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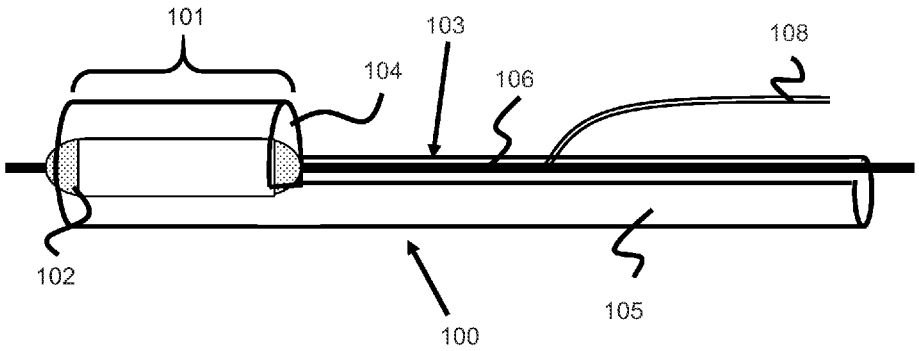

Figure 1c

(57) Abstract: A balloon catheter and balloon system particularly useful with drug-coated balloons is described. In some embodiments, the balloon catheter system includes various features designed to address problems with drug rubbing off due to contract friction during delivery of the balloon - including by utilizing a protective sleeve to shield the drug-coated balloon. In some embodiments, the balloon catheter system includes an inner high-pressure balloon and an outer drug-coated balloon to mitigate the time associated with performing vessel dilation.

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BALLOON CATHETER SYSTEMS

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 62/404,647 filed October 5, 2016 entitled *Balloon Catheter Systems*, and to U.S. Provisional Application Serial No. 62/414,520 filed October 28, 2016 entitled *Balloon Catheter Systems*, both of which are hereby incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] Stenosis or restenosis is a narrowing of a blood vessel due to the buildup of sclerotic material. Stenosis can cause a variety of vascular conditions associated with reduced blood flow including stroke, heart disease, or limb loss. Drug coated balloons utilizing a variety of anti-sclerotic drugs such as Paclitaxel, Sirolimus, and/or Zotarolimus are one way of treating stenosis – the balloons are inflated to compact the sclerosis and the drugs are delivered to the vessel wall to help treat the region. Often, significant amounts of the drugs can be lost from the balloon during loading and tracking through the guiding sheath. Further, even when sufficient drug coatings are delivered to a target site, the delivery may be further hindered by the failure of the cylindrical balloon to conform to an abnormal vessel profile (e.g., non-circular) or where calcification on the vessel is particularly dense.

[0003] In this regard, there is a need for a balloon catheter system that can improve drug loss from a balloon and thereby improve drug during delivery to the vessels of a patient. There is also a need for a balloon catheter that can provide improved treatment to a sclerotic region in which a typical balloon may not conform to the shape of the target region, a calcified sclerosis, or a relatively dense sclerosis.

SUMMARY OF THE INVENTION

[0004] In some embodiments, a protective sleeve for a drug coated balloon is described. The protective sleeve is useful to prevent a drug coating from rubbing off

of a balloon when inserted and tracked through a guiding sheath to a target treatment site.

[0005] In one embodiment, the protective sleeve is configured so that the drug coated balloon can be placed within a tubular section of the protective sleeve and the protective sleeve and enclosed drug coated balloon are pushed through the guiding sheath. In one embodiment, the protective sleeve includes a distal nose-cone to help prevent blood from rubbing off a drug coating from the balloon. In one embodiment, the tubular section of the protective sleeve housing the drug coated balloon can be narrowed to limit the balloon's exposure to blood.

[0006] In one embodiment, the protective sleeve has a relatively small length, being sized to cover only the drug-coated balloon itself as it is inserted into a hemostasis valve of the guiding sheath. In one embodiment, the protective sleeve is part of the balloon catheter assembly and can be removed from the balloon catheter and then placed into the hemostasis valve to aid with placing the drug coated balloon into the guiding sheath.

[0007] In some embodiments, a balloon catheter and balloon catheter system utilizing a protective sleeve is described. The protective sleeve is useful to prevent a drug coating from rubbing off of a balloon when tracked through a guiding sheath to a target treatment site.

[0008] In one embodiment, a balloon catheter system, including a balloon catheter, utilizes a protective sleeve in which the balloon catheter is placed prior to loading the balloon catheter through a guiding sheath. The balloon protective sleeve and the enclosed balloon are tracked through the guiding sheath. In one embodiment, the balloon catheter/balloon catheter system utilizes a distal nose cone which helps protect the balloon from blood during delivery of the balloon, where premature exposure to blood during delivery could otherwise push drug off the balloon. In one embodiment, the tubular section of the protective sleeve housing the drug coated balloon can be narrowed to limit the balloon's exposure to blood.

[0009] In one embodiment, a balloon catheter/balloon catheter system utilizes a relatively short-length protective sleeve which is sized to aid in placing the drug coated balloon within the hemostasis valve of the guiding sheath. In some embodiments, the protective sleeve can come pre-attached to the balloon catheter, in which the protective sleeve is removed from the balloon catheter and placed into the hemostasis valve to aid with placing the drug coated balloon into the guiding sheath.

[0010] In some embodiments, a balloon catheter is described. The balloon catheter has particular utility in treating stenotic regions of the vasculature which may have an irregularly shaped buildup of sclerosis, or stenotic regions with particularly thick or dense sclerosis.

[0011] In one embodiment, the balloon catheter utilizes a double balloon including an inner balloon and an outer balloon. The inner balloon is a high-pressure balloon and the outer balloon is drug-coated and highly compliant in order to conform to the stenotic vessel shape.

[0012] In one embodiment, a method of using a balloon catheter which includes a high-pressure inner balloon and a drug-coated, compliant outer balloon is described. The outer balloon is first inflated in order to conform to the stenotic vessel shape, the outer balloon delivers drugs to the sclerosis-containing vessel. The outer balloon is then deflated. The high-pressure inner balloon is then inflated in order to compress the sclerosis so that a relatively consistent lumen is formed within the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which:

[0014] Figure 1a illustrates a typical drug-coated balloon which is part of a balloon catheter.

[0015] Figure 1b illustrates a balloon protective sleeve according to one embodiment.

[0016] Figure 1c illustrates the drug-coated balloon of Figure 1a within the protective sleeve of Figure 1b.

[0017] Figure 2 illustrates the balloon protective sleeve of Figure 1 within a larger guiding sheath.

[0018] Figure 3a illustrates the distal end of the balloon protective sleeve of Figure 1.

[0019] Figure 3b illustrates a proximal cut-out section of the balloon protective sleeve of Figure 1.

[0020] Figure 4 illustrates a balloon within a balloon protective sleeve.

[0021] Figure 5 illustrates the balloon protective sleeve of Figure 1 being placed within a hemostasis valve of a guiding sheath.

[0022] Figure 6 illustrates a balloon protective sleeve utilizing a distal nose cone.

[0023] Figure 7 illustrates a side view of a balloon protective sleeve with a narrow distal section.

[0024] Figure 8 illustrates another view of the balloon protective sleeve of Figure 7.

[0025] Figure 9 illustrates a shortened balloon protective sleeve used solely to track the drug coated balloon through a hemostasis valve of a guiding sheath.

[0026] Figure 10 illustrates the shortened balloon protective sleeve of Figure 9 pre-mounted to a proximal region of a balloon catheter.

[0027] Figure 11 illustrates a drug coated balloon prior to being inserted into the shortened balloon protective sleeve of Figure 9.

[0028] Figure 12 illustrates a drug coated balloon being placed into the shortened balloon protective sleeve of Figure 9.

[0029] Figure 13 illustrates a drug coated balloon with the shortened balloon protective sleeve of Figure 9 being placed into the hemostasis valve of a guiding sheath.

[0030] Figure 14 illustrates a stenosis site within the vasculature.

[0031] Figure 15 illustrates a balloon catheter utilizing an inner and an outer balloon that can be used to treat the stenosis site of Figure 14.

DESCRIPTION OF EMBODIMENTS

[0032] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0033] Drug-coated balloons are used for a variety of vascular conditions, including stenosis – which is a condition where sclerotic material builds up in the blood vessels, affecting the normal circulation of blood through the vasculature. Restenosis is the continued occurrence of stenosis where treatment to treat the sclerosis is unsuccessful and results in the continued existence and buildup of sclerotic material within the vasculature.

[0034] One method of treating stenosis is the use of a drug coated balloon. These drug coated balloons can be used in several target areas, including for treatment of stenosis in the superficial femoral or popliteal arteries which are larger arteries in the legs. Typically, this procedure involves a balloon catheter having a drug coated balloon on its distal end. Various anti-sclerotic drugs can be coated onto the balloon,

such as Paclitaxel, Sirolimus, and/or Zotarolimus. The balloon is tracked through a larger guiding sheath to the target treatment site. The balloon is then delivered and inflated at the stenosis site to compress the sclerotic material and deliver drug to the vessel wall to prevent the future buildup of sclerotic material.

[0035] One complication with delivery of drug coated balloons is that the drug coating can rub off the balloon. This can occur primarily in two scenarios – first, when the drug coated balloon is initially placed through the hemostasis valve of the guiding sheath for entry into the guiding sheath (where most of the drug loss typically takes place). Second, when the drug coated balloon is being pushed through the guiding sheath. This drug loss is due to contact friction between the balloon and, respectively, the hemostasis valve and the inner surface of the guiding sheath. Drug loss during placement and tracking can limit the amount of drug that is available to treat the stenosis and can enhance the chance of continued stenosis or restenosis since less drug is available to treat the problem region.

