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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 April 2010 (08.04.2010)

PCT

(10) International Publication Number
WO 2010/037870 A1

(51) **International Patent Classification**:
A61M 29/02 (2006.01) *A61F 2/86* (2006.01)
A61B 17/22 (2006.01)

(21) **International Application Number**:
PCT/EP2009/062919

(22) **International Filing Date**:
5 October 2009 (05.10.2009)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
08165870.0 3 October 2008 (03.10.2008) EP

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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, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

WO 2010/037870 A1

(54) **Title**: INTRAVASCULAR TREATMENT DEVICE

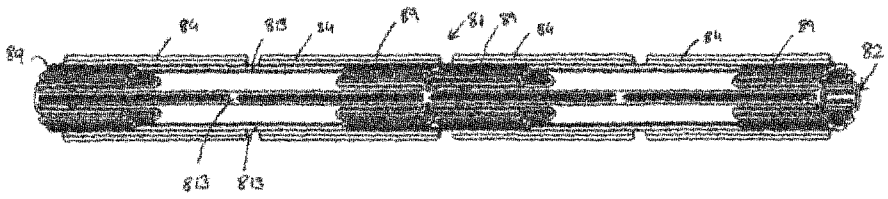


Figure 8

(57) **Abstract**: A collapsible treatment device (81) for treating a target area of a vessel wall within a human or animal body, having a mesh portion, preferably annular in shape (82) and with a contracted configuration allowing travel within the vessel to the target area and an expanded configuration allowing treatment of the target area. A treatment implement is on the mesh portion and a protuberance either as part of the mesh or provided on a sheath which protects the vessel from contact with the implement during travel within the vessel.

Title

Intravascular Treatment Device

Field of the Invention

[0001] The present invention relates to medical devices. In particular, the invention relates to a catheter-based medical device for the treatment of internal body cavities including vessels such as arteries/veins or other hollow organs.

Background to the Invention

[0002] There are many medical reasons to insert a medical device into the human body. To make a procedure during which a medical device is inserted minimally invasive it is desirable to use a device which does not require major surgical incision. Many devices are known which dilate or cut or score or inject at target sites within the body.

[0003] Often times to reduce trauma a medical device is inserted through an existing vessel in the body. For certain vessels no incision is required. For other vessels such as those forming the vasculature of the body, a minor incision is required to allow entry into an appropriate vessel. Once in an appropriate vessel the medical device may then be advanced along the vessel to a target site. The function of the medical device can then be used at the target site. Such functions include delivery of active substances, delivery of medical devices such as stents, dilation, scoring, abrasion, cutting, injection etc.

[0004] One target site which is often treated with such minimally invasive devices are lesions, including calcified lesions, and partial occlusions and full occlusions. Target sites may be found in any part of the vasculature including at bifurcation locations. Often coronary or peripheral arteries are treated for such lesions.

[0005] Many medical devices of the type described above are known and have been produced for particular end functions. Many are catheter-based devices.

[0006] In certain situations it may not be appropriate to implant a stent and a stand-alone dilation procedure may be preferred. Accordingly it has become desirable to provide devices which can obviate the requirement for a stent. Due to the benefit of treatment of any site being lost over time it is desirable to provide devices which are effective in preventing regression of an improved condition (such as improved luminal gain) at a treated target site. Additionally, in other situations a conventional angioplasty dilation catheter may not be capable of dilating a calcified (or difficult) target site and a specialist device that focuses the angioplasty force may be required for a successful procedure.

[0007] US Patent Publication No. 2004/0143287 describes a plaque-scoring catheter with a balloon on a distal end thereof. The device is said to comprise a non-axial scoring shell. This device is commercially available under the name AngioSculpt™ from Angioscore™ which is a ballon catheter-based device which includes nitinol wires each with angular corners which form scoring elements. The device is inflated to dilate vessels and to score lesions in the vessels. The device is said to increase luminal gain to a greater extent than by standard balloon dilation alone. The patent publication describes the scoring structure as being potentially a slotted cage. One embodiment describes expanding arings about a balloon. An embodiment is described where there are scoring implements on a trilobal balloon. There is still a danger of unintentional injury by the wires, cage or cutting implements or the blades on the balloon.

[0008] US Patent Publication No. **2007/0198047** describes a cutting balloon assembly with an inflatable balloon fixed to a distal end of a catheter. The device includes a covering which can expand and which has an array of cutting edges. The covering extends about and is raised above the outer surface of the balloon. The covering is described as being made from plastic or metal or a mesh of flexible woven polyurethane fibres. The covering expands with inflation of the balloon and contracts with deflation of the balloon. The covering is described as having a sharp outer surface which lacerates lesions etc. Given the sharp nature of the covering, even in the deflated state of the balloon, there is still a danger of injury along the travel path of the device within the body.

[0009] US Patent Publication No. **2005/0080478** describes a permanently implanted stent with cutting bars or blades. The ends of the blades are angled or bevelled to allow the blades to cut into blockages. There is still a danger of injury along the travel path within the body when inserting the stent.

[0010] US Patent Publication No. **2004/0215223** describes a cutting stent and balloon device wherein the balloon is provided with liquid crystal polymer fibrils to minimise longitudinal growth during inflation of the balloon. The balloon is employed to deliver the stent to a target area.

[0011] US Patent No. **7,279,002** describes a number of devices including an implantable stent with a cutting blade; a catheter with an inflatable balloon which has a cutting blade; and a sheath or sleeve which has a cutting blade. A sheath is described which can surround a stent. In certain embodiments at least a portion of the stent such as a portion of the blades are made from a shape-memory material. Blades are attached to the stent by adhesive or welding. A pre-programmed shape memory is described as useful for retraction of the blades from an expanded configuration. The

blades are also discussed as being possibly contained within a valley or trough of the stent or the balloon. In certain embodiments a sheath is provided between the balloon and the stent to prevent premature opening out of the blades with inflation of the balloon. The sheath is retracted to allow stent opening. Cutting blades may also be provided on a sheath fitted about a balloon. The sheath may alternatively be left upon the implanted stent where it biodegrades.

[0012] US Patent Publication No. **2006/0085025** describes an angioplasty balloon with a non-deployable stent. A number of substantially axially-arranged wires each with a sinusoidal bend are disposed about a balloon. A connecting circumferential wire joins the wires about the balloon. In one embodiment u-shaped connectors are provided between adjacent wires. Expansion of the balloon causes expansion of the wires. The device, and in particular the wires, are adapted to crack occlusions in vessels.

[0013] US Patent Publication No. **2005/0021070** describes a device for stent manipulation and in particular expanding a cell of a stent for such as in part of a stent that is implanted in one vessel but extends across an opening within that vessel to a branched vessel. The device has a similar structure to that described in US Patent Publication No. **2004/0143287** (supra) with an additional overtube which is proximate the wires of the stent and which can be utilised to control the compliance of the balloon part of the device.

[0014] European Patent Publication **EP 1 611 920** describes a stent that is adapted for permanent implantation. As such it is adapted to be biased toward its expanded configuration. One expanded it is not designed to be collapsible. Other parts are attached by welding to the exterior of the stent including one embodiment where a blade is attached. The preferred embodiment is where the device is composed of materials to allow the device to be absorbed by the human body after implantation. A flexible protective plate which is disposed on the side structure of the device is disclosed as a protective mechanism for the device. The plate has an outermost end in the radial direction which is higher than the outer most end of the structure which protects the device during delivery but presses open to allow cutting during stent expansion. A protective mechanism mounted to the catheter is also mentioned. No specific construction is however given. Furthermore there is no contemplation of removing the device from the body. It remains permanently or until it is absorbed by the body.

[0015] European Patent Publication No. **EP 0 533 511** describes a device which has a self-expandable mesh which is held within a catheter in an unexpanded configuration and pushed out of the catheter to expand. The mesh is rotated or scraped within the

vessel to remove materials. International (PCT) publication No. **WO 2008/036900** describes a device which is based on a balloon which is responsive to two inflation pressures, to unfurl/expand different parts of the balloon. This action is used to deploy microneedles. A small piece of mesh-like steel or nylon is utilised to bond, using adhesive, the microneedles to the exterior of a central section of the balloon. US Patent No. **US 5,653,684**, describes a catheter with an expandable wire mesh tip which is biased toward the expanded configuration. A wire is used to adjust the mesh position and expansion configuration. US Patent No. **US 4,885,003** describes a double mesh balloon catheter with an inner mesh which is rotatable relative to the outer mesh which functions like a shaver to cut away material in an occluded area. European patent publication **EP 1 935 376** describes a balloon catheter which has cutting blades on the outer surface thereof. The blades are covered by a resilient material, from which they are exposed during use. A rigid base can be provided as a rigid support for the blades to spread the cutting force required over a larger area of the balloon. US patent no. **US 6,626,861** describes a balloon catheter device that has an outer mesh sleeve made of woven material which is abrasive. The device may be moved to abrade obstructions for removal thereof. US patent no. **US 7,252,650** describes a balloon for a balloon catheter. The balloon is formed about a tube which can be used to inflate the balloon. The wall of the balloon is reinforced with fibres which limit the radial expansion of the balloon. The balloon can be furled by fibres which have memory for an unfurled configuration of the balloon.

[0016] Notwithstanding the state of the art, it would still be desirable to provide alternative catheter-based medical devices for the treatment of internal body cavities including vessels such as arteries/veins or other hollow organs. In particular it is desirable to avoid the requirement for a permanently implanted device. In particular it is desirable to provide a transient device that can be used for treatment at one or more sites and then removed after treatment is completed.

Summary of the Invention

[0017] In one embodiment the present invention relates to a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, comprising:

(i) a mesh portion having a contracted configuration allowing travel within the vessel to the target area and an expanded configuration allowing treatment of the target area;

(ii) at least one treatment implement carried on the mesh portion; and further comprising

(iii) at least one (collapsible) protuberance which protects the vessel from contact with the implement during travel within the vessel.

[0018] Desirably said at least one treatment implement is secured to the mesh portion. Such an arrangement of the treatment implements on the mesh ensures that the treatment implements are firmly fixed in place and are much less likely to become disengaged, thus avoiding the problem of loss of the implement due to detachment during movement of the device. Complete or partial detachment of the implement is thus substantially reduced as the implement is directly held in place by the mesh. It will be appreciated that the treatment implement may be secured to the mesh portion, for example, by machine forming, welding, or fixing into an implement holder formed on said mesh portion. The latter option is preferred.

[0019] Alternatively, the implement may comprise a flared end or collar dimensioned to secure said implement in the mesh portion. Desirably the mesh is provided with one or more insertion slots into which the implement(s) can be secured to the mesh. The treatment implement may be attached to the mesh by a snap-fit arrangement. Any inter-engaging formations would be suitable in this regard, for example, a peg on the mesh dimensioned to snap-fit into a recess on the treatment implement or vice versa. A restriction may be provided in the recess to prevent escape of the peg therefrom and/or the head of the peg can be enlarged to engage in the recess. This removes the necessity for directly fixing the implements to the mesh and allows for different relative movement of the mesh and the implements which may occur due to the use of different materials for each and/or differing amounts of movement of the mesh compared to the implement(s) in response to expansion/contraction of the device. Such differing relative movement can cause unwanted stresses in the device and potentially cause separation of the implements from the device which is very undesirable. The device of the invention is thus easily inserted into the body and advanced to a treatment site. The protuberance(s) will provide protection for the vessel wall from the, or each, implement.

[0020] Being collapsible the device of the invention is easily deployed and then retracted for removal from the vessel or to be moved to a further treatment site for

further treatment. The device of the invention, unlike other devices such as those based on stent constructions, is collapsible even after being deployed to the expanded configuration. Other devices are resiliently biased against contraction (and toward expansion) and thus retain the expanded configuration and are thus not collapsible.

[0021] The at least one protuberance may be formed by the mesh portion. Desirably, the device of the present invention may comprise a plurality of protuberances formed by the mesh portion. It is desirable that any protuberance is collapsible and collapses without requiring contact with a vessel wall. In particular it is desirably that as the device moves toward an expanded configuration that the protuberances are arranged to be collapsed by stretching forces imparted by expansion forces. This means that there is no requirement to impart pressure against the vessel wall to reveal one or more implements from a shielded position. This is desirable because stretching of the vessel by such forces may cause damage.

[0022] Preferably, the mesh portion comprises a main body which is annular. Further desirably, the mesh portion may comprise at least one element which follows a tortuous path, the element resiliently deforming under expansion by decreasing tortuosity of its path.

[0023] In a further embodiment the device of the present invention may comprise a protective sheath for protecting the vessel from contact with the implement during travel within the vessel. Desirably, said at least one protuberance which protects the vessel from contact with the implement during travel within the vessel is provided on the sheath. In any event it is desirable that any protuberance is on the sheath or the mesh. While in one configuration it is possible to do so, it is not desirable to have the protuberance(s) on the implement(s).

[0024] The at least one protuberance may deform to expose the implement in the expanded configuration of the device. Preferably, the protuberance may house the implement and the implement extends through the protuberance in the expanded configuration of the device.

[0025] The mesh portion of the device of the present invention may be embedded within the sheath. In an alternative embodiment the mesh portion may overlie the sheath. In yet a further embodiment the mesh portion may underlie the sheath. Desirably, the mesh portion overlies the sheath and the protuberance extends from the sheath past the mesh portion.

[0026] Preferably, the sheath is made of a resiliently deformable material such as an elastomeric material. The resilient expansion of the mesh provides additional bias towards the non-working configuration and thus the device of the invention returns to a

compact arrangement for travel within a vessel when returned to the non-expanded configuration. When combined with a resilient expansion of the sheath, the bias toward the non-working configuration is even greater.

[0027] The mesh portion of the device of the present invention may be machined from a tubular portion. Alternatively, the mesh portion may be formed by moulding.

[0028] In a further embodiment, the device of the present invention may comprise, for example, at least two annular mesh portions. A device comprising at least three annular mesh portions is also embraced by the present invention. In such embodiments the mesh portions of the device of the present invention may be integrally formed. Desirably, each mesh portion forms a turn within a helix. Alternatively, said annular mesh portions may not be integrally formed but are joined by one or more separate elements. Said one or more separate elements may comprise a treatment implement or a carrier for a treatment implement. It will be appreciated that the treatment implement may be secured to said separate elements or said carriers, for example, by machine forming, welding, or fixing into an implement holder formed on said separate elements or said carriers. An implement holder is preferred.

[0029] The device of the present invention may further comprise an expandable portion such as a balloon and the mesh portion is fitted over the expandable portion.

[0030] The mesh portion may be secured to a catheter over an expandable portion of the catheter such as a balloon of a balloon catheter. The mesh portion may be secured to a catheter at both ends of the expandable portion, and desirably at a position beyond the end(s) of the expandable portion. An interlocking ring structure may be formed to mate around the catheter/expandable portion so as to secure the mesh thereto. Desirably the interlocking ring structure is part of the mesh. The mesh portion may extend from the sheath so as to provide a series of longitudinal struts intermediate to the point of attachment of the mesh to the catheter and/or the sheath. Advantageously, the struts may provide additional support for a sheath which may be overlaid thereon. The regions occupied by the struts may be covered. For example, a material that is easily over-fitted thereto and then shrunk to fit or bonded thereto may be employed as a cover. The cover may aid in crossing a lesion as there will be a smoother transition when crossing a tight lesion with a covered strut.

[0031] The treatment implements carried on the mesh may extend from the sheath running parallel to a longitudinal axis of the device to provide a series of treatment implement longitudinal struts. The treatment implement struts may underlie the mesh struts. Thus, securing the mesh to the catheter will also secure the treatment implement to the catheter.

[0032] Desirably, the expandable portion such as a balloon may comprise a substantially cylindrical body with substantially conical end portions. The balloon body may comprise a tapered portion. Tapering is advantageous as it provides a profile which is easily moved in a vessel. This allows for dynamic and relatively unimpeded movement of the device trough a body vessel to a target site. The tapered balloon may match the anatomy of an artery, with the small end of the taper positioned distally within the artery and the large end positioned proximally within the artery. Thus, matching the natural reduction in diameter as arteries taper down the further removed from the heart they are. In a further embodiment, the present invention provides for a device wherein the sheath forms an inflatable balloon.

