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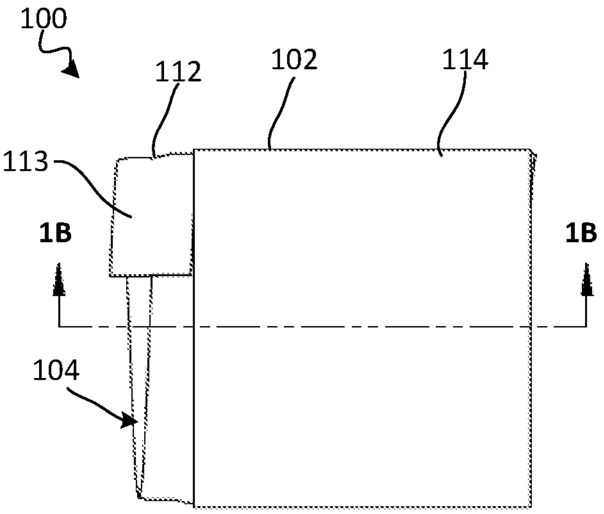

Figure 1A

(57) **Abstract**: Catheter shafts and associated devices, systems, and methods are disclosed herein, A representative catheter in accordance with an embodiment of the disclosure includes a generally tubular outer structure and an inner structure surrounded by the outer structure. The inner structure surrounds a catheter lumen. The inner structure includes overlapping edges such that, when the catheter is bent along its longitudinal axis, the over-lapping edges move relative to one another.

CATHETER SHAFT AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims priority to U.S. Provisional Application No. 62/269,372, filed on December 18, 2015, entitled "CATHETER SHAFT AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," the contents of which are hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology is directed generally to catheters. More specifically, the present technology relates to catheter shaft construction.

BACKGROUND

[0003] A wide variety of medical devices have been developed for intravascular use. Catheters, for example, are commonly used to facilitate navigation through and/or treatment within the anatomy of a patient. Because of the compromises involved between the mechanical, biological and chemical requirements for catheter performance, many existing catheters are a composite of two or more different materials in order to take advantage of the unique properties of the different materials. For example, a common composite catheter construction includes (1) an outer jacket made of a material that provides longitudinal rigidity to resist kinks and (2) a chemically-inert inner surface liner (typically a fluoropolymer) having a low coefficient of friction to ease delivery of one or more components through the shaft lumen. Inner liner materials, however, are significantly less flexible than the materials used for the outer jacket, and thus greatly affect the flexibility of the composite catheter shaft. For example, the modulus of elasticity of materials commonly used as inner surface liners is about 70,000 psi, while the modulus of elasticity for common outer jacket material(s) is about 2,900 psi. Although some conventional catheters are made with low durometer polymers, (e.g., extremely soft), such catheters generally have little kink resistance. Accordingly, a need exists for a kink-resistant catheter shaft with improved flexibility.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Figure 1A is a side view of a portion of a catheter shaft configured in accordance with the present technology, shown in an unstressed state.

[0005] Figure 1B is a cross-sectional view of the catheter shaft shown in Figure 1A, taken along line 1B-1B.

[0006] Figure 1C is an isolated, isometric view of an inner structure of the catheter shaft shown in Figures 1A-1B configured in accordance with the present technology.

[0007] Figure 1D is an enlarged view of a portion of the cross-sectioned catheter shaft shown in Figure 1B.

[0008] Figure 2A is an isometric view of the catheter shaft shown in Figures 1A-1C, shown bent along a curved axis.

[0009] Figure 2B is a side view of the catheter shaft shown in Figure 2A.

[0010] Figure 2C is an isometric front view of the catheter shaft shown in Figures 2A and 2B.

[0011] Figure 2D is a cross-sectional view of the catheter shaft shown in Figures 2A-2C taken along line 2D-2D of the view shown in Figure 2C.

[0012] Figure 2E is an enlarged view of a portion of the cross-sectioned catheter shaft shown in Figure 2D.

[0013] Figure 2F is an enlarged view of a portion of the cross-sectioned catheter shaft shown in Figure 2D.

[0014] Figure 3A is an isometric view of a catheter shaft configured in accordance with another embodiment of the present technology, shown bent along its axis.

[0015] Figure 3B is a side view of the catheter shaft shown in Figure 3A.

[0016] Figure 4A is an isolated, isometric view of an inner structure of the catheter shaft shown in Figures 3A-3B configured in accordance with the present technology, shown in an unstressed state.

[0017] Figure 4B is an isolated side view of the inner structure shown in Figure 4A.

[0018] Figure 4C is an isolated segment of the inner structure shown in Figures 4A-4B configured in accordance with the present technology.

DETAILED DESCRIPTION

[0019] The present technology is directed to catheters and associated methods of manufacture. Specific details of several embodiments of catheter devices, systems, and methods in accordance with the present technology are described below with reference to Figures 1A-4C. In one embodiment, the present technology includes a catheter shaft composed of a tubular outer structure and a helical inner structure surrounded by the outer structure. The inner structure can be formed of a strip of material wound around a central longitudinal axis such that the edges of the strip overlap to form a continuous tubular wall. In some embodiments, only an exposed portion of the strip defines an exterior surface of the continuous tubular wall. The exposed portion can be bonded to the outer structure while a remaining portion of the strip remains free to slide relative to the exposed portion. Accordingly, the catheter shaft of the present technology is significantly more flexible than a comparable shaft utilizing an inner structure made of a contiguous tube.