[0036] This is particularly problematic in larger arteries, such as the superficial femoral and popliteal arteries, since the stenotic regions can become particularly large and calcified due to the relatively larger vessel size and therefore may need a large drug dose to treat the target region. Drug loss is therefore a significant problem associated with the use of drug coated balloons.

[0037] Embodiments herein include protective sleeves designed to help protect the drug coated balloon during placement within the hemostasis valve of the guiding sheath as well as during tracking through the larger guiding sheath. For the purposes of the figures discussed in the description, unless noted otherwise anything on the left is considered “distal” or in the direction of the patient body/vasculature, while anything on the right is considered proximal or in the direction outside of the patient body/vasculature.

[0038] Figure 1a shows a typical drug-coated balloon catheter 103 having an inflatable drug-coated balloon 102 mounted on the distal end of the catheter 103 and in which a portion of the balloon has a drug coating 102A. Preferably, substantially all of the length and circumference of the balloon 102 includes the drug coating 102A.

Often, the proximal and distal tapered ends of the balloon 102 are free of the drug coating, since these portions are unlikely to contact the vessel.

[0039] The drug-coated balloon catheter 103 includes an elongated body portion 106 having a first lumen 106A located along all or a portion of the length of the body portion 106 and through which a guidewire 108 can be advanced (and/or a contrast agent or therapeutic material can be delivered within the patient). A second inflation lumen 106B extends from a proximal end of the body portion 106 to an opening within the balloon 102, allowing for delivery of inflation media during a procedure.

[0040] Balloon catheters also often include a separate rapid exchange port 106C at some distal location along the body portion 106 and lumen 106A to allow quicker placement and removal of the guidewire 108, as shown in Figure 1a. Balloon catheters 103 are typically placed into a hemostasis valve of a guiding sheath and then are delivered through the guiding sheath for delivery to a target treatment area, however, as discussed above, there is significant drug loss associated with these steps.

[0041] Figure 1b illustrates a protective sleeve 100 according to one embodiment to protect the drug-coated balloon 102 of the drug-coated balloon catheter 103 during placement through the hemostasis valve of the guiding sheath and passage through the guiding sheath. The protective sleeve 100 includes a distal tubular section 101 and a proximal body portion 105 having an arc-shaped channel or “half-pipe” shaped region 105A that extends to the proximal end of the body portion 105 that forms an opening 104 to the distal tubular section 101.

[0042] As best seen in Figure 1c, the balloon 102 is advanced within the distal tubular section 101, since both the proximal aperture 104 and internal diameter of the section 101 are larger than the deflated diameter of the balloon 102. The body portion 106 of the catheter 103 can be positioned within the non-tubular arc-shaped region 105A. Preferably, the protective sleeve 100 is placed over the catheter 103, with the balloon already inside of the distal tubular section 101 prior to placement within the hemostasis valve 112 of guiding sheath 110 and is then pushed through guiding sheath 110 – as shown in Figure 2.

[0043] Protective sleeve 100 provides an intermediate surface to protect the balloon from direct contact with the hemostasis valve 112 when the drug-coated balloon 102 enters the guiding sheath 110, as well as an intermediate surface to protect the drug-coated balloon 102 from direct contact with the inner diameter of the guiding sheath when tracked through said guiding sheath 110. Drug loss primarily occurs during placement through the hemostasis valve 112 (due to the reduced diameter of the hemostasis valve, as well as the rough texture of the hemostasis valve) and secondarily during tracking through the guiding sheath 110. The protective sleeve 100 reduces or eliminates these problems by protecting the drug-coated balloon 102 when it enters the hemostasis valve 112 and during tracking through the guiding sheath 110. The protective sleeve 100 should be sized to fit within the inner diameter of the guiding sheath 110 so it can be advanced through the guiding sheath 110. The external surface of the balloon protective sleeve 100 can utilize a hydrophilic or other friction-reducing coating to reduce friction with the external guiding sheath 110. The balloon protective sleeve 100 may also be made of a lubricious polymer to reduce friction between the overlying guiding sheath 110 and underlying protective sleeve 100.

[0044] The protective sleeve 100 is advanced by the physician at its proximal end to so as to also advance the enclosed balloon catheter 103 through guiding sheath 110. As previously discussed, the proximal section 105 of the protective sleeve 100 is not a fully enclosed tube like distal section 101, but rather an arc-shaped or "half-pipe" shaped region 105A. This configuration increases the ease of loading the drug coated balloon 102 since the balloon 102 must only be pushed through cut-out aperture 104 to access the distal tubular section 101 instead of being pushed through the entire length of the balloon protective sleeve 100, which would be the case if the entire length of the balloon protective sleeve 100 had a completely enclosed tubular shape. Since the body portion 106 resides in the arc-shaped portion 105A of the protective sleeve 100, the physician can advance both the sleeve 100 and the catheter 103 together by manipulating only the proximal end of the proximal body portion 105 (or optionally both proximal ends of the proximal body portion 105 and the catheter 103). In this way, the proximal body portion 105 can be thought of as a navigational

section since a user grips the proximal part of proximal body portion 105 to move protective sleeve 100 along with the enclosed balloon catheter 102 and drug coated balloon 102.

[0045] After passing through guiding sheath 110 and being placed at the target treatment site, the drug coated balloon 102 is exposed in one of a few ways. First, the protective sleeve 110 is pushed out from the guiding sheath 110 or the guiding sheath 110 is proximally withdrawn to expose the distal tubular section 101 of protective sleeve 100. Then, the protective sleeve 100 is retracted to expose drug coated balloon 102, the balloon catheter is pushed out from the protective sleeve 100, or both techniques can be performed together (in a dual push/pull method). Since the drug-coated balloon 102 is located within the protective sleeve 100, a small amount of drug loss due to friction between the drug-coated balloon 102 and the protective sleeve 100 may be possible, however this drug loss is much less than the amount that would otherwise occur without the sleeve 100. To further mitigate drug loss from the balloon 102, the inner surface of protective sleeve 100 may include a hydrophilic or otherwise friction-reducing coating, or be made of a lubricious polymer.

[0046] The distal end of the distal tubular section 101 may further include a radiopaque (e.g. tantalum) marker band 114, as seen in Figure 3a. Guiding sheaths 110 often include a marker band at about 3 cm from the distal tip so that a device delivered through the guiding sheath can be aligned with the distal tip to ensure proper placement relative to the guiding sheath 110. In this respect, the marker band 114, when aligned with the marker band of guiding sheath 110, helps the user ascertain that the protective sleeve is at the distal end of the guiding sheath.

[0047] The aperture 104 created between the distal tubular region 101 and the channel 105A can be formed from a generally perpendicular wall cut (i.e., a cut perpendicular to the elongated axis of the sleeve 100, as seen in Figure 1b, or can be cut at an angle that decreases in the proximal direction, as seen in Figure 3b (e.g., 45 degrees or an angle less than 90 degrees) to create a transition between the two regions 101, 105A. In one example, the protective sleeve 100 can be manufactured by cutting a portion of a tube between the aperture 104 and the proximal end of the

proximal section 105, thereby forming the arc-shaped or channel portion 105A. In another example, a distal tubular section 101 can be connected to an entire tube cut lengthwise to form the proximal portion 105.

[0048] Drug coated balloons are often pleated, as shown in Figure 4, to reduce the amount of drug that can potentially be lost. The pleat 116 includes an outer region 116A which may contact the surface overlying the balloon 102 and an inner region 116B which is protected from the overlying surface. This pleated design helps ensure the entire surface of the balloon is not exposed and thereby limits the amount of drug that is lost during placement and tracking.

[0049] The drug coated balloon 102, as discussed earlier, includes a lumen 106A that accommodates a guidewire 108, shown in Figure 1A, and provides a path for any subsequently introduced therapeutic materials that may be used in the treatment area. The proximal end of balloon 102 is connected to an inflation lumen 106B to allow inflation media (e.g. liquid contrast agent) to be injected through a port in the catheter body 106 to inflate the balloon 102 once deployed in the target treatment site in the vasculature.

[0050] Figure 5 shows the balloon and balloon protective sleeve 100 being placed within the hemostasis valve 112 of guiding sheath 110, for tracking through said guiding sheath 110. Various embodiments are contemplated regarding the placing of balloon within protective sleeve 100. In one embodiment, the balloon 102 is preplaced within distal tubular section 101 of protective sleeve 100 and sold as a package to the end user. In another embodiment, the end user physically places the balloon 102 within distal tubular section 101 of protective sleeve 100, for example by pushing the balloon 102 through aperture 104 of protective sleeve 100. Once the balloon is within the protective sleeve 100, the protective sleeve 100 is physically placed within the hemostasis valve 112 and pushed through guiding sheath 110 in the manner described earlier. Please note, in the embodiment where the end user would place the balloon within the distal tubular section 101 of protective sleeve 100, the balloon 102 may need to be placed within a temporary protective structure to prevent drug loss during the storage and shipping process – this temporary protective structure

would then be removed by the end user when said user places the balloon within the distal tubular section 101 of protective sleeve 100.