[0033] In yet a further embodiment, the present invention provides for a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the device comprising:

an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area to an expanded configuration allowing treatment of the target area, the mesh portion being constructed of a shape memory material which has memory for the contracted configuration and

at least one treatment implement carried on the mesh portion.

[0034] As will be appreciated by a person skilled in the art said collapsible treatment device may have one or more of the additional features of the device of the present invention described herein (*vide supra*).

[0035] As used herein the term shape memory material is intended as a reference to a material capable of returning to its original contracted shape once the expanding force acting on the material has been removed.

[0036] The present invention also provides for an expandable mesh for use with a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the mesh comprising:

an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area, to an expanded configuration allowing treatment of the target area, and

at least one treatment implement carried on the mesh portion, the mesh portion further comprising at least one (collapsible) protuberance which protects the vessel from contact with the implement during travel within the vessel.

[0037] Also embraced by the present invention is an expandable mesh for use with a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the mesh comprising:

(i) an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area, to an expanded configuration allowing treatment of the target area;

(ii) at least one treatment implement carried on the mesh portion; and

(iii) a sheath provided on the mesh the sheath comprising at least one (collapsible) protuberance which protects the vessel from contact with the implement during travel within the vessel.

[0038] Desirably, the expandable mesh of the present invention is constructed of a shape memory material which has memory for the contracted configuration. Preferably, in an annular configuration, the expandable mesh of the present invention is capable of considerable diametric expansion relative to its contracted state.

[0039] In all embodiments of the invention it is clear that the protuberance(s) can travel with the mesh and that when the device is moved to the contracted configuration the protuberance(s) act to once again protect the implement(s) on the mesh. In this respect it is desirable that any protuberance is resiliently biased away from its collapsed position toward its protective (erect) position. This is a distinct advantage over devices that are housed within a catheter or the like and are deployed by relative radial movement of the device out of the catheter. In such arrangements the device must be re-housed within the catheter before the vessel walls are shielded from contact with the device. In the present device shielding of the implements occurs concurrently with moving the device towards its collapsed position. For example as an inflation balloon deflates any protuberance is progressively released from the stretching force and progressively resumes its shielding position by moving toward its erect position.

[0040] In another aspect of the invention the implements are provided with a recession stop that prevents recession of the implement into the mesh and/or sheath and/or annular portion. For example the implement may settle into the device and not move to the same extent as the mesh. This means that the implement will not project past the mesh to the extent possible and thus reduce its effectiveness to be worked in a vessel. This retracted position is thus undesirable. By providing a recession stop such potential recession is avoided. The recession stop desirably is arranged to engage with the mesh. The mesh then provides sufficient support to prevent any reversion. In one arrangement the recession stop takes the form of one or more tabs. In another arrangement the recession stop takes the form of a pin.

[0041] The implements of the invention may be one or more of blades and needles. Desirably the implement is arranged so that a working end thereof is directly radially outwardly at least in a working configuration of the device.

[0042] The device of the present invention may be provided with a delivery tube therein for delivery of any desired fluid to the vessel, for example a therapeutic fluid including drug materials. The tube will be sufficiently flexible not to interfere to any substantial extent with collapsing/expansion of the device. The delivery tube may be carried on the mesh of the present invention, for example the delivery tube may be laced through the mesh. This allows the delivery tube to move in tandem with expansion and contraction of the mesh. The delivery tube may be disposed beneath the surface of the sheath. The delivery tube may be exposed on the outer surface of the sheath. The tubing may be provided with a series of apertures therein to allow for release of a therapeutic agent or fluid within the tubing into the surrounding vessel. In embodiments where the drug delivery tubing is disposed beneath the sheath, the tubing apertures may be provided in registration with a series of sheath apertures to allow for movement of, for example diffusion of, the therapeutic material out of the tubing and into the surrounding vessel.

[0043] The tubing may be employed to deliver or infuse therapeutic agents in to the vessel at the location of the device. As no needles are required to inject the therapeutics there is no need for protective protuberances to conceal the tubing in embodiments where the tubing is exposed to the surface.

[0044] The sheath may be secured to a catheter by any number of methods known by a person skilled in the art. For example, a tie such as a thread may be wrapped tightly around the ends of the sheath and the sheath subsequently glued to the catheter.

[0045] The invention extends to a device, mesh and various assembles described herein with reference to and as illustrated in the accompanying drawings. It will be appreciated that the products which are the subject of the present invention are suitable for over-fitting to a balloon catheter, as will be described below. The device will be desirably resiliently biased against expansion by the balloon and thus will return to the contracted configuration easily when expansive force applied by the balloon is removed. Desirably the mesh of the invention surrounds substantially all of the balloon. Where a sheath is present desirably substantially all of the balloon is surrounded by both the mesh and the sheath.

Brief Description of the Drawings

[0046] **Figure 1** shows an end (sectional) view of an expandable mesh of the present invention.

[0047] **Figure 2** shows an end (sectional) view of an assembly comprising a mesh and sheath for inclusion in a device of the present invention.

[0048] **Figure 3** shows a similar view to Figure 2 and of a further embodiment of the invention which is similar to that of Figure 2.

[0049] **Figure 4** shows a similar view to Figures 2 and 3 of a further embodiment of the invention which is similar to that of those Figures.

[0050] **Figure 5** shows a flattened out top plan view of a mesh of the present invention.

[0051] **Figure 6** shows a flattened out top plan view of an alternative mesh arrangement to that of Figure 5.

[0052] **Figure 7** shows an enlarged view of the **part A** of the device of Figure 6.

[0053] **Figure 8** shows a perspective view of a mesh of the invention forming an annular shape and comprises a series of mesh portions.

[0054] **Figure 9** shows a perspective view of a device which is similar in construction to that of Figure 8.

[0055] **Figure 10** shows an enlarged view of the **part A** of the device of Figure 9.

[0056] **Figure 11** shows a perspective view of a further embodiment of a collapsible treatment device in the expanded configuration.

[0057] **Figure 12** shows a perspective view the mesh device of the invention applied to a balloon catheter device such as an angioplasty balloon device.

[0058] **Figure 13** shows an end sectional view of a mesh device of the invention with blades attached thereto.

[0059] **Figure 14** shows an end sectional view of a mesh device of the invention with needles attached thereto.

[0060] **Figure 15(a)-(b)** shows two end-sectional views of a combined sheath/mesh device of the invention undergoing expansion (top to bottom) and contraction (bottom to top).

[0061] **Figure 16(a)-(c)** shows respective side views of a blades of the invention;

[0062] **Figure 17** shows an enlarged view of part of the blade of Figure 16(b).

[0063] **Figure 18** shows an enlarged view of part of the blade of Figure 16(c).

[0064] **Figure 19** shows how the blade of Figure 16(b) and Figure 17 engages with a mesh.

[0065] **Figure 20** shows how the blade of Figure 16(c) and Figure 18 engages with a mesh.

[0066] **Figure 21** shows a cross section of a tapered balloon catheter utilised to inflate the sheath.

[0067] **Figure 22** shows the embodiment illustrated in Figure 21 having blades carried thereon.

[0068] **Figure 23** shows a balloon catheter having a sheath according to the present invention thereon with struts extending from the sheath.

[0069] **Figure 24** shows a close up of the struts of Figure 23.

[0070] **Figure 25** shows and embodiment in which the struts of Figure 24 are covered.

[0071] **Figure 26** shows a further magnification of the struts of Figure 23.

[0072] **Figure 27** shows a snap-fit arrangement for attaching a blade to the expandable mesh of the present invention.

[0073] **Figure 28** shows a close up of the snap-fit arrangement illustrated in Figure 27.

[0074] **Figure 29** shows a schematic of the mating of the blade with the expandable mesh of the present invention.

[0075] **Figure 30** shows a blade attached to the mesh at a plurality of loci.

[0076] **Figure 31** shows a horizontal section of a device according to the present invention having a drug delivery tube therein.

[0077] **Figure 32** shows a 3-dimensional perspective of the device in Figure 31.

[0078] **Figure 33** shows a horizontal section of the device in Figures 31 and 32.

[0079] **Figure 34** shows an expandable mesh according to the present invention having a drug delivery tube and a snap-fit blade incorporated into the mesh.

Detailed Description of the Drawings

[0080] One of the principal inventive concepts of the present invention is to provide a mesh which provides additional retractive force against the expandable portion (to move it towards the non-working configuration) in combination with one or more protective protuberances which protect one or more implements (such as blades or needles) during insertion toward the target site and which flatten to expose said implement(s) when the device is expanded to a working configuration. The protuberances are desirably on the sheath or on the mesh.

[0081] One embodiment of the present invention is shown in **Figure 1**. Figure 1 shows an end (sectional) view of an expandable mesh of the present invention. The mesh 1 comprises a mesh portion in the form of an annular body 2 which defines a cavity 3. An expandable portion such as a balloon (for example of a balloon catheter

such as an angioplastly balloon) can be inserted in cavity 3. It is desirable that the mesh 1 is made from a shape memory material. In the embodiment the mesh is provided with a treatment implement in the form of a blade 4. The mesh 1 further comprises two protuberances 5,6 each on opposing sides of the blade. As shown in the embodiment it is desirable that the protuberances are integrally formed with the annular body 2. In particular as is shown it is desirable that the protuberances are also meshed. The two protuberances 5, 6 protect the blade 4 from contact with a vessel wall during insertion of the device. As will be described in more detail below for other embodiments, when the mesh is overfitted on a device and the cavity 3 is occupied by an expandable portion such as a balloon, expansion of the balloon causes the annular body 2 to expand and flatten, the protuberances in the form of ears or lobes 5, 6 will tend to flatten out thus exposing the blade 4 for treatment of a target site. The reverse process occurs with deflation when the protuberances 5, 6 return to their original shape to shield the treatment implement. The entire mesh 2, including protuberances 5, 6 is thus resiliently deformable with a bias toward the contracted configuration. If desired the device can further comprise one or more delivery reservoirs 7 formed within the protuberances. The delivery reservoirs 7 are for delivery of a medicament such as a therapeutic solution. The device can be configured so that the collapsing action of a protuberance expels the therapeutic solution. The device of Figure 1 could be adapted to have additional protuberances shielding one or more additional implements. These could for example be circumferentially arranged about the mesh 2. For example three sets approximately 120^0 apart may be utilised. It will be appreciated that the implement may be integrally formed with the mesh. However such an arrangement while desirable may be expensive. An alternative is to catch at least part of the implement, such as a base thereof, beneath the mesh. This may be achieved by partial insertion through the mesh. For example it may extend partially through the mesh from underneath. The problem of loss of the implement due to detachment during movement of the device is thus substantially reduced as the implement is directly held in place by the mesh.

[0082] A further embodiment of the present invention is shown in **Figure 2**. Figure 2 shows an end (sectional) view of an assembly for forming part of a device of the present invention. In this embodiment the assembly 20 comprises a mesh (or mesh portion) in the form of an annular body 22 which defines a cavity 23. An expandable portion such as a balloon (for example of a balloon catheter such as an angioplasty balloon) can be inserted in cavity 23. It is desirable that the mesh 22 is made from a shape memory material. The mesh 22 is embedded within a sheath 27. The sheath 27 is made of a resiliently deformable material such as an elastomeric material and is

generally annular in shape. A plurality of implements are circumferentially spaced about the device. In the embodiment there are four implements approximately 90^0 apart, in the form of blades 24. The blades 24 are carried on the mesh 22 and are held in place by the mesh. This may be achieved in any suitable arrangement as set out above. For example the blade or a carrier therefor extends through the sheath 27 so that the mesh and the implement are connected by one or more connecting portions extending through the sheath 27.

[0083] In the embodiment the sheath 27 further comprises four pairs of protuberances in the form or ears or lobes 25,26 each protuberance on opposing sides of a respective blade 24. As shown in the embodiment it is desirable that the protuberances 25,26 are integrally formed around the annular body 22. In the embodiment the protuberances are non-hollow lobes. The protuberances collapse on expansion of the device to reveal the blades 24 as described for other embodiments.

[0084] The arrangement of the blades on the mesh ensure that the blades are firmly fixed in place and are much less likely to become disengaged. Furthermore the resilient expansion of the mesh provides additional bias towards the non-working configuration and thus the device of the invention returns to a compact arrangement for travel within a vessel when returned to the non-expanded configuration. When combined with a resilient expansion of the sheath the bias toward the non-working configuration is even greater.

[0085] **Figure 3** shows a yet further embodiment of the invention which is similar to that of Figure 2. Figure 3 shows an end (sectional) view of an assembly for forming part of a device of the present invention. In this embodiment the assembly 30 comprises a mesh (or mesh portion) in the form of an annular body 32 which defines a cavity 33. An expandable portion such as a balloon (for example of a balloon catheter such as an angioplasty balloon) can be inserted in cavity 33. It is desirable that the mesh 32 is made from a shape memory material. The mesh 32 is positioned beneath a sheath 37. As with other embodiments the sheath 37 is made of a resiliently deformable material such as an elastomeric material. A plurality of implements are circumferentially spaced about the device. In this embodiment there are four implements approximately 90^0 apart, in the form of blades 34. The blades 34 are carried on the mesh 32 as described above for other embodiments. For example each blade or a carrier therefor extends through the sheath 37 so that each implement and the mesh are connected by one or more connecting portions extending through the sheath 37.

[0086] As above the sheath 37 further comprises protuberances in the form or ears or lobes 35,36 each protuberance on opposing sides of a respective blade 24. In fact in

the embodiment there are two pairs of protuberances 35,36 and each extends between two blades to provide shielding for two blades at the same time. As shown in the embodiment it is desirable that the protuberances 25,26 are integrally formed with the sheath 37. In the embodiment the protuberances are (closed) hollow lobes providing an enclosed space 38 allowing a given enclosed space or protuberance to provide a conduit or reservoir. The protuberances collapse on expansion of the device to reveal the blades 34 as described for other embodiments. The collapsing action may also be used to expel therapeutic fluids as described above.

[0087] Again the arrangement of the blades on the mesh ensure that the blades are firmly fixed in place and are much less likely to become disengaged. Furthermore the resilient expansion of the mesh provides additional bias towards the non-working configuration and thus the device of the invention returns to a compact arrangement for travel within a vessel when returned to the non-expanded configuration. When combined with a resilient expansion of the sheath the bias toward the non-working configuration is even greater.

[0088] **Figure 4** shows an embodiment similar to those described above. An assembly 40 comprises a mesh (or mesh portion) in the form of an annular body 42 which defines a cavity 43 for an expandable portion such as a balloon. cavity 43. The mesh 42 is positioned above (and around) a sheath 47. As with other embodiments the sheath 47 is made of a resiliently deformable material such as an elastomeric material. A plurality of implements are circumferentially spaced about the device. In the embodiment there are four implements approximately 90^0 apart, in the form of blades 44. The blades 44 are carried on the mesh 42 as described above for other embodiments. The mesh sits close about the sheath 47.

[0089] As above the sheath 47 further comprises protuberances in the form of ears or lobes 45,46 each protuberance on opposing sides of a respective blade 44. In fact in the embodiment there are two pairs of protuberances 45,46 and each extends between two blades to provide shielding for two blades at the same time. As shown in the embodiment it is desirable that the protuberances 45,46 are integrally formed with the sheath 47. In the embodiment the protuberances are (closed) hollow lobes providing an enclosed space 48 allowing a given enclosed space or protuberance to provide a conduit or reservoir. The protuberances collapse on expansion of the device to reveal the blades 44 as described for other embodiments. The collapsing action may also be used to expel therapeutic fluids as described above.

[0090] In the embodiment the mesh 42 is outside the annular body of the sheath but does not extend beyond the protuberances. In this way the implements 44 are still

shielded even though the mesh is external to the sheath. If desired the mesh can extend through the protuberances where they join the sheath, but in many embodiments the mesh will not extend through the protuberances but extend about same.

[0091] Again the arrangement of the blades on the mesh ensure that the blades are firmly fixed in place and the resilient expansion of the mesh provides additional bias towards the non-working configuration.

