[19] Patents Registry
The Hong Kong Special Administrative Region
香港特別行政區
專利註冊處

[11] 40036552 B
EP 3752235 B1

[12] **STANDARD PATENT (R) SPECIFICATION**
轉錄標準專利說明書

[21] Application no. 申請編號
62021025895.5

[22] Date of filing 提交日期
18.02.2021

[51] Int. Cl.
A61M 25/06 (2006.01) A61M 25/00 (2006.01)

[54] GUIDE EXTENSION CATHETER
引導延伸導管

[30] Priority 優先權
14.02.2018 US 62/630,321

[43] Date of publication of application 申請發表日期
28.05.2021

[45] Date of publication of grant of patent 批予專利的發表日期
15.07.2022

[86] International application no. 國際申請編號
PCT/US2019/016235

[87] International publication no. and date 國際申請發表編號及日期
WO2019/160695 22.08.2019

EP Application no. & date 歐洲專利申請編號及日期
EP 19705680.7 01.02.2019

EP Publication no. & date 歐洲專利申請發表編號及日期
EP 3752235 23.12.2020

Date of grant in designated patent office 指定專利當局批予專利日期
06.04.2022

[73] Proprietor 專利所有人
Teleflex Life Sciences Limited
171, Old Bakery Street
Valletta VLT 1455
MALTA

[72] Inventor 發明人
BRENIZER, Joshua
PETERSON, Dean
WENDLE, Mark

[74] Agent and / or address for service 代理人及/或送達地址
MARKS & CLERK
Level 9, Cyberport 1
100 Cyberport Road, Pok Fu Lam
HONG KONG

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 3 752 235 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
06.04.2022 Bulletin 2022/14

(21) Application number: **19705680.7**

(22) Date of filing: **01.02.2019**

(51) International Patent Classification (IPC):
A61M 25/06 *(2006.01)* ***A61M 25/00*** *(2006.01)*

(52) Cooperative Patent Classification (CPC):
A61M 25/0023; A61M 25/0662; A61M 25/0009; A61M 25/0012; A61M 2025/0004

(86) International application number:
PCT/US2019/016235

(87) International publication number:
WO 2019/160695 (22.08.2019 Gazette 2019/34)

(54) **GUIDE EXTENSION CATHETER**

FÜHRUNGSVERLÄNGERUNGSKATHETER

CATHÉTER D'EXTENSION DE GUIDAGE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **14.02.2018 US 201862630321 P**

(43) Date of publication of application:
23.12.2020 Bulletin 2020/52

(73) Proprietor: **Teleflex Life Sciences Limited**
Valletta VLT-1455 (MT)

(72) Inventors:
- **BRENIZER, Joshua**
  Minneapolis, MN 55369 (US)
- **PETERSON, Dean**
  Minneapolis, MN 55369 (US)
- **WENDLE, Mark**
  Minneapolis, MN 55369 (US)

(74) Representative: **Thorpe, Aled Daniel**
Marks & Clerk LLP
15 Fetter Lane
London EC4A 1BW (GB)

(56) References cited:
WO-A1-2016/191415
WO-A1-2017/019900
US-A1- 2009 264 865
US-A1- 2014 018 773
US-A1- 2014 276 618

EP 3 752 235 B1

Description

CLAIM OF PRIORITY

[0001] Benefit of priority is hereby claimed to U.S. Provisional Patent Application Serial No. 62/630,321, entitled "GUIDE EXTENSION CATHETER" and filed on February 14, 2018.

TECHNICAL FIELD

[0002] This patent document relates to medical devices. More particularly, but not by way of limitation, this patent document relates to guide extension catheters for use with guide catheters.

BACKGROUND

[0003] A guide catheter can be employed to gain access to a blood vessel and deliver interventional devices, such as guidewires, balloon catheters, stents or stent catheters, beyond the guide catheter's distal end. Poor alignment between the guide catheter and the ostia of the blood vessel can make it difficult to deliver interventional devices to a target location within or distal to the vessel. To improve coaxial alignment between the guide catheter and the blood vessel, a narrower guide extension catheter may be used. A growing desire to use larger guide catheters in tandem with smaller guide extension catheters increases the likelihood of stent-device interaction at the transition of the guide extension catheter.

[0004] US 2009/264865 A1 discloses an insertion assisting tool inserted into a catheter and positioned ahead of the catheter so as to assist an insertion of the catheter. The insertion assisting tool includes: a distal end portion whose end is tapered and which has a guide wire lumen opening at a tip end and a proximal end of the distal end portion; and a shaft extending from a part of a proximal-end surface of the distal end portion to a proximal end of the insertion assisting tool.

[0005] US 2014/018773 A1 discloses a medical device including a guide extension catheter that includes a proximal member having a proximal outer diameter. A distal sheath member is attached to the proximal member and has a proximal sheath portion and a distal sheath portion. The proximal sheath portion has an outer diameter greater than the proximal outer diameter and has a first cross-sectional profile. The distal sheath portion has a second cross-sectional profile different from the first cross-sectional profile.

[0006] WO 2017/019900 A1 discloses a guide catheter extension device for use with a standard guide catheter and is made up of a flexible, elongate extension catheter having a tapered tip portion at a distal end, an opening at a proximal end, and a body portion extending between the two. The extension catheter has a longitudinal slit extending from the distal tip portion toward the proximal opening.

[0007] WO 2016/191415 A1 discloses a percutaneous device that includes a tube member, a push member, and a fixation mechanism such as a fixation balloon. The tube member can define a lumen, sized and shaped to receive one or more interventional medical devices therethrough and has an outer diameter smaller than a lumen of a guide catheter. The push member can be attached at least to a proximal end portion of the tube member for slidably positioning a distal end portion of the tube member within and beyond a distal end of the guide catheter.

[0008] US 2014/276618 A1 discloses a boosting catheter for positioning through a conventional guiding catheter into the vasculature of a patient, the boosting catheter having a distal tubular member and a proximal elongated shaft coupled to the distal tubular member.

OVERVIEW

[0009] The present inventors recognize that there is a need to provide guide extension catheters that are compatible with larger guide catheters for performing interventional procedures in challenging anatomy, e.g., narrow blood vessels, often harboring robust occlusions. A guide extension catheter that includes tapered guide extension tubing can be used in conjunction with a guide catheter to access discrete regions of coronary or peripheral vasculature and to facilitate accurate placement of interventional devices without causing collar transition interactions. The guide extension catheter can also include a slidable manipulation member and/or in some examples, a concave track leading into the guide extension tubing.

[0010] Guide extension catheters and related methods are disclosed in this patent document, whereby a method is not claimed.

[0011] A guide extension catheter can comprise an elongate tube member (also referred to as guide extension tubing) and a push member. At least a portion of the guide extension tubing can be tapered, enabling interventional devices to be funneled to distal portions of the extension tubing, which can be sized smaller to fit into distal vessels.

[0012] These and other embodiments and features of the present guide extension catheters will be set forth, at least in part, in the following Detailed Description. This Overview is intended to provide non-limiting embodiments of the present subject matter-it is not intended to provide an exclusive or exhaustive explanation of the disclosed embodiments. The Detailed Description below is included to provide further information about the present guide extension catheters.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] In the drawings, like numerals can be used to describe similar features and components throughout the several views. The drawings illustrate generally, by way of example, but not by way of limitation, various embod-

iments discussed in this patent document.

FIG. **1** illustrates a plan view of a guide catheter advanced through an aorta to an ostium of a coronary vessel.

FIG. **2** illustrates a plan view of a guide extension catheter, as constructed in accordance with at least one embodiment, used in conjunction with a guide catheter for the delivery of an interventional device into an occluded vessel for treatment.

FIG. **3** illustrates a side view of a guide extension catheter, as constructed in accordance with at least one embodiment, partially within a sectioned guide catheter.