[0051] Other embodiments of the protective sleeve 100 can forego cut-out region 105A and instead is entirely tubular. With this embodiment, it would be beneficial for the protective sleeve 100 to be sold/delivered pre-loaded with the drug coated balloon 102 to the end-user to minimize the effort needed to track the balloon through a fully tubular protective structure.

[0052] The earlier discussion highlighted placement of a drug-coated balloon 102 within a guiding sheath 110, as well as tracking the balloon 102 through the guiding sheath 110, as the primary scenarios where drug loss can occur. However, exposure to blood can also cause drug loss from the drug coated balloon 102. Generally, once the drug-coated balloon 102 is tracked to the distal end of the guiding sheath 110, the distal part of the drug-coated balloon 102 may contact blood even before the balloon 102 is deployed, and the pressurized flow of blood may cause of the drug coating 102A to be removed from the balloon 102. The protective sleeve 100 can address some of these issues by limiting the amount of balloon surface which the blood can contact due to the surface area of the protective sleeve 100. However the protective sleeve 100 alone may not entirely prevent drug loss due to blood contact. Figures 6-8 describe various embodiments to reduce this drug loss due to blood contact/blood flow.

[0053] In Figure 6, a nose cone 118 is attached to the distal end of catheter body 106, past the distal end of balloon 102 that helps block or redirect direct blood flow contact with the balloon 102, thereby further reducing loss of the drug coating 102A. The nose cone 118 is either disposed around the catheter body 106 or includes a passage through it that is aligned with the lumen 106A, such that the nose cone 118 provides an outlet for a guidewire or other agents advanced through the lumen 106A. Preferably, the nose cone 118 can be a proximally-increasing conical shape as pictured or similar ramped shape so that the proximal end of the cone has the greatest thickness to prevent blood from prematurely contacting the balloon during delivery, while the distal end has a smaller profile in order to not materially impede blood flow

once the balloon is placed within the vasculature. However, a variety of shapes are contemplated including cones, cylinders, elliptical, ovular, and/or bullet-like shapes.

[0054] In one embodiment, the nose cone 118 is located within the balloon protective sleeve 100 and the proximal end of the nose cone 118 has a diameter similar to the inner diameter of the balloon protective sleeve 100, thereby preventing blood from contacting the drug-coated balloon 102. In another embodiment, the nose cone 118 is located distal to balloon protective sleeve 110 and the proximal end of nose cone 118 is has a diameter similar to the inner diameter of guiding sheath 110.

[0055] Blood-induced drug coating loss can also be addressed by narrowing the distal end of the balloon protective sleeve so that there is less available space for the blood to contact the drug-coated balloon 102. Figures 7-8 illustrate one such embodiment, in which a balloon protective sleeve 200 has a diametrically narrowed distal section 220 relative to the proximal portion of the distal tubular section 201. The narrowed distal section 220 accommodates all of the balloon 102 or solely the distal part of the balloon as the balloon 102 is being housed within the protective sleeve while tracking through the guiding sheath 110. Narrowed distal section 220 has a smaller diameter compared to the rest of the distal tubular section 201 (which accommodates the balloon 102) of protective sleeve 200 and therefore sits tighter relative to the balloon, limiting the space for blood to enter. This mitigates the chance that blood can enter and remove the drug coating 102A from the balloon 102.

[0056] Narrowed distal section 220 shown in Figures 7-8 can be used instead of the nose cone 118 shown in Figure 6, or can be used along with nose-cone 118 to provide multiple levels of protection to help prevent blood from pushing or washing the drug coating 102A off of the balloon.

[0057] Various embodiments of the narrowed distal section 220 embodiment are contemplated. For instance, the entire section that the drug-coated balloon 102 is located within can be relatively narrow. Alternatively, just a distal part is narrowed such that a proximal section of the balloon 102 is located in an enlarged proximal section while the distal section of the balloon is located within a narrowed section 220.

[0058] An alternative embodiment utilizing the narrowed distal section 220 described above can utilize a fuller distal section that the balloon sits within (sized similar to tubular section 101 in Figures 1-2), then a smaller narrowed distal section 220 beyond this balloon, where the narrowed section would limit the amount of blood that could enter the protective sleeve and contact the drug coated balloon 102.

[0059] The earlier description discussed how the balloon catheter 103 (of which drug coated balloon 102 is a part), is tracked through guiding sheath 110 by pushing/pulling the proximal end of the protective sleeve 100, which in turn conveys the balloon catheter 100 (and drug coated balloon 102) since the balloon catheter is contained within protective sleeve 100. The proximal section 105 of the protective sleeve 100 is not tubular in several of the embodiments to ease placement of the drug coated balloon 102 within the protective sleeve 100. However, one drawback to this arrangement is that since the proximal part 105 of the protective sleeve 100 is cut-away to form a channel 105A, there is less axial strength or kink resistance to the protective sleeve 100 due to the smaller cross-sectional area.

[0060] In Figures 7-8, the proximal section 205 of the protective sleeve has a greater curvature to the arc of its channel 205A compared to the channel 105A shown in the embodiment of Figures 1-3b, which is accomplished by making a more scalloped cut at region 204 (i.e., a cut of increased circumference/width) to define the entry point for the drug coated balloon. This scalloped cut is defined by a divot or inward tapered cut region 204a which creates enough of a gap, entry, space, or port to accommodate the drug coated balloon 102 within the distally placed tubular section 201, which may not otherwise fit due to the relatively narrow channel 105A opening. This proximal section 105 with a smaller opening of the channel 205A may be used in any of the protective sleeve embodiments to augment the push strength of the protective sleeve.

[0061] The primary locations in which loss of the drug coating can occur when tracking a drug coated balloon through a guiding sheath, as discussed earlier, are during placement within a hemostasis valve 112 of a guiding sheath 110 as well as during tracking through the guiding sheath 110 – where the hemostasis valve 112 is the location where the greatest amount of drug coating 102A is lost. Loss of drug

coating 102A occurs due during placement through the hemostasis valve 112 for a few reasons. First, the smaller diameter of the hemostasis valve 112 compared to the guiding sheath diameter causes increased contact friction with the balloon 102 when the balloon 102 is placed through the hemostasis valve 112. Second, the hemostasis valve port is not smooth which can promote loss of drug coating 102A due to friction. Third, drug-coated balloons 102 are fairly soft, meaning the physician generally must grip the balloon 102 to propel it through the hemostasis valve 112, which causes loss of the drug coating due to touch. Finally, retrograde blood flow through the hemostasis valve 112 can also cause drug loss due to contact with blood. The following embodiments are directed to a relatively shorter protective sleeve that functions solely to protect the drug coated balloon 102 when its inserted into the hemostasis valve 112 – which is the primary scenario where blood loss occurs, but does necessarily not protect the balloon 102 while it is tracked through the guiding sheath 110.

[0062] Figure 9 illustrates a shortened protective sleeve 300 which can also be considered an insertion sleeve 300 since the function of the sleeve is to protect the drug-coated balloon 102 solely during insertion through the hemostasis valve 112 of a guiding sheath 110. Since protective sleeve 300 only protects the balloon during insertion into the hemostasis valve 112 it can be much shorter than protective sleeve embodiments 100 and 200 in Figures 1-8 which must span the complete length of the guiding sheath 110.

[0063] The protective sleeve 300 can be placed over the balloon 102 when the balloon 102 is placed inside the hemostasis valve 112 of guiding sheath 110 to protect the drug-coated balloon from drug loss when being placed within said hemostasis valve 112. The protective sleeve 300 has a thin cut 301 extending along its entire length (e.g. a cut 301a defining an opening that is 0.002 inches or less), forming a cross-sectional c-shape instead of a completely oval/circular shape. One end of protective sleeve 300 is preferably flared or radially opened to form a flared end 305 (i.e., the cut 301A increases in width in the proximal direction). In one example, the protective sleeve 300 is formed as a cylinder but the cut 301A in section 305 is larger than cut 301 in the rest of the sleeve causing flared end 305 to adopt its flared shape - meaning the larger shape of the flared end is due to the larger cut used in region

305. As shown in Figure 9, cut 301A is tapered such that the cut size in end section 301C is larger than the cut size in section 301B. In one example, the cut-size in end section 301C defines an opening of about 0.17 inches to about 0.23 inches. The protective sleeve 300 is about 2.75-3.25 inches in length and the flared end is about 0.5 to 1 inch in length. In another example, protective sleeve 300 is about 3 inches, about 7.62 centimeters, or about 8 centimeters in length and flared end 305 is about 0.75 inches in length. Protective sleeve 300 can be formed from a variety of materials including a polymeric material such as Pebax 7233 SA01. In one example, protective sleeve 300 has an inner diameter of about 0.1 inches and an outer diameter of about 0.115 inches. Since protective sleeve 300 is generally formed from a cylinder which is given a larger cut in region 301C to adopt the flared end 305 as described earlier, the protective sleeve diameter can be thought of as the outer diameter of the sleeve plus the size of the cut. Using this approach, the protective sleeve's flared end 305 diameter is about 0.285 inches to 0.345 inches, or about 0.315 inches – while the protective sleeve's diameter in the non-flared portion of the sleeve is about 0.115 inches to 0.12 inches, or about 0.117 inches.

[0064] Figure 10 shows an embodiment in which the protective sleeve 300 is pre-placed on the proximal part of the balloon catheter 103, where the balloon catheter 100 is sold to the end user with the protective sleeve 300 already located on the proximal part of said balloon catheter 100. The proximal end of protective sleeve 300 (which coincides with flared end 305) would sit over the enlarged strain relief 303 of the balloon catheter 103.