I. Selected Embodiments of Catheter Shafts

[0020] Figures 1A and 1B are side and cross-sectional views, respectively, of a portion of a composite catheter shaft 100 (also referred to herein as "the shaft 100") configured in accordance with the present technology shown in an unstressed state. Referring to Figures 1A-1B together, the catheter shaft 100 includes a generally tubular sidewall 102 that defines a lumen 104 therethrough. The lumen 104 is configured to slidably receive and facilitate the passage therethrough of one or more medical devices, such as catheters, cannulas, access ports, guidewires, implants, infusion devices, stents and/or stent-grafts, intravascular occlusion devices, clot retrievers, stent retrievers, implantable heart valves, and other suitable medical devices and/or associated delivery systems. Additionally, the lumen 104 can be configured to receive one or more fluids therethrough, such as radiopaque dye, saline, drugs, and the like.

[0021] The size of the lumen 104 can vary depending on the desired characteristics of the shaft 100. For example, in some embodiments the shaft 100 can have an inner diameter (e.g., lumen diameter) between about 0.01 inches and about 0.5 inches, and in some embodiments between about 0.2 inches and about 0.4 inches. Although the shaft 100 shown in Figures 1A-1B has a generally round (e.g., circular) cross-sectional shape, it will be appreciated that the shaft 100 can include other cross-sectional shapes or combinations of shapes. For example, the cross-sectional shape of the shaft 100 can be oval, oblong, rectangular, square, triangular, polygonal, and/or any other suitable shape and/or combination of shapes.

[0022] As shown in Figures 1A-1B, the sidewall 102 of the shaft 100 includes an outer structure 114 and an inner structure 112 surrounded by the outer structure 114. An end portion of the outer structure 114 has been removed in Figures 1A-1B to better illustrate the structural features of the inner structure 112; generally, the outer structure 114 surrounds the inner structure 112 along the entire length of the inner structure 112. In some embodiments, the outer structure 114 can be an elongated polymer tube. Suitable materials for the outer structure 114 include Pebax® (poly ether block amide), polyoxymethylene (POM), polybutylene terephthalate (PBT), polyether block ester, polyether block amide (PEBA), fluorinated ethylene propylene (FEP), polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polyurethane, polytetrafluoroethylene (PTFE), polyether-ether ketone (PEEK), polyimide, polyamide, polyphenylene sulfide (PPS), polyphenylene oxide (PPO), polysulfone, nylon, perfluoro(propyl vinyl ether) (PFA), polyether-ester, platinum, polymer/metal composites, etc., or mixtures, blends or combinations thereof.

[0023] Figure 1C is an isolated isometric view of the inner structure 112 alone without the outer structure 114. As shown in Figures 1A-1C, the inner structure 112 can be a single strip 113 of material wound around a central longitudinal axis A such that the edges of the strip 113 overlap to form a continuous/contiguous (e.g., gap-free) tubular wall having a discontinuous exterior surface 125 in a longitudinal direction. The inner structure 112 and/or strip 113 can be made of a material having a low coefficient of friction, such as a fluoropolymer and/or a lubricious polymer (e.g., high density polyethylene (HDPE), polytetrafluoroethylene (PTFE), and/or a copolymer of tetrafluoroethylene with perfluoroethers such as perfluoroalkoxy (PFA), perfluoropropyl vinyl ether, and/or perfluoromethyl vinyl ether). Other suitable materials can include PEEK, PE, PP, or a copolymer of tetrafluoroethylene, FEP, etc. In many embodiments of the present technology, the inner structure material(s) has a higher melting point than the outer structure material(s).

[0024] As shown in the enlarged, cross-sectional view of the shaft 100 in Figure 1D, the wound strip 113 has an overlapping region 122 that defines a subduction zone and a non-overlapping region 140. In the embodiment shown in Figures 1A-1D, a width of the overlapping region 122 is generally the same along the length of the shaft 100. In other embodiments, a width of the overlapping region 122 can vary along the length of the shaft 100.

In a representative embodiment, when the shaft 100 is in an unstressed state, about 50% or less of the strip 113 covered. Such a configuration avoids gradually increasing a thickness of the inner structure 112 in a given longitudinal direction. In other embodiments, the percentage of overlap can be more than 50%. The amount of overlap (or pitch of a helical strip) may be varied along the length of the shaft to create regions of different and/or changing stiffness.

[0025] The overlapping region 122 includes an outer portion 124 of the strip 113 and an inner portion 126 of the strip 113 positioned radially inwardly of the outer portion 124, as shown in Figure 1D. The outer portion 124, inner portion 126, and non-overlapping region 140 together define a width w of the strip 113. Additionally, a thickness of the inner structure 112 can be the sum of the thicknesses of the outer portion 124 and the inner portion 126 (labeled t_o and t_i, respectively), or two times a thickness of the strip 113.