FIGS. **4-6** illustrate cross-sectional views along the length of a guide extension catheter, as constructed in accordance with at least one embodiment, within a guide catheter.

FIG. **7** illustrates a side view of a guide extension catheter, as constructed in accordance with at least one embodiment, and an interventional device partially within a sectioned guide catheter.

[0014] The drawings are not necessarily to scale. Certain features and components may be shown exaggerated in scale or in schematic form, and some details may not be shown in the interest of clarity and conciseness.

DETAILED DESCRIPTION

[0015] This patent document discloses guide extension catheters to be placed within guide catheters for providing support and guidance in a vessel when percutaneously advancing interventional devices, such as guidewires, balloon catheters, stents or stent catheters. A guide extension catheter is configured to be passed through a main lumen of a guide catheter so that its distal end portion can be extended past a distal end of the guide catheter and into the desired vessel while its intermediate portions remain within the guide catheter. The guide extension catheter improves the ability of the guide catheter to remain seated in the desired vessel's ostium or branch during an interventional procedure.

[0016] It is believed that the present guide extension catheters will find great utility by interventional cardiologists performing percutaneous transluminal coronary interventions. Although the remainder of this patent document generally discusses and illustrates such uses, it should be understood that the guide extension catheters can also be used for treating other non-coronary diseased vessels or other hollow structures (e.g., biliary tract, ureter, etc.) throughout a patient's body where interventional devices are or can be employed.

[0017] Minimally-invasive cardiac interventions are utilized throughout the world and include the use of a guidewire **112** and a guide catheter **102,** as illustrated in FIG. **1.** The guidewire **112** is an elongate, small-diameter member designed to navigate vessels to reach a diseased site or vessel segment of interest. Guidewires come in two basic configurations: solid steel or nitinol core wires and solid core wire wrapped in a smaller wire coil or braid. The guide catheter **102** is an elongate tube member defining a main lumen **104** along its length. The guide catheter **102** can be formed of polyurethane, for example, and can be shaped to facilitate its advancement to a coronary ostium **106** (or other region of interest within a patient's body). In the embodiment of FIG. **1,** a 6F, 7F or 8F guide catheter **102,** where F is an abbreviation for the French catheter scale (a unit to measure catheter diameter (1F=⅓mm)), can be inserted at a femoral or radial artery and advanced through an aorta **108** to a position adjacent to the ostium **106** of a coronary artery **110.**

[0018] In a typical procedure, the guidewire **112** and guide catheter **102** are advanced through the arch **114** of the aorta **108** to the ostium **106.** The guidewire **112** or, alternatively, a more flexible treatment guidewire replacing guidewire **112** is then advanced beyond the ostium **106** and into the coronary artery **110.** The diameter and rigidity of the guide catheter's distal end **116** oftentimes does not permit the guidewire or a later-inserted interventional device to be advanced beyond the ostium **106** and into the coronary artery **110.**

[0019] Maintaining the position of the guide catheter's distal end **116** at the ostium **106** can facilitate the guidewire **112** or other interventional device successfully reaching the diseased site (e.g., a stenotic lesion **118)** through its further distal advancement. With the guide catheter **102** in position, force can be applied to the guidewire's proximal end to push the guidewire **112** to and beyond the lesion **118,** and a treating catheter (optionally including a balloon or stent) can be passed over the guidewire **112** to treat the site. The application of force to the guidewire **112** or the treating catheter can sometimes cause the guide catheter **102** to dislodge from the ostium **106** of the coronary artery **110,** and, in such instances, the guidewire or treating catheter must be further distally advanced independently of the guide catheter's alignment and support to reach the lesion **118.** This can occur in the case of a tough stenotic lesion **118** or tortuous anatomy, where it is difficult to pass the guidewire **112** or the treating catheter to and beyond the lesion. A heart's intrinsic beat can also cause the guide catheter's distal end **116** to lose its positioning or otherwise be shifted so that it no longer is positioned to align and support the guidewire **112** or the treating catheter into the portion of the coronary artery **110** including the lesion **118.**

[0020] As illustrated in FIG. **2,** the present guide extension catheter **200** can improve access to a coronary artery **210** and a stenotic lesion **218.** The guide extension catheter **200** can include a relatively flexible elongate tube member **220** and a push member **222** having a collective length that is greater than a length of a guide cath-

eter **202** (e.g., 130cm-175cm). An outer diameter of the tube member **220** can be sized to permit insertion of its distal end portion **224** into a coronary artery or its branches containing the lesion **218,** thereby providing alignment and support for an interventional device (e.g., a treating catheter) beyond the distal end **216** of the guide catheter **202** to the lesion and beyond. The extension of the tube member **220** into the smaller-sized artery or branch also serves to maintain the position of the guide catheter **202** at an artery's ostium **206** during a procedure.

[0021] The operating physician can advance the narrow, distal end portion **224** of the tube member **220** over a guidewire **212** and through and beyond the guide catheter's distal end **216** into the coronary artery **210.** A wider, proximal end portion **226** of the tube member **220** can remain within the guide catheter **202.** The physician can then deliver the treating catheter over the guidewire **212,** through a main lumen **204** of the guide catheter **202,** and through a lumen **228** of the tube member **220** until the working portion of the treating catheter is located beyond the distal end portion **224** of the tube member. The operating physician can then treat the lesion **218** using standard techniques.

[0022] In general, the lumen **228,** and hence the tube member **220,** can be sized and shaped to pass one or more interventional devices such as the guidewire and the treating catheter therethrough. The cross-sectional shape of the lumen **228** can vary along the length of the tube member **220.** For instance, the proximal portion **226** of the tube member can have a larger diameter than the distal portion **224.** The proximal and distal portions can be separated by a tapered portion **225.** The length of each cross-sectionally-sized portion of the tube member **220** can also vary, and in some examples, the distal portion **224** of the tube member is the longest. The largest outer diameter of the tube member **220** can assume maximum cross-sectional dimensions that allow the tube member **220** to coaxially slide into and through the guide catheter **202.** In other embodiments, the outer cross-sectional dimensions of the tube member **220** can be less than the allowable maximum. For example, in an 8F guide catheter, the tube member **220** can have a 7F, 6F, 5F, 4F or lesser diameter, depending on the location along the tube member. In some embodiments, the largest diameter of the lumen **228** of the tube member **220** is not more than about one French size smaller than a diameter of the lumen **204** of the guide catheter **202.** In some examples, the difference in diameter between the proximal portion **226** and distal portion **224** of the tube member may be about 1F, 2F, 3F, or 4F. The length of the tube member **220** can be substantially less than the length of the guide catheter **202;** however, the tube member **220** can be designed with any length according to a desired application, such as about 6 cm-45 cm.