[0065] Proximal flare 305 is useful for a couple purposes. First, the flare provides a slightly enlarged region to better fit over strain relief 303. Second, the proximal flare 305 provides a smoother entry for the drug coated balloon when said balloon is loaded through said protective sleeve 300. Comparing Figures 9 and Figure 10, cut 301 would sit on the bottom of protective sleeve 300 shown in Figure 10. The user can simply remove protective sleeve 300 from the balloon catheter 1, and then place the protective sleeve 300 within the hemostasis valve of the guiding sheath – in a manner that will be explained in more detail below.

[0066] The method of using protective sleeve 300 is shown in Figures 11-13. Please note, as pertains to the figures anything on the left side would be considered distal and anything on the right side would be considered proximal. Protective sleeve 300 is first removed from the proximal section of balloon catheter 103 so that the distal section of said balloon catheter 103 is later be placed through said protective sleeve 300. Due to the presence of the cut 301, this removal can occur by applying force against the cut 301 (referring to Figure 10, one pulls upwards to remove sleeve 300 since cut 301 is located on the bottom of the sleeve 300).

[0067] Generally, drug coated balloons come pre-shipped in a protective tube 307 during shipping and handling to protect the drug after manufacture. This protective tube 307 must be removed prior to using the drug coated balloon/balloon catheter, prior to placement within the hemostasis valve of the guiding sheath. The distal part of the balloon catheter, which includes the drug coated balloon which is located at the distal end of the balloon catheter 103 around balloon catheter lumen 103 is shown in Figure 11. The distal part of the balloon catheter including surrounding protective tube 307 is inserted through the protective sleeve 300, so that the distal part of the balloon catheter and distal part of protective tube 307 sits past the distal end of protective sleeve 300. Protective tube 307 is then pulled distally (to the left) as shown in Figure 12 to remove the protective tube 300 from the balloon 102. After this, as shown in Figure 13, the protective sleeve 300 is then placed within the hemostasis valve 112 of guiding sheath 110 so that the protective sleeve 300 is positioned through the entire hemostasis valve 112. The balloon catheter is then pushed distally (in a leftward direction) to propel the balloon 102 through the hemostasis valve 112 and into the guiding sheath 110. Once the entire balloon 102 is past the hemostasis valve 112 and is loaded into the guiding sheath, the protective sleeve 300 is proximally retracted (pulled to the right) and removed (e.g. by pulling against the cut, so pulling upwards in Figure 13 to remove the entire sleeve 300) and the rest of the balloon catheter 103 is pushed through the hemostasis valve 112 and into the guiding sheath 110.

[0068] Alternative embodiments have a shortened protective sleeve 300 as a separate element that is unconnected to balloon catheter 103; however pre-placement on balloon catheter 103 would provide a more convenient format to locate the

shortened protective sleeve 300 as part of a balloon catheter system or kit. Alternative embodiments may also utilize a pre-scored or pre-weakened region in place of cut 301, in which the user applies enough pressure to tear open region 301.

[0069] The primary benefit of insertion sleeve/protective sleeve 300 is that it protects the drug coated balloon 102 from contact with the reduced diameter and roughened area of the hemostasis valve 112, thus mitigating the issue of drug loss during placement through said hemostasis valve 112. One additional advantage of the cut section 301 of the protective sleeve 300 is that when the sleeve is placed into a small-diameter tube, the ends of the tube can overlap to fit the smaller profile. Since the hemostasis valve 112 has a reduced diameter compared to the rest of the guiding sheath, the protective sleeve 300 can curl over itself to fit this reduced diameter (meaning the protective sleeve 300 can conform to fit a much smaller diameter hemostasis valve – by contrast, a non-cut tube could not fit into a hemostasis valve with a smaller diameter than the tube for obvious reasons). The earlier description discussed one cause of drug loss being exposure to blood. The ability of the protective sleeve 300 to contract to fit the hemostasis valve 300 means there is less exposed surface area of the drug coated balloon available exposed to blood, further minimizing the chance of drug falling off the balloon during placement.

[0070] In the protective sleeve embodiments of Figures 1-8 in which the protective sleeve extends the length of the guiding sheath and includes a distal tubular section to support the drug coated balloon, the sleeves must be relatively long since they are positioned within the guiding sheath 110. The distal tubular sections 101, 201 must also be sized similar to the length of the drug coated balloons. Drug coated balloons 102 can be anywhere from 40-200 millimeters in length depending on the size of the vascular area treated, so the distal tubular sections 101, 201 must be at least this size to accommodate the balloon. One advantage of the insertion sleeve/protective sleeve 300 is that it is relatively short since it only must be large enough to span hemostasis valve 112 of the guiding sheath. In some examples, as discussed earlier, the protective sleeve 300 is about 3 inches, 7.62 centimeters, or about 8 centimeters in length.

[0071] When sclerotic material builds up in a vessel, it often adopts awkward shapes - as shown in the vessel cross section shown in Figure 14 in which vessel 400 has sclerotic material 402 which leaves a smaller vessel cross section 404 for blood flow. The sclerotic buildup narrows the space that blood can flow through the vessel, diminishing blood flow through the vessel in a phenomenon called stenosis – which can cause a variety of complications. Typical treatment procedures can proceed in a couple ways. One treatment option uses a high-pressure balloon to inflate and compress the sclerosis to try to restore regular blood flow to the vessel. However, if the sclerosis is particularly dense or if stenosis keeps recurring (a phenomenon known as restenosis), this method is not useful.

[0072] A second treatment option is to use a drug-coated balloon to apply drug to the vessel wall and sclerotic material to try to treat the stenosis. However, the irregular profile of the sclerotic material can make it difficult to effectively apply the drug equally around the vessel since it would be difficult for the balloon to adopt the awkward shape to conform to vessel cross-section 404 – in fact, inserting a drug coated balloon by itself would result in the drug-coated balloon only touching the "narrowest" part of the sclerotic region which is a very inefficient way to deliver the drugs. Additionally, the presence of a thick sclerotic layer would make it difficult for the drug to reach the wall of the blood vessel. Physicians often use a pre-dilation step to address this problem, where a first high-pressure balloon is inserted into the sclerotic region and expanded in order to compress the sclerosis and produce a consistent circular lumen – once there is a consistent circular lumen, it is much easier for the drug coated balloon to adopt a circular shape to treat the area. Once the pre-dilation step is completed a second balloon – a drug coated balloon which can be coated with anti-sclerotic drug such as Paclitaxel, Sirolimus, and/or Zotarolimus is then inserted and inflated to contact the sclerosis and vessel wall, and deliver drugs to said sclerosis and tissue. This procedure can take a substantial amount of time since a first balloon must be tracked through a guiding sheath and delivered to the target site and inflated for the pre-dilation step and then be deflated and withdrawn through the guiding sheath. Then a drug-coated balloon must be tracked through the guiding sheath and placed at the target site, expanded to deliver the drug, and then removed and withdrawn. The extra-

step of pre-dilation takes extra time and can increase the risk of complications such as stroke in circumstances where there is significant narrowing of the blood vessels due to sclerosis. The following embodiments deal with a dual-balloon microcatheter system which includes both a dilation balloon and a compliant drug-coated balloon so that the dilation and drug delivery can take place simultaneously.

[0073] Figure 15 illustrates a balloon catheter system 405 having two balloons. The two-balloon system utilizes an outer, primary, highly-compliant drug coated balloon 406 and an inner, secondary, high-pressure balloon 408. The inclusion of two balloons on one balloon catheter eliminates the need for a separate pre-dilation step since the inner balloon can dilate the vessel while the outer balloon can then conform to the stenosis after dilation and therefore there is no need for two separate balloon catheters and the time associated with tracking two separate balloon catheters through the vasculature to treat the stenosis.

[0074] In one embodiment, the two balloons are concentric, as is shown in Figure 15. The balloon catheter contains two inflation lumens, one (408a) to inflate the inner balloon and the other (408b) to inflate the outer balloon – while a third lumen 410 provides access for a guidewire or additional therapeutic materials. Typical inflation media such as liquid contrast agent can be used to inflate the balloons. The inner balloon is a high-pressure balloon and should be high strength in order compress the sclerosis, thereby dilating the vessel. Conventional high-pressure balloon material such as nylon can be used for this inner/secondary balloon 408. The outer balloon 406 is highly conformable and is meant to conform to the shape of the sclerotic region in order to ensure even drug delivery throughout the entire sclerotic region. Soft, compliant material is therefore ideal for the inner/primary balloon; Polyblend 18-45 may be used for the inner/primary balloon.

[0075] The method of use of the dual-balloon catheter system 406 to treat a sclerotic region like the one shown in Figure 14 is described, as follows. The primary, compliant outer drug-coated balloon 406 is first inflated and due to the compliant nature of the balloon, this balloon can generally conform to the shape of the sclerotic region to deliver drug to the region – however depending on the nature of the stenotic

shape it may not completely comply with the shape if the shape is particularly complex or irregular. The physician can observe the treatment site through fluoroscopy to determine how well the compliant, drug-coated balloon conforms to the vessel shape. If dilation is needed to get a consistent, circular shape or to compress the sclerosis, then the primary, outer balloon 406 is deflated and the secondary, inner high-pressure balloon 408 is then inflated. Since the outer balloon 406 is located over the inner balloon 408, the outer balloon 406 maintains contact with the sclerosis, but the force from the inner-high pressure balloon further compresses the sclerosis and creates a consistent, open lumen for blood flow through the vessel. Note that even if outer drug-coated balloon 406 is complying to the stenosis shape, it may still be desirable to use a dilation procedure to decrease the amount of stenosis buildup and "open" up the vessel for blood flow – the inclusion of the high pressure inner balloon 408 allows this to be done while utilizing the same balloon catheter.