[0092] **Figure 5** shows one example of a mesh of the invention. In particular Figure 5 shows a flattened out top plan view of a mesh 52 of the present invention. The mesh 52 comprises a number of elements 59 each of which follows a tortuous path. In the embodiment the tortuous path is a path with a series of s-bends. The mesh is made from a resiliently deformable material and in particular a shape-memory material. Each element resiliently deforms under expansion (indicated by arrows 510) by decreasing tortuosity of its path. The distance between ends of the element increases as the element is extended.

[0093] A series of elements 59 are provided (in a side-by-side configuration) so as that the mesh 52 comprises a series of mesh portions 512 and is substantially continuous in a circumferential direction and an axial direction. Such an arrangement is suitable for applying to an expandable portion of a balloon catheter. It will be appreciated that the mesh 52 can be arranged in an annular manner for fitting over such an expandable portion. Implements, in the form of blades 54, are provided on the mesh. In the embodiment they, together with the elements 59, have been cut from a tubular piece. In other arrangements the implements can be welded to the mesh. Alternatively instead of implements being provided on the mesh directly implement holders can be provided. Such a mesh is suitable for use in any embodiment of the present invention. When utilised in the embodiment of Figure 1 the mesh will be formed to provide both an annular shape and one or more protuberances thereon for shielding the implement.

[0094] **Figure 6** shows an alternative mesh arrangement to that of Figure 5. In Figure 6 the mesh 62 comprises a series of discreet, spaced apart mesh portions 612. In particular the mesh portions are not integrally formed but are joined by one or more separate elements. Each portion 612 is formed by a tortuous element 69. In the embodiment an implement in the form of the blade 64 forms a support which joins the mesh portions together. The arrangement shown includes four discrete parts of the mesh. While such an arrangement may be used in any embodiment of the invention it is desirable to utilise such a mesh arrangement with an embodiment such as that

described in Figure 2 with the mesh embedded in a sheath. To help with anchoring the mesh anchor points 613 are desirably provided on the free ends of the elements 69. As discussed in relation to Figure 5 the mesh portions can expand (circumferentially about the device) as indicated by arrows 610.

[0095] **Figure 7** is an enlarged view of the **portion A** of the device shown in Figure 6. In Figure 7 the mesh portion 612 is more clearly seen as is the tortuous path of the element 69.

[0096] **Figure 8** shows a perspective view of a device 81 which is similar in construction to that of Figures 5-7. Figure 8 shows a mesh comprising an annular portion 82, which comprises a series of mesh portions 89 joined by a plurality of structural members 813 (in the embodiment there are four of them which are spaced 90^0 apart). The structural members 813 join the mesh portions together to form the annular arrangement shown. As is a desirable arrangement the structural members 813 carry the implements 84.

[0097] The arrangement of Figure 8 can be arranged so that the annular body is (i) buried in a sheath such as shown in Figure 2; (ii) beneath the sheath such as shown in Figure 3 or above the sheath such as shown in Figure 4. While the mesh layout differs from that of Figures 5 and 6 it will be appreciated that those mesh patterns are also suitable for forming an annular mesh arrangement. As with the other embodiments of the invention it is desirable that in a contracted configuration the implements are shielded by protuberances.

[0098] **Figure 9** shows a perspective view of a device 91 which is similar in construction to that of Figures 5-7 and in particular Figure 8. Figure 9 shows a mesh comprising an annular portion 92, which comprises a series of mesh portions 99 joined by a plurality of structural members 913 (in the embodiment 4 of them spaced 90^0 apart). The structural members 913 join the mesh portions together to form the annular arrangement shown. As is a desirable arrangement the structural members 913 carry the implements. In the embodiment the implements take the form of needles 915, in particular microneedles suitable for injecting fluids into the wall of a vessel in which the device is placed. An enlarged view of **portion A** of the device is shown in **Figure 10**.

[0099] The arrangement of Figure 9 can be arranged so that it is buried in a sheath, beneath the sheath or above the sheath. As with the other embodiments of the invention it is desirable that in a contracted configuration the implements are shielded by protuberances on the sheath.

[00100] As best seen from Figure 10 it is desirable that the device further comprises conduits which are in fluid communication with the needles 915 for example to supply a

therapeutic fluid. In one simple construction seen in Figures 9 and 10 the conduits 916 are formed on or as part of the structural members 913.

[00101] **Figure 11** shows a further embodiment of a collapsible treatment device 1101 for treating a target area of a vessel wall of a vessel within a human or animal body. The device is similar in construction to previous embodiments but is shown in the expanded (working) configuration. In the expanded configuration each (s-shaped) element 1109 has opened out under expansive pressure from within a cavity 1103. This increases the distance between the respective loops in the tortuous path formed by member 1109 and results in a more zig-zag pattern. In the expanded configuration the bias of the members 1109 is toward the contracted configuration with tight looping of the member.

[00102] Again structural members 1113 are provided to join the mesh portions together and they also carry implements, in this case blades 1104. The implements are thus carried on a structural element of the mesh. The material forming the elements 1109 is desirably a material which has memory for the contracted configuration.

[00103] **Figure 12** shows the mesh device of the invention applied to a balloon catheter device such as an angioplasty balloon device. The device includes a catheter 1220, and expandable portion on the device in the form of a balloon 1221 and a collapsible treatment device 1201 which has a form similar to that of Figure 11. As with Figure 11 the device in Figure 12 is shown in an expanded configuration. Expansion of the balloon brings the device into its working configuration. Desirably the balloon catheter device will further comprise a sheath having protuberances which protect, in the non-working configuration, the implements, and which retract (flatten) to expose the implements for use in the working configuration thereof.

[00104] As with all embodiments of the invention, and in contrast to devices which are adapted to deploy, for example to deliver and deploy a stent in a constricted part of a vessel to open it up, the devices of the present invention and in particular the mesh or mesh portion forms a permanent part of the device (and is non-releasable). The device can travel to a target site, be expanded to a working configuration, used to treat the target site, return to a non-working or travel configuration under bias from the sheath and mesh, and be re-expanded to treat a further target site.

[00105] **Figure 13** shows one example of how blades 1304 can be fitted to a mesh 1302. The mesh is arranged in an annular shape. A base portion of each blade 1304 has a flared head or collar 1325 which is dimensioned to hold the blade 1304 to the mesh.

[00106] **Figure 14** shows a similar arrangement with one example of how needles 1404 can be fitted to a mesh 1402. The mesh is arranged in an annular shape. A base portion of each needle 1404 has a flared head or collar 1425 which is dimensioned to hold the needle 1404 to the mesh 1402. As described above the needles can be supplied with fluid through a conduit.

[00107] **Figure 15** shows expansion of a mesh and sheath (top to bottom sequence (a) to (b)) and the sequence for contraction (bottom to top sequence (b) to (a)). As indicated by the double-headed arrow expansion followed by contraction can be repeated as many times as is desirable.

[00108] In Figure 15 it can be seen that both the mesh 1502 and the sheath 1507 expand under an expansive force. This has a number of effects, firstly the diameter **d** of the cavity 1503 increases, the wall thickness of the sheath 1507 decreases, and the protuberances 1505,1506 flatten. These effects mean that the implements in the form of blades 1504 move closer to the vessel wall and undergo greater exposure [from their shielded position in (a) until they are fully exposed in (b)].

[00109] Figure 16(a)-(c) shows respective side views of a blades of the invention. In **Figure 16(a)** a series of blades 164 which can be used with the present invention. The blades 164 are carried on a common carrier in the form of an elongate implement support which may be a rod 1631. The rod 1631 may additionally function as structural support elements (such as those shown as item 813 in Figure 8). The embodiment of implements shown in Figure 16(a) are however adapted to be inserted through a mesh from underneath, with the blades 164 extending through the mesh. In such an arrangement the implements can be bonded to the mesh, but the implement support will prevent the blades detaching from the mesh as it will be trapped beneath the mesh. Bonding to the mesh is desirable in such an instance to ensure that the mesh and the implements move in tandem. As can be seen slots or grooves 1633 define the space between the adjacent implements.

[00110] **Figure 16(b)** shows an array of implements in the form of blades 164 which are formed as a unitary piece, being joined by integrally formed connecting pieces 1632. Tabs 1630 are provided in the spaces between respective implements. An enlarged view of one pair of tabs 1630 is shown in **Figure 17**. As shown in **Figure 19** the implements 164 are inserted through a structural member 1613 of a mesh portion from underneath. In particular the implements 164 extend through slots 1640 in the structural member and stand proud thereof. The mesh does not therefore interfere with the working action of the implements. As the arrows 1641 indicate, the tabs 1630 can be turned over, for example by bending over the structural member thus securing the

array of implements securely to the structural member. This means the implements move in tandem with the structural element. This prevents recession of the implements which would otherwise reduce the exposure of the implements above the structural element. It will be appreciated that a structural member is not required where the implements are secured directly to a mesh. If desired additional fixture (between the mesh and the implements and/or the tabs) can be achieved using a suitable adhesive material.

[00111] **Figure 16(c)** shows an array of implements in the form of blades 164 which are formed as a unitary piece, being joined by integrally formed connecting pieces 1632. Again spaces 1633 are provided between the blades 164. In this embodiment apertures 1650 are formed in the blades 164. This is best seen from the enlarged view of part of the blade shown in **Figure 18**.

[00112] **Figure 20** shows how the blade of Figure 16(c) and Figure 18 engages with a mesh. The implements 164 are inserted through a structural member 1613 of a mesh portion from underneath. In particular the implements 164 extend through slots 1640 in the structural member and stand proud thereof. A pin 1651 can be inserted in each aperture 1650 thus securing the array of implements securely to the structural member. This means the implements move in tandem with the structural element. This prevents recession of the implements which would otherwise reduce the exposure of the implements above the structural element. It will be appreciated that a structural member is not required where the implements are secured directly to a mesh. If desired additional fixture (between the mesh and the implements and/or to fix the pin in place) can be achieved using a suitable adhesive material.

[00113] **Figure 21** illustrates in cross section, an embodiment in which a tapered balloon 2152 connected to a catheter tube in particular hypotube 2153 is inflatable within sheath 2107. The mesh (not shown) may lie in or under the sheath 2107 in this embodiment. The tapered balloon confers a tapered profile on the surrounding sheath 2107. Tapering of the device from the sheath apex 2155 to the distal catheter end 2154 is particularly advantageous as it provides a profile which is easily moved in a vessel. This allows for dynamic and relatively unimpeded movement of the device trough a body vessel to a target site. The sheath may be secured to the catheter by any number of methods known by a person skilled in the art. For example, a tie such as a thread may be wrapped tightly around the ends of the sheath and the sheath subsequently glued to the catheter.

[00114] The tapered balloon may match the anatomy of an artery, with the small end of the taper positioned distally within the artery and the large end positioned proximally within the artery. Thus matching the natural reduction in diameter as arteries taper down the further removed from the heart they are.

[00115] In **Figure 22** the tapered balloon is provided with a blade 2204 carried thereon.

[00116] A related tapered balloon catheter device is shown in **Figure 23**. A tapered balloon (not shown) is connected to catheter hypotube 2353. Intermediate the catheter hypotube 2353 and the sheath 2307 (and at a proximal end of the balloon) are a series of radial struts 2357. The radial struts form part of an anchoring structure for anchoring the mesh to the catheter. Similarly, a series of radial struts 2356 are disposed intermediate the distal catheter end 2354 and the sheath 2307. The struts provide structural support to the device helping secure the mesh (and in turn the sheath) in position. The sheath 2307 has blades 2304 carried thereon. The mesh (not shown) may lie in or under the sheath 2107 in this embodiment. The mesh is thus attached at proximal and distal ends of the balloon to the catheter. This results in a secure attachment to the catheter.

[00117] A magnified view of the distal end of the catheter is provided in **Figure 24**. The struts 2456 intermediate the distal catheter end 2454 and the sheath 2407 form an interlocking ring structure 2458 on the outer circumference of tapered balloon 2452 (attached to the distal end of the catheter 2454) so as to secure the struts to the catheter. A similar arrangement is provided to secure struts 2357 in Figure 23 to the catheter.

[00118] In order to minimise any damage that may be caused by exposed struts 2356 and 2357 (for example in the configuration shown in Figure 23,) the regions occupied by the struts may be covered. This will also aid in crossing a lesion, as there will be a smoother transition when crossing a tight lesion with a covered strut. For example a material that is easily over-fitted thereto and then shrunk to fit or bonded thereto may be employed as a cover. For example a suitable heat-shrink material such as a suitable thermoplastic material may be used as a cover. Alternatively the thermoplastic could be heat bonded over the struts and where appropriate to the catheter for example an outer surface thereof. Desirably such a cover adopts a suitable shape to match the conical profile of the device. For example, **Figure 25** depicts a heat shrunk thermoplastic cover 2559 adopting a tapered frusto-conical shape to sit between catheter distal end 2554 and sheath 2507. An analogous thermoplastic cover is desirably used to cover, for example affixed over, the struts 2357 of Figure 23.

[00119] A magnification of strut 2456 in Figure 24 is provided in **Figure 26**. The struts are constructed of two different materials. The underlying part of the strut is composed of the blade anchor material 2660. An upper part of the strut is formed by mesh anchor material 2661.This arrangement may be advantages as the blade and mesh will have an additional safety feature, whereby an extra mode of attachment is provided for. This could limit any potential structural complication.

[00120] **Figure 27** illustrates an inventive snap-fit mechanism for attaching a blade 2704 to the mesh 2702. In this embodiment the blade slots into and is attached to the mesh. Mesh portion 2709 is provided with peg-like projections 2762. The peg like projections are shaped for engagement with complimentary shaped recesses 2763 on blade 2704. A magnified view of the mesh pegs 2762 proximate to the blade 2704 recesses 2763 is shown in **Figure 28**. In Figure 28 there are two projecting pegs 2862 which are shaped to fit into blade recesses 2863. Blade recesses 2863 are provided with retaining members in the form of restrictions 2864 such that once the peg 2862 has been forced into recess 2863, the restricting action of restrictions 2864 hinders escape of the peg 2862 from the recess 2863.

[00121] **Figure 29** illustrates two stages of the action of mating mesh peg projections 2962 of mesh 2902 with blade recesses 2963 of blade 2904. The bold vertical arrow 2965 indicates the application of a pushing force to the under surface of blade 2904 such that the mesh pegs 2962 mate with recesses 2963. Once in the mated configuration restrictions 2964 secure the peg 2962 in the recess preventing escape therefrom. It will be appreciated that this form of mechanical attachment allows for differing relative movement of the implement(s) and the mesh which is desirable as discussed above. The peg 3062 has an enlarged head 2966. The enlarged head of peg 3062 is secured in the blade recess 2963 by restrictions 2964 in the recess 2963.

[00122] The embodiments illustrated in Figures 27 to 29 depict twin mesh pegs mating with twin blade recess. A skilled person in the art would appreciate a single peg mating with a single recess would be equally as effective. In **Figure 30** a mesh 3002, provide with a series of mesh portions 3009 has a blade 3004 carried thereon. The blade 3004 is secured to the mesh by means of a single peg projection 3062 mating with a single blade recess 3063. . As is desirable for all embodiments there are a plurality, desirably at least three, for example at a distal intermediate and proximal location along the mesh of such mating points at cooperating loci along the length of the mesh 3002 and the blade 3004 so as to enable secure attachment of the blade 3004 to the mesh 3002 at a plurality of different locations. The mating points may be evenly spaced along the length of the blade and the mesh. Alternatively, there may be

irregular spacing between each mating point at its neighbour. Desirably, spacing between each mating point and its neighbour is equidistant.

[00123] **Figure 31** illustrates an embodiment of the present invention adapted for drug delivery proximate to the site of device implantation. The end (sectional) view of an assembly for forming part of a device of the present invention comprises a mesh (or mesh portion) in the form of an annular body 3102 which defines a cavity 3103. An expandable portion such as a balloon (for example of a balloon catheter such as an angioplasty balloon) can be inserted in cavity 3103. It is desirable that the mesh 3102 is made from a shape memory material. The mesh 3102 is embedded within a sheath 3107. The sheath 3107 is made of a resiliently deformable material such as an elastomeric material and is generally annular in shape. In the embodiment there are two implements diametrically opposed, in the form of blades 3104. The blades 3104 are carried on the mesh 3102 and are held in place by the mesh. This may be achieved in any suitable arrangement as set out above.

