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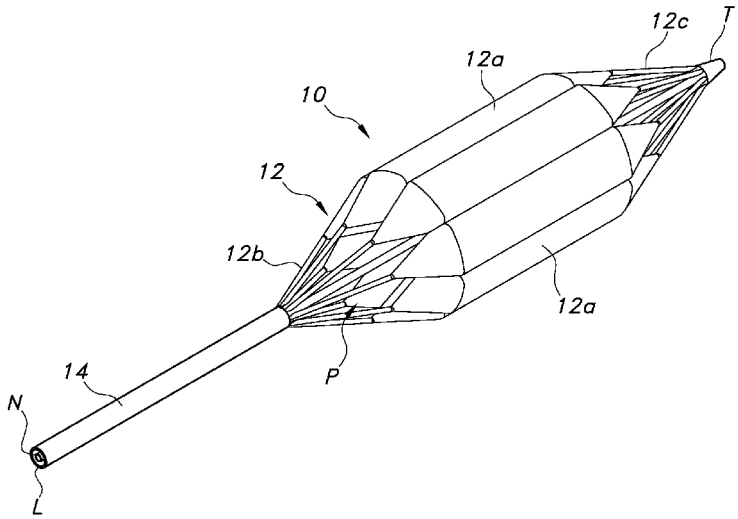
(54) Title: INFLATABLE PERFUSION BALLOON WITH OUTER MESH AND RELATED METHODS



(57) Abstract: An apparatus for performing a medical procedure in the vasculature comprises an inflatable perfusion balloon including a passage for transmitting fluid in an inflated condition of the balloon. A metal or wire mesh is positioned along or over at least a portion of the inflatable balloon. The mesh may allow fluid to flow through the wire mesh into the passage when the balloon is inflated. The mesh may comprise a wire sock or sleeve, and may comprise a shape memory material, such as Nitinol. Related methods are also disclosed.

INFLATABLE PERFUSION BALLOON WITH OUTER MESH AND RELATED METHODS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/143,472, the disclosure of which is incorporated herein by this reference.

INCORPORATION BY REFERENCE

[0001] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

[0002] Expandable devices, such as balloons, are widely used in medical procedures. In the case of a balloon, it is inserted into the body, typically on the end of a catheter, until the balloon reaches the area of interest. Adding pressure to the balloon causes the balloon to inflate. In one variation of use, the balloon creates a space inside the body when the balloon inflates.

[0003] Balloons may be used in the heart valves, including during Balloon Aortic Valvuloplasty (BAV) and Transcatheter Aortic Valve Implantation (TAVI). The balloons can be used to open a stenosed aortic valve. A stenosed valve may have hard calcific lesions, which may require the use of a robust balloon to "crack" the lesions. Additionally, a precise inflated balloon diameter may be desired for increased control.

[0004] Balloons may be used to move plaque away from the center of a vascular lumen toward the vasculature walls, such as during an angioplasty or a peripheral vasculature procedure. During this procedure, a balloon tipped catheter is placed in a vascular obstruction. As the balloon is inflated, the vessel constriction is dilated, resulting in improved blood flow.

[0005] For the traditional approach, two basic types of balloons are utilized: One is a high pressure, low-compliance balloon. The other is a lower pressure, high-compliance balloon.

[0006] High-compliance medical balloons are often composed of urethane, latex, silicone, PVC, Pebax, and other elastomers. As the pressure in a high-compliant balloon is increased, the balloon dimensions expand. Once the pressure is reduced, the high-compliance medical balloon may return to its original shape, or near its original shape. High-compliance medical balloons can easily expand several times in volume between zero inflation pressure and burst.

[0007] Traditional high-compliance medical balloons can be inadequate for many reasons. High-compliance, or highly elastic medical balloons typically cannot reach high pressures because their walls have a low tensile strength and their walls thin out as the balloon expands. In some instances, high-compliance medical balloons provide insufficient force to complete a procedure. Exceeding the rated pressure of a high-compliance medical balloon creates an excessive risk of balloon failure which can lead to serious complications for the patient. Moreover, high-compliance medical balloons also have poor shape control. As a high-compliance medical balloon expands, it may assume a shape dictated mostly by the particulars of the environment inside the patient rather than the clinical goals. In some cases, this can be contrary to what the medical practitioner desires. Many medical procedures, such as BAV and TAVI in particular, are predicated on forming a particular balloon shape reliably.

[0008] Low-compliance, high pressure medical balloons substantially retain their shape under comparatively high pressures. PET (polyethylene terephthalate) is the most common material for use in high pressure low-compliance balloons. PET is commonly used for high-performance angioplasty balloons. PET is stronger than other polymers, can be molded into a variety of shapes and can be made very thin (e.g., 5 μm to 50 μm (0.0002 in. to 0.002 in.)), thus giving these balloons a low profile. PET is very stiff so balloons made from PET may be difficult to pack or fold into a small diameter and may have poor trackability (i.e., the ability to slide and bend over a guidewire deployed through a tortuous vessel). Further, balloons made from PET, while stronger than most other balloons made from homogenous polymers, may still not be strong enough to hold pressures sufficient to complete certain medical procedures. Additionally, with a large balloon diameter (For example, 20 mm or greater), a PET balloon still has excessive compliance for procedures such as BAV and TAVI.

[0009] Nylon balloons are an alternative material for low-compliance, high pressure balloons. However, these nylon balloons are typically weaker than PET balloons and so can contain less pressure. Nylon readily absorbs water, which can have an adverse effect on Nylon's material properties in some circumstances. Nylon has improved puncture resistance over PET and is more flexible than PET.

[00010] Fiber-reinforced composite balloons are another alternative low-compliance, high pressure medical balloon. Such fiber-reinforced composite balloons can advantageously sustain high pressures, provided precise shape control, and are highly resistant to tear and puncture. The manufacturing process for fiber-reinforced balloons, however, can be complicated and expensive, requiring the application of multiple different layers of fibers in order to achieve the desired support.

Often, at least one of these layers consists of a fabric de-convolution pattern layer wrapped around a base balloon. Such forming and wrapping of the fabric pattern layer can be cumbersome, labor and equipment intensive, and time consuming. Such a fabric may also require the formation of openings to accommodate fluid flow, which can lead to further manufacturing difficulties and may also weaken the fabric.

[00011] Thus, there exists the need to create a reinforced perfusion balloon that can be manufactured quickly and easily while still maintaining its ability to withstand high pressures, provide precise shape control, and allow for the desired perfusion to occur in an efficient and effective manner.

SUMMARY OF THE DISCLOSURE

[00012] In general, a perfusion balloon including an outer mesh is proposed. More specifically, an inflatable perfusion balloon includes a passage for allowing fluid flow in an inflated condition of the balloon. A mesh, such as a woven or non-woven wire structure, is positioned over or along at least a portion of the balloon allows fluid to flow through the mesh into the passage when the balloon is inflated. The technical effect of this approach is to create a reinforced perfusion balloon that can be manufactured quickly and easily while still maintaining its ability to withstand high pressures, provide precise shape control, and allow for the desired perfusion to occur in an efficient and effective manner.

[00013] According to the following aspects of the disclosure, the technical effects may be achieved by an apparatus for performing a medical procedure in the vasculature comprising an inflatable perfusion balloon including a passage for transmitting fluid in an inflated condition of the balloon, and a wire mesh positioned over at least a portion of the inflatable balloon. In one embodiment, the balloon comprises a first cell and a second cell in a single cross-section of the balloon. A space is provided between the first cell and the second cell, and openings in the wire mesh allow fluid to flow from external to the balloon, into the space, and to the passage. The passage may be surrounded by the first and second cells, and the wire mesh overlies the first and second cells of the balloon. The first and second cells may each include an inflation lumen, which may be formed by a proximal next at least partially covered by the wire mesh.

[00014] The wire mesh may comprise a metal and/or a shape-memory material, such as Nitinol, and may include one or more helical wires. The balloon may include tapered end regions and a central region, the wire mesh extending along at least the central region of the balloon. The wire

mesh may comprise a reticulated structure including one or more openings in fluid communication with the passage when the balloon is inflated.

[00015] According to a further aspect of the disclosure, an apparatus for performing a medical procedure in the vasculature includes an inflatable perfusion device including a first balloon and a second balloon in a single cross-section of the device and a wire mesh positioned over at least a portion of the first and second balloons along the single cross-section of the device. The first and second balloons may comprise first and second cells of a single balloon, and the wire mesh may comprise a metal and/or a shape memory material.

[00016] Each balloon may comprise tapered end portions and a central portion, the wire mesh extending along at least the central portions of the balloons. The wire mesh may include openings in fluid communication with the passage when the device is inflated. Specifically, the wire mesh may include at least one opening positioned between the first and second balloons. Each balloon may also comprise a proximal neck for receiving a fluid for causing the balloon to inflate, and wherein the wire mesh at least partially covers the proximal necks.

[00017] A further aspect of the disclosure pertains to an apparatus for performing a medical procedure in the vasculature. The apparatus comprises an inflatable perfusion balloon, and a wire sock positioned over at least a portion of the balloon. In one embodiment, the wire sock comprises a metal mesh, and the balloon comprises tapered end portions and a central portion, the wire sock or metal mesh extending along at least the central portion of the balloon. The wire sock may have one or more openings in fluid communication with the passage when the device is inflated.

[00018] Still another aspect of the disclosure pertains to an apparatus for performing a medical procedure in the vasculature. The apparatus comprises an inflatable perfusion balloon including a passage for transmitting fluid in an inflated condition of the balloon. A sleeve comprising a shape memory material is positioned over at least a portion of the inflatable balloon. The sleeve may comprise a wire mesh and/or a shape memory material, such as Nitinol. The balloon may comprise plural cells in a single cross section.