[0076] Other double balloon systems are additionally contemplated. For instance, a dual lumen inflation system can be used with two balloons where the balloons are positioned longitudinally adjacent with respect to each other (i.e., proximally/distally of each other). One balloon is a compliant drug-coated balloon, and a second linearly displaced balloon is a high-pressure balloon. With this system, the balloons can be used in either order (e.g. either the compliant, drug-coated balloon or the high-pressure balloon could be inflated and used first). The catheter can be linearly moved so that either the first balloon or the second balloon is aligned with the sclerotic region.

[0077] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A protective sleeve which protects a drug-coated balloon catheter during passage through a guiding sheath comprising:

a distal tubular section sized to accommodate a drug-coated balloon of the drug-coated balloon catheter;

a navigational section comprising an open channel proximally connected to the distal tubular section, the navigational section sized to accommodate an elongated catheter body of the balloon catheter;

wherein the navigational section is pushed or pulled to move the distal tubular section and the drug-coated balloon catheter through a guiding sheath.

2. The protective sleeve of claim 1 wherein the distal tubular section has a proximal tapered end extending to a top of the open channel, creating an entry port for the drug-coated balloon to access the distal tubular section.

3. The protective sleeve of claim 1 wherein the open channel has a first width extending along a proximal portion of the navigational section, and wherein the channel portion has a second width disposed immediately adjacent the distal tubular section, wherein said second width is larger than said first width.

4. The protective sleeve of claim 1 further comprising a radiopaque marker band at the distal section of the distal tubular section.

5. The protective sleeve of claim 1 wherein the distal tubular section further includes a distal portion having a first diameter and a proximal portion having a second diameter; wherein said first diameter is smaller than said second diameter.

6. The protective sleeve of claim 5 wherein the distal portion is sized to accommodate at least part of the drug-coated balloon.

7. A balloon protection system for protecting a drug-coated balloon catheter during passage through a guiding sheath comprising:

a protective sleeve adapted for passage through the guiding sheath having:

a distal tubular section sized to accommodate the drug-coated balloon;

a channel section having an open, arc-shaped cross-section and being disposed proximally adjacent to the distal tubular section;

wherein the channel section is pushed or pulled to move the protective sleeve and drug-coated balloon catheter through the guiding sheath.

8. The system of claim 7 wherein the drug-coated balloon is coated with one of Paclitaxel, Sirolimus, or Zotarolimus.

9. The system of claim 7 further comprising a nose-cone at the distal end of said drug-coated balloon catheter, wherein the nose-cone has a ramped shape such that the proximal end of the nose-cone is thicker than the distal end of the nose-cone.

10. The system of claim 7 wherein a proximal end of the distal tubular section is angled at 90 degrees or less relative to a longitudinal axis of the protective sleeve.

11. The system of claim 7 wherein the channel section has a first width extending along its proximal portion, and wherein the channel portion has a second width disposed immediately adjacent the distal tubular section, wherein said second width is larger than said first width.

12. The system of claim 7 further comprising a radiopaque marker band at the distal section of the protective sleeve.

13. The system of claim 7 wherein the distal tubular section further includes a distal portion having a first diameter and a proximal portion having a second diameter; wherein said first diameter is smaller than said second diameter.

14. The system of claim 13 wherein at least part of the drug-coated balloon is positioned within the distal portion of the distal tubular section.

15. A balloon catheter adapted for inserting a drug-coated balloon through a hemostasis valve of a guiding sheath comprising:

a strain relief tube near the proximal end of the balloon catheter;

a protective sleeve removably mounted to the strain relief tube, the protective sleeve having a generally tubular shape, a longitudinal opening extending along the length of the protective sleeve, and a flared end sized to be positioned over a portion of the strain relief tube;

wherein the longitudinal opening along the length of the protective sleeve allows said protective sleeve to be removed from the strain relief and inserted through the hemostasis valve of the guiding sheath to protect the drug-coated balloon as the drug-coated balloon is inserted through said hemostasis valve.

16. The drug-coated balloon catheter of claim 15 wherein the drug-coated balloon is coated with one of Paclitaxel, Sirolimus, or Zotarolimus.

17. The drug-coated balloon of claim 15 wherein the longitudinal opening in the flared end of the protective sleeve is larger than the longitudinal opening in the rest of the protective sleeve.

18. The drug-coated balloon of claim 17 wherein the longitudinal opening in the rest of the protective sleeve is about 0.002 inches.

19. The drug-coated balloon of claim 17 wherein the longitudinal opening in the flared end of the protective sleeve is tapered throughout the flared end and has a maximum opening size of 0.017 inches to 0.023 inches.

20. The drug-coated balloon of claim 17 wherein the diameter in the flared end of the protective sleeve is 0.285 inches to 0.345 inches while the diameter in the rest of the protective sleeve is 0.115 inches to 0.12 inches.