[0023] The push member **222** can be operably attached to the proximal end portion **226** of the tube member **220** and can extend proximally from this attachment to a handle (also referred to as a manipulation) member **230** accessible to an operating physician outside of a patient's body. The handle member **230** and the push member **222** can allow the physician to position the tube member **220** between a first position, entirely within the guide catheter **202,** and the illustrated second position, in which the tube member's distal end **224** extends beyond that of the guide catheter **202** and into the coronary artery **210.**

[0024] FIG. **3** illustrates a side view of a guide extension catheter **300** partially positioned within a guide catheter **302.** This side view illustrates in greater detail the components of the extension catheter **300,** including a relatively flexible elongate tube member **320** and a push member **322,** as well as the distinct portions of the tube member defined by different diameters. For instance, the tube member **320** in the example shown defines a narrow distal portion **324,** a tapered middle portion **325,** and a wider proximal portion **326.** The proximal portion **326** is connected to a concave track **328** which defines variable degrees of enclosure along its length. As further shown, the push member **322** can be coupled with a manipulation member **330** configured to facilitate pushing of the extension catheter **300** into the guide catheter **302.**

[0025] The diameter variation of the tube member **320** uniquely equips the guide extension catheter **300** for complex percutaneous coronary interventional cases performed in distal, narrow blood vessels. Such cases may require a relatively large guide catheter, e.g., 7F or 8F, in combination with a smaller guide extension profile, e.g., 5F or 6F. Embodiments of the tube member **320** can include a proximal end portion **326** having a diameter of about 7F or 8F, which narrows along tapered portion **325** to a diameter of about 6F in the distal end portion **324.** The length of each portion of tube member **320** can vary. In one embodiment, the proximal end portion **326** may be about 5 cm long, the tapered portion **325** may be about 5 mm long, and the distal end portion **324** may be about 20 cm long. In other examples, the length of the proximal portion **326** may range from about 1 cm to about 10 cm, the length of the distal portion **324** may range from about 10 cm to about 30 cm, and the length of the tapered portion **325** may range from about 2 mm to about 20 mm. Generally, the narrow distal end portion **324** constitutes the majority of the length of the tube member **320,** and in some examples, may be at least twice as long as the tapered portion **325** and the proximal portion **326** combined. The length of the tapered portion **325** may be modified without adjusting the difference in diameter between the proximal and distal end portions of the tube member **320,** such that the pitch of the tapered surfaces is steeper for shorter tapered portions and more gradual for longer tapered portions.

[0026] The tube member **320** can be formed from an inner polymer layer, an outer polymer layer, and a reinforcement member (e.g., braid or coil) disposed between the polymer layers. The inner polymer layer can be composed of, or coated with, silicone, polytetrafluoroethylene (PTFE) or another lubricious material to provide a slip-

pery surface for received interventional devices. The outer polymer layer can include one or more flexible materials, such as polyurethane, polyethylene or polyolefin of sequentially diminishing durometers along the tube member's length, and it can be coated with a friction-reducing material (e.g., a hydrophilic material) to facilitate insertion and trackability through vasculature and a guide catheter. The reinforcing braid or coil can be formed of stainless steel, nitinol or a platinum alloy, for example, and can extend between the polymer layers along at least a portion of the tube member's length.

[0027] Methods of manufacturing the guide extension catheters described herein may involve stretching an inner PTFE lining of the tapered, elongate tube member **320.** Because the PTFE lining may require excess stretching relative to manufacturing of comparable, but non-tapered tube members, the outer surface of the lining can be etched to maintain the desired polymer chemistry of the PTFE, thereby ensuring adhesion between the fluoropolymers of the lining and an outer polymer layer (e.g., Pebax®) wrapping.

[0028] The reinforcement member disposed between the polymer layers of the elongate tube member **320** can be configured and assembled in multiple ways. For example, if the reinforcement member disposed between the polymer layers of the elongate member **320** is a coil, three general types of coils may be used, each coil coupled with other components of the tube member **320** in a distinct manner. If the size of the coil matches the smaller distal portion **324** of the tube member **320,** the coil can be first loaded over the distal portion **324** and then turned up against the pitch of the tapered portion **325.** By turning the coil against the pitch of the tapered portion **325,** the coil diameter will be enlarged such that the coil can be loaded over the taper and the larger diameter of the proximal portion **326.** If the size of the coil is larger, such that it approximately matches the larger diameter of the proximal portion **326,** the coil can be first loaded onto the proximal portion **326** and then turned down to match the smaller diameter of the tapered **325** portion and distal portion **324.** If the size of the coil is between the smaller diameter of the distal portion **324** and the larger diameter of the proximal portion **326,** coupling the coil to the tube member **320** may involve a hybrid approach of winding the coil up and down the pitch of the tapered portion **325.**

[0029] In certain embodiments, the push member **322** can include a plurality of segments or portions having different stiffness and flexibility profiles to provide the guide extension catheter **300** with a desired combination of pushing force and vessel placement capabilities. In some examples, the push member **322** can include three segments **334, 336, 338** having different stiffness and flexibility profiles: relative high stiffness and low flexibility at a proximal end portion of the push member, relative medium stiffness and flexibility at a proximal end portion of the push member, and relative low stiffness and high flexibility at a distal portion of the push member. In some embodiments, the length of the first segment **334** makes up between 50% to 90% of the entire length of the guide extension catheter **300,** the length of the third segment **338** makes up between 2% to 10% of the catheter's length, and the remaining length can be attributed to the second segment **336.** More or less segments of differing stiffness and flexibility profiles can also be used and accomplished through variation of one or more of materials, geometrical shapes or geometrical sizes of the push member **322.** The push member **322** can be an elongated solid wire of constant or varying dimensions and can made of a polymeric or metallic material, such as high tensile stainless steel (e.g., 304V, 304L or 316LV), mild steel, nickel-titanium alloys, nickel-chromium-molybdenum alloys, nickel-copper alloys, nickel-tungsten alloys or tungsten alloys. The push member **322** can be coated with a hydrophilic, silicone or other friction-reducing material. A handle member (FIG. **2)** at the push member's proximal end can be formed of a polycarbonate material, for example.

[0030] The manipulation member **330** facilitates pushing of the extension catheter **300** through the guide catheter **302.** As shown, the manipulation member **330** can comprise a tab, which may be cylindrical, that is slidable along the push member **322.** In operation, the manipulation member **330** can be initially positioned proximal to the elongate tube member **320,** and then slid proximally along the push member **322** as the extension catheter **300** is urged distally, toward the treatment site. In some examples, the manipulation member **330** is engageable with the push member **322** via a compressive force applied by a user, e.g., a manual force applied by a user's thumb.

[0031] The concave track **328** can be eccentrically coupled to a distal end portion **340** of the push member **322** at its periphery or circumference and can provide a smooth transition between the tube member **320** and the push member **322.** The concave track **328** can be bonded between or integrated with the proximal end portion **326** of the tube member **320** and/or the distal end portion **340** of the push member **322.** Metallic or polymeric structures forming the concave track **328** can become less stiff and more flexible in a proximal-to-distal direction to provide a gradual flexibility transition between the more rigid push member **322** and the more flexible tube member **320.**

[0032] The degree of enclosure defined by the concave track **328** can vary along the length of the track. In an embodiment, a first segment **328a** of the concave track **328** can define an approximately 200° enclosure, a second segment **328b** of the concave track can define an approximately 170° enclosure, and a third segment **328c,** closer to the tube member **320,** can define an approximately 200° enclosure, which transitions to 360° just before reaching the most proximal end of the tube member's proximal portion **326.** Accordingly, the concave track **328** may transition, proximally to distally, from more enclosed to less enclosed, and back to more enclosed before reaching the proximal end portion **326** of the tube member **320.** The specific degree of enclosure defined by

each portion of the concave track **328** may vary. For example, the degree of enclosure defined by each portion may be increased or decreased by up to 5°, 10°, 15°, 20°, 25°, 30°, 40°, 50°, 60°, or more. The intermediary valley of the concave track, i.e., the second segment **328b,** along with the embedded push member **322,** may be urged to one side of the guide catheter's inner wall surface such that the track **328** and push member **322** may be concentrically aligned within guide catheter **302,** thereby providing a clear path through the guide catheter and into the tube member **320** for a guidewire and a treating catheter. This clear path can eliminate twisting and prevent a guidewire, e.g., guidewire **212,** from becoming entangled with, e.g., wrapped around, the push member **322** during use of the guide extension catheter **300.** Alleviation of twisting may be especially apparent in operations requiring multiple, simultaneously inserted guidewires.