[00019] Yet another aspect of the disclosure pertains to an apparatus for performing a medical procedure in the vasculature. The apparatus comprises an inflatable perfusion balloon including a passage for transmitting fluid when the balloon is inflated, and a compressive mesh positioned over at least a portion of the inflatable balloon.

[00020] Still a further aspect of the disclosure pertains to an apparatus for performing a medical procedure in the vasculature. The apparatus comprises an inflatable perfusion balloon including a

passage for transmitting fluid when the balloon is inflated, and a metal mesh positioned over at least a portion of the inflatable balloon.

[00021] Yet another aspect of the disclosure pertains to a method of forming a perfusion balloon. As noted above, the method may comprise providing a wire mesh over the perfusion balloon. This can be done by winding a wire over an outer surface of the balloon, or inserting the perfusion balloon into a tube formed of the wire mesh. The method may also include attaching the wire mesh to the perfusion balloon. The wire mesh may also be used to provide a compressive force on the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[00022] Figure 1 is a perspective view of an inflatable device in the expanded condition;

[00023] Figure 2 is a perspective view of an inflatable device in the expanded condition including an outer mesh;

[00024] Figure 3 is a side view of the device in an uninflated condition;

[00025] Figure 4 is a side view of the device in an inflated condition;

[00026] Figure 5 is a cross-sectional view taken along line 5-5 of Figure 4; and

[00027] Figure 6 is a perspective view showing an uninflated balloon being inserted into a flexible sock or sleeve.

DETAILED DESCRIPTION

[00028] The invention disclosed pertains to an inflatable device in the nature of a balloon and, in particular, a perfusion balloon. The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings.

[00029] Figure 1 shows an inflatable device 10 including a balloon 12 supported by a catheter shaft 14. It can be understood that the balloon 12 of the device 10 may have multiple inflatable cells 12a in a single cross-section, which may be individual, separately inflatable balloons (each having a separate inflation lumen, as noted) or parts of a single balloon. The latter may be achieved by a segmented, elongated structure that is folded in a manner that causes the cells 12a to surround passage P extending along a central axis X, along which fluid such as blood may continue to flow, even when the balloon 12 is fully inflated (which may be done through a single inflation lumen, or each balloon could have its own inflation lumen). A full description of this type of balloon may be

found in International Patent Application Publication No. WO2012099979A1. However, other forms of perfusion balloons could also be used, such as for example a tube-shaped balloon, one having a peripheral (e.g., helical) channel for purposes of allowing fluid flow to occur during inflation, an annular or tubular balloon, or any combination of these technologies.

[00030] The balloon 12 may be formed of any suitable material, including but not limited to urethane, latex, silicone, PVC, Pebax, and other elastomers, PET, Nylon, other polymers, and any combination of the foregoing. Examples of materials useful in making compliant (or elastic) balloons include various polymeric materials (including materials already known to be useful for making compliant medical balloons), e.g., elastomeric membranes having a high degree of linearity (non-plasticity) for a wide range of stress and strain values. Such materials include various Silicones, latex, Kraton, various thermoplastic elastomers (TPE's) particularly styrene-ethylene/butylene-styrene block copolymers (SEBS)-based TPE's (such as C-Flex), polysiloxane modified SEBS and their associated families, polyvinylchloride (PVC), crosslinked polyolefins such as polyethylene, and various polyurethanes. Examples of materials used in making noncompliant balloons (e.g., inelastic balloons) include many of the polyamides (e.g., the Nylons), thermoplastic polyamides, polyesters, polyphenylene sulfides, ultra-high molecular weight polyethylene, and PET.

[00031] In the illustrated embodiment using the multi-cellular balloon 12, each cell 12a includes a proximal neck 12b in communication with an inflation lumen L and a distal neck 12c. In any case, the device 10 may also include a guidewire lumen N extending along the central axis X, which may form part of a catheter tube 14 to which the balloon 12 may be attached (such as at a distal end thereof at the necks 12c, and in connection with a tip T).

[00032] In order to constrain the cells 12a in this configuration, a wire mesh 16 is provided along an outer surface thereof. The wire mesh 16 may be positioned atop the balloon 12 (over cells 12a in particular), and may be provided as a winding, as discussed below, or as an open-ended, flexible wire sock, tube, or sleeve for receiving the balloon 12 in the folded configuration. The wire mesh 16 may be arranged to form the balloon 12 in a particular shape, such as one having generally conical or tapering end portions C and a central barrel portion B. This barrel portion B is also sometimes referred to as the "working" portion of the balloon 12 because it is the structure that makes contact with the valve or other part of the vasculature being treated.

[00033] For purposes of this disclosure, the term "mesh" is intended to refer to a material having an open texture with spaced holes, and "wire" means the mesh comprises one or more filaments or a similar thin flexible members. In one particular embodiment, the wire mesh 16 is arranged such that the holes comprise a greater part of the area of the mesh than the solid material forming it. In other

words, the mesh is more open than closed, and thus promotes the free flow of fluid while still provided a restraint for the underlying balloon 12.

[00034] The mesh 16 may be formed of a material capable of expanding with the balloon(s) during inflation, such as a metal (including one that is radiopaque) or a combination of metal and polymer or plastic materials. In one particular embodiment, the mesh 16 is made of a shape memory material or alloy, such as Nitinol. This type of material may be annealed such that it can maintain a particular shape based on temperature (such as a low profile at body temperature).

[00035] The mesh 16 may be applied to the balloon 12 as a preformed sock, as indicated in Figure 6, or may be applied to the balloon by winding a wire or wire-like material around the balloon 12 (possibly in a helical or spiral manner, as illustrated, in a single pass or double pass, and at a constant or variable pitch). All or portions of the mesh 16 may be connected to the balloon 12, such as by using an adhesive. The mesh 16 may be formed of woven wires or filaments, or non-woven wires or filaments, or may be cut from a piece of tubing (such as by forming openings in it). While the mesh 16 is shown as being arranged on the bias (that is, with wires or filaments that are angled or inclined), some of the filaments or wires may be substantially parallel to the central or longitudinal axis X, and others may be substantially perpendicular to it (such as would be the case if a screen-type material with regular, square openings were applied over the balloon 12, such as along the central portion B).

[00036] The mesh 16 may be a forming member configured to shape the balloon 12 in either (or both) the inflated or un-inflated states. In some variations, the mesh 16 may provide a compression force on the balloon 12. For example, the force of the mesh 16 may help compress the balloon from the expanded state shown in Figure 4 into the unexpanded state shown in Figure 3. Alternatively, a sheath (not shown) could be used to compress the mesh 16 after deflating the balloon 12.

[00037] The mesh 16 may extend along the entire balloon 12, as perhaps best understood from Figures 2, 3, and 4. Alternatively, the mesh 16 could extend over only a part of the balloon 12 (such as along all or part of the barrel portion B). The mesh 16 may also be provided in multiple portions or segments over all or part of the balloon 12 (that is, more than one piece of mesh may be used in connection with the balloon 12, including either in an overlapping or serial arrangement). A portion of the mesh 16 may also be provided with a gap or space with another portion of the mesh 16.

[00038] As can be appreciated, the mesh 16 includes a plurality of openings and, thus, forms a reticulated structure. The mesh 16 may be applied in a regular pattern, as shown, or may be irregular (such that, for example, wider openings are provided at some locations and smaller

openings at others, including along the same or different portions of the balloon 12). The size and shape of the openings in the mesh 16 will depend on the manner in which it is formed.

[00039] Regardless of the material used or form of it, the openings in the mesh 16 allow fluid to flow from an exterior region of the balloon 12 to an interior region, such as in the space or passage interior of the balloon inner surfaces juxtaposed with the central axis X. This not only includes flow from the proximal and distal ends of the balloon 12 if the mesh covers the tapered portions, but also along the central portion and within spaces between the cells 12a or balloons. In particular, the mesh 16 includes one or more openings O (see Figure 4) positioned in juxtaposition or proximity to the gap between adjacent cells 12a that allows fluid to flow through any gap G or space formed between adjacent cells 12a (see Figure 5), thus resulting in an enhanced level of perfusion and simplifying the construction without sacrificing the desirable features of a retainer (jacket or shell) for holding the cells together, both prior to and during inflation.

[00040] As can be appreciated, the disclosure also pertains to a method of forming a perfusion balloon. As noted above, the method may comprise providing a wire mesh over the perfusion balloon. This can be done by winding a wire over an outer surface of the balloon, or inserting the perfusion balloon into a tube formed of the wire mesh. The method may also include attaching the wire mesh to the perfusion balloon. The wire mesh may also be used to provide a compressive force on the balloon.

[00041] The foregoing discussion is intended to provide an illustration of the inventive concepts, and is not intended to limit the invention to any particular mode or form. Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one), and plural elements can be used individually. Characteristics disclosed of a single variation of an element, the device, the methods, or combinations thereof can be used or apply for other variations, for example, dimensions, burst pressures, shapes, materials, or combinations thereof. Any species element of a genus element can have the characteristics or elements of any other species element of that genus. Terms like "generally" or "substantially" mean that the value may vary depending on the circumstances, such as up to 10% of a given condition. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination, along with any obvious modifications.

CLAIMS

1. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a passage for transmitting fluid flowing through the vasculature in an inflated condition of the balloon; and

a wire mesh positioned over at least a portion of the inflatable perfusion balloon.