[0026] The outer portion 124 can have an outer surface 124a facing radially outwardly and an inner surface 124b opposite the outer surface 124a and facing the lumen 104. The inner portion 126 has an outer surface 126a facing radially outwardly and an inner surface 126b opposite the outer surface 126a and facing the lumen 104. In the embodiment shown in Figures 1A-1D, the outer surface 124a of the outer portion 124 is bonded or otherwise fixed to the outer structure 114 along all or a portion of the length of the outer portion 124. The shaft 100 can include a gap 118 between adjacent turns of the outer portion 124 and the outer structure 114. The inner surface 124b of the outer portion 124 abuts the outer surface 126a of the inner portion 126 along all or a portion of their respective lengths. Because the strip 113 is made of a material having a low coefficient of friction, the inner surface 124b of the outer portion 124 can contact the outer surface 126a of the inner portion 126, yet retain the ability to slide relative to the outer surface 126a (and vice versa) when the shaft 100 is bent along its axis A. Additionally, the inner surface 126b of the inner portion 126 can define the shaft lumen 104, as shown in Figure 1D.

[0027] Figures 2A-2C are an isometric view, a side view, and an isometric front view, respectively, of the catheter shaft 100 in accordance with the present technology, shown bent along axis A (e.g., a curved axis upon bending). Figure 2D is a cross-sectional view of the catheter shaft shown in Figures 2A-2C taken along line 2D-2D of the view shown in Figure 2C, and Figures 2E and 2F are enlarged views of a portion of the cross-sectioned catheter shaft 100 shown in Figure 2D. Referring to Figures 2A-2F together, when the shaft 100 bends or deforms, the outer structure 114 deforms elastically and forces the fixed outer portion 124 to move and bend with it. As the outer portion 124 moves, the inner portion 126 slides along the inner surface 124b of the outer portion 124. Along portions of the shaft 100 experiencing tensile forces, the width of the overlapping region 122 decreases, as shown in Figure 2E. Along portions of the shaft 100 experiencing compressive forces, the width of the overlapping region 122 increases, as shown in Figure 2F, as the outer portion 124 subducts with respect to the inner portion 126.

[0028] The catheter shaft 100 of the present technology provides several advantages over existing catheters. For example, the helical or spiral geometry of the inner structure 112, as well as the inner structure's 112 interrupted bonding with the outer structure 114, greatly increases the overall flexibility of the inner structure 112 as compared to a continuous tube made of the same material and having the same thickness. As such, the catheter shaft 100 of the present technology is significantly more flexible than conventional catheter shafts. For example, in some embodiments, the bending stiffness of the shaft 100 may be 25% less than that of a comparable composite catheter shaft (e.g., a shaft having the same outer structure and an inner structure made of a continuous tube made of the same material, having the same thickness and the same inner diameter). In some embodiments, the bending stiffness may be between about 30% and about 60% less than that of a comparable composite catheter. In some embodiments, the inner structure may provide less than about 50%, and in other embodiments less than about 25%, of the total bending stiffness of the composite catheter. Such improved flexibility is most dramatic in larger diameter catheters (assuming wall thickness does not vary based on diameter), such as guide catheters. For a given bend radius and wall thickness, the walls of catheters with a large ID are subject to greater strain than the walls of small ID catheters.

II. Selected Methods of Manufacture

[0029] In one embodiment of manufacturing a catheter shaft in accordance with the present technology, a strip of material is provided. In some embodiments, the strip can be made of the desired inner structure material, such as PTFE. The strip can be a PTFE tape, a longitudinally-cut PTFE tube (described in greater detail below), or other polymer structures in a strip form. For example, in some embodiments, the strip is constructed by splitting the wall of a polymer tube along a helical path about the tube's longitudinal axis. In any of the foregoing embodiments, the strip of material may be wound around a mandrel. In a representative embodiment, the strip is wound from the proximal end to the distal end such that the strips' free edges or steps face distally within the lumen. The strip can be wound in this manner to provide a smoother path through the lumen for one or more devices delivered therethrough. In other embodiments, the strip can be wound from its distal end to its proximal end.

[0030] The strip can be wound to have a desired pitch angle (e.g., the distance between successive turns of the strip). The pitch angle affects the flexibility of the resulting wound structure since the pitch angle affects the amount of overlapping regions per unit length of the shaft, which in turn affects the width of bonded strip that (eventually) undergoes bending stress. In some embodiments, the maximum pitch angle to achieve 50% coverage can be governed by the equation max pitch angle = $\tan^{-1}(2\pi D/w)$, and the minimum pitch angle to achieve no overlap can be governed by the equation min pitch angle = $\tan^{-1}(\pi D/w)$, where D is the desired inner diameter for the shaft and w is the width of the strip of material.