[0033] In some embodiments, the concave track **328** can define a partially cylindrical opening, e.g., resembling a half-pipe, and having a length of about 1cm to about 18 cm, 20 cm, 22 cm, 24 cm, 26 cm, or more. In one example, the concave track **328** may be about 17 cm long. In various embodiments, the length of each discernible portion **328a, 328b, 328c** of the concave track **328** may range from about 1 cm, 2 cm, 4 cm, 6 cm, 8 cm, 10 cm, or 12 cm. The length of each portion **328a, 328b, 328c** may be the same or different. The concave track **328** is accessible from a longitudinal side defined transverse to a longitudinal axis of the tube member **320** and provides a larger area to receive an interventional device into the tube member than an area associated with an opening oriented perpendicular to the longitudinal axis of the tube member **320.** Optionally, the concave track **328** can be sized larger than the proximal end portion **326** of the tube member **320** to more effectively align and funnel a treating catheter across the coupling transition and into the tube member **320.** This larger size of the concave track **328** can be accomplished by incorporating a nickel-titanium alloy, for example, which can expand post-implant to a size of the guide catheter's inner wall surface.

[0034] Markers on the push member **322** and/or the tube member **320** can allow an operating physician to identify positioning of the guide extension catheter's components relative to patient anatomy, the guide catheter **302,** and any international devices used during a procedure. For example, one or more depth markers can be printed on an outer surface of the push member **322** and can be positioned at predetermined lengths relative to a distal end of the tube member **320.** One or more radiopaque marker bands can be positioned on the tube member **320.** The marker bands can be composed of tungsten, platinum or an alloy thereof and can have a metallic band structure. Alternatively, for space conservation reasons, the marker bands can be formed by impregnating portions of the tube member **320** with a radiopaque filler material, such as such as barium sulfate, bismuth trioxide, bismuth carbonate, powdered tungsten, powdered tantalum or the like. A first marker band can be positioned slightly distal to a fully-round entrance of the tube member **320** and a second marker band can be positioned near the tube member's distal end, for example.

[0035] FIG. **4** illustrates a cross-sectional view of a proximal end portion **434** of a push member **422,** such as along line **4-4** of FIG. **3,** within a guide catheter **402.** The cross-section can be defined by an arcuate first surface **444** configured to engage an inner wall surface **446** of the guide catheter **402** along an arc length (l_1) (e.g. 0.76 mm (0.030 in)) defined by a guide catheter central angle (α) of at least 20 degrees, at least 30 degrees, at least 40 degrees, at least 50 degrees or at least 60 degrees, with greater arc lengths (l_1) associated with greater central angles (α). The arcuate or curved shape of the first surface **444** follows the inner wall surface **446** of the guide catheter **402** providing smooth relative movements between the guide extension catheter and the guide catheter. The arcuate shape of the first surface **444** can also help to maximize axial or column strength of the push member **422** for force transfer from an operating physician to the rest of the guide extension catheter without reducing the effective delivery area **448** within the guide catheter **402** through which an interventional device can be advanced. In an embodiment, the first surface **444** can have the same or substantially the same radius of curvature (r_1) as the guide catheter's inner wall surface **446,** such as a radius of curvature of about 0.89 mm (0.035 in).

[0036] A second surface **450** of the proximal end portion's cross-section, which is positioned opposite the first surface **444,** can be flat or substantially flat and have a length (l_2) (e.g. 0.66 mm (0.026 in)) that is less than the arc length (l_1) of the first surface. The second surface **450** can be spaced furthest from the first surface at its center point (c_2). In an embodiment, the center point (c_2) of the second surface **450** is at least 0.25 mm (0.010 in) (e.g. 0.36 mm (0.014 in)) from a center portion (*c1*) of the first surface **444.** In an embodiment, a distance between center points (c_1, c_2) of the first and second surfaces **444, 450** can be between 40-60% of the arc length (l_1) of the first surface.

[0037] The cross-section at the proximal end portion of the push member **422** can be further defined by third and four arcuate surfaces **452, 454** that connect the first and second surfaces **444, 450.** The third and four surfaces **452, 454** can have a radius of curvature ($r_{3,4}$) less than the radius of curvature (r_1) of the first surface **444.** In an embodiment, the radius of curvature (n) of the first surface (e.g. 0.89 mm (0.035 in)) is at least three times greater than the radius of curvature ($r_{3,4}$) of the third and fourth surfaces (e.g. 0.25 mm (0.010 in)).

[0038] It has been found that this cross-sectional configuration of the proximal end portion **434** of the push member **422** can be desirable for a number of reasons. The configuration, which resembles a bread loaf in its cross-sectional shape, can increase the push force ca-

pability and the torque control of the push member **422** as compared to a flat rectangular ribbon. Accordingly, greater axial and rotational force applied by the operating physician to the push member's proximal end portion **434** can be transmitted to the tube member. In this manner, the tube member can more reliably be urged through obstructions or into a tortuous portion of the patient's vasculature.

[0039] FIG. **5** illustrates a cross-sectional view of an intermediate portion **536** of a push member **522,** such as along line **5-5** of FIG. **3,** within a guide catheter **502.** As shown, the intermediate portion **536** can be circular or oval in cross-section and defined by a circumferential surface **537,** which can reduce the tendency for a guidewire to become engaged with the push member **522** during use. In an embodiment, the circumferential surface **537** has a diameter of about 0.33 mm (0.013 in).

[0040] Alternatively, the intermediate portion **536** can be rectangular in cross-section and defined by first, second, third and fourth flat surfaces, or can be bread loaf in cross-section and defined by three arcuate surfaces and one flat surface like the proximal end portion. In these alternative embodiments, a distance change between center points of the first and second surfaces at the push member's proximal end portion (FIG. **4)** to center points of the first and second surfaces at the push member's intermediate portion is less than a distance change between center points of the third and fourth surfaces at the push member's proximal end portion to center points of the third and fourth surfaces at the push member's intermediate portion.

[0041] Yet another alternative, the intermediate portion **536** can have a cross-section defined by arcuate first and second surfaces. An arcuate first surface can have the same or substantially the same radius of curvature as the guide catheter's inner wall surface. An arcuate second surface can extend from a first end of the first surface to a second end of the first surface. Regardless of shape, the cross-section of the intermediate portion **536** of the push member can define an area less than an area of the cross-section of the proximal end portion (FIG. **4)** of the push member **522.**

[0042] FIG. **6** illustrates a cross-sectional view of a distal end portion **638** of a push member **622,** such as along line **6-6** of FIG. **3,** within a guide catheter **602.** The distal end portion **638** can be rectangular in cross-section and defined by first, second, third and fourth flat surfaces **656, 658, 660, 662.** The cross-section of the distal end portion **638** can define an area less than an area of the cross-section of the proximal end (FIG. **4)** and intermediate (FIG. **5)** portions of the push member **622.**

[0043] In an embodiment, the first and second surfaces **656, 658** have a length of 0.51 mm (0.020 in), and the third and fourth surfaces **660, 662** have a length of 0.25 mm (0.010 in). The cross-section of the stiffer proximal end portion can gradually transition along the length of the push member **622** to the more flexible cross-section of the distal end portion **638,** which can couple to a tube member **620.** The flattened rectangular cross-section of the distal end portion **638** can provide sufficient attachment surface area to attach the push member **622** to the tube member **620.** Alternatively, the distal end portion **638** can be bread loaf in cross-section and defined by three arcuate surfaces and one flat or substantially flat surface like the proximal end portion.

[0044] FIGS. **4-6** illustrate that the push member **422, 522, 622** of a guide extension catheter can be designed to be sufficiently small taking up relatively little space within the lumen of a guide catheter, while still being sufficiently sized and configured for exceptional pushability and kink resistance when advancing the extension catheter during an interventional procedure. Accordingly, use of the present guide extension catheters allows for an interventional device to be advanced through and beyond the guide catheter to reach a desired distal target location for intervention.