[00124] In the embodiment the sheath 3107 further comprises two pairs of protuberances in the form or ears or lobes 3105,3106 each protuberance on opposing sides of a respective blade 3104. As shown in the embodiment it is desirable that the protuberances 3105,3106 are integrally formed with the sheath 3107. In the embodiment the protuberances are non-hollow lobes. The protuberances collapse on expansion of the device to reveal the blades 3104 (and return to the erect position when expansive force is removed) as described for other embodiments.

[00125] The two blade arrangement on the mesh is designed to provide a device having improved bending characteristics than a three or four blade device.

[00126] The embodiment is further provided with tubing 3167. Two tubing members are desirably provided at a position about the device intermediate the implements and may be provided diametrically opposite one another. The tubing 3167 delivers therapeutic agents to the target vessel. The tubing 3167 can be a component attached to the mesh 3102 for example as described with reference to implements or it could be integrated with the mesh 3102. The tubing 3167 is desirably housed within the sheath 3107 as shown in this embodiment as this provides protection for a vessel from contact with the tubing during travel of the device within the vessel. Alternatively, the tubing 3167 can be exposed on the external surface of the sheath 3107. The tubing 3167 may be employed to deliver or infuse therapeutic agents in to the vessel at the location of the device. As no needles are required to inject the therapeutics there is no need for protective protuberances to conceal the tubing 3167 in embodiments where the tubing is exposed to the surface.

[00127] A 3-dimensional perspective of the embodiment shown in Figure 31 is provided in **Figure 32**. The device comprises a mesh (or mesh portion) in the form of an annular body 3202 which defines a cavity 3203. An expandable portion such as a balloon (for example of a balloon catheter such as an angioplasty balloon) can be inserted in cavity 3203. The mesh 3202 is embedded within a sheath 3107. The sheath 3207 is made of a resiliently deformable material such as an elastomeric material and is generally annular in shape. In the embodiment blades 3204 are carried on the mesh 3202 and are held in place by the mesh. The blades 3204 are concealed by protuberances 3205,3206. Two tubing members 3265 are disposed directly opposite one another.

[00128] The sheath comprises a plurality of drug delivery apertures 3268 which provide a direct channel from corresponding release apertures in the tubing 3267 to release therapeutic materials to the surrounding vessel. Thus, therapeutic agents can passively diffuse from the tubing 3267 into the surrounding vessel through drug delivery apertures 3268, without the need for injection.

[00129] A horizontal section of the device shown in Figure 32 is illustrated in **Figure 33**. The mesh 3302 acts as support that holds the tubing 3365 and blades 3304 in the correct position. Attaching the blades 3304 and the tubing 3367 to the mesh 3302 causes them to return to their original position after balloon deflation.

[00130] The sheath 3307 does not need to conceal the drug delivery tubing 3367. However, in the embodiment illustrated in Figure 33 the tubing 3367 is disposed under the sheath 3307. The drug delivery apertures 3368 allow for diffusion of therapeutic materials infused into tubing 3367.

[00131] A mesh 3402 having tubing 3467 attached by lacing through apertures in the mesh is illustrated in **Figure 34**. The tubing 3467 is threaded through (over and under the mesh) the mesh 3402 thus fixing it in place. The tubing 3467 is provided with drug deliver apertures 3469 for releasing therapeutic materials from the tubing 3467. In the embodiment shown no sheath is provided and the tubing 3467 is exposed to the vessel. In embodiments with a sheath the skilled person would appreciate that drug deliver apertures 3469 could be placed in register to directly underlay corresponding apertures on the sheath. Figure 34 is also provided with the snap-fit blade 3404 arrangement described in Figures 27 to 30.

[00132] The words “comprises/comprising” and the words “having/including” when used herein with reference to the present invention are used to specify the presence of stated features, integers, steps or components but do not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

[00133] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub-combination.

Claims

1. A collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, comprising
    (i) a mesh portion having a contracted configuration allowing travel within the vessel to the target area and an expanded configuration allowing treatment of the target area;
    (ii) at least one treatment implement carried on the mesh portion; and further comprising
    (iii) at least one protuberance which protects the vessel from contact with the implement during travel within the vessel.

2. A device according to Claim 1 wherein the protuberance is formed by the mesh portion.

3. A device according to Claim 1 or Claim 2 comprising a plurality of protuberances formed by the mesh portion

4. A device according to Claim 1 wherein the mesh portion comprises a main body which is annular.

5. A device according to any preceding claim wherein the mesh portion comprises at least one element which follows a tortuous path, the element resiliently deforming under expansion by decreasing tortuosity of its path.

6. A device according to any preceding claim further comprising a protective sheath for protecting the vessel from contact with the implement during travel within the vessel.

7. A device according to Claim 6 wherein said at least one protuberance which protects the vessel from contact with the implement during travel within the vessel is provided on the sheath.

8. A device according to any preceding claim wherein the protuberance deforms to expose the implement in the expanded configuration of the device.

9. A device according to anyone of Claim 1 to 5 wherein the protuberance houses the implement and the implement extends through the protuberance in the expanded configuration of the device.

10. A device according to any one of Claims 6 to 9 wherein the mesh portion is embedded within the sheath.

11. A device according to any one of Claims 6 to 9 wherein the mesh portion overlies the sheath.

12. A device according to any one of Claims 6 to 9 wherein the mesh portion underlies the sheath.

13. A device according to any one of Claims 6 to 9 wherein the mesh portion overlies the sheath and the protuberance extends from the sheath past the mesh portion.

14. A device according to any preceding claim wherein the device further comprises an expandable portion such as a balloon and the mesh portion is fitted over the expandable portion.

15. A device according to Claim 14 wherein the mesh portion is fitted over the expandable portion so as to secure both the mesh and the expandable portion to a catheter.

16. A device according to Claims 14 or 15 wherein the expandable portion is tapered.

17. A device according to any preceding claim wherein the mesh portion is machined from a tubular portion.

18. A device according to any preceding claim wherein the mesh portion is formed by moulding.

19. A device according to any preceding claim comprising at least two annular mesh portions.

20. A device according to any preceding claim comprising at least three annular mesh portions.

21. A device according to Claim 19 or 20 wherein the mesh portions are integrally formed.

22. A device according to any one of Claims 19 to 21 wherein each mesh portion forms a turn within a helix.

23. A device according to Claim 19 or Claim 20 wherein said annular mesh portions are not integrally formed but are joined by one or more separate elements.

24. A device according to Claim 23 wherein said one or more separate elements comprises a treatment implement or a carrier for a treatment implement.

25. A device according to any one of Claims 6 to 24 wherein the sheath forms an inflatable balloon.

26. A device according to any preceding Claim further comprising drug delivery tubing.

27. A device according to Claim 26 wherein the drug delivery tubing is disposed on the outer surface of the sheath.

28. A device according to Claim 26 wherein the drug delivery tubing is disposed within the sheath.

29. A device according to Claims 26 to 28 wherein the drug delivery tubing is carried on the mesh.

30. A collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the device comprising:

an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area to an expanded configuration allowing treatment of the target area,

the mesh portion being constructed of a shape memory material which has memory for the contracted configuration, and

at least one treatment implement carried on the mesh portion.

31. A device according to Claim 30 which has one or more of the additional features of Claims 1 to 29.

32. An expandable mesh for use with a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the mesh comprising:

an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area, to an expanded configuration allowing treatment of the target area, and

at least one treatment implement carried on the mesh portion, the mesh portion further comprising at least one protuberance which protects the vessel from contact with the implement during travel within the vessel.

33. An expandable mesh for use with a collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the mesh comprising:

(i) an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area, to an expanded configuration allowing treatment of the target area;

(ii) at least one treatment implement carried on the mesh portion; and

(iii) a sheath provided on the mesh the sheath comprising at least one protuberance which protects the vessel from contact with the implement during travel within the vessel.