[0031] Once the strip is wound around the mandrel as desired, a tube of material (e.g., a polymer commonly used for the outer structure) is positioned over the wound strip. Next, a heat-shrinkable tube (e.g., a fluoropolymer) can be positioned over the tube. The assembly (e.g., the mandrel, the wound strip, the tube, and the heat-shrinkable tube) is then gradually heated from its distal end to its proximal end (or vice versa) to fuse the tube with the strip. The amount of calories absorbed by the assembly, and the rate at which the calories are transferred to the mandrel, will depend on the geometry of the assembly (e.g., the length of the assembly, the diameter of the assembly, the thickness of the materials used, etc.). The temperature can be high enough to shrink the heat-shrinkable tube and raise the temperature of the tube material above its glass transition temperature (e.g., between about 380°F and about 440°F), yet low enough so as not to affect the durometer of the tube material and affect its resultant molecular weight (thereby changing the mechanical properties of the resultant outer structure). Also, the duration of heat application can be monitored to avoid for applying too high of a temperature for too long, which may cause the tube material to flow between the overlapping portion of the strip and into the lumen thereby raising the coefficient of friction within the catheter lumen. Additionally, the mandrel material can be chosen to provide a heatsink to quickly remove heat from the melted tube and freeze it before the tube material flows between the overlaps. For example, in some embodiments the mandrel is a steel tube, and the wall thickness of the tube can be varied to add or subtract heat transfer rate. Once the assembly has cooled, the heat shrinkable tube can be removed and the newly-formed composite shaft can be removed from the mandrel.

[0032] In any of the devices and methods disclosed herein, the inner structure is formed of a polymer tube (e.g., a PTFE tube) that is cut into strips in a direction parallel to the longitudinal axis of the tube. The width of the strip is then (πD) where D is the tubing diameter. The thickness of the strip is the wall thickness of the tubing. Another method of creating strip from tubing is to slice the tube helically. The maximum width of the strip is then $(\pi D)/(\tan\Theta)$, where Θ is the angle of the helix from the tube axis.

[0033] Before cutting the tube, the tube can be etched on only its exterior surface to increase the coefficient of friction between the exterior surface of the tube and other polymers (i.e., the outer structure material) that may be bonded to the exterior surface of the tube. The tubing may be etched with a strong base (e.g., sodium hydroxide, potassium hydroxide, sodium/ammonia, etc.) by immersing the tube in liquid etchant as an on-line process during extrusion, or as a batch process after extrusion. The latter method includes plugging the ends of the PTFE tubing before immersion or otherwise keeping the open ends out of the liquid etchant. This way, only one surface of the polymer tubing material is etched while the other surface is not etched.

III. Additional Embodiments

[0034] Figures 3A and 3B are isometric and side views, respectively, of a catheter shaft 300 (also referred to herein as "the shaft 300") configured in accordance with another embodiment of the present technology, shown bent along its axis A. As shown in Figures 3A and 3B, the shaft 300 can include an outer structure 314 and an inner structure 312 surrounded by the outer structure 314. Figures 4A and 4B are side and isometric views of the inner structure 312 isolated from the shaft 300. In the embodiment shown in Figures 3A-4B, the inner structure 312 is formed of a plurality of overlapping segments 315, such as rings. An isolated segment 315 is shown in Figure 4C. The segments 315 can have a generally cylindrical or conical shape. Additionally, referring to Figure 4B, individual segments 315 can have an outer portion 326 having an inner diameter and an inner portion 326 having an outer diameter that fits within the inner diameter of the outer portion 326. The segments 315 can be arranged as shown in Figure 4B such that the inner portion 326 of one segment 315 is received within the outer portion 324 of an immediately adjacent segment 315. The inner portions 326 accordingly overlap the outer portions 324 in a manner similar to the embodiments described above with respect to Figures 1A-2F. The outer portions 326 are fixed to the outer structure 314, but inner portions 326 can slide over the inner surface of the outer portions 326. As a result, the shaft 300 is expected to have similar advantages to those described above with respect to the shaft 100.

IV. Examples

[0035] The following examples are illustrative of several embodiments of the present technology:

1. A catheter, comprising:
a generally tubular outer structure; and
an inner structure surrounded by the outer structure and that surrounds a catheter lumen.

2. The catheter of example 1, wherein the inner structure includes over-lapping edges.

3. The catheter of example 1 or example 2, wherein the inner structure is non-continuous in a longitudinal direction.

4. The catheter of any one of examples 1-3, wherein the inner structure has freely sliding interfaces with itself.

5. The catheter of any one of examples 1-4, wherein the inner structure provides less than 50% of the total bending stiffness of the catheter.

6. The catheter of any one of examples 1-5, wherein the inner structure has portions that slide tangentially during bending of the catheter.

7. A catheter, comprising
a generally tubular outer structure, the outer structure having an outer surface and an inner surface; and
an inner structure surrounded by the outer structure, the inner structure having a relaxed state and a stressed state, and wherein—

the inner structure is composed of a strip of material that is helically wound around a central longitudinal axis to form a generally tubular member defining a lumen, wherein the strip has an outer surface and an inner surface,

a first portion of the strip overlaps a second portion of the strip along the longitudinal axis of the strip,

only a portion of the outer surface is bonded to the inner surface of the outer structure, and

when the catheter is bent along its longitudinal axis, the second portion is configured to slide relative to the first portion.

8. The catheter of example 7, wherein the inner structure includes over-lapping edges.

9. The catheter of example 7 or example 8, wherein the inner structure is non-continuous in a longitudinal direction.

10. The catheter of any one of examples 7-9, wherein the inner structure provides less than 50% of the total bending stiffness of the catheter.