2. The apparatus of claim 1, wherein the balloon comprises a first cell and a second cell in a single cross-section of the balloon.

3. The apparatus of claim 2, wherein a space is provided between the first cell and the second cell, and openings in the wire mesh allow fluid to flow from external to the balloon, into the space, and to the passage.

4. The apparatus of claim 2, wherein the passage is surrounded by the first and second cells, and the wire mesh overlies the first and second cells of the balloon.

5. The apparatus of claim 2, wherein the first and second cells each include an inflation lumen.

6. The apparatus of any of the foregoing claims, wherein the wire mesh comprises a metal.

7. The apparatus of any of the foregoing claims, wherein the wire mesh comprises a shape-memory material.

8. The apparatus of any of the foregoing claims, wherein the balloon comprises tapered end regions and a central region, the wire mesh extending along at least the central region of the balloon.

9. The apparatus of any of the foregoing claims, wherein the wire mesh comprises a reticulated structure including one or more openings in fluid communication with the passage when the balloon is inflated.

10. The apparatus of any of the foregoing claims, wherein the balloon comprises a plurality of cells, each including a proximal neck for receiving an inflation fluid, wherein the wire mesh at least partially covers the proximal necks of the cells.

11. The apparatus of any of the foregoing claims, wherein the wire mesh comprises a helical wire.

12. The apparatus of claim 1, wherein the wire mesh comprises a metal.

13. The apparatus of claim 1, wherein the wire mesh comprises a shape-memory material.

14. The apparatus of claim 1, wherein the balloon comprises tapered end portions and a central portion, the wire mesh extending along at least the central portion of the balloon.

15. The apparatus of claim 1, wherein the wire mesh comprises a reticulated structure including one or more openings in fluid communication with the passage when the balloon is inflated

16. The apparatus of claim 1, wherein the balloon comprises a plurality of cells, each including a proximal neck for receiving an inflation fluid, and wherein the wire mesh at least partially covers the proximal necks of the cells.

17. The apparatus of claim 1, wherein the wire mesh comprises a helical wire.

18. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a first balloon and a second balloon in a single cross-section of the balloon; and

a wire mesh provided to at least a portion of the first and second balloons of the inflatable perfusion balloon.

19. The apparatus of claim 18, wherein the first and second balloons comprise first and second cells of a single balloon.

20. The apparatus of claim 18, wherein the wire mesh comprises a metal.

21. The apparatus of claim 18, wherein the wire mesh comprises a shape-memory material.

22. The apparatus of claim 18, wherein each balloon comprises tapered end portions and a central portion, the wire mesh extending along at least the central portions of the balloons.

23. The apparatus of claim 18, wherein the wire mesh includes openings in fluid communication with the passage when the balloon is inflated.

24. The apparatus of claim 18, wherein the wire mesh includes at least one opening positioned between the first and second balloons.

25. The apparatus of claim 18, wherein each balloon comprises a proximal neck for receiving a fluid for causing the balloon to inflate, and wherein the wire mesh at least partially covers the proximal necks.

26. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a passage for transmitting fluid flowing through the vasculature in an inflated condition of the balloon; and

a wire sock positioned over at least a portion of the inflatable perfusion balloon.

27. The apparatus of claim 26, where the wire sock comprises a metal mesh.

28. The apparatus of claim 26, wherein the balloon comprises tapered end portions and a central portion, the wire sock extending along at least the central portion of the inflatable perfusion balloon.

29. The apparatus of claim 26, wherein the wire sock includes openings in fluid communication with the passage when the device is inflated.

30. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a passage for transmitting fluid flowing through the vasculature in an inflated condition of the balloon; and

a sleeve comprising a shape memory material provided to at least a portion of the inflatable perfusion balloon.

31. The apparatus of claim 30, wherein the sleeve comprises a wire mesh.

32. The apparatus of claim 30, wherein the shape memory material comprises Nitinol.

33. The apparatus of claim 30, wherein the inflatable perfusion balloon comprises plural cells in a single cross-section.

34. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a passage for transmitting fluid flowing through the vasculature when the perfusion balloon is inflated; and

a compressive mesh positioned over at least a portion of the inflatable perfusion balloon.

35. An apparatus for performing a medical procedure in the vasculature, comprising:

an inflatable perfusion balloon including a passage for transmitting fluid flowing through the vasculature when the balloon is inflated; and

a metal mesh positioned over at least a portion of the inflatable perfusion balloon.

36. A method of forming a perfusion balloon, comprising:

providing a wire mesh over the perfusion balloon.

37. The method of claim 36, wherein the providing step comprises winding a wire over an outer surface of the perfusion balloon.

38. The method of claim 36, wherein the providing step comprises inserting the perfusion balloon into a tube formed of the wire mesh.