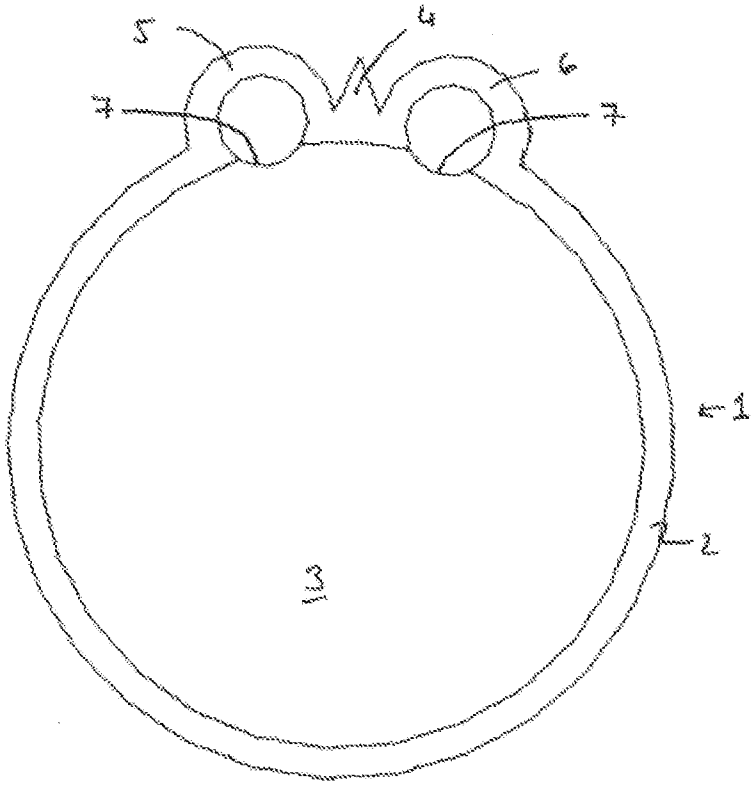


Figure 1

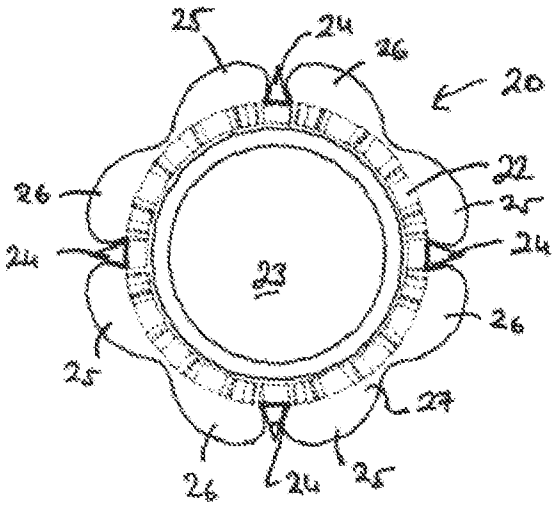


Figure 2

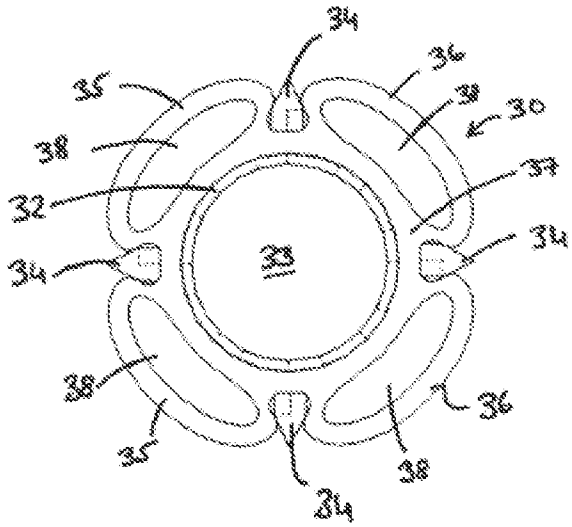


Figure 3

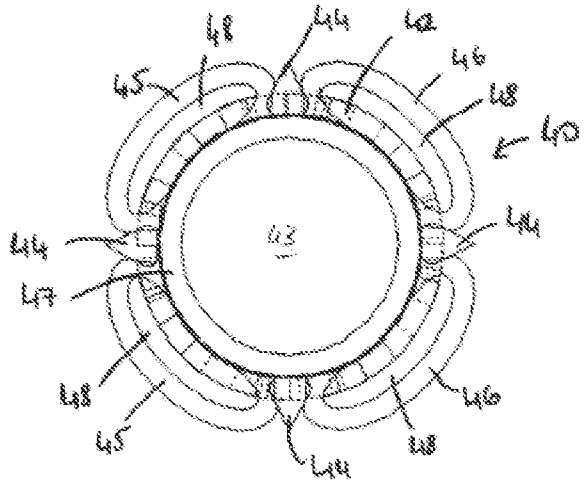


Figure 4

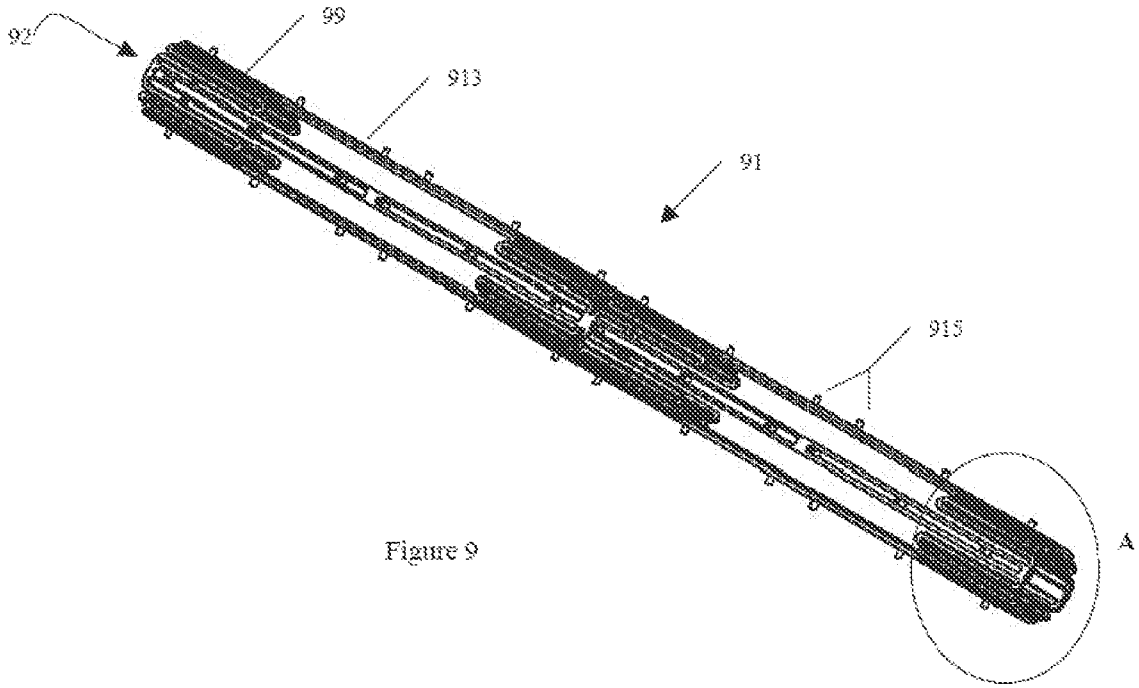


Figure 9

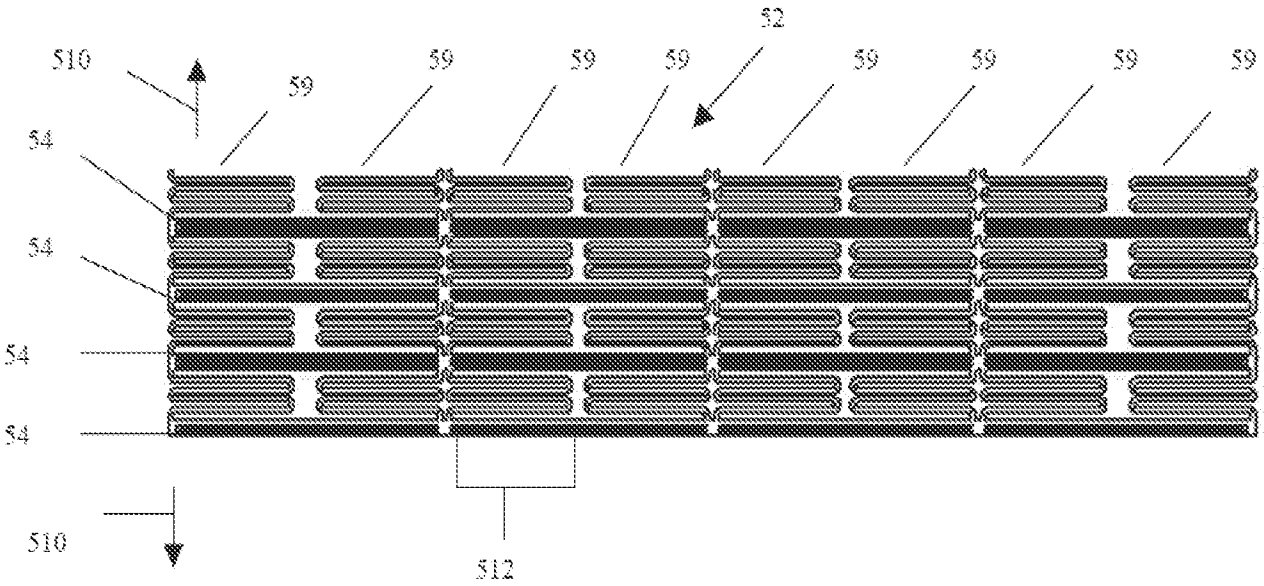


Figure 5

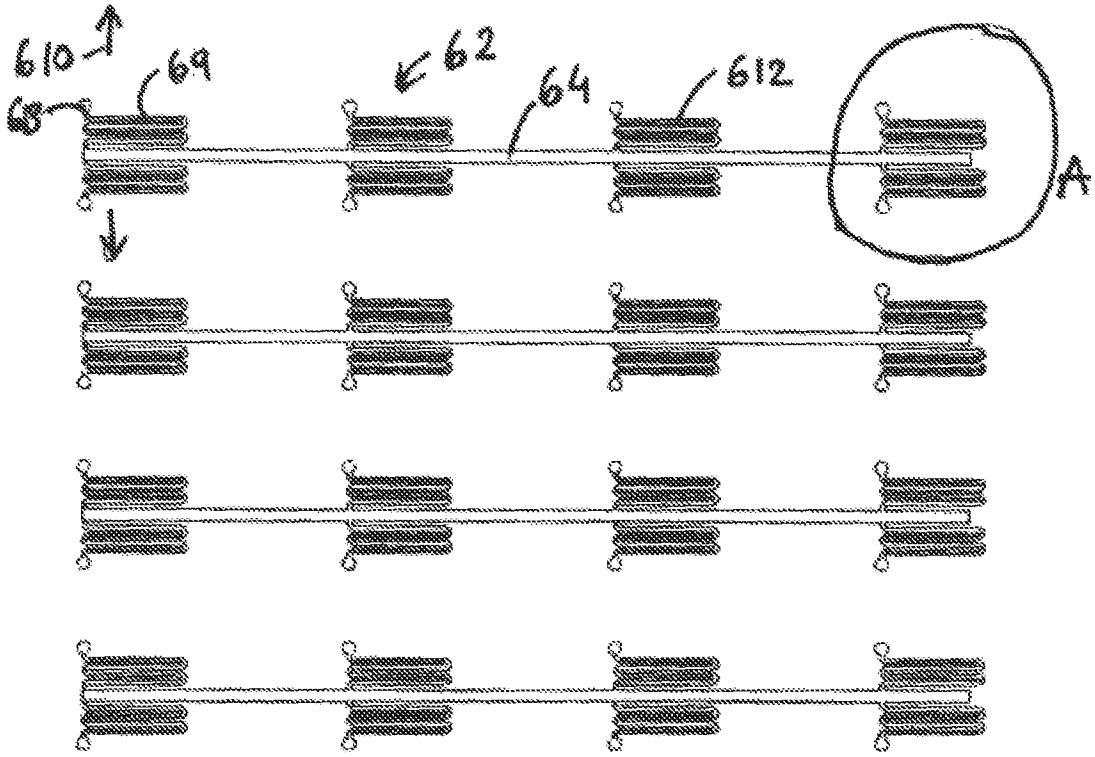


Figure 6

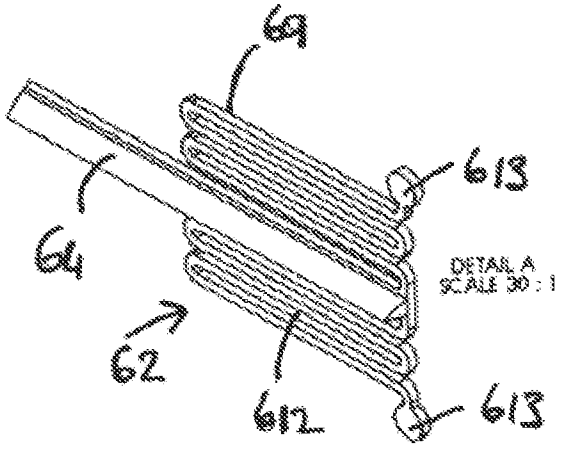


Figure 7

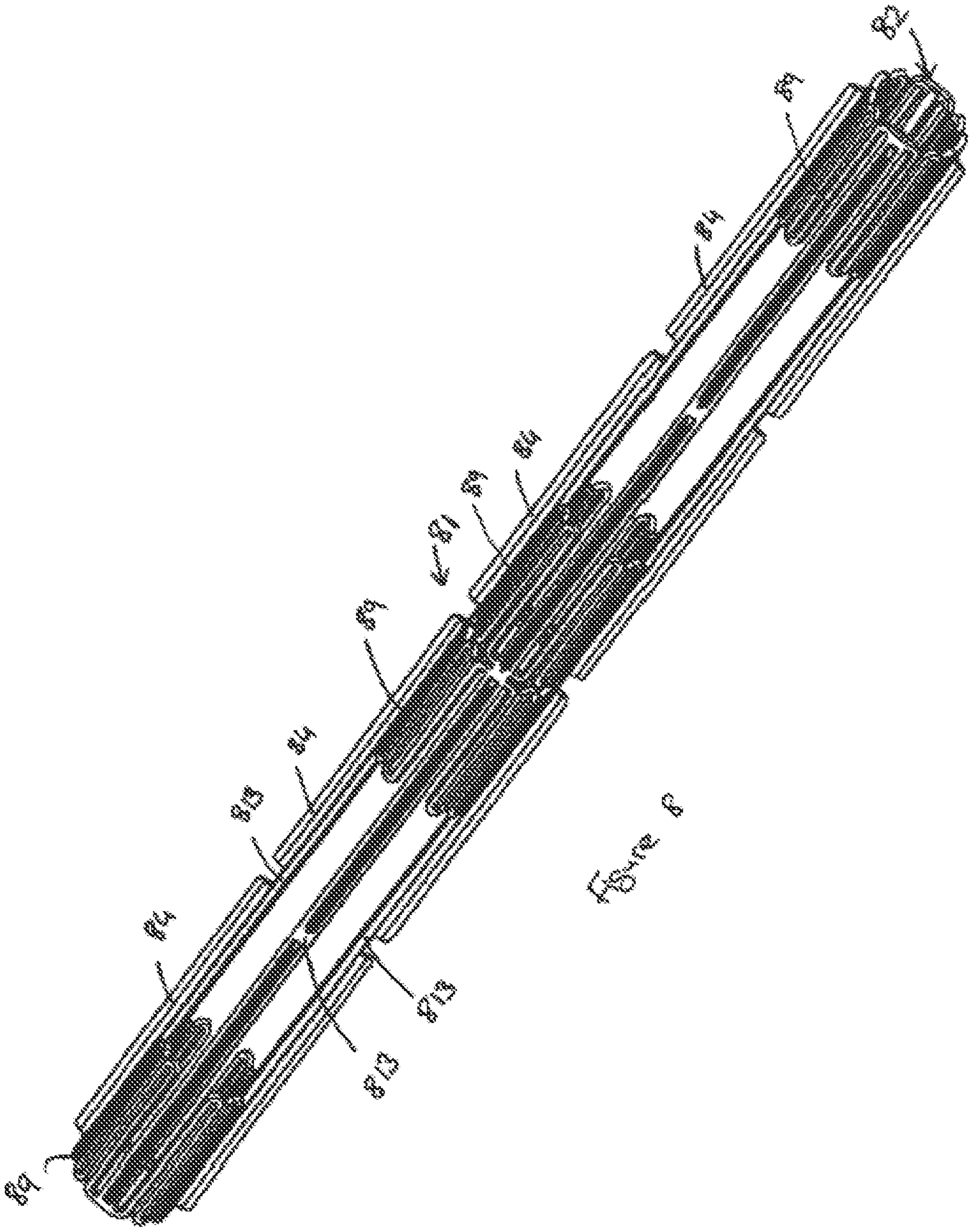


Figure 8

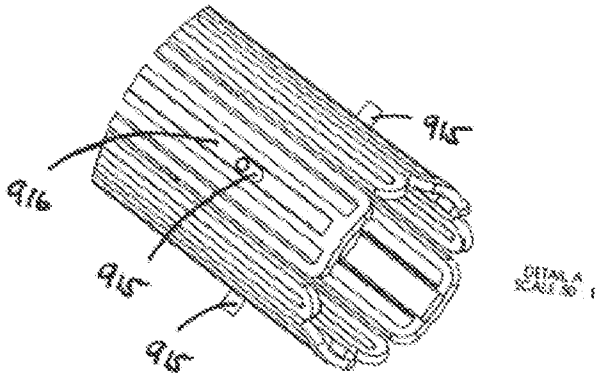


Figure 10

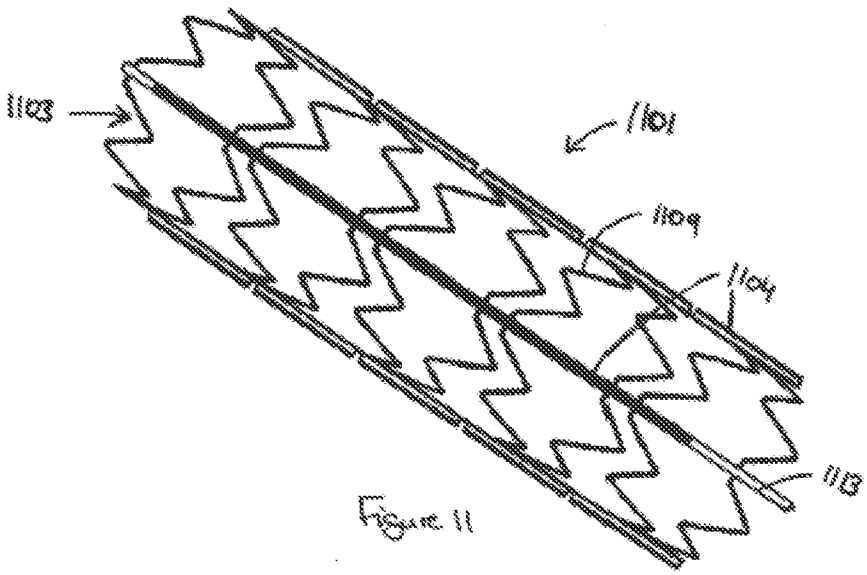


Figure 11

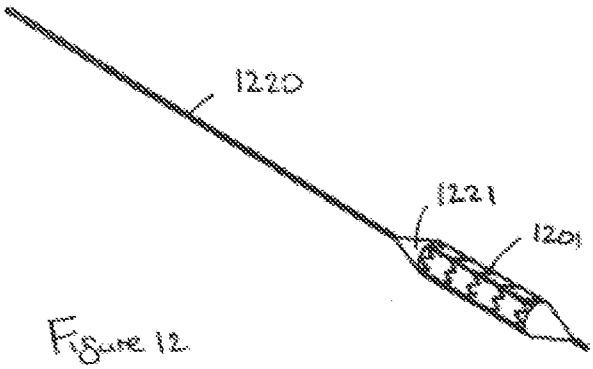


Figure 12

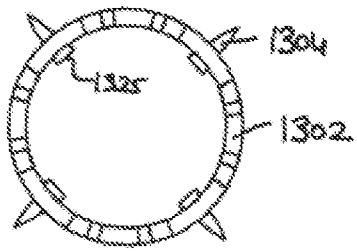


Figure 13

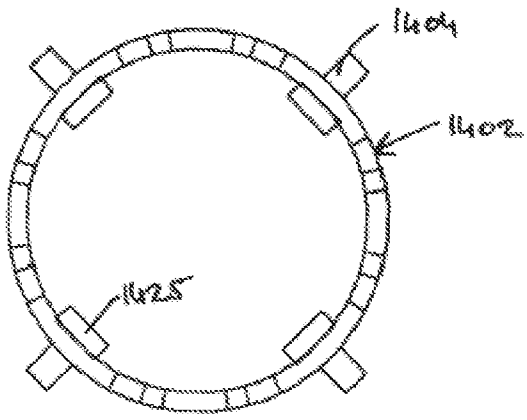
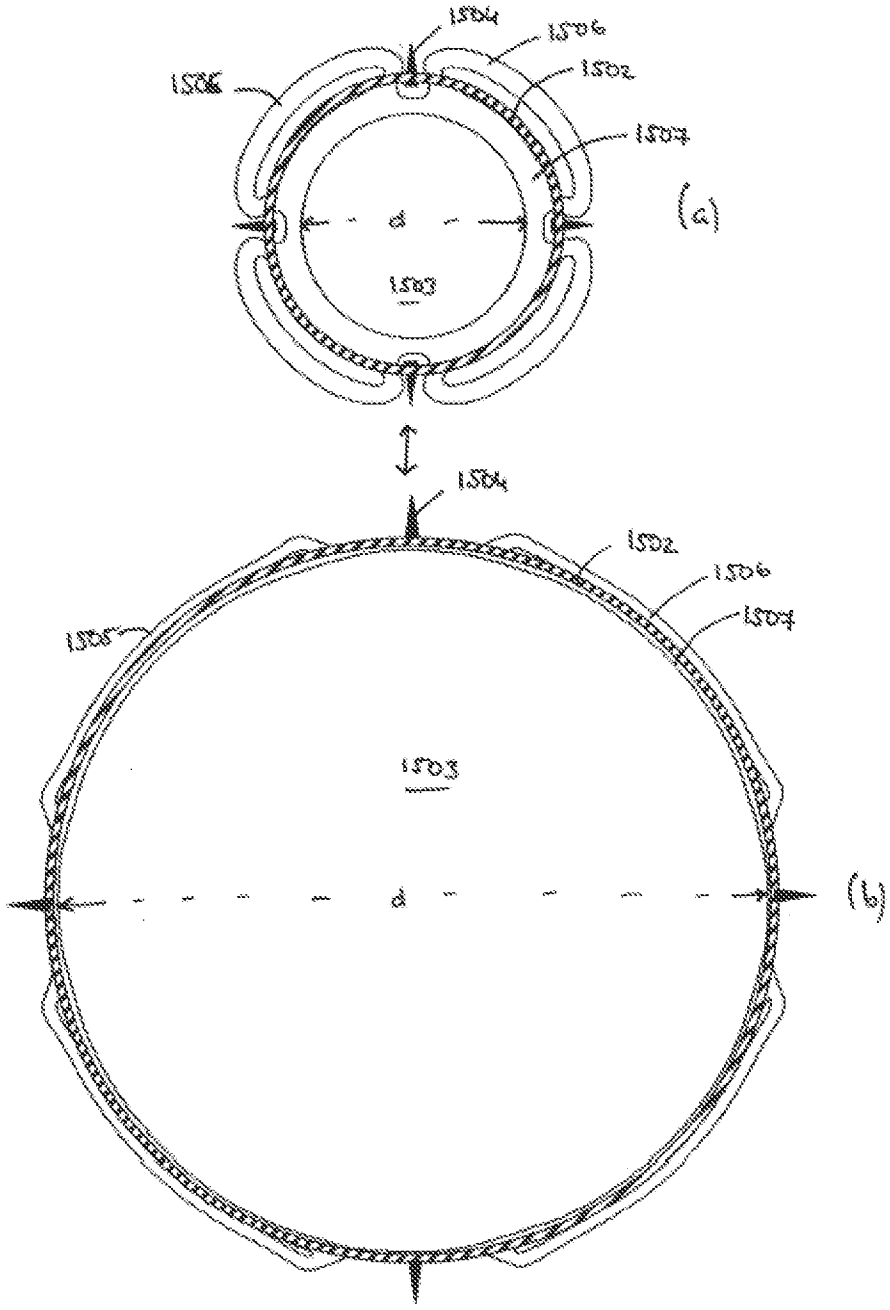