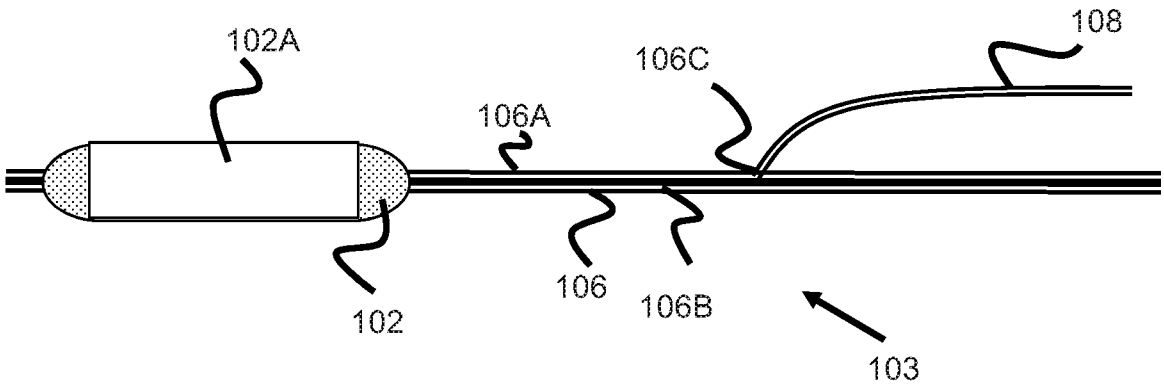

Figure 1a

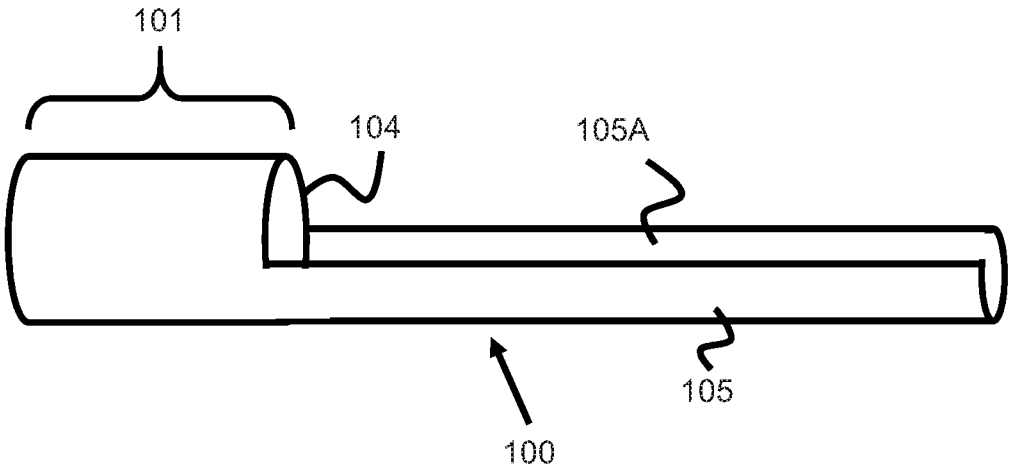

Figure 1b

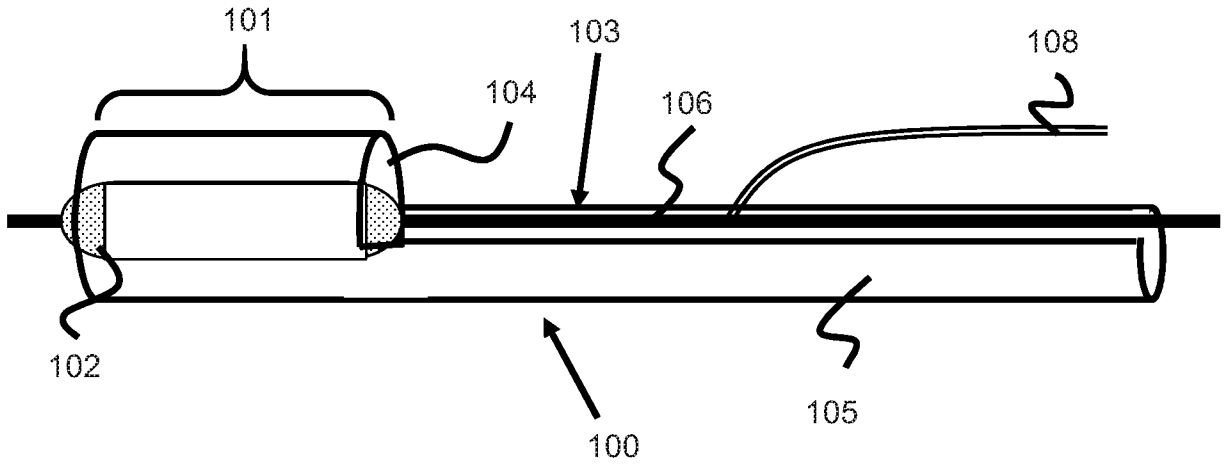

Figure 1c

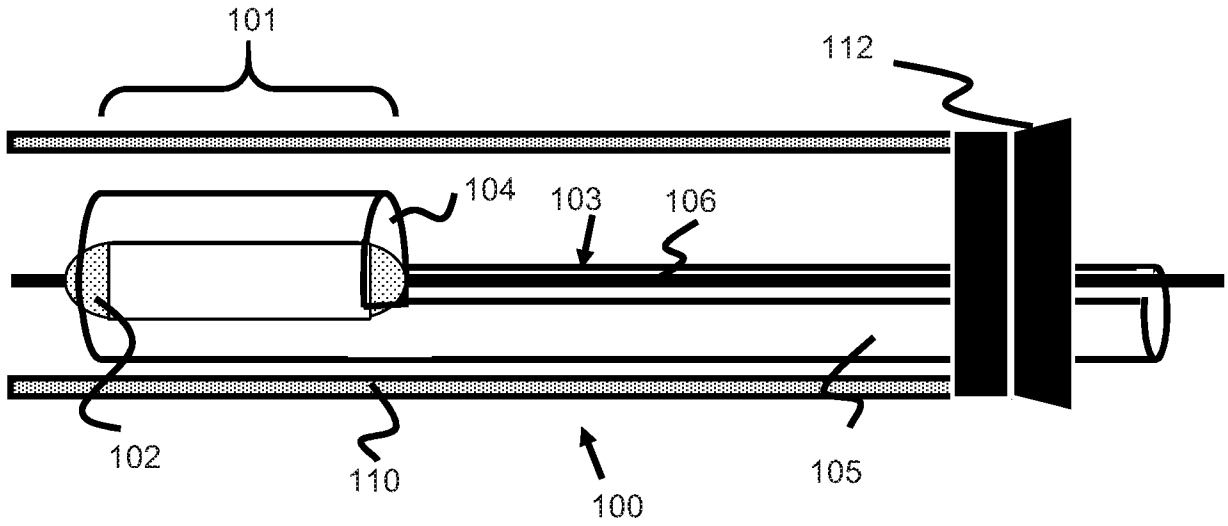

Figure 2

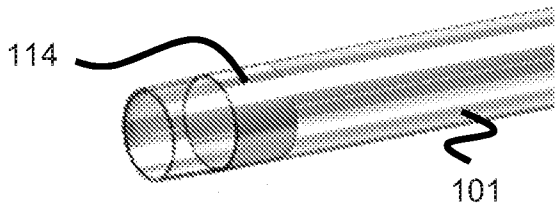

Figure 3a

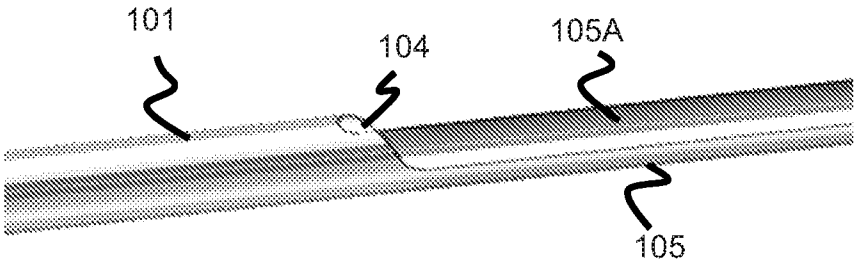

Figure 3b

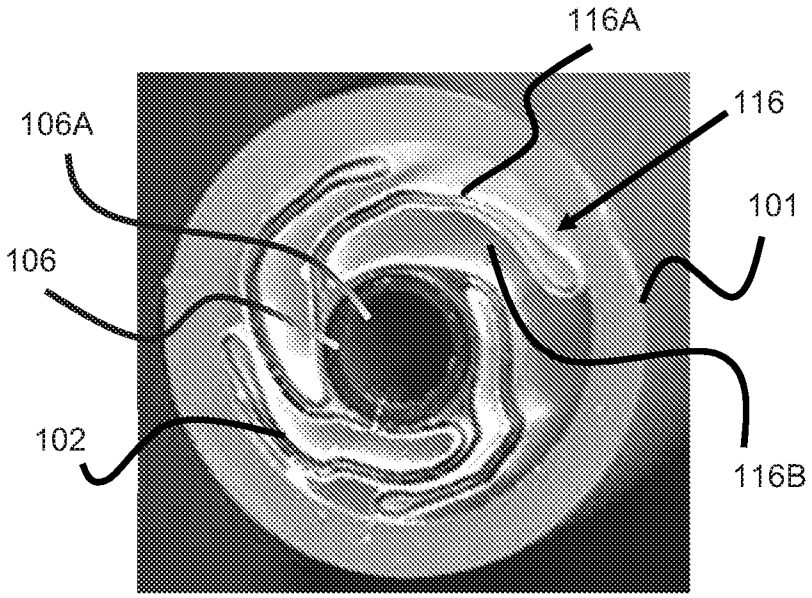

Figure 4

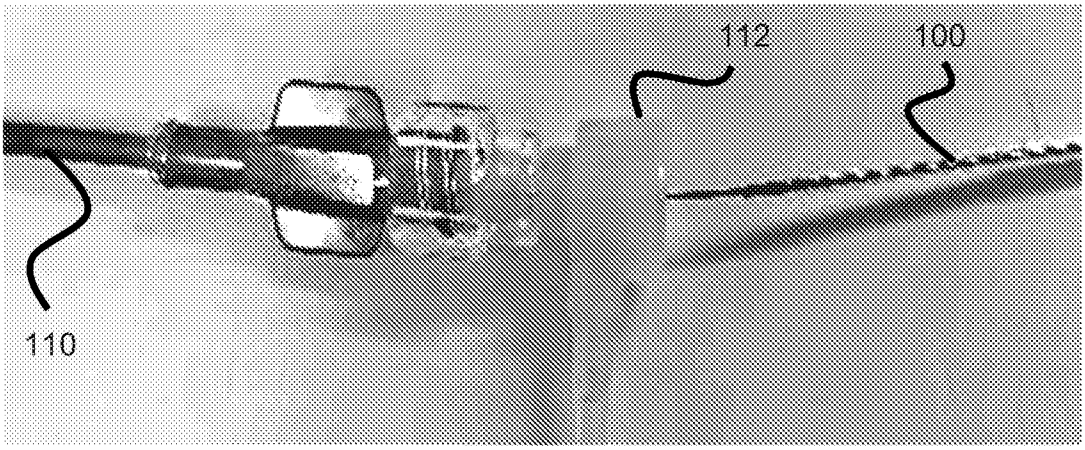

Figure 5

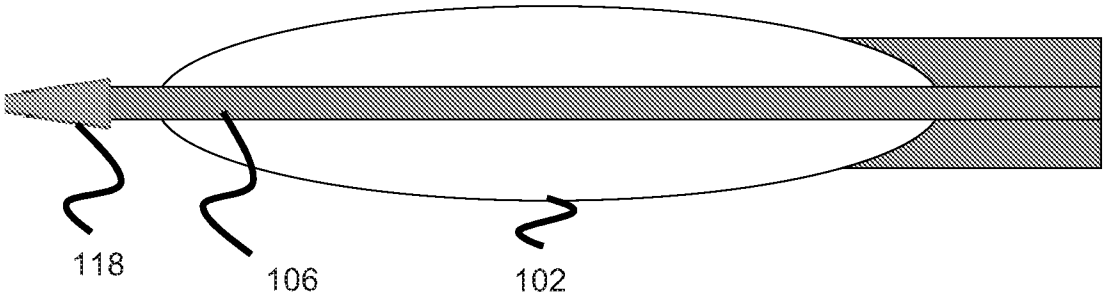

Figure 6

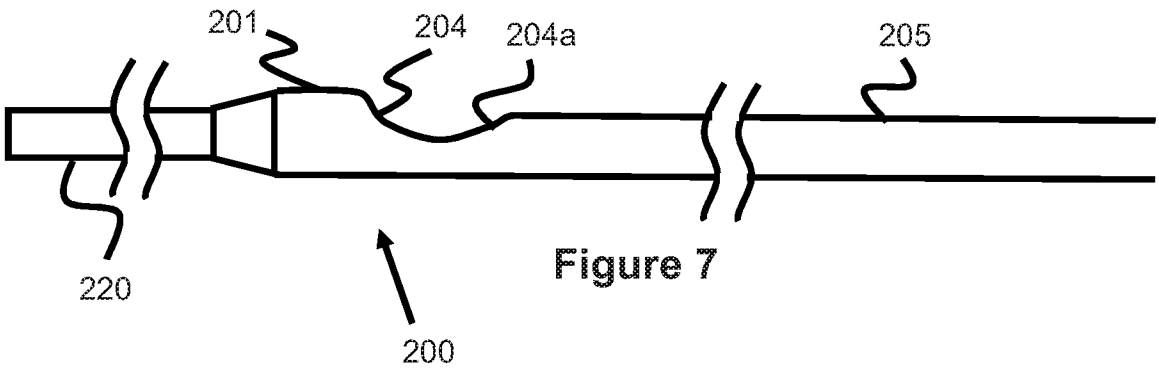

Figure 7

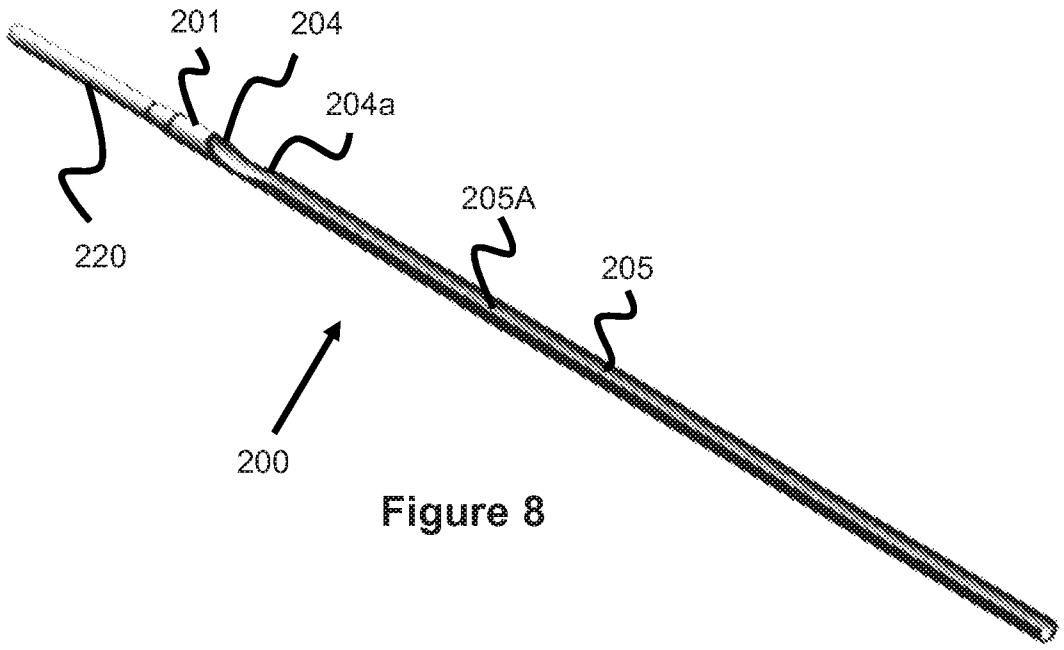

Figure 8

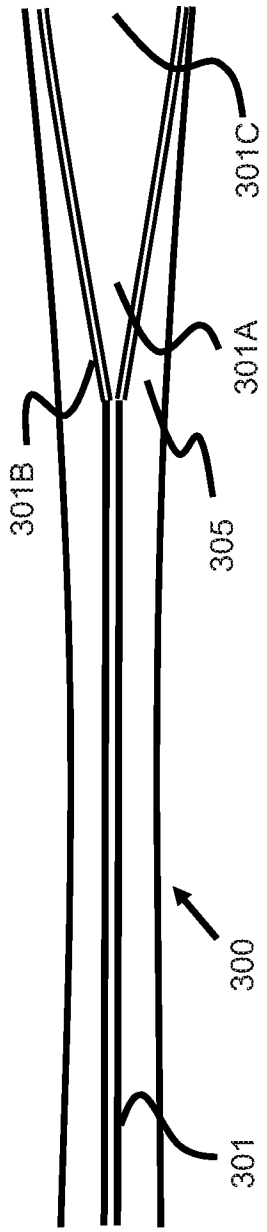

Figure 9

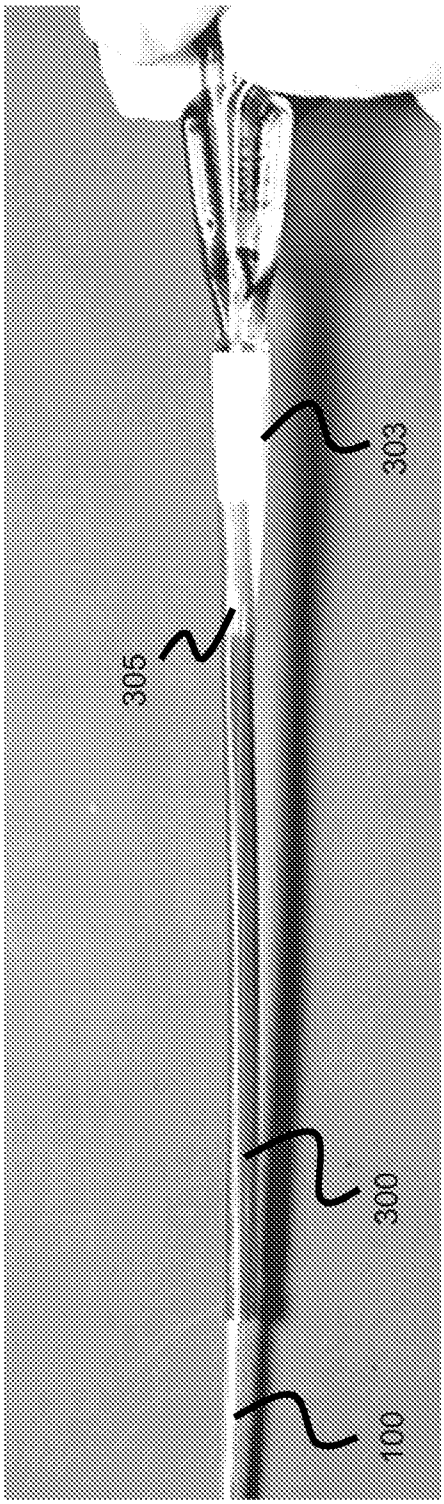

Figure 10

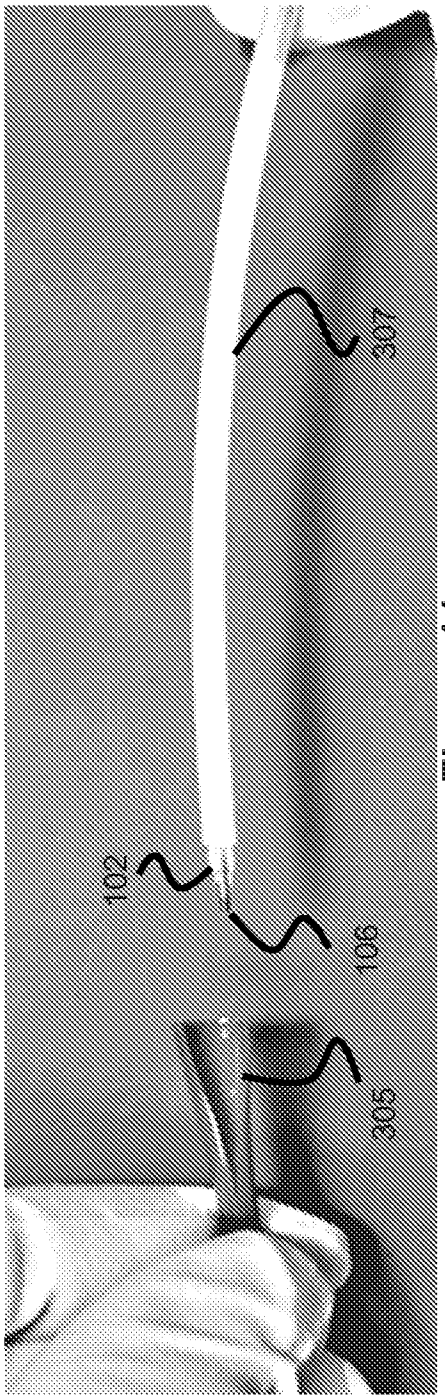

Figure 11

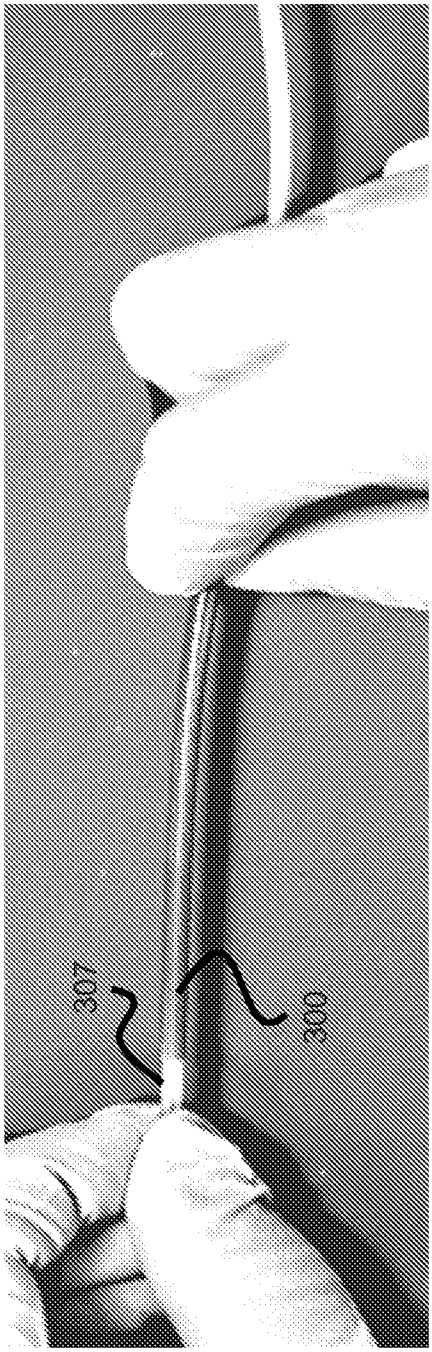

Figure 12

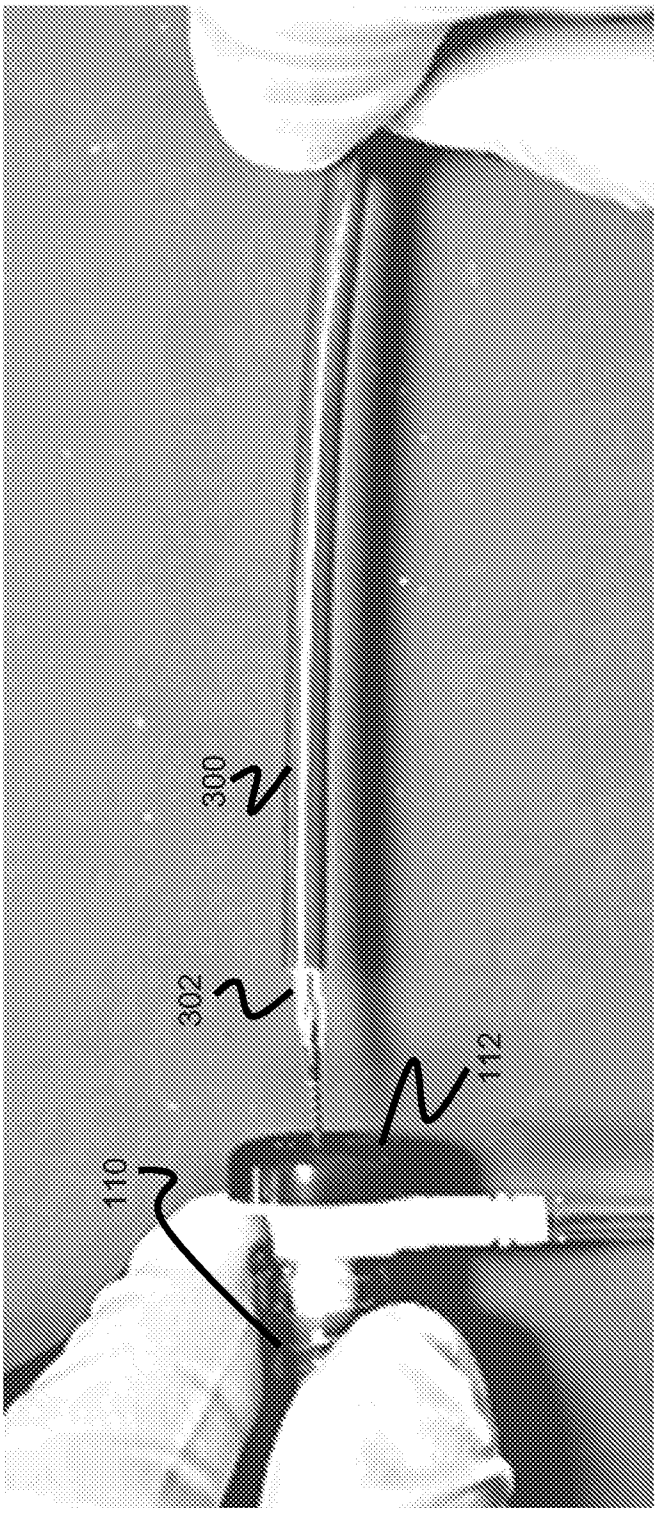

Figure 13

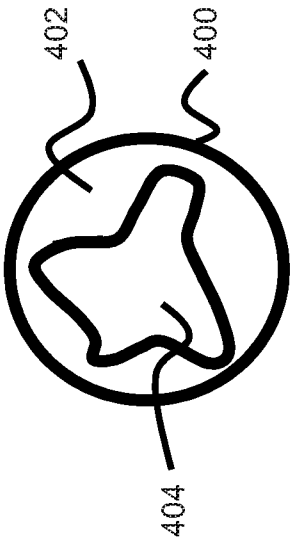

Figure 14

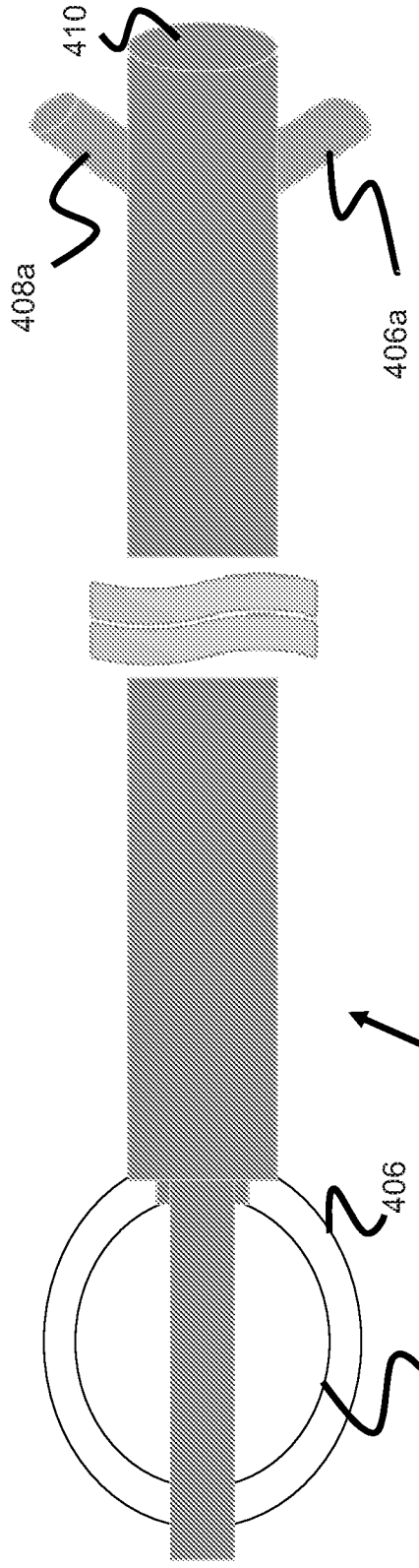

Figure 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/055422

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet(s).

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/055422

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/00; A61F 2/95; A61F 2/962; A61F 2/966 (2018.01)

CPC - A61B 17/12022; A61B 2017/1205; A61F 2/962; A61F 2/966 (2018.01)

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)

See Search History document

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