39. The method of any of claims 36-38, further including the step of attaching the wire mesh to the perfusion balloon.

40. The method of any of claims 36-39, further including the step of compressing the wire mesh over the balloon.

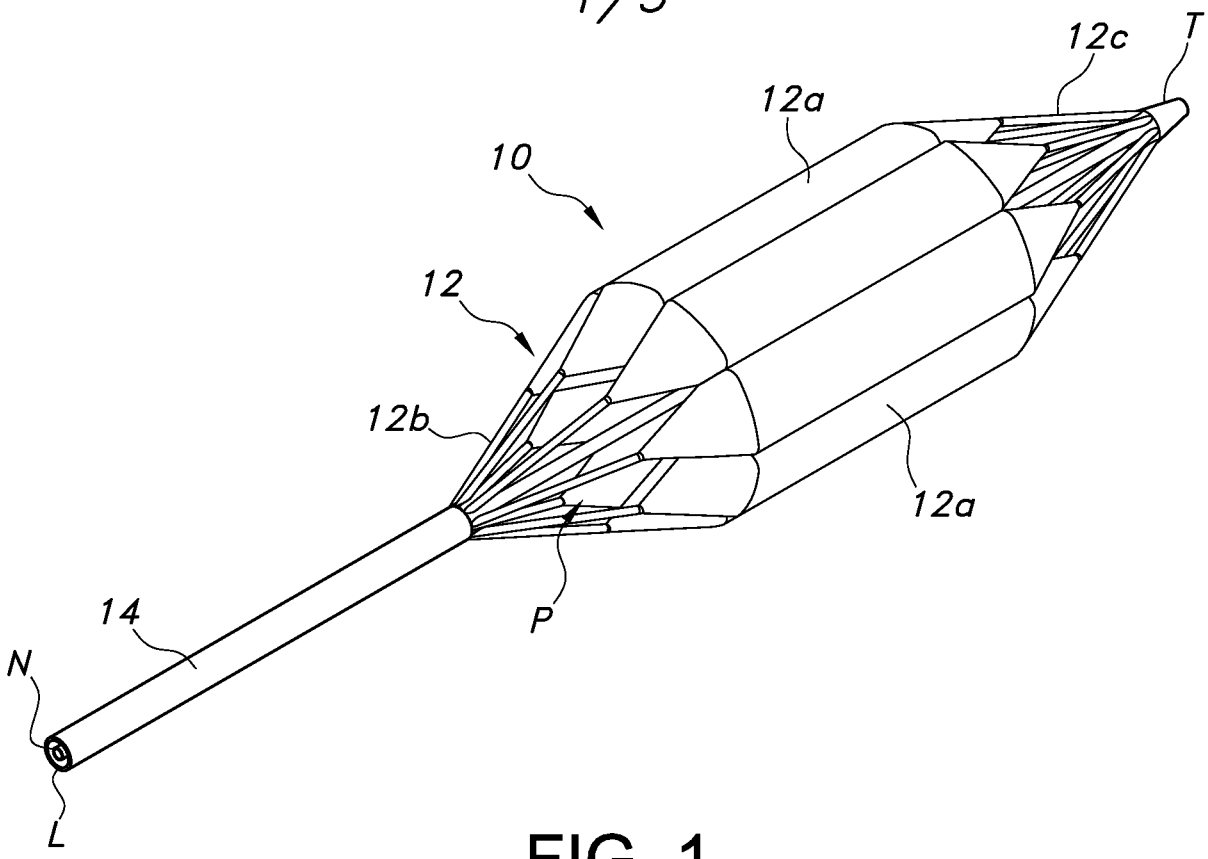


FIG. 1

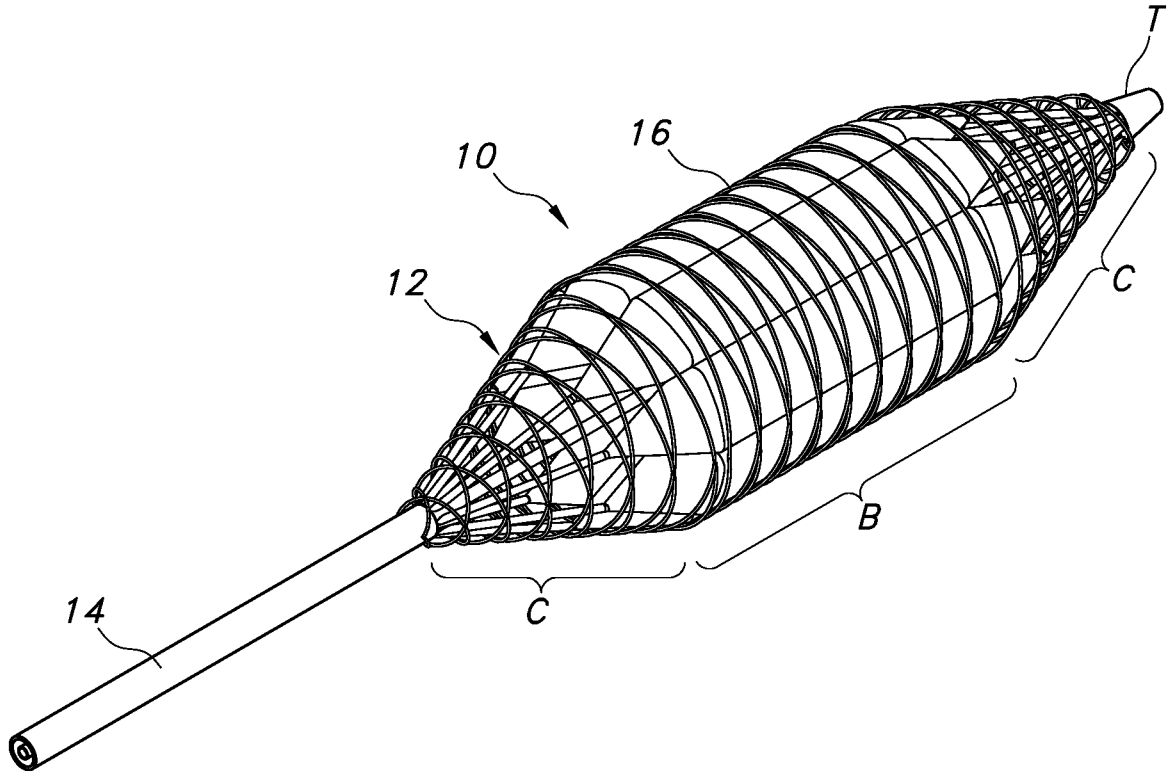


FIG. 2

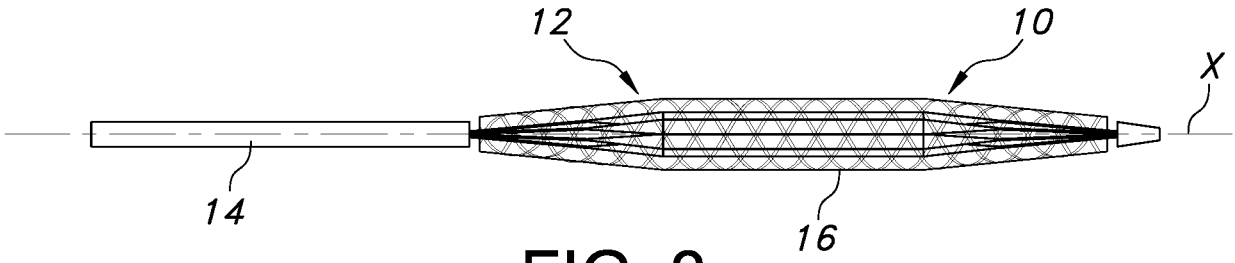


FIG. 3

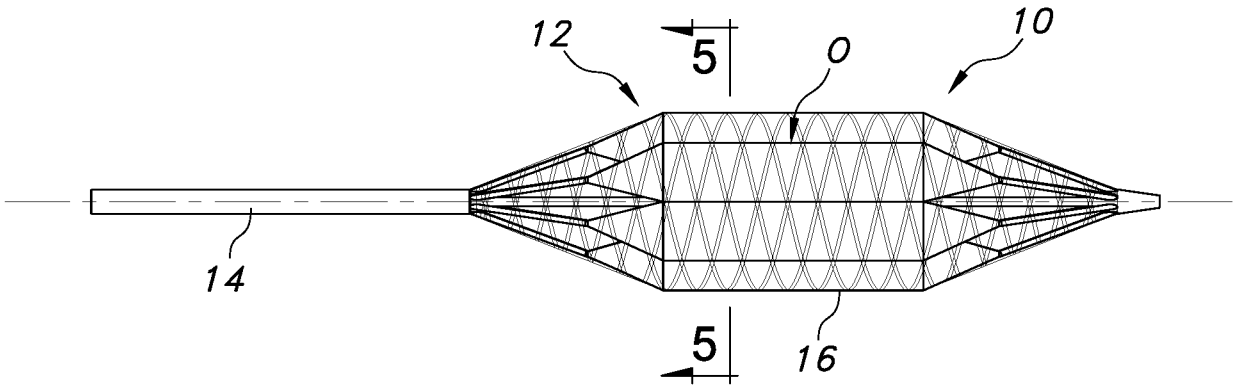


FIG. 4

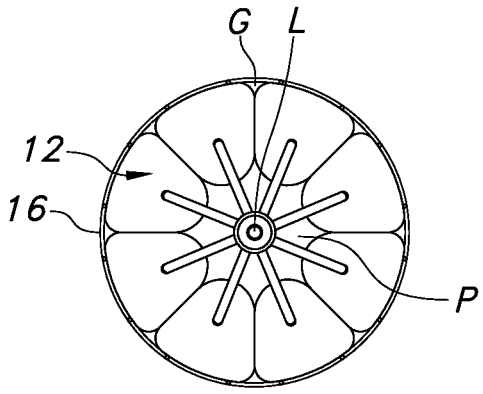


FIG. 5

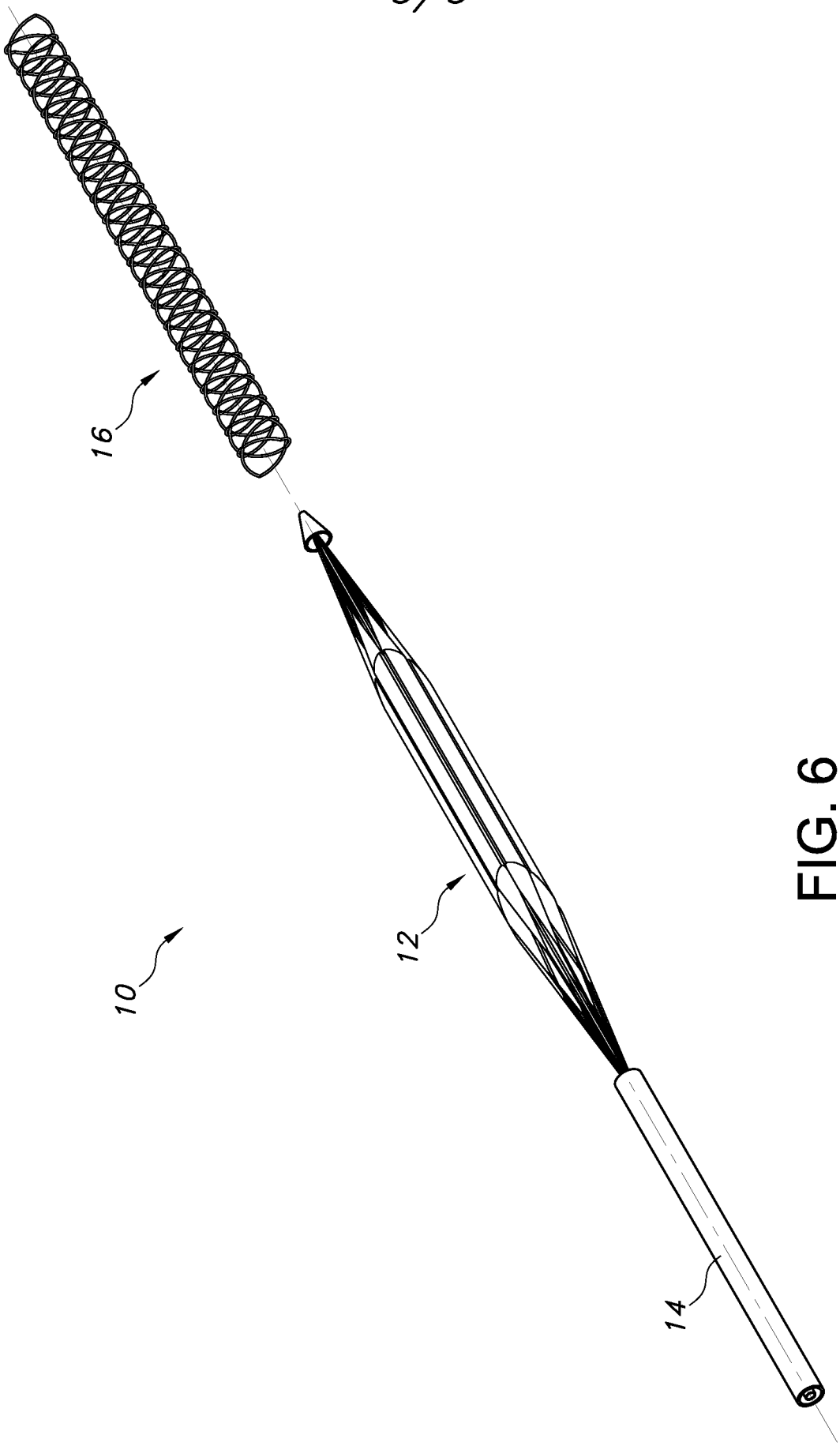


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/26158

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F2/958; A61M29/02, 25/10 (2016.01)
CPC - A61M25/1002, 25/1006, 25/10; A61F2/958
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)
IPC(8): A61F2/958; A61M29/02, 25/10 (2016.01)
CPC: A61M25/1002, 25/1006, 25/10; A61F2/958

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Orbit; Google/Google Scholar; PubMed/MEDLINE; Ebscohost: mesh*, fiber*, metal*, memory*, Nitinol*, filament*, balloon*, infus*, perfus*, wind*, annular*, sock*, sleeve*, reinforc*.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/099979 A1 (LOMA VISTA MEDICAL, INC) July 26, 2012; abstract; paragraphs [0151]. [0175], [0181]; figures 17, 23A-24A; 23B-24B	1-6, 12-36, 38, 39/36, 39/38
X	WO 2014/176422 A1 (LOMA VISTA MEDICAL, INC) October 30, 2014; abstract; claims 42-43, figure 16	36-37, 39/37
A	EP 2 241 284 A1 (NATIONAL UNIVERSITY OF IRELAND) October 20, 2010; entire document	1-6, 12-39
A	US 2011/0144742 A1 (MADRID, G et al) June 16, 2011; entire document	1-6, 12-39

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 June 2016 (08.06.2016)	11 JUL 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/26158

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.: 7-11, 40
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:

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 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.