Figure 14



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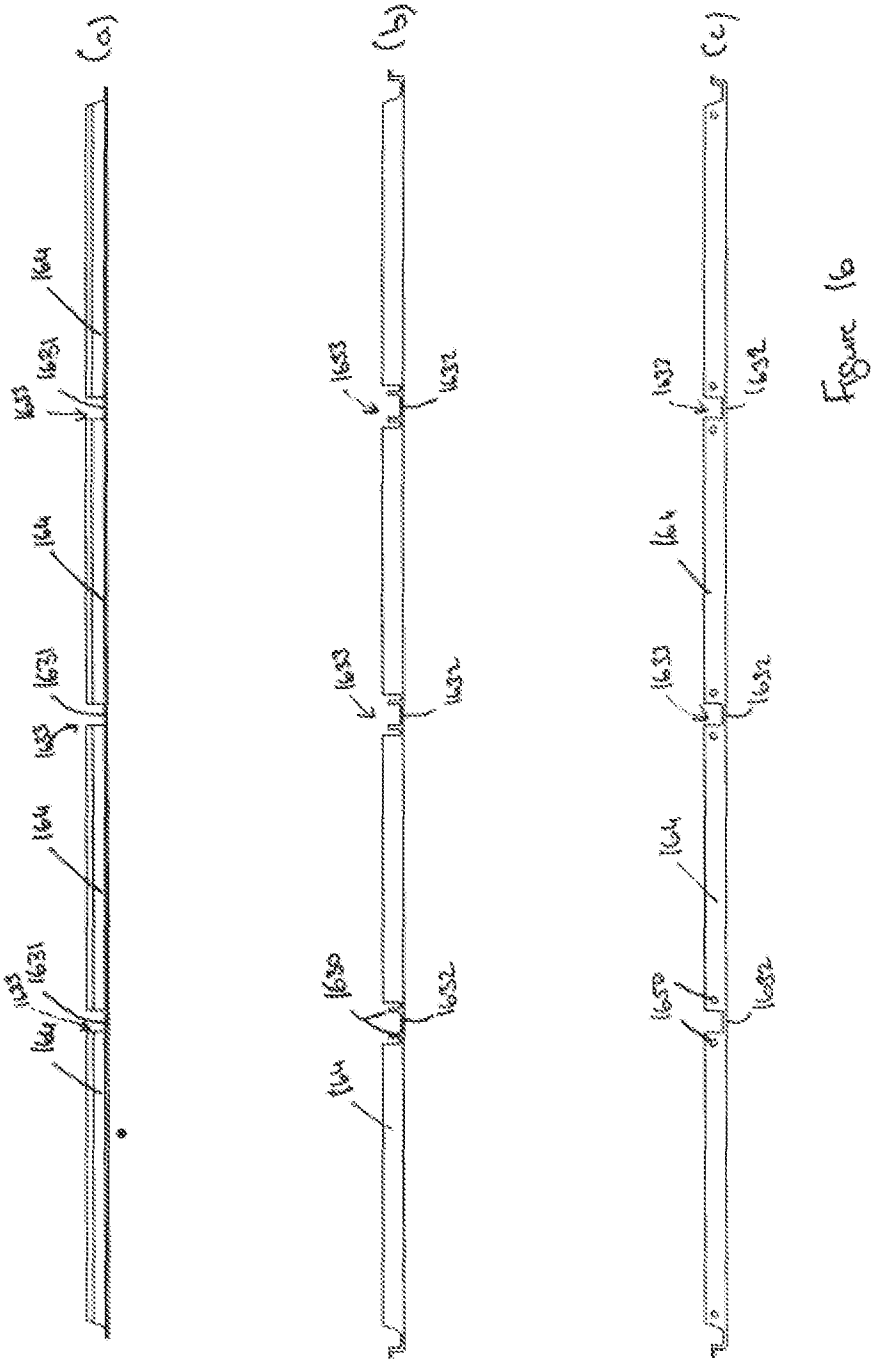