USPC - 604/93.01; 604/96.01; 604/103.02; 623/1.11 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2016/0074632 A1 (BIOTRONIK AG) 17 March 2016 (17.03.2016) entire document	1, 2, 4-10, 12-14
Y	US 2015/0352340 A1 (BAYER INTELLECTUAL PROPERTY GMBH) 10 December 2015 (10.12.2015) entire document	1, 2, 4-10, 12-14
Y	US 2007/0219612 A1 (ANDREAS et al) 20 September 2007 (20.09.2007) entire document	2, 9
A	US 2009/0227949 A1 (KNAPP et al) 10 September 2009 (10.09.2009) entire document	3, 11
A	US 5,876,374 A (ALBA et al) 02 March 1999 (02.03.1999) entire document	1-14
A	US 9,445,929 B2 (INTACT VASCULAR INC) 20 September 2016 (20.09.2016) entire document	1-14

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 January 2018	01 FEB 2018
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/055422

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees need to be paid.

Group I, claims 1-14 are drawn to a balloon catheter protection system comprising a navigational section and a channel section configured to be pushed or pulled.
Group II, claims 15-20 are drawn to a balloon catheter adapted to be inserted through a hemostasis valve comprising a strain relief tube with a flared end.

The inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, a navigational section comprising an open channel proximally connected to the distal tubular section, the navigational section sized to accommodate an elongated catheter body of the balloon catheter; wherein the navigational section is pushed or pulled to move the distal tubular section and the drug-coated balloon catheter through a guiding sheath, a channel section having an open, arc-shaped cross-section and being disposed proximally adjacent to the distal tubular section; wherein the channel section is pushed or pulled to move the protective sleeve and drug-coated balloon catheter through the guiding sheath, are not present in Group II; and the special technical features of Group II, a strain relief tube near the proximal end of the balloon catheter, a flared end sized to be positioned over a portion of the strain relief tube; wherein the longitudinal opening along the length of the protective sleeve allows said protective sleeve to be removed from the strain relief and inserted through the hemostasis valve of the guiding sheath to protect the drug-coated balloon as the drugcoated balloon is inserted through said hemostasis valve, are not present in Group I.

Groups I and II share the technical features of a balloon protection system comprising a protective sleeve adapted for passage of a drug-coated catheter. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2016/0074632 A1 to Biotronik AG teaches of a balloon protection system (Abstract, para. [0006]) comprising a protective sleeve (Fig. 2A-2C, sleeve 25, para. [0026]) adapted for passage of a drug-coated catheter (Fig. 2A-2C, wherein the sleeve 25 contains catheter 21, wherein the catheter 21 has a drug-coated portion 23b, para. [0026]-[0027]).

Since none of the special technical features of the Group I and II inventions are found in more than one of the inventions, unity is lacking.