(19)中华人民共和国国家知识产权局

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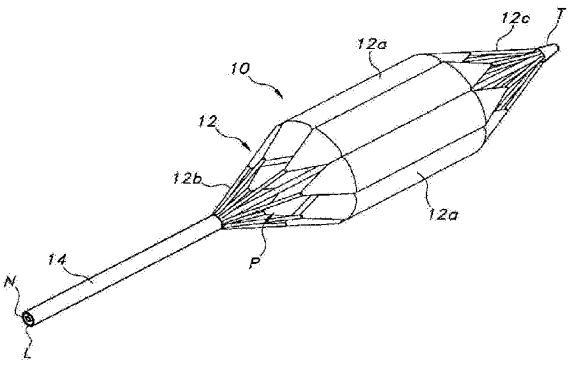
权利要求书3页 说明书5页 附图3页

(54)发明名称

具有外部网的可膨胀灌注球囊以及相关方法

(57)摘要

本申请公开了一种用于在脉管系统中执行医疗处理过程的装置，其包括可膨胀灌注球囊，该可膨胀灌注球囊包括用于在球囊膨胀状态中传输流体的通道。金属网或线网定位成沿可膨胀球囊的至少一部分或在至少一部分上面。当球囊膨胀时，网可允许流体流过线网进入通道。网可以包括线护套或套筒，并可以包括形状记忆材料，例如镍钛诺。还公开了相关方法。



CN 107427378 A

1.一种用于在脉管系统中执行医疗处理过程的装置,包括:

可膨胀灌注球囊,所述可膨胀灌注球囊包括通道,用于在球囊膨胀的状态中传输流过脉管系统的流体;和

线网,所述线网位于可膨胀灌注球囊的至少一部分上面。

2.根据权利要求1所述的装置,其中:球囊包括在所述球囊的单个截面中的第一小室和第二小室。

3.根据权利要求2所述的装置,其中:在第一小室和第二小室之间设置有空间,且在线网中的开口允许流体从外部流向球囊,进入所述空间,并流入通道。

4.根据权利要求2所述的装置,其中:通道由第一小室和第二小室包围,线网覆盖在球囊的第一小室和第二小室上面。

5.根据权利要求2所述的装置,其中:第一小室和第二小室各自包括膨胀内腔。

6.根据前述任意一项权利要求所述的装置,其中:所述线网包括金属。

7.根据前述任意一项权利要求所述的装置,其中:线网包括形状记忆材料。

8.根据前述任意一项权利要求所述的装置,其中:球囊包括锥形端部区域和中心区域,线网至少沿球囊的中心区域延伸。

9.根据前述任意一项权利要求所述的装置,其中:线网包括网状结构,所述网状结构包括当球囊膨胀时与通道流体连通的一个或多个开口。

10.根据前述任意一项权利要求所述的装置,其中:球囊包括多个小室,各小室包括近侧颈部,用于接收膨胀流体,所述线网至少局部覆盖小室的近侧颈部。

11.根据前述任意一项权利要求所述的装置,其中:线网包括螺旋线。

12.根据权利要求1所述的装置,其中:线网包括金属。

13.根据权利要求1所述的装置,其中:线网包括形状记忆材料。

14.根据权利要求1所述的装置,其中:球囊包括锥形端部部分和中心部分,线网至少沿球囊的中心部分延伸。

15.根据权利要求1所述的装置,其中:线网包括网状结构,所述网状结构包括当球囊膨胀时与通道流体连通的一个或多个开口。

16.根据权利要求1所述的装置,其中:球囊包括多个小室,各小室包括近侧颈部,用于接收膨胀流体,所述线网至少局部覆盖小室的近侧颈部。

17.根据权利要求1所述的装置,其中:线网包括螺旋线。

18.一种用于在脉管系统中执行医疗处理过程的装置,包括:

可膨胀灌注球囊,所述可膨胀灌注球囊包括在球囊的单个截面中的第一球囊和第二球囊;以及

线网,所述线网设置在可膨胀灌注球囊的第一球囊和第二球囊的至少一部分上。

19.根据权利要求18所述的装置,其中:第一球囊和第二球囊包括单个球囊的第一小室和第二小室。

20.根据权利要求18所述的装置,其中:线网包括金属。

21.根据权利要求18所述的装置,其中:线网包括形状记忆材料。

22.根据权利要求18所述的装置,其中:各球囊包括锥形端部部分和中心部分,线网至少沿球囊的中心部分延伸。

23.根据权利要求18所述的装置，其中：线网包括当球囊膨胀时与通道流体连通的开口。

24.根据权利要求18所述的装置，其中：线网包括位于第一球囊和第二球囊之间的至少一个开口。

25.根据权利要求18所述的装置，其中：各球囊包括近侧颈部，用于接收用于使球囊膨胀的流体，线网至少局部覆盖所述近侧颈部。

26.一种用于在脉管系统中执行医疗处理过程的装置，包括：

可膨胀灌注球囊，所述可膨胀灌注球囊包括通道，用于在球囊的膨胀状态中传输流过脉管系统的流体；以及

线护套，所述线护套位于可膨胀灌注球囊的至少一部分上面。

27.根据权利要求26所述的装置，其中：线护套包括金属网。

28.根据权利要求26所述的装置，其中：球囊包括锥形端部部分和中心部分，线护套至少沿可膨胀灌注球囊的中心部分延伸。

29.根据权利要求26所述的装置，其中：线护套包括当设备膨胀时与通道流体连通的开口。

30.一种用于在脉管系统中执行医疗处理过程的装置，包括：

可膨胀灌注球囊，所述可膨胀灌注球囊包括通道，用于在球囊膨胀状态中传输流过脉管系统的流体；以及

套筒，所述套筒包括形状记忆材料，所述形状记忆材料设置在可膨胀灌注球囊的至少一部分上。

31.根据权利要求30所述的装置，其中：套筒包括线网。

32.根据权利要求30所述的装置，其中：形状记忆材料包括镍钛诺。

33.根据权利要求30所述的装置，其中：可膨胀灌注球囊包括在单个截面中的多个小室。

34.一种用于在脉管系统中执行医疗处理过程的装置，包括：

可膨胀灌注球囊，所述可膨胀灌注球囊包括通道，用于当灌注球囊膨胀时传输流过所述脉管系统的流体；以及

压缩网，所述压缩网位于可膨胀灌注球囊的至少一部分上面。

35.一种用于在脉管系统中执行医疗处理过程的装置，包括：

可膨胀灌注球囊，所述可膨胀灌注球囊包括通道，用于当球囊膨胀时传输流过脉管系统的流体；以及

金属网，所述金属网位于所述可膨胀灌注球囊的至少一部分上面。

36.一种形成灌注球囊的方法，包括：

将线网设置在灌注球囊上面。

37.根据权利要求36所述的方法，其中：设置步骤包括将线缠绕在灌注球囊的外表面上。

38.根据权利要求36所述的方法，其中：设置步骤包括将灌注球囊插入由线网形成的管中。

39.根据权利要求36-38中任意一项所述的方法，还包括：将线网附接在灌注球囊上的

步骤。

40.根据权利要求36-39中任意一项所述的方法，还包括将线网压缩在球囊上面的步骤。

具有外部网的可膨胀灌注球囊以及相关方法

[0001] 本申请要求美国临时专利申请No.62/143472的优先权，该文献的内容结合到本申请中，作为参考。

[0002] 参引

[0003] 本说明书中提及的所有出版物和专利申请都结合到本申请中，作为参考，就像各出版物或专利申请都特别和分别指出被本文结合，作为参考。

背景技术

[0004] 可充胀装置例如球囊广泛用于医疗处理过程中。在球囊情况下，通常在导管的端部插入身体内，直到球囊到达所关注的区域。向球囊增加压力而导致球囊膨胀。在一种使用的变化形式中，当球囊膨胀时该球囊在身体内部产生空间。

[0005] 球囊可以用于心脏瓣膜中，包括球囊主动脉瓣膜成形术(BAV)和经导管的主动脉瓣植入术(TAVI)。球囊能够用于打开狭窄的主动脉瓣。狭窄的瓣膜可能具有硬的钙化病变部，这可能需要使用坚固的球囊来使得病变部“破裂”。另外，为了增加控制，可能希望有精确的膨胀球囊直径。

[0006] 球囊可以用于使得斑块离开血管腔的中心朝向脉管系统的壁运动，例如在血管成形术或外周脉管系统的过程中。在该处理过程中，将有尖端球囊的导管放置在血管的阻塞处。当球囊膨胀时，血管收缩处将扩张，从而导致改善血液流动。

[0007] 对于传统的方法，使用两种基本类型的球囊：一种是高压、低柔顺性的球囊，另一种是低压、高柔顺性球囊。

[0008] 高柔顺性的医疗球囊通常由聚氨酯、乳胶、硅树脂、PVC、Pebax和其它弹性体构成。当高柔顺性球囊中的压力增加时，球囊尺寸扩展。一旦压力降低，高柔顺性的医疗球囊就可能返回它的初始形状，或者接近它的初始形状。高柔顺性的医疗球囊能够很容易地在零膨胀压力和爆裂之间体积扩展几倍。