Figure 16

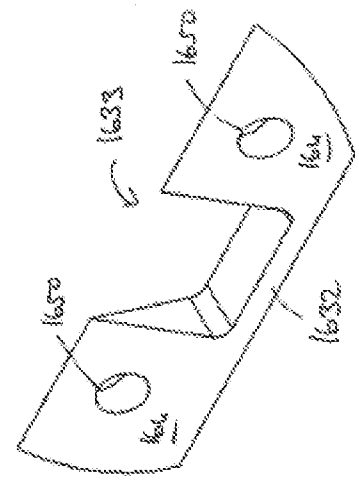

Figure 16

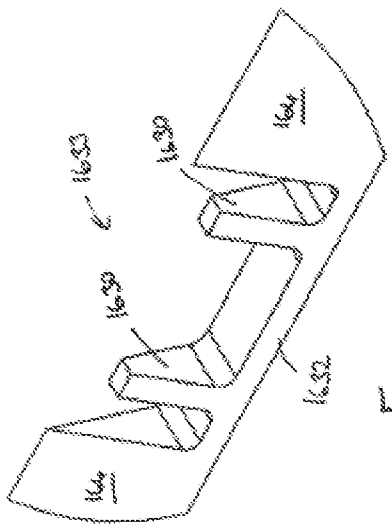

Figure 17

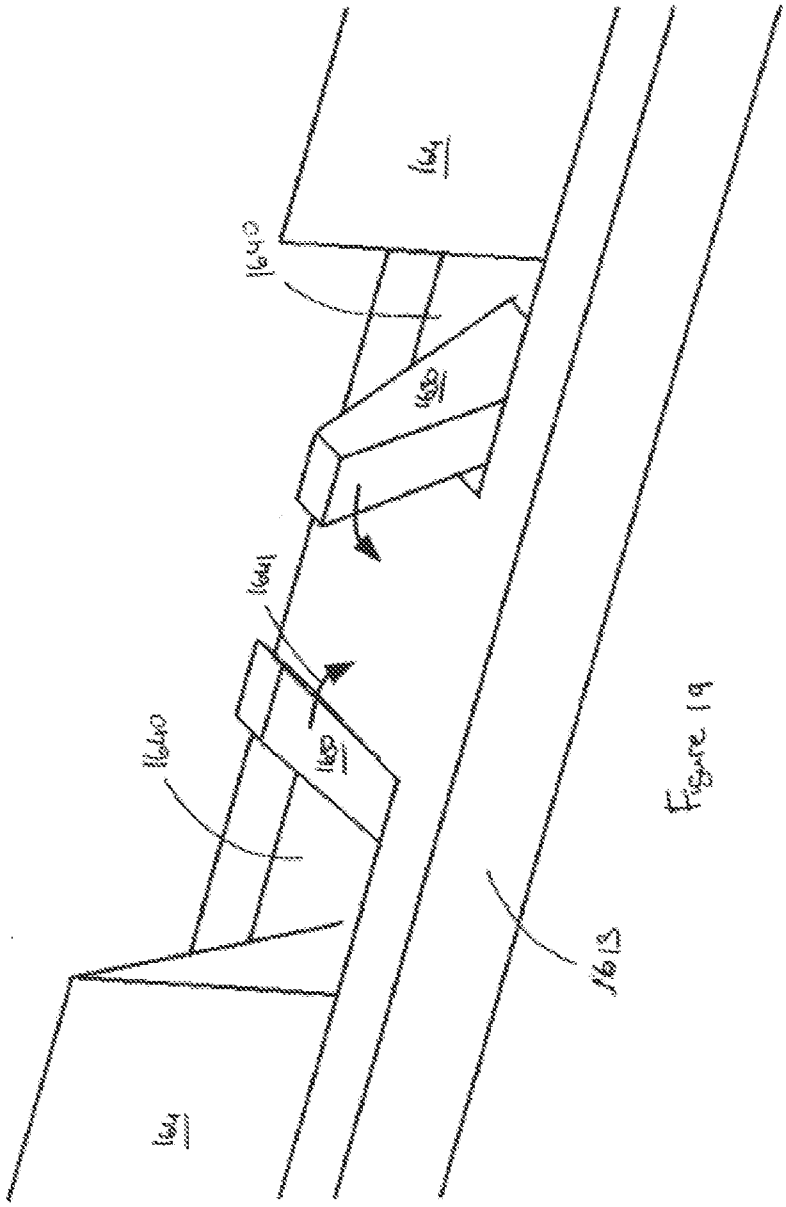

Figure 19

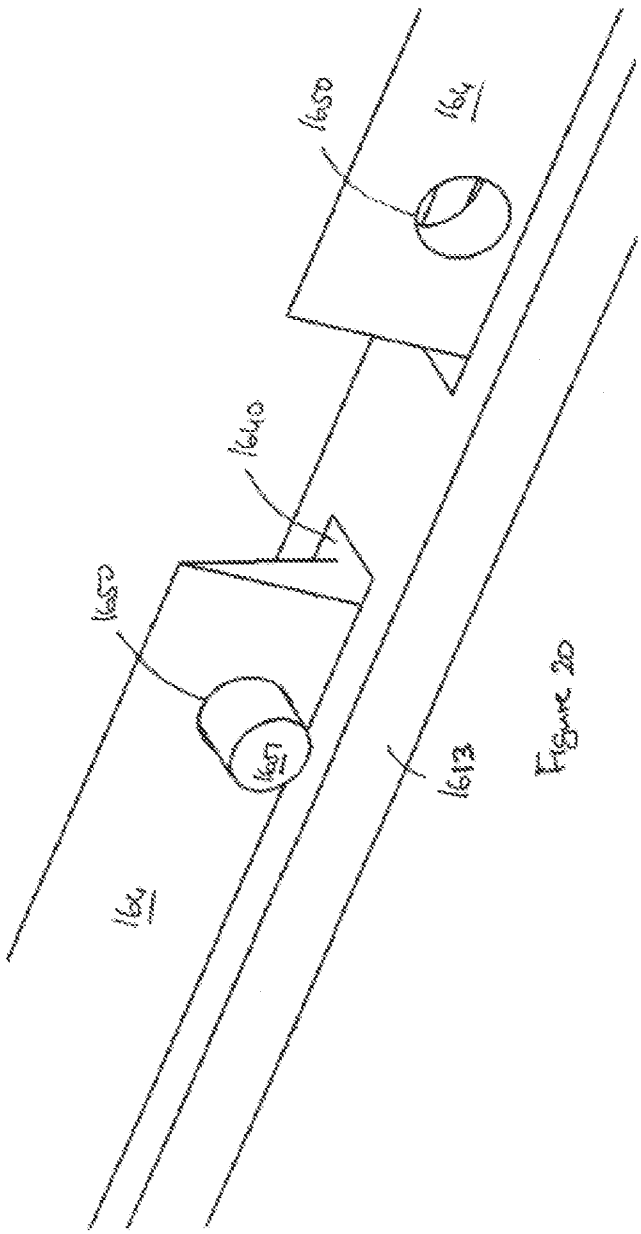

Figure 2D

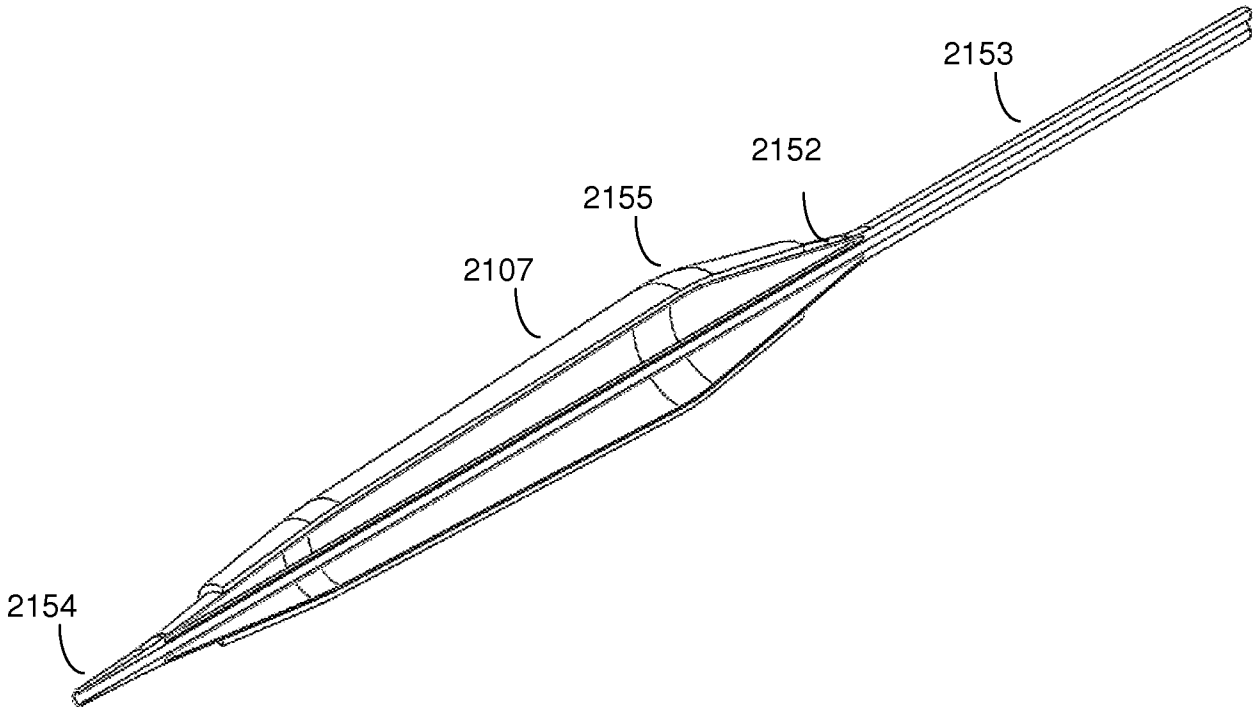

Figure 21

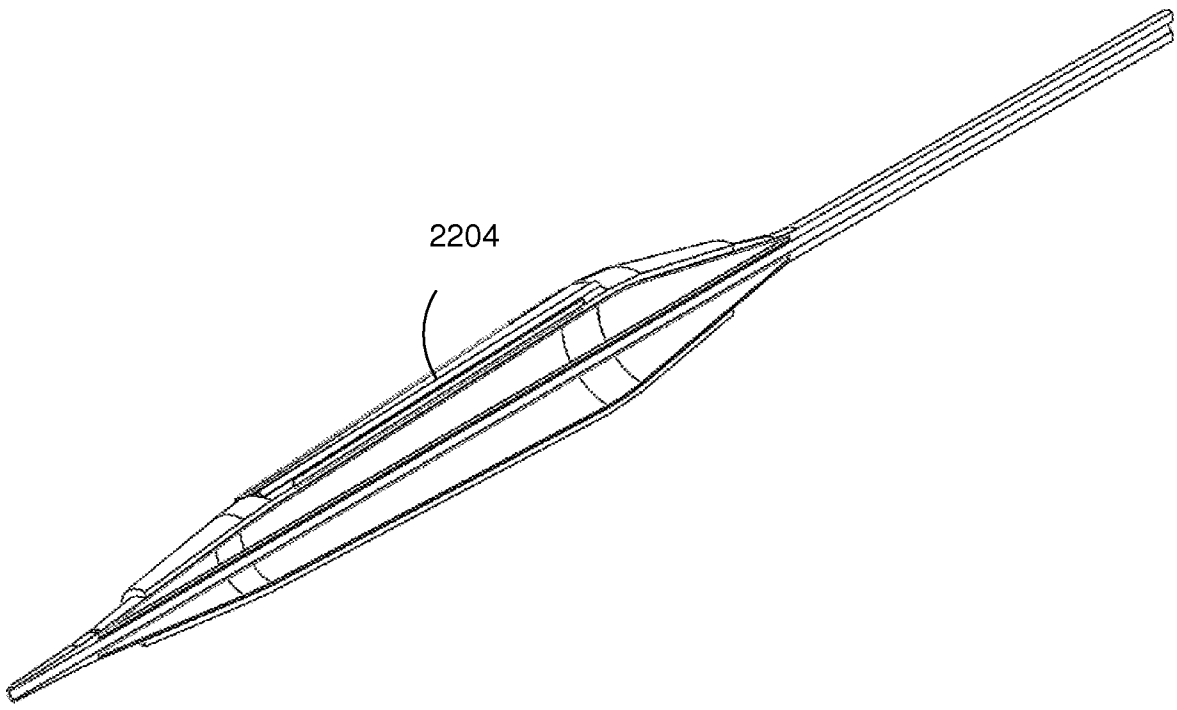

Figure 22

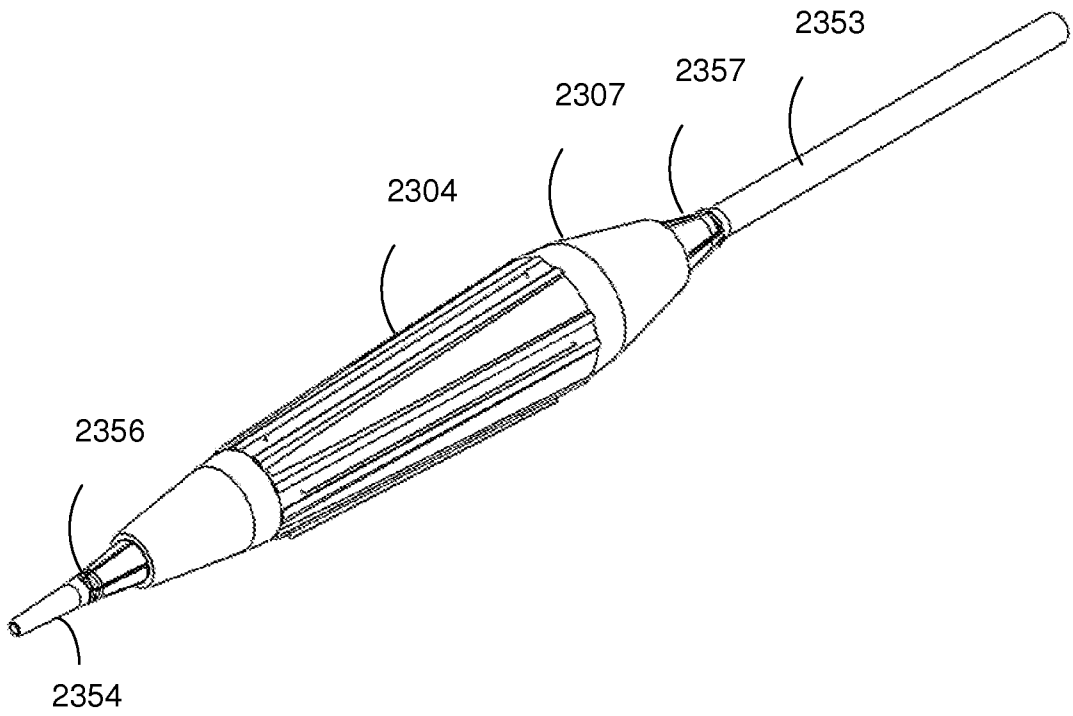

Figure 23

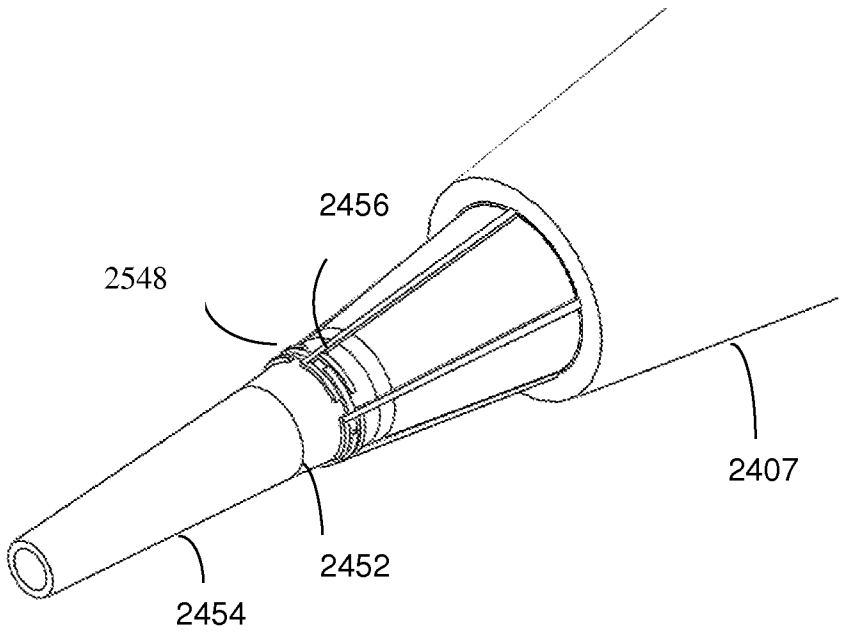

Figure 24

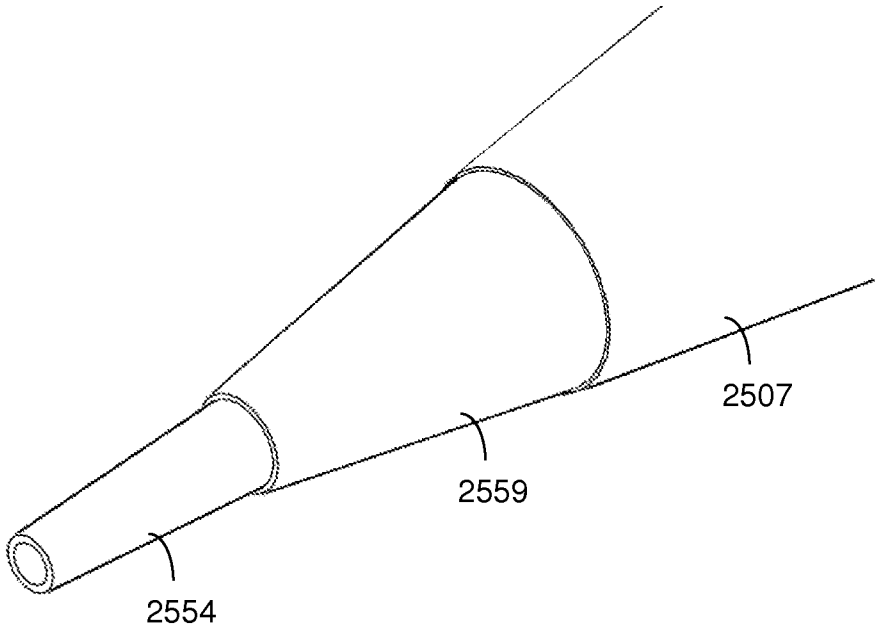

Figure 25

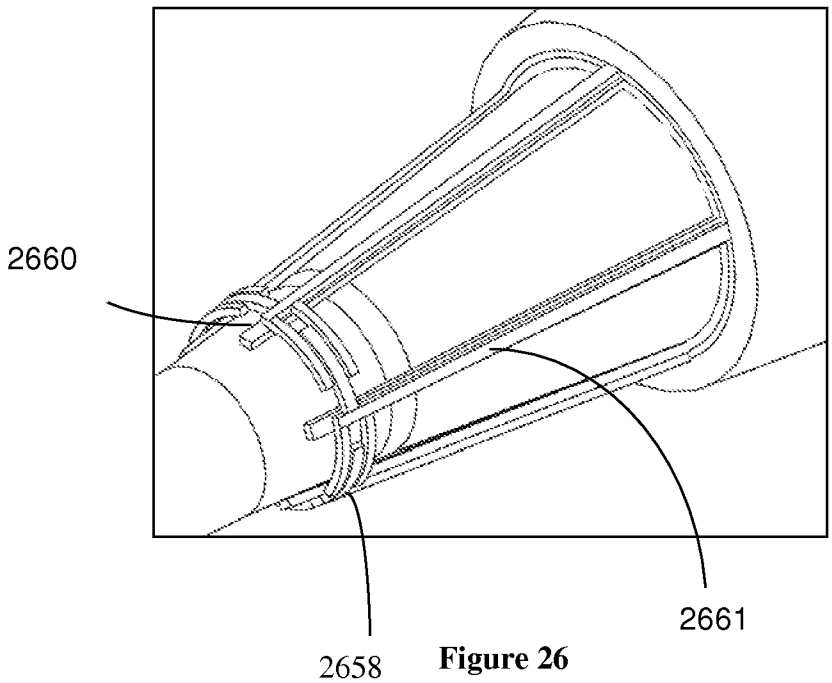

Figure 26

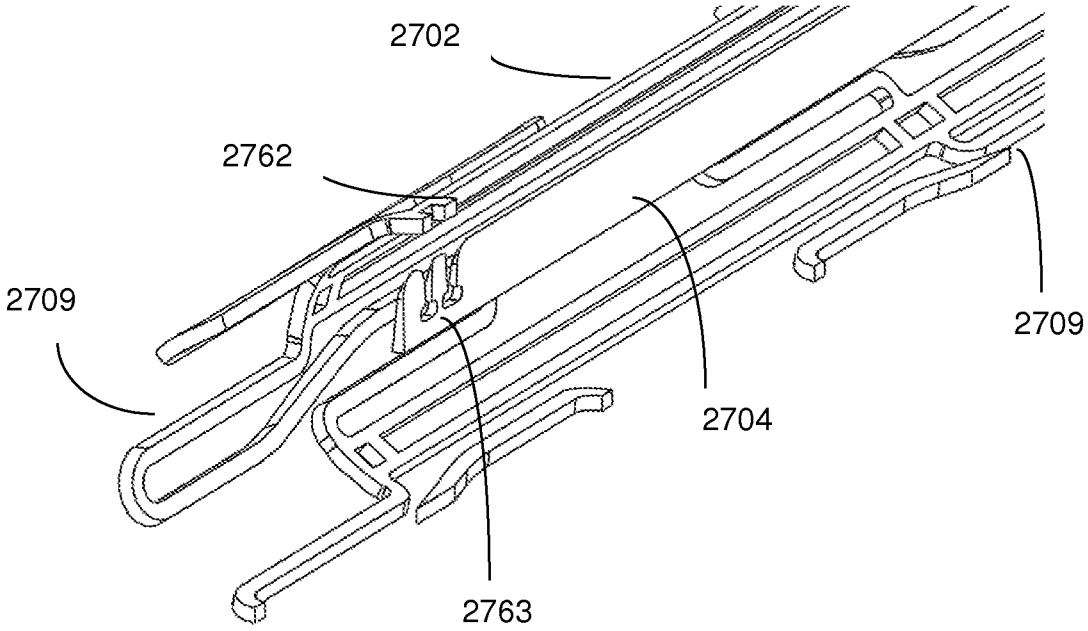

Figure 27

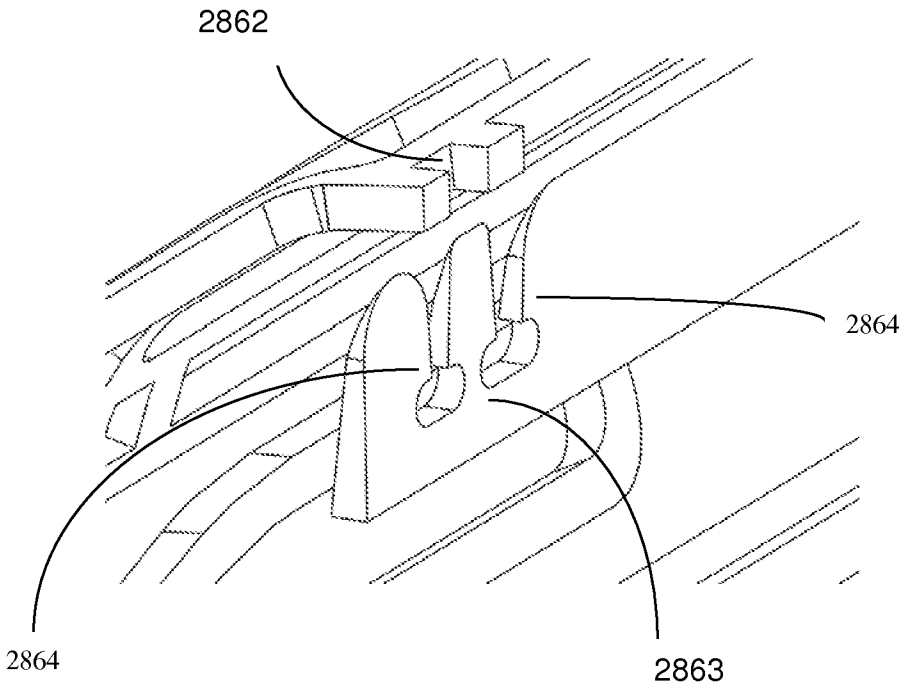

Figure 28

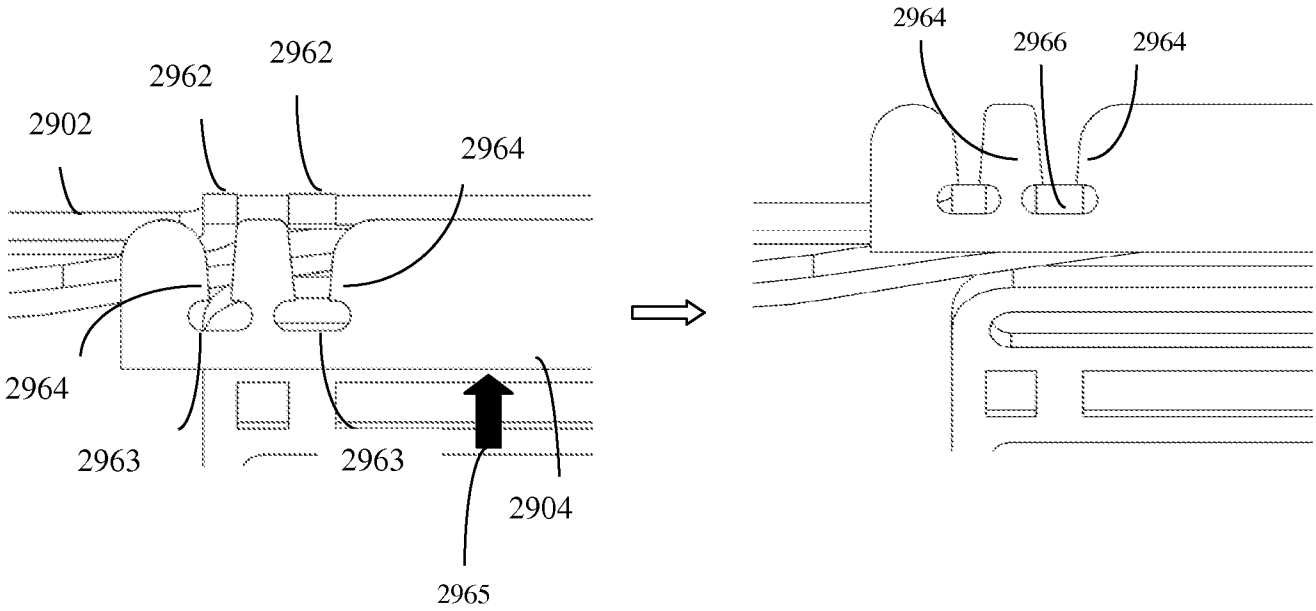

Figure 29

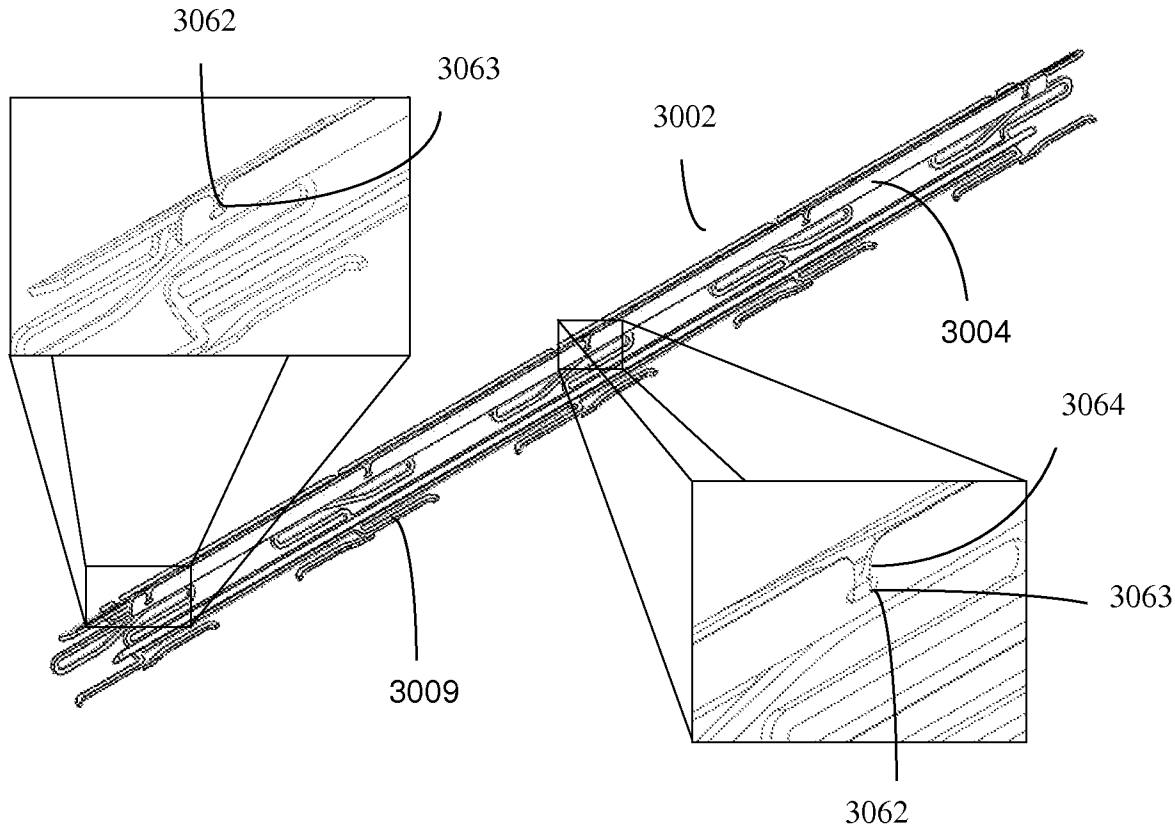

Figure 30

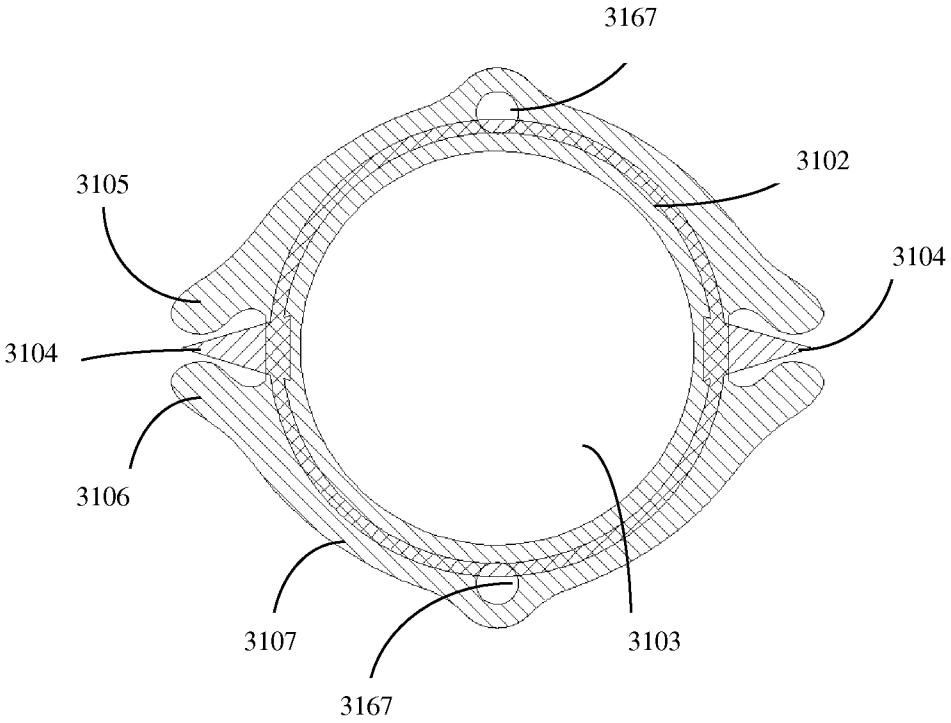

Figure 31

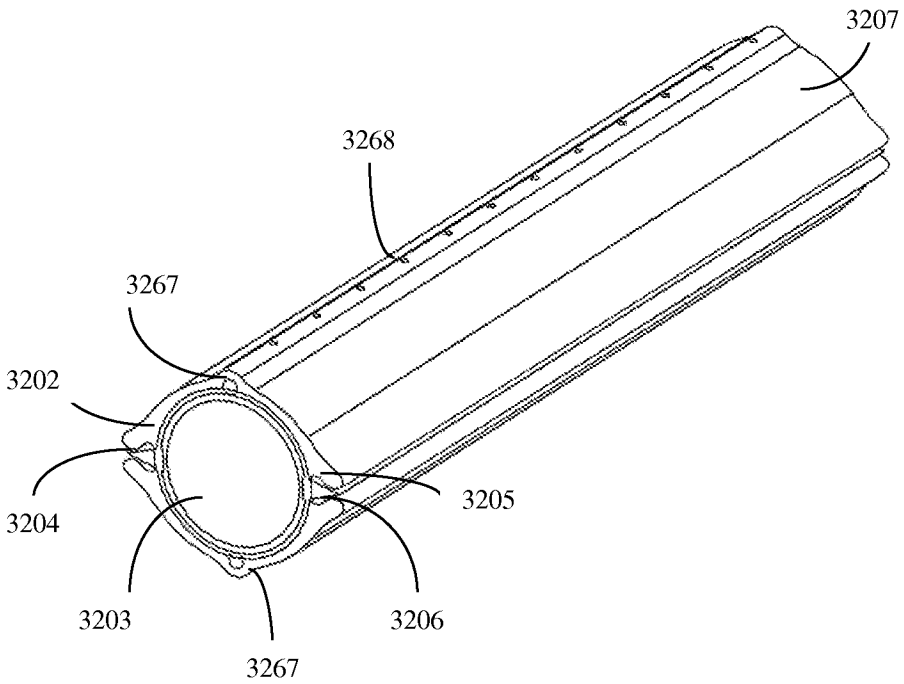

Figure 32

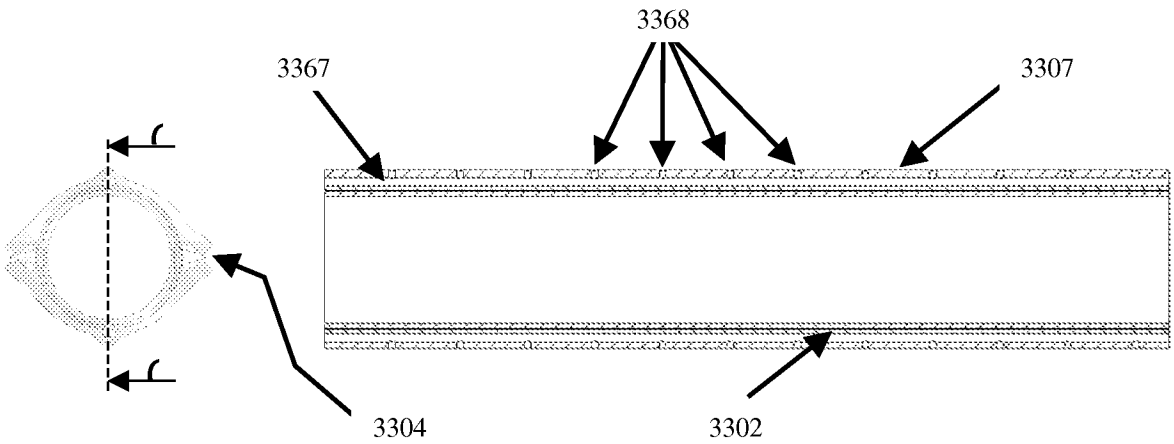

Figure 33

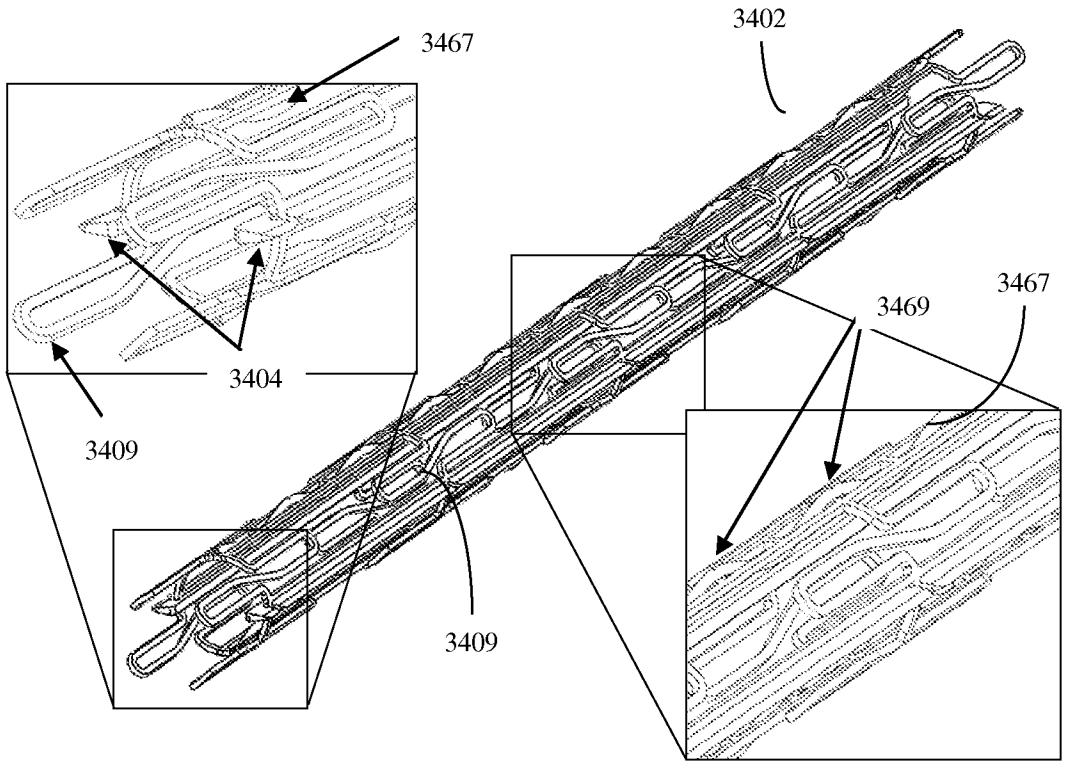

Figure 34

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/062919

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M29/02 A61B17/22 A61F2/86

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 611 920 A (KANEGAFUCHI CHEMICAL IND [JP]) 4 January 2006 (2006-01-04) the whole document	1-9, 14-15, 17-18, 25,32-33
X	EP 0 533 511 A (SCHMITZ RODE THOMAS [DE]) 24 March 1993 (1993-03-24) column 3, line 53 - column 5, line 27; figures 1-7	1,6-7, 12,14, 32-33
X	WO 2008/036900 A (MERCATOR MEDSYSTEMS INC [US]; SEWARD KIRK PATRICK [US]; GANDIONCO ISID) 27 March 2008 (2008-03-27) paragraphs [0044] - [0067]; figures 1a-5	1,6,9, 11, 14-15, 25-29

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2010	26/02/2010

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

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 653 684 A (LAPTEWICZ JOSEPH E [US] ET AL) 5 August 1997 (1997-08-05) column 3, line 7 - column 17, line 56; figures 1-14	1,4,6-7, 12,33
X A	US 4 885 003 A (HILLSTEAD RICHARD A [US]) 5 December 1989 (1989-12-05) column 4, line 43 - column 5, line 38; figure 4 column 3, line 12 - column 4, line 2; figures 1-3	1-3,26, 28,32 33
X	EP 1 935 376 A (BOSTON SCIENT LTD [BB]) 25 June 2008 (2008-06-25) paragraph [0030]; figure 1 paragraphs [0051], [0052]; figure 10 paragraphs [0037] - [0042]; figures 3a-4b	1,4, 14-16,32
X,P	WO 2009/046206 A (ANGIOSCORE INC [US]; OZDIL FERIDUN [US]; DOTY DAVID [US]; RAFFIN TOM A) 9 April 2009 (2009-04-09) the whole document	1,6-8, 14-15, 23, 26-29,33
A	US 2004/034384 A1 (FUKAYA KOHEI [JP]) 19 February 2004 (2004-02-19) paragraphs [0087] - [0104]; figures 11-22	1-25
A	US 2005/119678 A1 (O'BRIEN DENNIS [US] ET AL) 2 June 2005 (2005-06-02) abstract; figures 1-10	1-14, 17-25
A	US 2005/137616 A1 (VIGIL DENNIS M [US]) 23 June 2005 (2005-06-23) abstract; figures 1-7	1-14, 17-25