11. The catheter of any one of examples 7-10, wherein the first portion slides tangentially relative to the second portion during bending of the catheter.

12. The catheter of any one of examples 7-11, wherein the strip of material is formed from a polymer tube that has been cut in a direction parallel to a longitudinal axis of the tube.

13. The catheter of any one of examples 7-11, wherein the strip of material is formed from a polymer tube that has been cut in a helical direction.

14. The catheter of any one of examples 7-13, wherein the polymer tube has an etched exterior surface and an inner surface that is not etched.

14. The catheter of any one of examples 7-13, wherein the polymer tube is a PTFE tube.

V. Conclusion

[0036] Many embodiments of the present technology can be used to access or treat targets located in tortuous and narrow vessels, such as certain sites in the neurovascular system, the pulmonary vascular system, the coronary vascular system, and/or the peripheral vascular system. The catheter shaft of the present technology can also be suited for use in the digestive system, soft tissues, and/or any other insertion into an organism for medical uses.

[0037] It will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1A-4C can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. For example, a single catheter shaft can include an inner structure having a helical portion (as shown in Figures 1A-2F) and a segmented portion (as shown in Figures 3A-4C). A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described above with reference to Figures 1A-4C. For example, the catheters of the present technology can be used with any of the clot treatment devices and associated devices, systems, and methods disclosed in U.S. Patent Application No. 14/299,933, filed June 9, 2014, and U.S. Patent Application No. 13/843,742, filed March 15, 2013, and U.S. Patent Application No. 14/735,110, filed June 9, 2015, all of which are incorporated herein by reference in their entireties. Additionally, in some embodiments, the catheter shaft of the present technology can include additional structures and/or layers. For example, in a particular embodiment, the shaft includes an additional structure or material positioned between the inner structure and the outer structure. Moreover, in a particular embodiment, the shaft includes more than one strip.

CLAIMS

I/We claim:

1. A catheter, comprising:

a generally tubular outer structure; and

an inner structure surrounded by the outer structure and that surrounds a catheter lumen, wherein the inner structure includes over-lapping edges.

2. A catheter, comprising:

a generally tubular outer structure; and

an inner structure surrounded by the outer structure, wherein the inner structure is non-continuous in a longitudinal direction.

3. A catheter, comprising:

a generally tubular outer structure; and

an inner structure surrounded by the outer structure, wherein the inner structure has freely sliding interfaces with itself.

4. A catheter, comprising:

a generally tubular outer structure; and

an innermost structure surrounded by the outer structure, wherein the innermost structure provides less than 50% of the total bending stiffness of the catheter.

5. A catheter, comprising

a generally tubular outer structure; and

an inner structure surrounded by the outer structure, wherein the inner structure has portions that slide tangentially during bending of the catheter.

6. A catheter, comprising

a generally tubular outer structure, the outer structure having an outer surface and an inner surface; and an inner structure surrounded by the outer structure, the inner structure having a relaxed state and a stressed state, and wherein—

the inner structure is composed of a strip of material that is helically wound around a central longitudinal axis to form a generally tubular member defining a lumen, wherein the strip has an outer surface and an inner surface,

a first portion of the strip overlaps a second portion of the strip along the longitudinal axis of the strip,

only a portion of the outer surface is bonded to the inner surface of the outer structure, and

when the catheter is bent along its longitudinal axis, the second portion is configured to slide relative to the first portion.