[0009] 由于多种原因，传统的高柔顺性医学球囊可能不足够。高柔顺性或高弹性的医疗球囊通常不能达到高压，因为它们的壁具有低拉伸强度，且当球囊扩展时它们的壁变薄。在一些情况下，高柔顺性的医疗球囊提供的力不足以完成处理过程。超过高柔顺性医疗球囊的额定压力产生过高的球囊失效危险，该球囊失效可能导致患者的严重并发症。而且，高柔顺性的医疗球囊还有较差的形状控制。当高柔顺性的医疗球囊扩展时，它可能呈现主要由患者的内部环境特征(而并不是临床医生的目标)来决定的形状。在某些情况下，这可能与医生所希望的相反。特别是，很多医疗处理过程(例如BAV和TAVI)都以可靠形成特殊球囊形状为基础。

[0010] 低柔顺性、高压的医疗球囊在相当高压力下都基本保持它们的形状。PET(聚对苯二甲酸乙二醇酯)是用于高压低柔顺性球囊的最常用材料。PET通常用于高性能的血管成形术球囊。PET比其它聚合物更强，能够模制成多种形状，并能够制成非常薄(例如5μm至50μm(0.0002英寸至0.002英寸))，从而使这些球囊有较低型面。PET非常硬，因此由PET制成的球囊可能很难打包或折叠成小直径，并可能有较差的跟踪能力(即，在穿过曲折血管配置的导

丝上滑动和弯曲的能力)。而且,由PET制成的球囊尽管比由均质聚合物制成的大多数其它球囊更强,但仍然并不强到足以保持足够压力来完成特定医疗处理过程。另外,在球囊直径较大(例如,20mm或更大)的情况下,对于处理过程例如BAV、TAVI,PET球囊仍然有过大的柔顺性。

[0011] 尼龙球囊是用于低柔顺性高压球囊的可选材料。不过,这些尼龙球囊通常比PET球囊更弱,因此能够有较低压力。尼龙很容易吸水,这可能在一些情况下对尼龙的材料特性有不利影响。尼龙具有优于PET的抗穿刺性,且比PET更有柔性。

[0012] 纤维增强复合材料球囊是另一种可选的低柔顺性高压医疗球囊。这种纤维增强复合材料球囊能够有利地维持高压,提供精确的形状控制,并高度抗撕裂和穿刺。不过,纤维增强球囊的制造处理可能复杂和昂贵,需要施加多个不同的纤维层,以便获得所希望的支承。通常,这些层中的至少一个包括环绕基部球囊包绕的织物去卷积图形层。这样形成和包绕织物图形层可能很麻烦、费力和设备密集、且耗时间。这种织物还可能需要形成开口以便适应流体流动,这可能导致制造更困难,并也可能削弱织物。

[0013] 因此,还需要发明一种增强灌注球囊,该增强灌注球囊能够快速和容易地制造和同时仍然使它保持承受高压、提供精确的形状控制并能够以高效和有效的方式进行所希望的灌注的能力。

发明内容

[0014] 通常,本申请提供了一种包括外部网的灌注球囊。更具体地说,可膨胀灌注球囊包括通道,用于允许在球囊的膨胀状态下的流体流动。网(例如编织或非编织线结构)定位在球囊的至少一部分上或者沿着球囊的至少一部分,当球囊膨胀时允许流体流过网进入通道内。该方法的技术效果是产生一种增强的灌注球囊,该灌注球囊能够快速和容易地制造,同时仍然使它保持承受高压的能力,提供精确的形状控制,并能够以高效和有效的方式进行所希望的灌注。

[0015] 根据本发明的以下方面,该技术效果可以通过一种用于在脉管系统中执行医疗处理过程的装置来实现,该装置包括可膨胀灌注球囊,该可膨胀灌注球囊包括:通道,用于在球囊膨胀状态中传输流体;以及线网,该线网定位在可膨胀球囊的至少一部分上面。在一个实施例中,球囊包括在该球囊的单个截面中的第一小室和第二小室。在第一小室和第二小室之间设置空间,在线网中的开口允许流体从外部流向球囊,进入该空间内,并流向通道。通道可以由第一和第二小室包围,且线网覆盖在球囊的第一和第二小室上。第一和第二小室可以各自包括膨胀内腔,该膨胀内腔可以由近侧颈部形成,该近侧颈部至少局部由线网覆盖。

[0016] 线网可以包括金属和/或形状记忆材料,例如镍钛诺,并可以包括一个或多个螺旋线。球囊可以包括锥形端部区域和中心区域,线网至少沿球囊的中心区域延伸。线网可以包括网状结构,该网状结构包括当球囊膨胀时与通道流体连通的一个或多个开口。

[0017] 根据本发明的还一方面,用于在脉管系统中执行医疗处理过程的装置包括可膨胀灌注装置,该可膨胀灌注装置包括在装置的单个截面中的第一球囊和第二球囊以及沿该装置的单个截面位于第一和第二球囊的至少一部分上面的线网。第一和第二球囊可以包括单个球囊的第一和第二小室,线网可以包括金属和/或形状记忆材料。

[0018] 各球囊可以包括锥形端部部分和中心部分，线网至少沿球囊的中心部分延伸。线网可以包括当装置膨胀时与通道流体连通的开口。具体地说，线网可以包括位于第一和第二球囊之间的至少一个开口。各球囊还可以包括近侧颈部，用于接收用于使球囊膨胀的流体，其中，线网至少局部覆盖该近侧颈部。

[0019] 本发明的还一方面涉及一种用于在脉管系统中执行医疗处理过程的装置。该装置包括可膨胀灌注球囊和位于该球囊的至少一部分上面的线护套(sock)。在一个实施例中，线护套包括金属网，球囊包括锥形端部部分和中心部分，线护套或金属网至少沿球囊的中心部分延伸。线护套可以有在装置膨胀时与通道流体连通的一个或多个开口。

[0020] 本发明的还一方面涉及一种用于在脉管系统中执行医疗处理过程的装置。该装置包括可膨胀灌注球囊，该可膨胀灌注球囊包括用于在球囊的膨胀状态中传输流体的通道。包括形状记忆材料的套筒位于可膨胀球囊的至少一部分上面。套筒可以包括线网和/或形状记忆材料，例如镍钛诺。球囊可以包括在单个截面中的多个小室。

[0021] 本发明的还一方面涉及一种用于在脉管系统中执行医疗处理过程的装置。该装置包括：可膨胀灌注球囊，该可膨胀灌注球囊包括用于在球囊膨胀时传输流体的通道；以及压缩网，该压缩网位于可膨胀球囊的至少一部分上面。

[0022] 本发明的还一方面涉及一种用于在脉管系统中执行医疗处理过程的装置。该装置包括：可膨胀灌注球囊，该可膨胀灌注球囊包括用于在球囊膨胀时传输流体的通道；以及金属网，该金属网位于可膨胀球囊的至少一部分上面。

[0023] 本发明的还一方面涉及一种形成灌注球囊的方法。如上所述，该方法可以包括在灌注球囊上面提供线网。这能够通过将线缠绕在球囊的外表面上面或者将灌注球囊插入由线网形成的管中而完成。该方法还可以包括将线网附接在灌注球囊上。线网也可以用于在球囊上提供压缩力。

附图说明

[0024] 图1是可膨胀装置在扩展状态中的透视图；

[0025] 图2是可膨胀装置在扩展状态中的透视图，该可膨胀装置包括外部网；

[0026] 图3是装置在未膨胀状态中的侧视图；

[0027] 图4是装置在膨胀状态中的侧视图；

[0028] 图5是沿图4中的线5-5的剖视图；以及

[0029] 图6是表示插入柔性护套或套筒中的未膨胀球囊的透视图。

具体实施方式

[0030] 公开的本发明涉及一种成球囊性质的可膨胀装置，特别是灌注球囊。本发明的新颖特征在后面的权利要求中特别阐述。通过参考下面阐述示例实施例的详细描述以及附图，将更好地理解本发明的特征和优点，本发明原理应用于该示例实施例中。

[0031] 图1表示了可膨胀装置10，该可膨胀装置10包括由导管轴14支承的球囊12。应当理解，装置10的球囊12可以有在单个截面中的多个可膨胀小室12a，这些可膨胀小室12a可以是单独的、可分开膨胀的球囊(各可膨胀球囊有分开的膨胀内腔，如所述)，或者是单个球囊的部件。小室可以通过分段的细长结构来实现，该细长结构进行折叠，以使得小室12a环绕

沿着中心轴线X延伸的通道P，流体例如血液可以沿该通道P继续流动，即使当球囊12完全膨胀时(该膨胀可以通过单个膨胀内腔来完成，或者各球囊可以有它自身的膨胀内腔)。这种球囊的完整说明可以在国际专利申请公开WO2012099979A1中找到。不过，也可以使用其它形式的灌注球囊，例如管形球囊、具有外周(例如螺旋形)槽道的球囊(目的是在膨胀过程中允许流体流动)、环形或管状球囊、或这些技术的任何组合。