Y A	US 7 252 650 B1 (ANDREWS GEOFFREY THOMAS [GB] ET AL) 7 August 2007 (2007-08-07) column 3, line 10 - column 4, line 67	30-31 1-14, 17-25
A	US 4 921 484 A (HILLSTEAD RICHARD A [US]) 1 May 1990 (1990-05-01) column 4, line 47 - column 5, line 60; figure 6 column 3, line 13 - column 4, line 46; figures 1-4	1,26,28, 30,32-33
Y	US 6 626 861 B1 (HART CHARLES C [US] ET AL) 30 September 2003 (2003-09-30) the whole document	30-31
A	US 5 456 667 A (HAM KEVIN [US] ET AL) 10 October 1995 (1995-10-10) column 6, line 50 - column 7, line 14	30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2009/062919

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-29, 32-33

Collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, comprising
(i) a mesh portion having a contracted configuration allowing travel within the vessel to the target area and an expanded configuration allowing treatment of the target area,
(ii) at least one treatment implement carried on the mesh portion, and further comprising
(iii) at least one protuberance which protects the vessel from contact with the implement during travel within the vessel; and
an expandable mesh which is expandable from a contracted configuration allowing travel within the vessel to the target area to an expanded configuration allowing treatment of the target area, and at least one treatment implement carried on the mesh portion, the mesh portion further comprising at least one protuberance which protects the vessel from contact with the implement during travel within the vessel; and
an expandable mesh which is expandable from a contracted configuration allowing travel within the vessel to the target area to an expanded configuration allowing treatment of the target area, and at least one treatment implement carried on the mesh portion, and a sheath provided on the mesh the sheath comprising at least one protuberance which protects the vessel from contact with the implement during travel within the vessel.

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2. claims: 30-31

Collapsible treatment device for treating a target area of a vessel wall of a vessel within a human or animal body, the device comprising an expandable mesh portion which is expandable from a contracted configuration allowing travel within the vessel to the target area to an expanded configuration allowing treatment of the target area, the mesh portion being constructed of a shape memory material which has memory for the contracted configuration and at least one treatment implement carried on the mesh portion.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/062919

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1611920 A	04-01-2006	AT 431171 T	15-05-2009
		CA 2518207 A1	23-09-2004
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