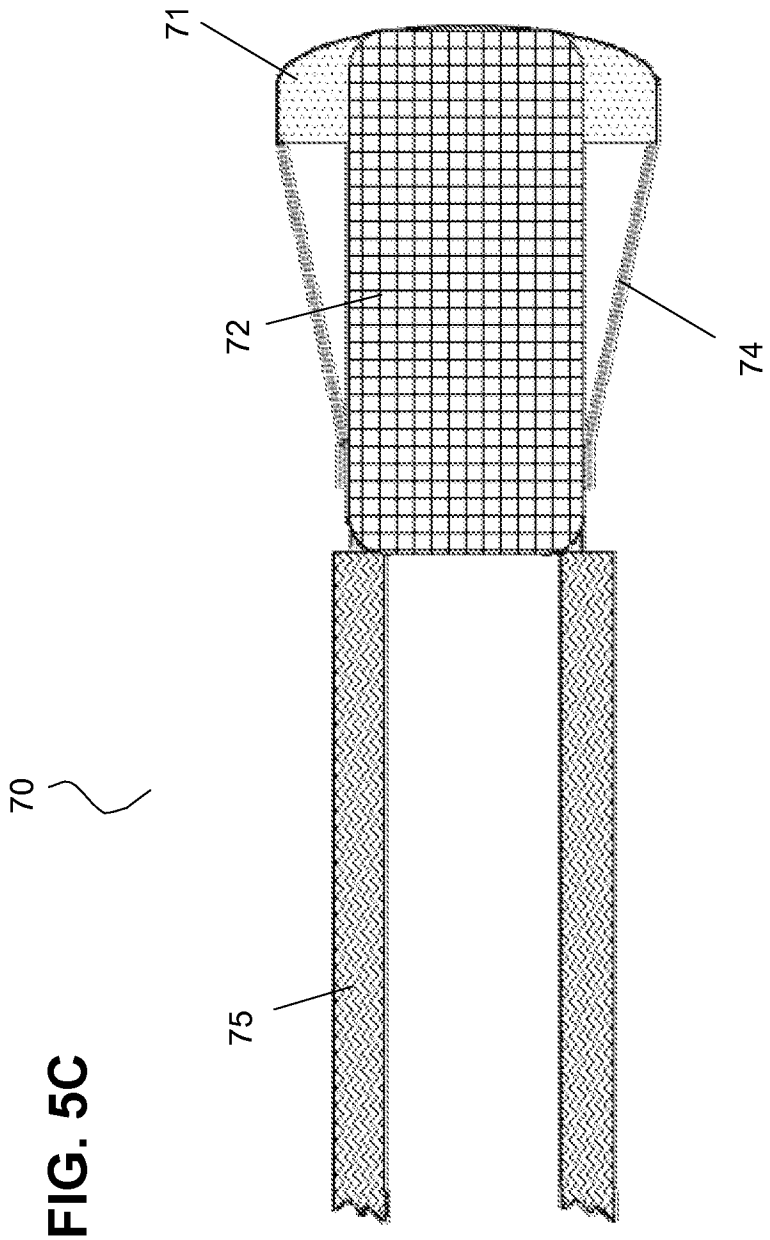

FIG. 5C

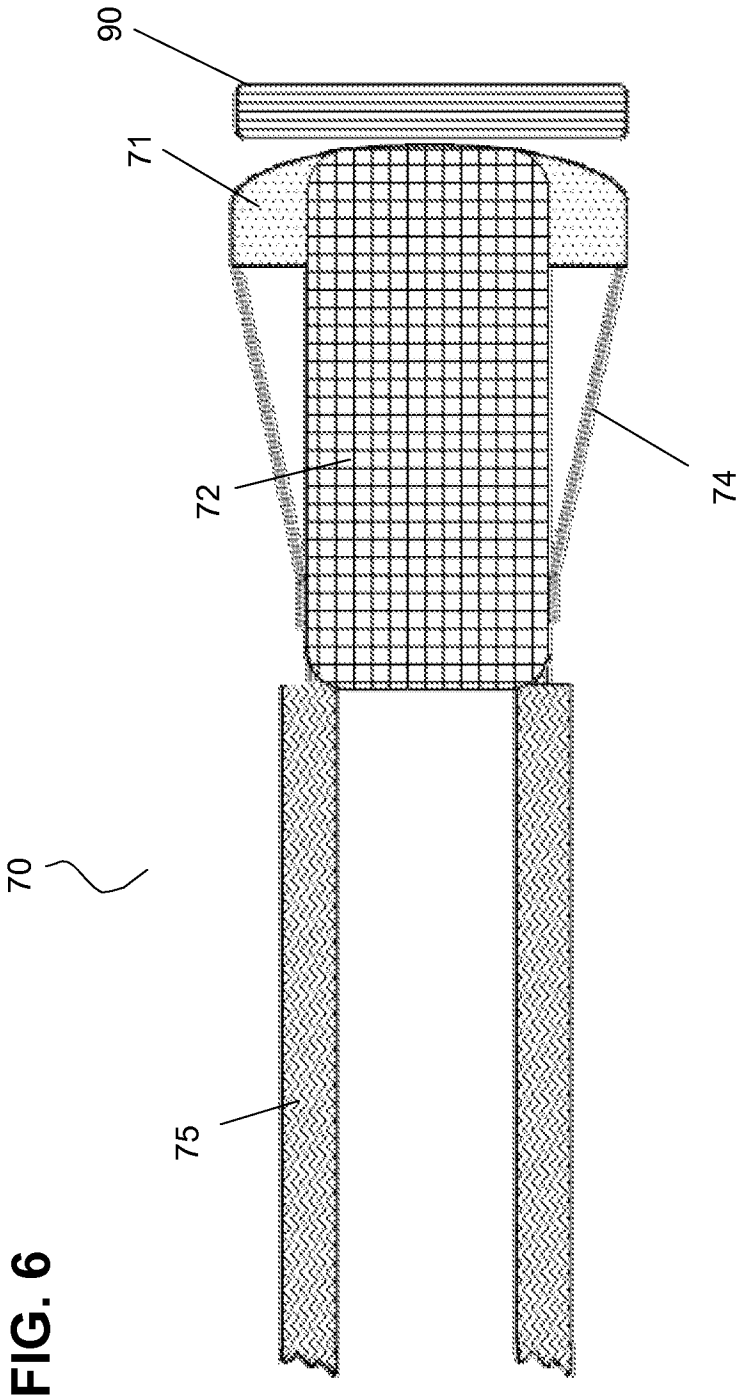

FIG. 6