[0032] 球囊12可以由任何合适的材料形成，包括但不局限于：聚氨酯、乳胶、硅酮、PVC、Pebax和其它弹性体、PET、尼龙、其它聚合物、以及上述的任何组合。用于制造柔顺性(或弹性)球囊的材料示例包括多种聚合物材料(包括已知可用于制造柔顺性医疗球囊的材料)，例如，具有高度线性(非塑性)的弹性体膜，用于较宽范围的应力和应变值。这些材料包括各种硅酮、乳胶、Kraton、多种热塑性弹性体(TPE)，特别是基于TPE的苯乙烯-乙烯/丁烯-苯乙烯嵌段共聚物(SEBS)(如C-Flex)、聚硅氧烷改性的SEBS以及它们的相关族、聚氯乙烯(PVC)、交联聚烯烃例如聚乙烯以及多种聚氨酯。用于制造非柔顺性球囊(例如非弹性球囊)的材料示例包括很多聚酰胺(例如尼龙)、热塑性聚酰胺、聚酯、聚苯硫醚、超高分子量聚乙烯和PET。

[0033] 在使用多小室球囊12的所示实施例中，各小室12a包括：近侧颈部12b，该近侧颈部12b与膨胀内腔L连通；以及远侧颈部12c。在任何情况下，装置10还可以包括沿中心轴线X延伸的导丝内腔N，该导丝内腔N可以形成导管14的一部分，球囊12可以附接在该导管14上(例如在颈部12c的远端处，并与尖端T连接)。

[0034] 为了约束这种结构的小室12a，沿它的外表面提供了线网16。线网16可以位于球囊12的顶上(特别是在小室12a上面)，并可以提供为线圈(如后面所述)，或者提供为端部开口的柔性线护套、管或套筒，该柔性线护套、管或套筒用于接收处于折叠结构的球囊。线网16可以布置为形成特殊形状的球囊12，例如具有大致圆锥形或锥形端部部分C和中心筒部分B的球囊。该筒部分B有时也称为球囊12的“工作”部分，因为它是与进行治疗的脉管系统的瓣膜或其它部分接触的结构。

[0035] 为了本发明的目的，术语“网”将表示具有开口结构(有间隔开的孔)的材料，“线”的意思是网包括一个或多个细丝或类似的细柔性部件。在一个特殊实施例中，线网16布置成使得孔包括网的面积的更大部分(与形成网的固体材料相比)。换句话说，网与闭合相比更开放，因此促进流体自由流动，同时仍然提供用于下面球囊12的约束。

[0036] 网16可以由能够在膨胀过程中与球囊一起膨胀的材料来形成，例如金属(包括辐射不能透过的金属)或者金属和聚合物或塑料材料的组合。在一个特殊实施例中，网16由形状记忆材料或合金(例如镍钛诺)制成。这种类型的材料可以退火，以使得它能够根据温度而保持特殊形状(例如在体温下的低型面)。

[0037] 如图6中所示，网16可以作为预先形成的护套而施加在球囊12上，或者可以通过环绕球囊12缠绕线或线状材料(可能成螺旋形或螺线形的方式，如图所示，为单程或双程，以恒定节距或可变节距)而施加在球囊上。网16的全部或一部分可以与球囊12连接，例如通过使用粘接剂。网16可以由编织线或细丝、或者非编织线或细丝来形成，或者可以从一根管来切割(例如通过在其中形成开口)。尽管网16表示为偏斜布置(即，具有成角度或倾斜的线或细丝)，但是一些细丝或线可以基本平行于中心或纵向轴线X，其它细丝或线可以基本垂直于它(例如，当将具有规则正方形开口的屏状材料施加在球囊12上时的情况，例如沿中心部

分B)。

[0038] 网16可以是设置成使得球囊12在膨胀状态或未膨胀状态(或两者)中成形的形成部件。在一些变化形式中,网16可以在球囊12上提供压缩力。例如,网16的力可以帮助将球囊从图4所示的扩展状态压缩成图3所示的未扩展状态。也可选择,护壳(未示出)可以用于在球囊12收缩之后压缩该网16。

[0039] 网16可以沿着整个球囊12延伸,如从图2、3和4可以最好理解。也可选择,网16可以只在球囊12的一部分上延伸(例如沿着筒部分B的全部或一部分)。网16还可以提供为在球囊12的全部或一部分上的多个部分或区段(也就是,多于一个网可以与球囊12结合使用,包括交叠或顺序地布置)。网16的一部分也可以与网16的另一部分设置有间隙或空间。

[0040] 应当知道,网16包括多个开口,因此形成网状结构。如图所示,网16可以施加成规则图形,或者可以是不规则(因此,例如在某些位置设置有较宽的开口,在其它位置设置有较小开口,包括沿球囊12的相同或不同部分)。网16中的开口的尺寸和形状将取决于它形成的方式。

[0041] 不管它使用的材料或形式如何,网16中的开口允许流体例如在球囊内表面内部的空间或通道中(与中心轴线并置)从球囊12的外部区域流向内部区域。这不仅包括来自球囊12的近端和远端的流(当网覆盖锥形部分时),还包括沿中心部分以及在小室12a或球囊之间的空间内的流。特别是,网16包括一个或多个开口O(见图4),该开口O定位成与相邻小室12a之间的间隙并列或邻近,这允许流体流过在相邻小室12a之间形成的任何间隙G或空间(见图5),从而导致提高的灌注水平,并简化结构,而不会牺牲保持器(护罩或外壳)的所希望特征,该保持器用于在膨胀之前和膨胀过程中将小室保持在一起。

[0042] 应当知道,本发明还涉及一种形成灌注球囊的方法。如上所述,该方法可以包括在灌注球囊上面提供线网。这能够通过将线缠绕在球囊的外表面上或者将灌注球囊插入由线网形成的管中而完成。该方法还可以包括将线网附接在灌注球囊上。线网还可以用于在球囊上提供压缩力。

[0043] 前述说明将提供本发明构思的示例说明,而并不将本发明限制于任何特殊模式或形式。本文中介绍为单数的任何元件能够是多个(即,介绍为“一个”的任何元件能够多于一个),且多个元件能够单独地使用。对于元件、装置、方法或它们的组合的单个变化形式而公开的特征能够用于或应用于其它变化形式,例如尺寸、爆裂压力、形状、材料或它们的组合。一类元件中的任何种元件能够有该类元件的任何其它种元件的特征或元素。术语例如“通常”或“基本上”意味着该值可能根据情况而变化,例如直到给定条件的10%。用于实施本发明的上述结构、元件或完整组件和方法、它们的元件以及本发明方面的变化形式可以以任何组合与任意明显变化形式一起来相互组合和变化。