[0045] FIG. **7** illustrates a side view of a guide extension catheter **700** positioned within a guide catheter **702** and used in conjunction with a guidewire **712** and a treating catheter **764.** With the guidewire **712** and the guide catheter **702** positioned as desired, a tube member **720** of the guide extension catheter **700** can be backloaded from its narrow distal end portion **724** onto a proximal end of the guidewire **712** and advanced through a hemostasis valve coupled to the guide catheter **702.** As shown, the tube member **720** of the guide extension catheter **700** can be advanced beyond a distal end **716** of the guide catheter **702** under fluoroscopy. When so arranged, portions of the tube member **720** can engage an ostium and extend within a portion of a coronary artery to help maintain the position of the guide catheter **702** as the treating catheter **764** is advanced. The variable degree of enclosure provided by the concave track **728** at portions **728a, 728b,** and **728c** may prevent twisting of the guidewire **712.**

[0046] The above Detailed Description is intended to be illustrative and not restrictive. The above-described embodiments (or one or more features or components thereof) can be used in varying combinations with each other unless clearly stated to the contrary. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above Detailed Description. Also, various features or components have been grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter can lie in less than all features of a particular disclosed embodiment.

Closing Notes:

[0047] The above Detailed Description includes references to the accompanying drawings, which form a part of the Detailed Description. The Detailed Description should be read with reference to the drawings. The drawings show, by way of illustration, specific embodiments

in which the present guide extension catheters and related methods can be practiced. These embodiments are also referred to herein as "examples."

[0048] Certain terms are used throughout this patent document to refer to particular features or components. As one skilled in the art will appreciate, different people may refer to the same feature or component by different names. This patent document does not intend to distinguish between components or features that differ in name but not in function. For the following defined terms, certain definitions shall be applied unless a different definition is given elsewhere in this patent document. The terms "a," "an," and "the" are used to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." The term "or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not B," "B but not A," and "A and B." All numeric values are assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" refers to a range of numbers that one of skill in the art considers equivalent to the recited value (i.e., having the same function or result). In many instances, the term "about" can include numbers that are rounded to the nearest significant figure. The recitation of numerical ranges by endpoints includes all numbers and sub-ranges within and bounding that range (e.g., 1 to 4 includes 1, 1.5, 1.75, 2, 2.3, 2.6, 2.9, etc. and 1 to 1.5, 1 to 2, 1 to 3, 2 to 3.5, 2 to 4, 3 to 4, etc.). The terms "patient" and "subject" are intended to include mammals, such as for human or veterinary applications. The terms "distal" and "proximal" are used to refer to a position or direction relative to an operating physician. "Distal" and "distally" refer to a position that is distant from, or in a direction away from, the physician. "Proximal" and "proximally" refer to a position that is near, or in a direction toward, the physician. And the term "interventional device(s)" is used to include, but is not limited to, guidewires, balloon catheters, stents and stent catheters.

[0049] The scope of the present guide extension catheters should be determined with reference to the appended claims, along with the full scope to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended; that is, a device that includes features or components in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms "first," "second" and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

[0050] The Abstract is provided to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

Claims

1. A guide extension catheter (300) for use with a guide catheter (302), **characterized in that**: the guide extension catheter comprising:

   an elongate tube member (320) defining a lumen and three portions, each portion having a different diameter;
   a push member (322) eccentrically coupled relative to the tube member (320) and extending proximally therefrom for slidably positioning the tube member (320) within and partially beyond a distal end of the guide catheter (302);
   a concave track (328) coupled to the tube member (320) and the push member (322), the concave track (328) defining a partially cylindrical opening leading into the tube member (320); and
   a slidable manipulation member (330) coupled with the push member (322), the slidable manipulation member (330) comprising a tab that defines a hole through which the push member (322) is urged during insertion of the guide extension catheter (300) through the guide catheter (302).

2. The guide extension catheter of claim 1, wherein:

   a distal portion (324) has a first diameter,
   a proximal portion (326) has a second diameter which is larger than the first diameter but smaller than a lumen of the guide catheter (302), and
   a tapered portion (325), positioned between the distal portion (324) and the proximal portion (326), has a variable diameter.

3. The guide extension catheter of claim 2, wherein the first diameter is about 6F or less.

4. The guide extension catheter of any one of claims 2 or 3, wherein the second diameter is about 7F or greater.

5. The guide extension catheter of any one of claims 2-4, wherein the distal portion (324) is at least twice as long as the proximal portion (326) and the tapered portion (325) combined.

6. The guide extension catheter of any one of claims 2-5, wherein the tapered portion (325) is about 2 cm long or less.

7. The guide extension catheter of any one of claims 1-6, wherein the concave track (328) defines an intermediary track portion (328b) that is less enclosed than a distal track portion (328c) and a proximal track portion (328a).

8. The guide extension catheter of any one of claims 1-7, wherein the elongate tube member (320) includes a reinforcement member comprising a coil.

9. The guide extension catheter of claim 8, wherein the coil, in a relaxed state, defines a diameter that approximately matches the second diameter.

10. The guide extension catheter of claim 9, wherein the coil is wound down over the tapered portion (325) during assembly.

11. The guide extension catheter of claim 8, wherein the coil, in a relaxed state, defines a diameter that approximately matches the first diameter.

12. The guide extension catheter of claim 11, wherein the coil is wound up over the tapered portion (325) during assembly.

13. The guide extension catheter of claim 8, wherein the coil, in a relaxed state, defines a diameter that is between the first diameter and the second diameter.

14. The guide extension catheter of claim 13, wherein the coil is wound up over the proximal portion (326) and wound down over the distal portion (324) during assembly.

15. The guide extension catheter of any one of claims 1-14, wherein the elongate tube member (320) comprises an inner polymer layer, wherein the inner polymer layer is stretched during assembly of the elongate tube member (320) and wherein after stretching, an outer surface of the inner polymer layer is etched.

Patentansprüche

1. Führungsverlängerungskatheter (300) zur Verwendung bei einem Führungskatheter (302), **dadurch gekennzeichnet, dass**: der Führungsverlängerungskatheter Folgendes umfasst:

   ein längliches Röhrenelement (320), das ein Lumen und drei Abschnitte definiert, wobei jeder Abschnitt einen anderen Durchmesser aufweist;
   ein Stoßelement (322), das exzentrisch mit Bezug auf das Röhrenelement (320) angeschlossen ist und sich proximal davon zum gleitbaren Positionieren des Röhrenelements (320) innerhalb eines distalen Endes des Führungskatheters (302) und teilweise darüber hinaus erstreckt,
   eine konkave Führungsbahn (328), die an das Röhrenelement (320) und das Stoßelement (322) angeschlossen ist, wobei die konkave Führungsbahn (328) eine teilweise zylindrische Öffnung definiert, die in das Röhrenelement (320) führt; und
   ein gleitbares Manipulationselement (330), das an das Stoßelement (322) angeschlossen ist, wobei das gleitbare Manipulationselement (330) eine Lasche umfasst, die ein Loch definiert, durch das das Stoßelement (322) während des Einführens des Führungsverlängerungskatheters (300) durch den Führungskatheter (302) hindurchgedrückt wird.

2. Führungsverlängerungskatheter nach Anspruch 1, wobei:

   ein distaler Abschnitt (324) einen ersten Durchmesser aufweist,
   ein proximaler Abschnitt (326) einen zweiten Durchmesser aufweist, der größer als der erste Durchmesser, jedoch kleiner als ein Lumen des Führungskatheters (302) ist, und
   ein sich verjüngender Abschnitt (325), der zwischen dem distalen Abschnitt (324) und dem proximalen Abschnitt (326) positioniert ist, einen variablen Durchmesser aufweist.

3. Führungsverlängerungskatheter nach Anspruch 2, wobei der erste Durchmesser etwa 6 F oder weniger beträgt.

4. Führungsverlängerungskatheter nach einem der Ansprüche 2 oder 3, wobei der zweite Durchmesser etwa 7 F oder mehr beträgt.