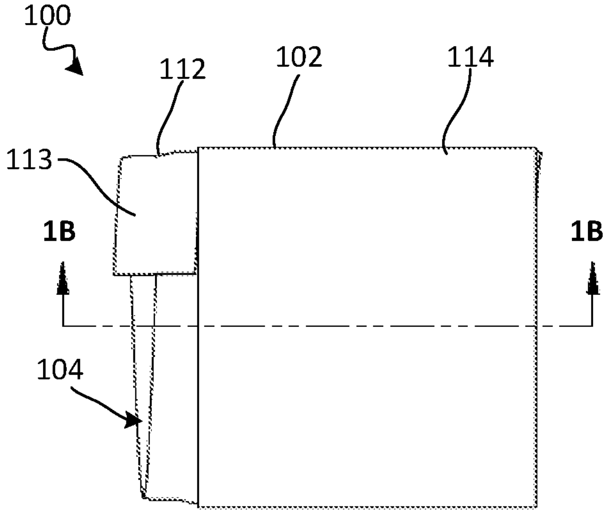

Figure 1A

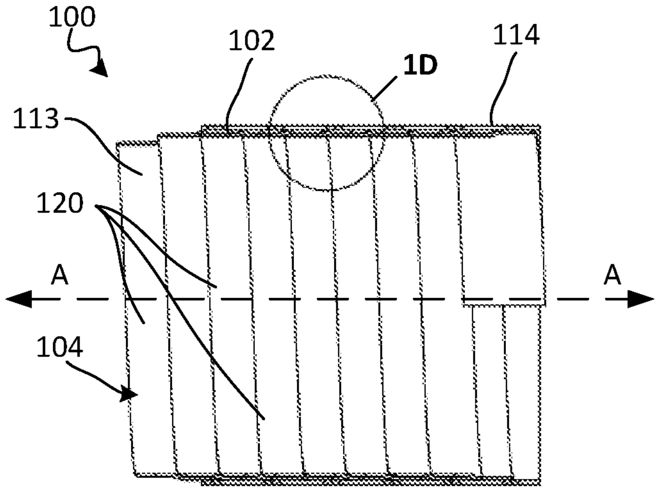

Figure 1B

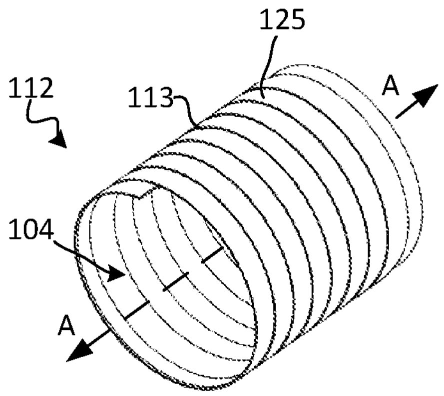

Figure 1C

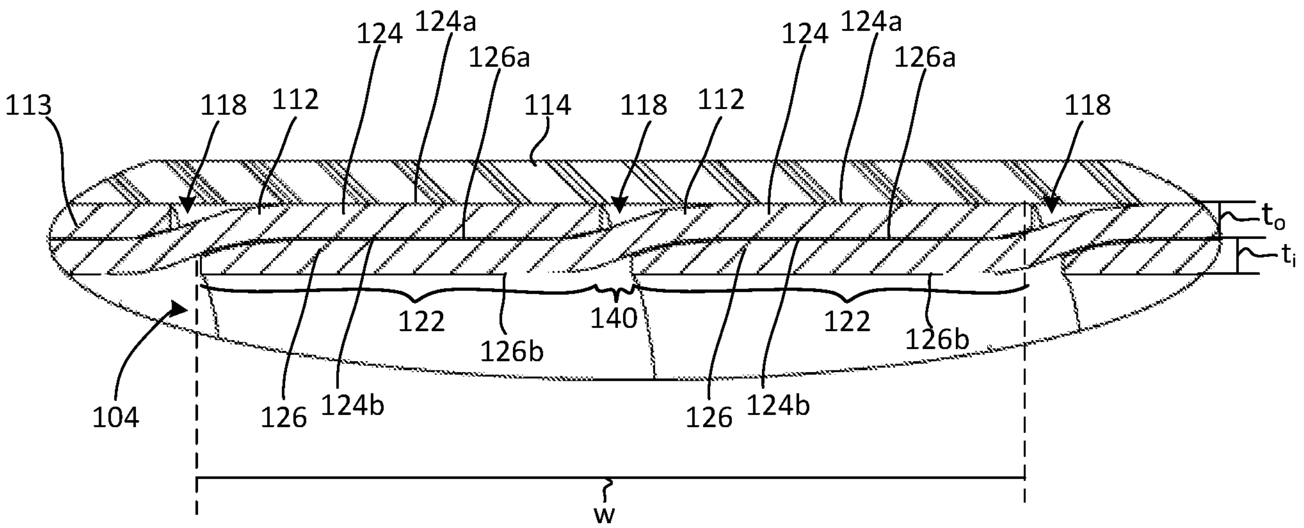

Figure 1D

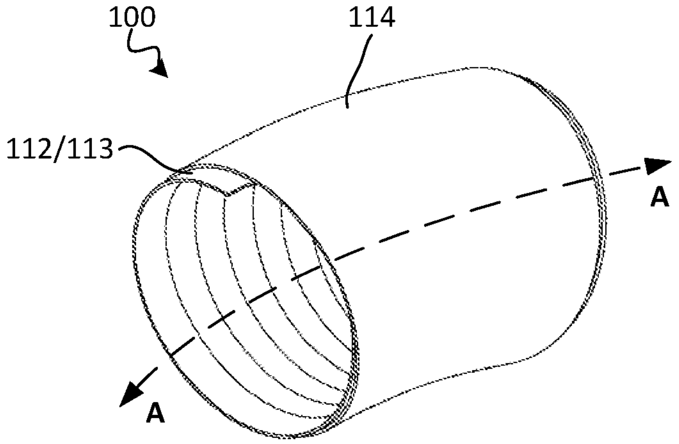

Figure 2A

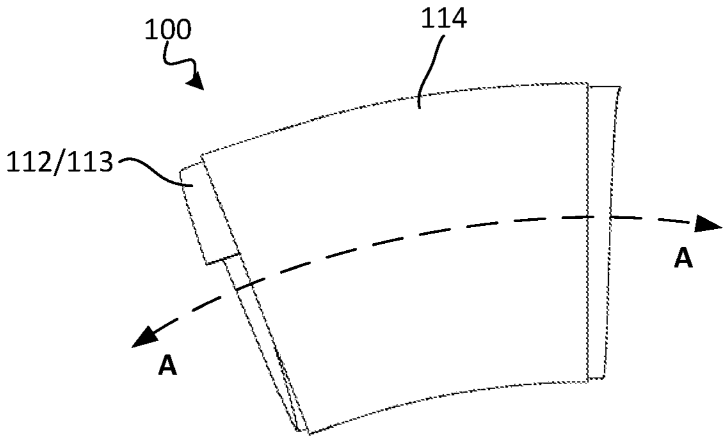

Figure 2B

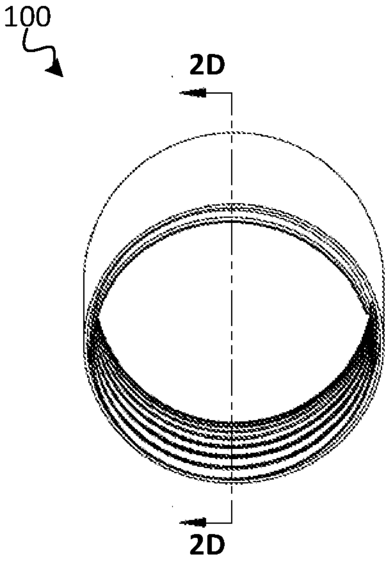

Figure 2C

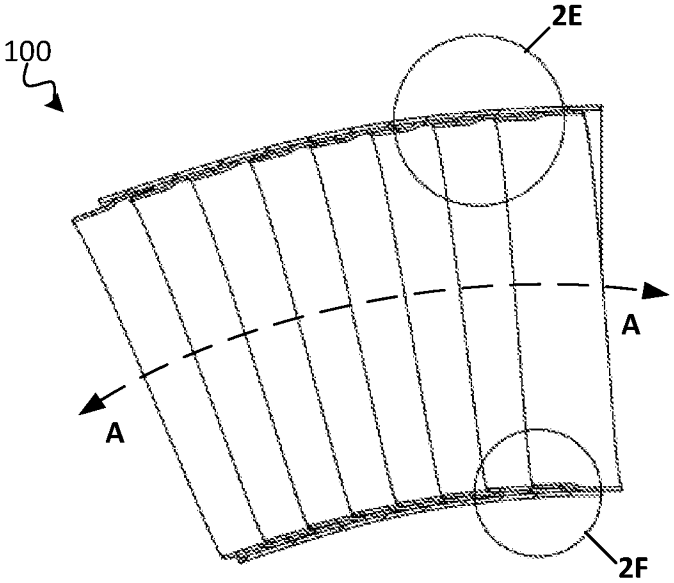

Figure 2D

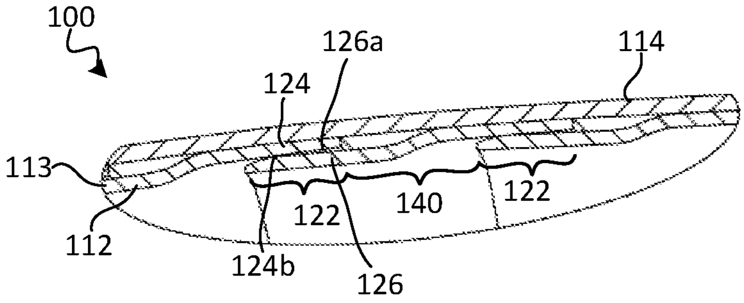

Figure 2E

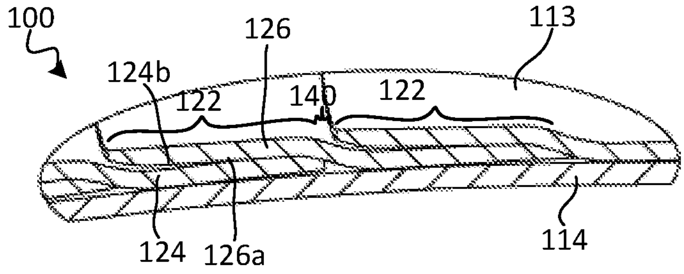

Figure 2F

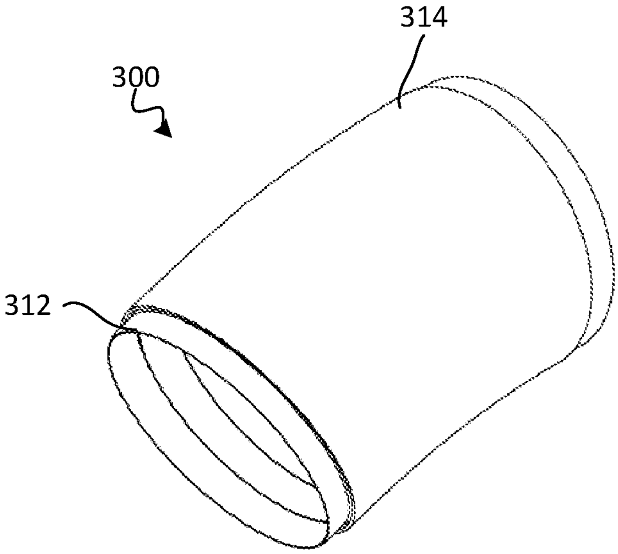

Figure 3A

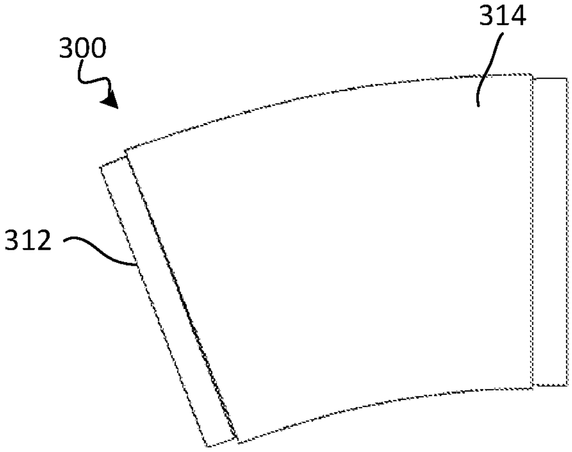

Figure 3B

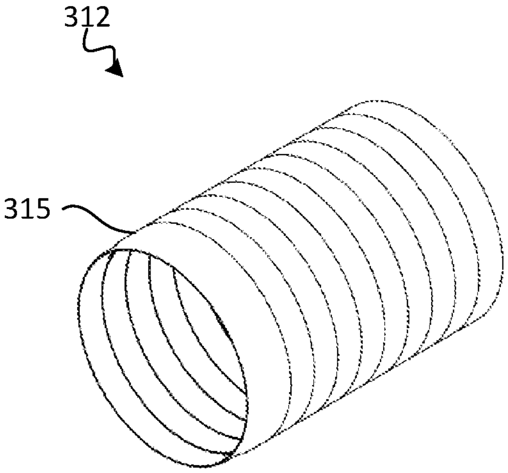

Figure 4A

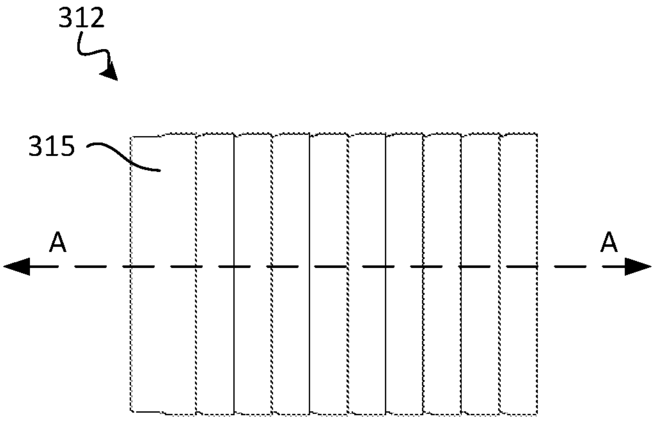

Figure 4B

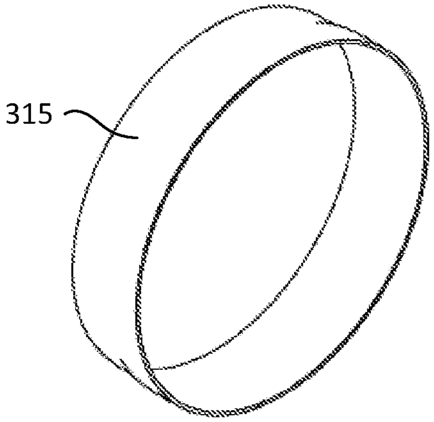

Figure 4C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/067628

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/00(2006.01)i