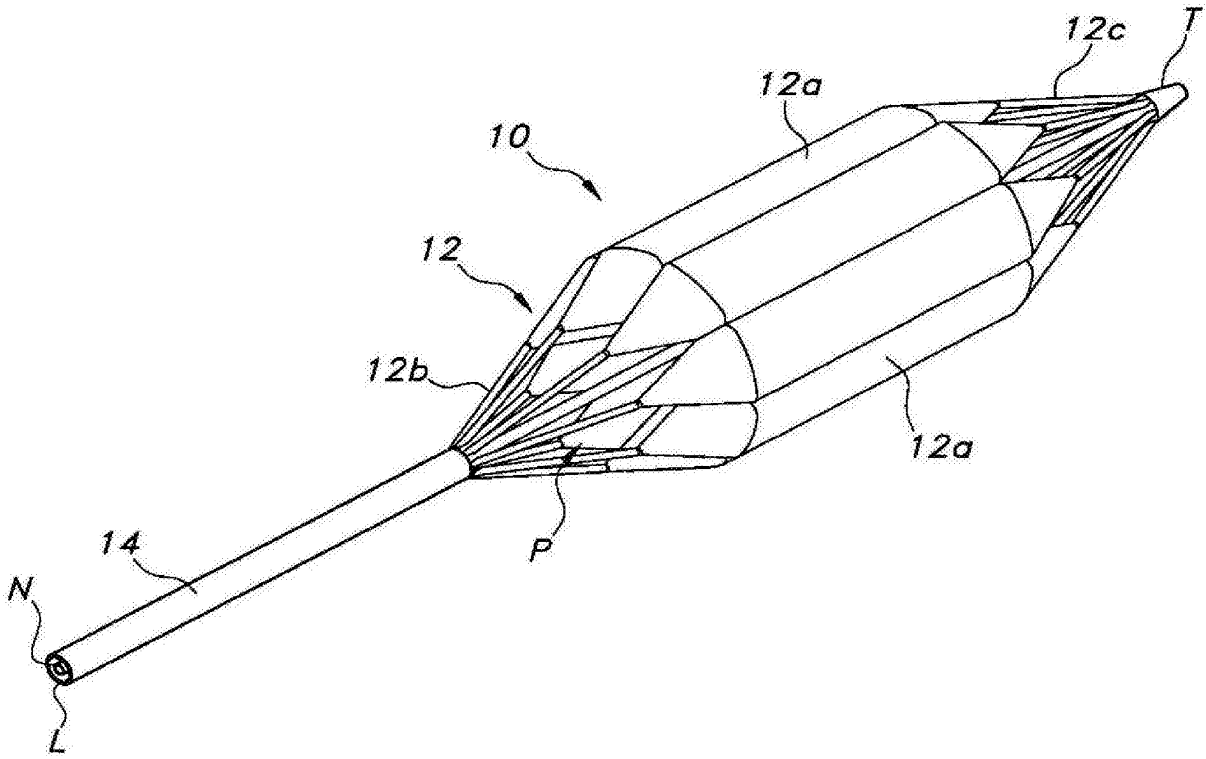


图1

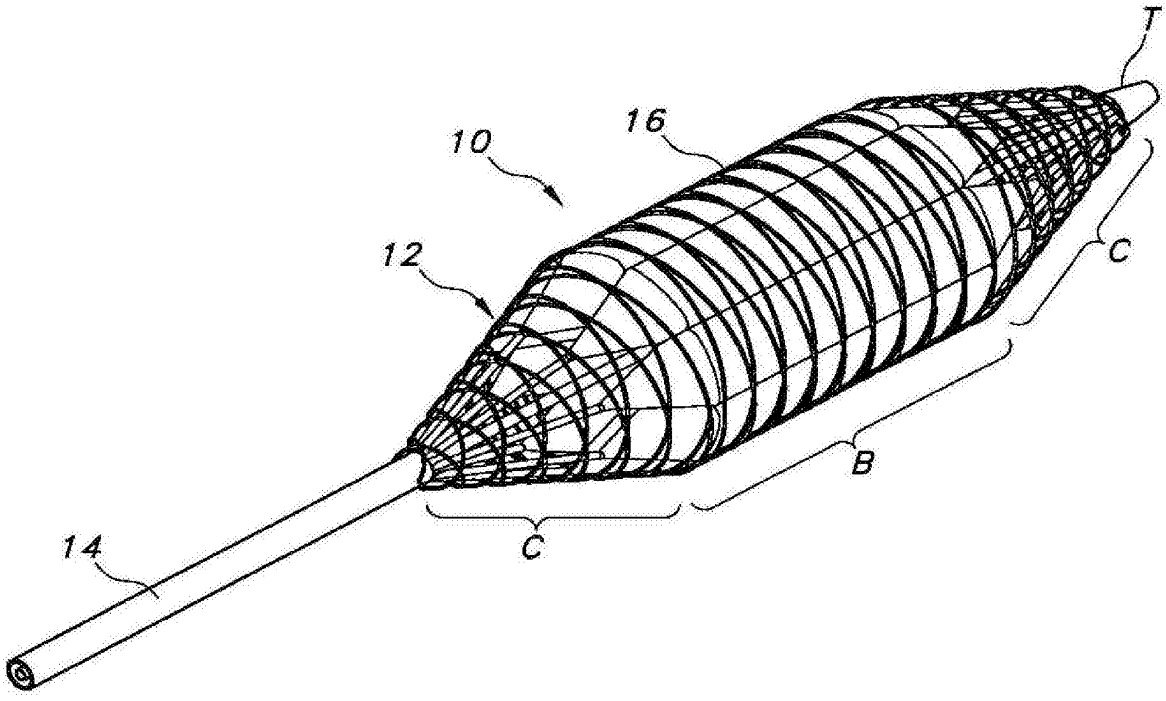


图2

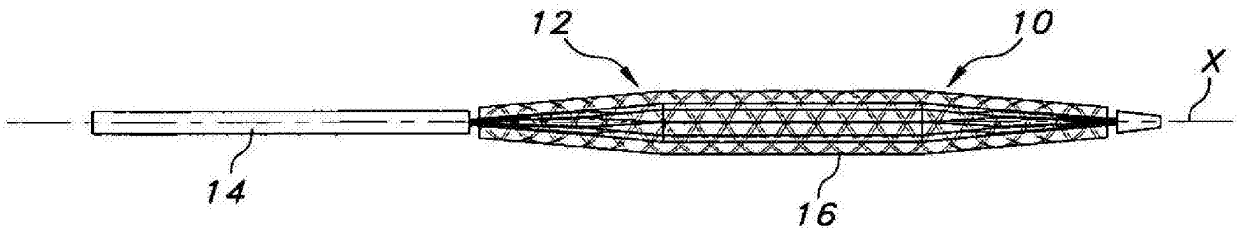


图3

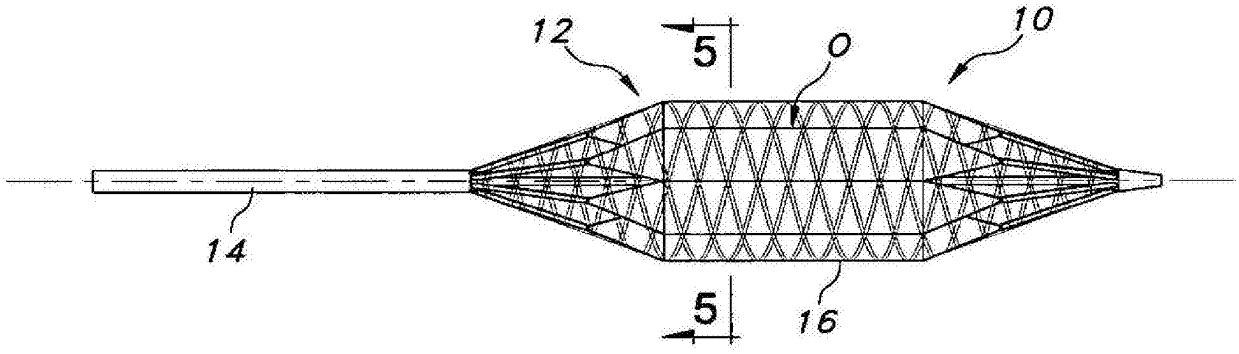


图4

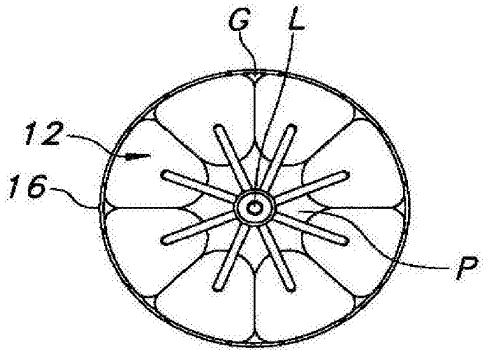


图5

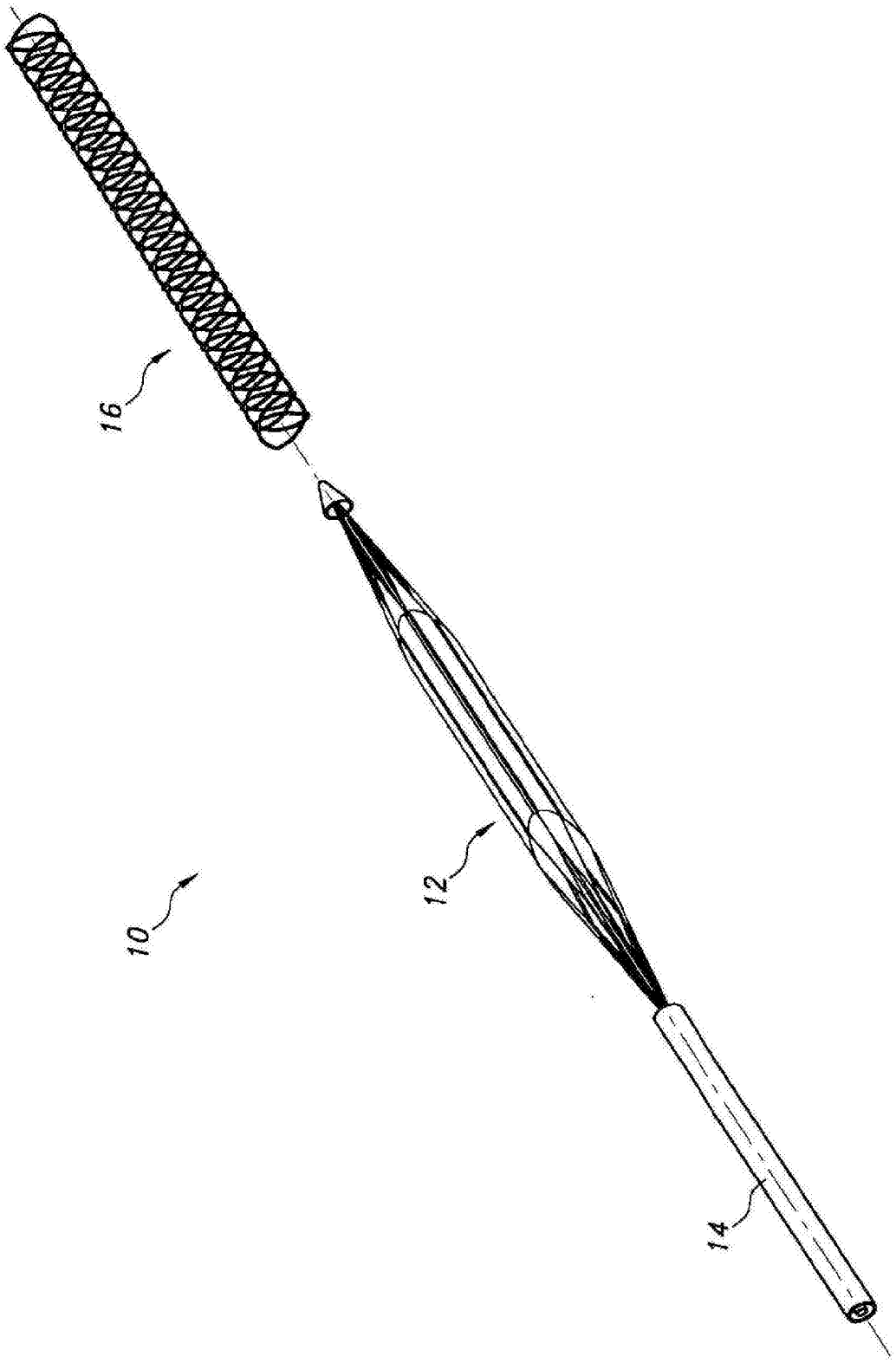


图6