5. Führungsverlängerungskatheter nach einem der Ansprüche 2-4, wobei der distale Abschnitt (324) mindestens zweimal so lang wie der proximale Abschnitt (326) und der sich verjüngende Abschnitt (325) kombiniert ist.

6. Führungsverlängerungskatheter nach einem der Ansprüche 2-5, wobei der sich verjüngende Abschnitt (325) eine Länge von etwa 2 cm oder weniger aufweist.

7. Führungsverlängerungskatheter nach einem der Ansprüche 1-6, wobei die konkave Führungsbahn (328) einen intermediären Führungsbahnabschnitt (328b) definiert, der weniger umschlossen ist als ein distaler Führungsbahnabschnitt (328c) und ein proximaler Führungsbahnabschnitt (328a).

8. Führungsverlängerungskatheter nach einem der Ansprüche 1-7, wobei das längliche Röhrenelement (320) ein Verstärkungselement umfasst, das eine Spule umfasst.

9. Führungsverlängerungskatheter nach Anspruch 8, wobei die Spule, in einem entspannten Zustand, einen Durchmesser definiert, der ungefähr dem zweiten Durchmesser gleichkommt.

10. Führungsverlängerungskatheter nach Anspruch 9, wobei die Spule während des Zusammenbauens über den sich verjüngenden Abschnitt (325) abgewickelt wird.

11. Führungsverlängerungskatheter nach Anspruch 8, wobei die Spule, in einem entspannten Zustand, einen Durchmesser definiert, der ungefähr dem ersten Durchmesser gleichkommt.

12. Führungsverlängerungskatheter nach Anspruch 11, wobei die Spule während des Zusammenbauens über den sich verjüngenden Abschnitt (325) abgewickelt wird.

13. Führungsverlängerungskatheter nach Anspruch 8, wobei die Spule, in einem entspannten Zustand, einen Durchmesser definiert, der zwischen dem ersten Durchmesser und dem zweiten Durchmesser liegt.

14. Führungsverlängerungskatheter nach Anspruch 13, wobei die Spule während des Zusammenbauens über den proximalen Abschnitt (326) und über den distalen Abschnitt (324) abgewickelt wird.

15. Führungsverlängerungskatheter nach einem der Ansprüche 1-14, wobei das längliche Röhrenelement (320) eine innere Polymerschicht umfasst, wobei die innere Polymerschicht während des Zusammenbauens des länglichen Röhrenelements (320) gestreckt wird und wobei, nach dem Strecken, eine äußere Oberfläche der inneren Polymerschicht geätzt wird.

Revendications

1. Cathéter d'extension de guidage (300) pour l'utilisation avec un cathéter de guidage (302), **caractérisé en ce que** : le cathéter d'extension de guidage comprend :

un élément formant tube (320) allongé définissant une lumière et trois portions, chaque portion ayant un diamètre différent ;
un élément de poussée (322) accouplé de manière excentrique par rapport à l'élément formant tube (320) et s'étendant de manière proximale depuis celui-ci pour le positionnement de manière à pouvoir coulisser de l'élément formant tube (320) à l'intérieur et partiellement au-delà d'une extrémité distale du cathéter de guidage (302) ;
une piste concave (328) accouplée à l'élément formant tube (320) et à l'élément de poussée (322), la piste concave (328) définissant une ouverture partiellement cylindrique conduisant dans l'élément formant tube (320) ; et
un élément de manipulation pouvant coulisser (330) accouplé à l'élément de poussée (322), l'élément de manipulation pouvant coulisser (330) comprenant un onglet qui définit un trou à travers lequel l'élément de poussée (322) est poussé durant l'insertion du cathéter d'extension de guidage (300) à travers le cathéter de guidage (302).

2. Cathéter d'extension de guidage selon la revendication 1, dans lequel :

une portion distale (324) a un premier diamètre,
une portion proximale (326) a un second diamètre qui est supérieur au premier diamètre mais plus petit qu'une lumière du cathéter de guidage (302), et
une portion conique (325), positionnée entre la portion distale (324) et la portion proximale (326), a un diamètre variable.

3. Cathéter d'extension de guidage selon la revendication 2, dans lequel le premier diamètre est d'environ 6F ou moins.

4. Cathéter d'extension de guidage selon l'une quelconque des revendications 2 ou 3, dans lequel le second diamètre est d'environ 7F ou plus.

5. Cathéter d'extension de guidage selon l'une quelconque des revendications 2 à 4, dans lequel la portion distale (324) est au moins deux fois aussi longue que la portion proximale (326) et la portion conique (325) combinées.

6. Cathéter d'extension de guidage selon l'une quelconque des revendications 2 à 5, dans lequel la portion conique (325) a une longueur d'environ 2 cm ou moins.

7. Cathéter d'extension de guidage selon l'une quelconque des revendications 1 à 6, dans lequel la piste concave (328) définit une portion de piste intermédiaire (328b) qui est moins enfermée qu'une portion de piste distale (328c) et qu'une portion de piste proximale (328a).

8. Cathéter d'extension de guidage selon l'une quelconque des revendications 1 à 7, dans lequel l'élément formant tube (320) allongé comprend un élément de renforcement comprenant une bobine.

9. Cathéter d'extension de guidage selon la revendication 8, dans lequel la bobine, dans un état relâché, définit un diamètre qui correspond approximativement au second diamètre.

10. Cathéter d'extension de guidage selon la revendication 9, dans lequel la bobine est déroulée sur la portion conique (325) durant l'assemblage.

11. Cathéter d'extension de guidage selon la revendication 8, dans lequel la bobine, dans un état relâché, définit un diamètre qui correspond approximativement au premier diamètre.

12. Cathéter d'extension de guidage selon la revendication 11, dans lequel la bobine est enroulée sur la portion conique (325) durant l'assemblage.

13. Cathéter d'extension de guidage selon la revendication 8, dans lequel la bobine, dans un état relâché, définit un diamètre qui est compris entre le premier diamètre et le second diamètre.

14. Cathéter d'extension de guidage selon la revendication 13, dans lequel la bobine est enroulée sur la portion proximale (326) et déroulée sur la portion distale (324) durant l'assemblage.

15. Cathéter d'extension de guidage selon l'une quelconque des revendications 1 à 14, dans lequel l'élément formant tube (320) allongé comprend une couche de polymère interne, la couche de polymère interne étant étirée durant l'assemblage de l'élément formant tube (320) allongé et une surface externe de la couche de polymère interne étant gravée après l'étirage.