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 25/00; B29C 53/58; B23P 11/00; B29C 63/06; B32B 37/02; F16F 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: catheter, outer structure, inner structure, strip, over-lapping portion, sliding, bending, flexibility, stiffness

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012-0101480 A1 (INGLE, F. et al.) 26 April 2012 See paragraphs [0029]-[0060]; claims 1-15,17-20; figures 1-11B.	1,2,4
A		3,5,6
A	US 2010-0121312 A1 (GIELENZ, G. et al.) 13 May 2010 See the whole document.	1-6
A	US 5873866 A (KONDO, M. et al.) 23 February 1999 See the whole document.	1-6
A	US 2008-0088055 A1 (ROSS, C. D.) 17 April 2008 See the whole document.	1-6
A	US 2009-0160112 A1 (OSTROVSKY, I.) 25 June 2009 See the whole document.	1-6

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

* Special categories of cited documents:
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"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
10 April 2017 (10.04.2017)

Date of mailing of the international search report
10 April 2017 (10.04.2017)

Name and mailing address of the ISA/KR
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012-0101480 A1	26/04/2012	None	
US 2010-0121312 A1	13/05/2010	EP 2184081 A1	12/05/2010
		EP 2184081 B1	16/01/2013
US 5873866 A	23/02/1999	JP 08-191792 A	30/07/1996
		JP 08-313821 A	29/11/1996
		JP 08-327915 A	13/12/1996
		JP 3123393 B2	09/01/2001
		JP 3265890 B2	18/03/2002
		JP 3480124 B2	15/12/2003
		US 5762995 A	09/06/1998
US 2008-0088055 A1	17/04/2008	US 2006-0074401 A1	06/04/2006
		US 7306585 B2	11/12/2007
		US 7674421 B2	09/03/2010
		WO 2006-039392 A2	13/04/2006
		WO 2006-039392 A3	01/06/2006
US 2009-0160112 A1	25/06/2009	EP 2234663 A1	06/10/2010
		US 8636270 B2	28/01/2014
		WO 2009-079545 A1	25/06/2009