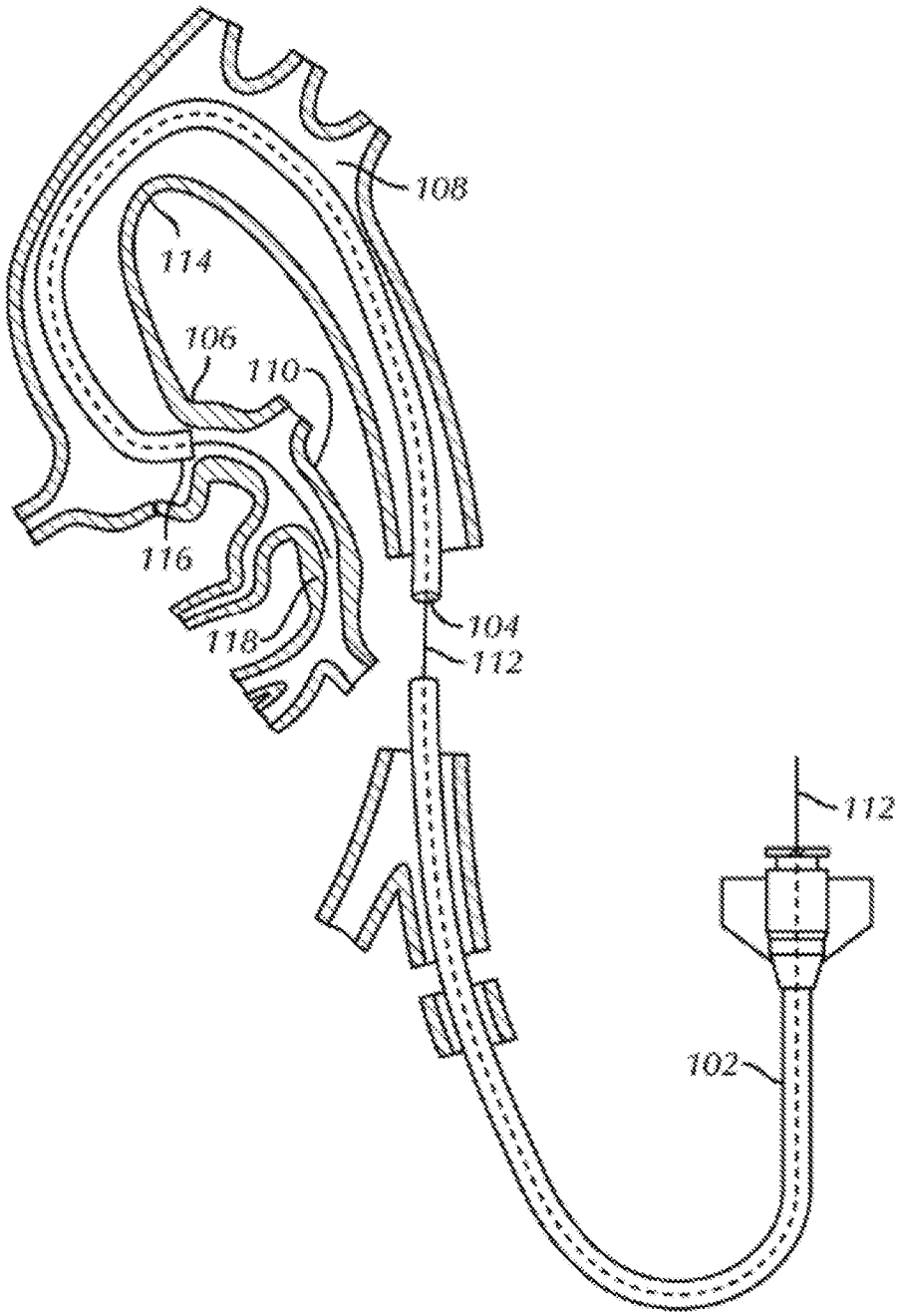

FIG. 1

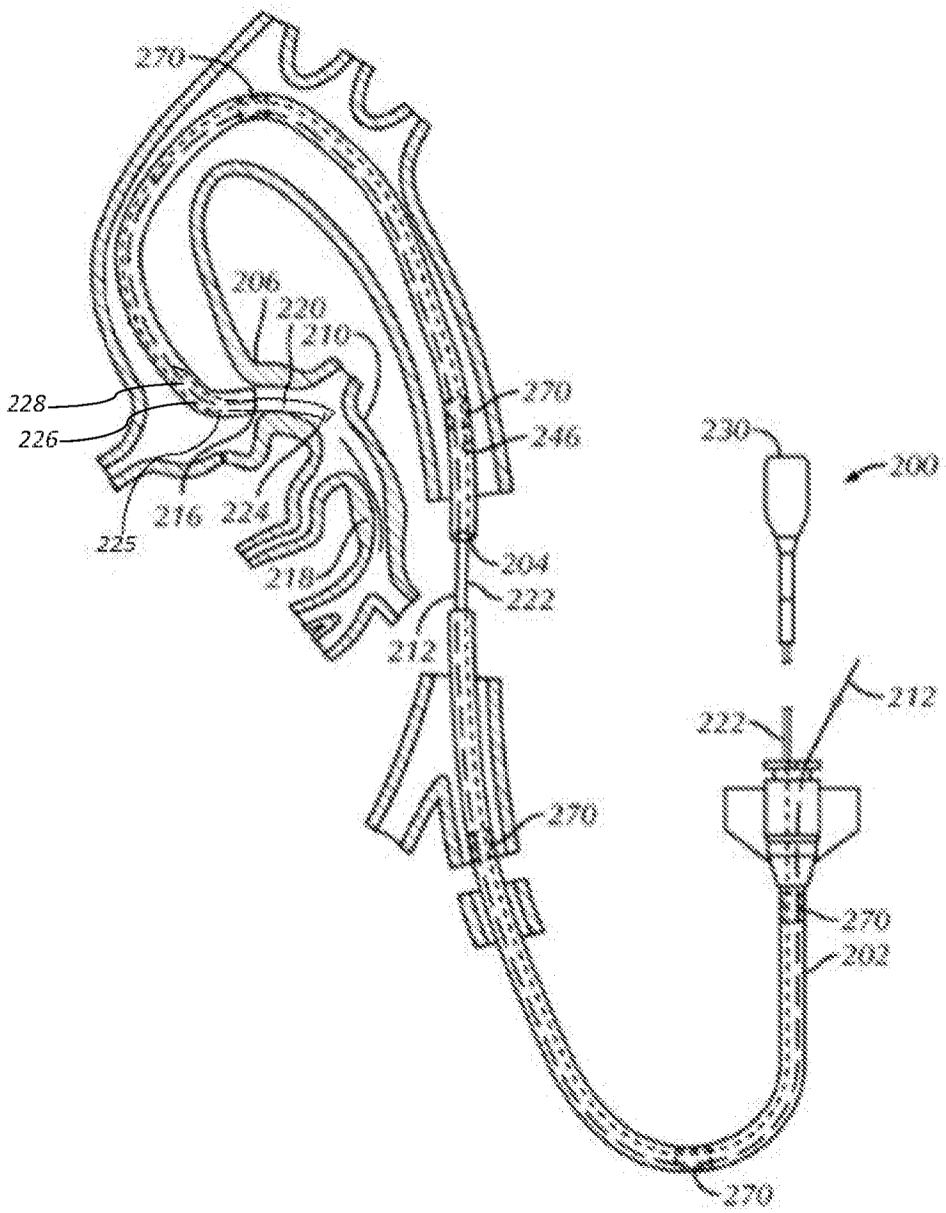
270
206
220
210
228
226
216
224
225
218
270
246
204
222
212
230
200
212
222
270
270
202
270

FIG. 2

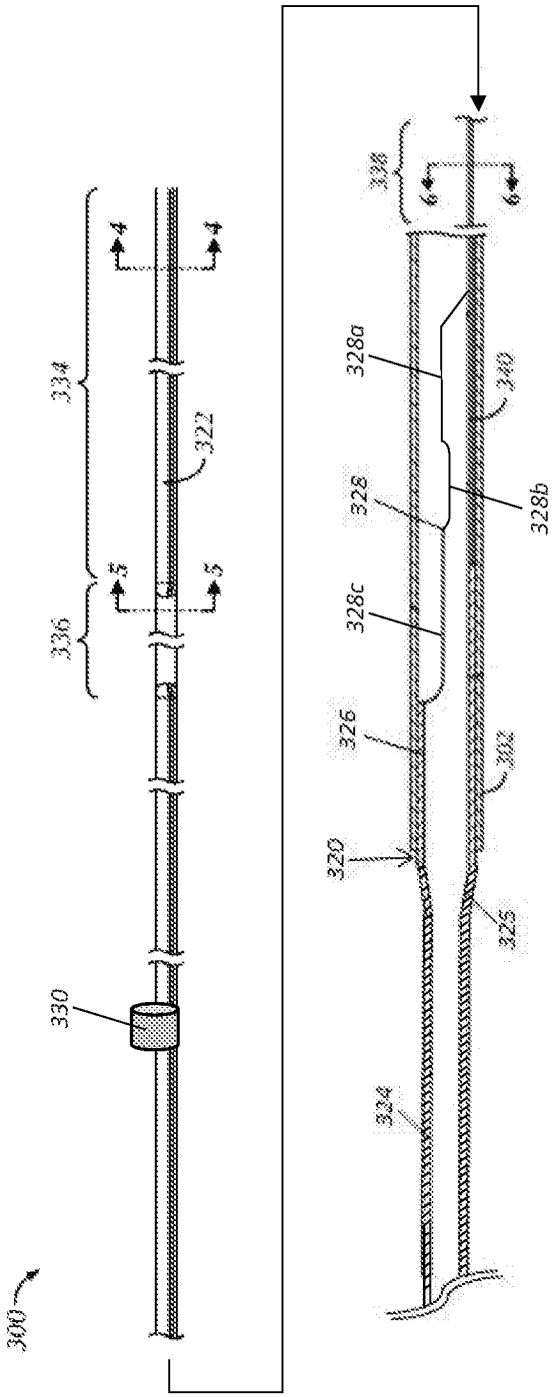
300
330
334
336
322
4
4
5
5
6
6
328a
328
328b
328c
326
320
324
302
340
325

FIG. 3

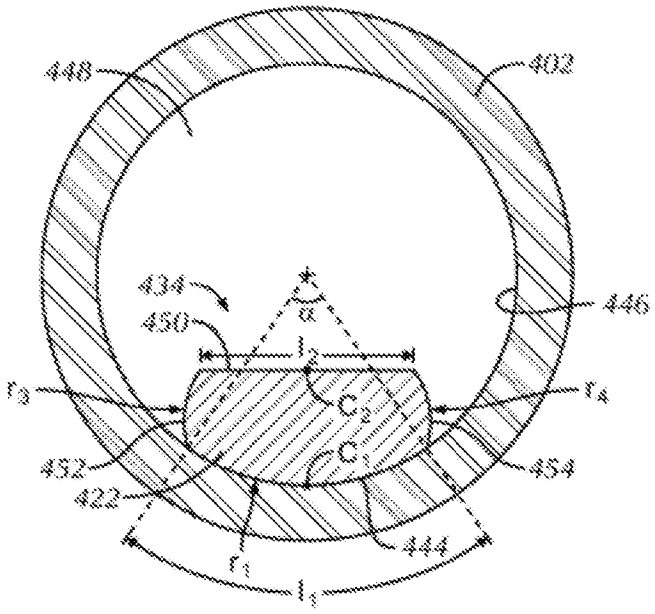
448
402
434
450
α
446
l_2
r_3
r_4
C_2
C_1
452
454
422
444
r_1
l_1

FIG. 4

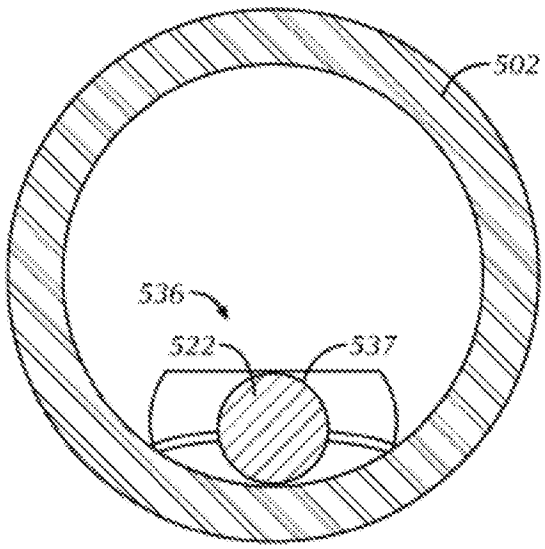
502
536
522
537

FIG. 5

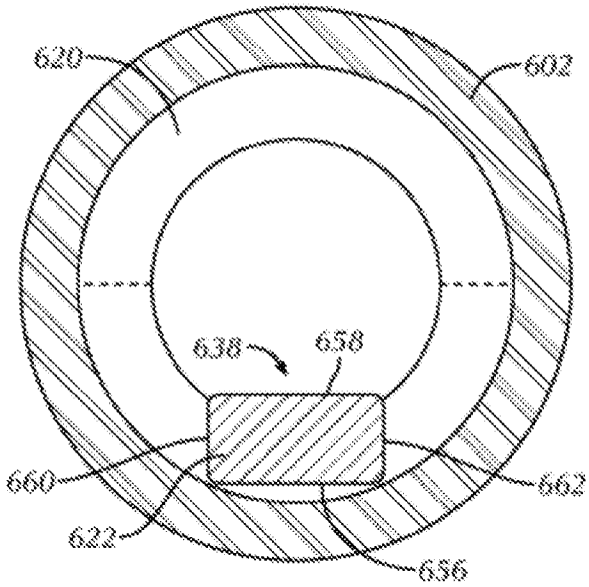

FIG. 6

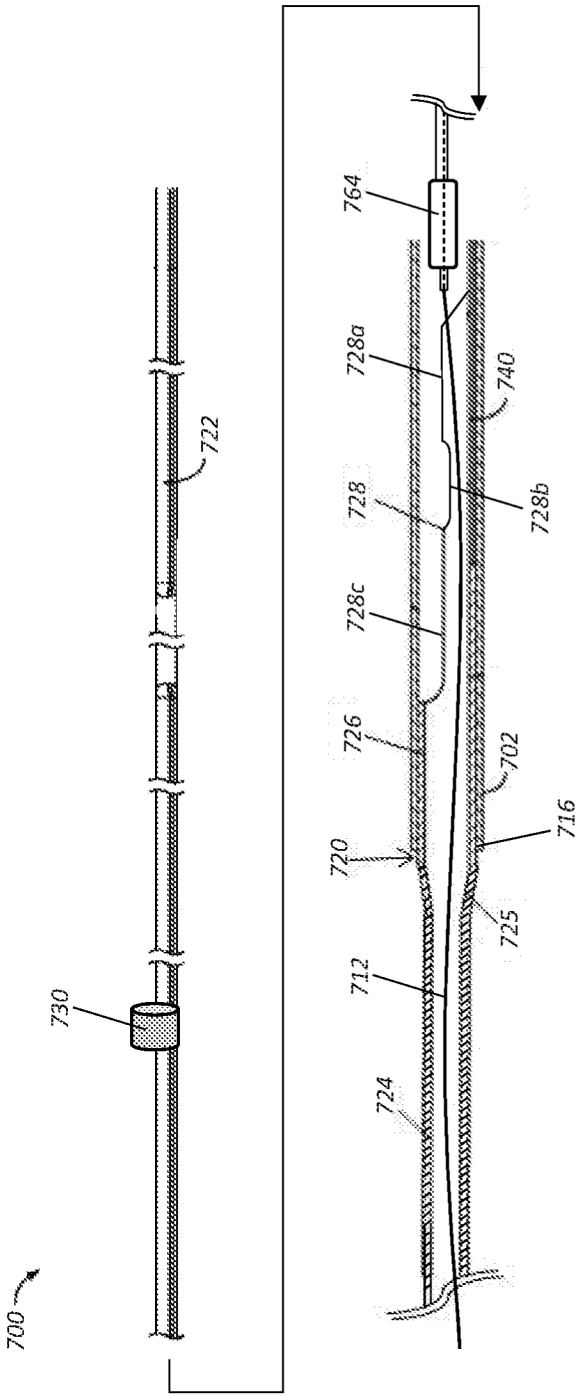
700
730
722
764
728a
740
728
728b
728c
726
702
716
720
725
712
724

FIG. 7

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 62630321 **[0001]**
- US 2009264865 A1 **[0004]**
- US 2014018773 A1 **[0005]**
- WO 2017019900 A1 **[0006]**
- WO 2016191415 A1 **[0007]**
- US 2014276618 A1 **[0008]**