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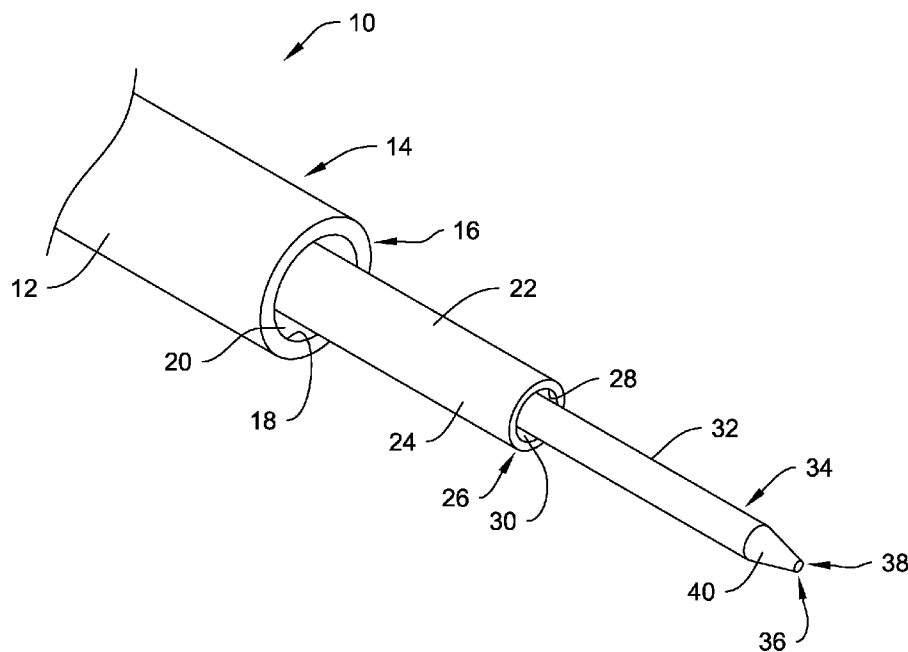
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(54) **Title:** APPARATUS AND METHOD FOR TREATING OCCLUDED VASCULATURE



(57) **Abstract:** Occluded vasculature (284) such as occluded arterial vasculature can be recanalized using a device (10) that is configured to penetrate an occlusion while limiting a distance that said penetration structure can extend in orde to limit inadvertent vascular damage. The device can include an elongate sha (12) of a guidewire and a stylet (32) disposed within a lumen of the elongat shaft (20) such that the stylet is selectively actuatable within the elongat shaft .

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APPARATUS AND METHOD FOR TREATING OCCLUDED VASCULATURE

Cross Reference

5 This is a continuation-in-part of U.S. Application Serial No. 10/877,340, filed on June 24, 2004, the entire disclosure of which is incorporated herein by reference.

Technical Field

10 The invention relates generally to medical devices and more specifically to medical devices configured for recanalization of occluded vasculature.

Background

A number of patients suffer from vascular occlusions. Vascular occlusions can occur in the coronary arteries as well as in peripheral arteries such as those found
15 in a patient's legs. Occlusions can be partial occlusions that reduce blood flow through the occluded portion of an artery. Occlusions can also be total occlusions, which substantially reduce or even completely eliminate blood flow through the occluded portion of the artery. Total occlusions such as chronic total occlusions can be difficult to traverse with existing catheters and guidewires, as they can include stiff
20 or tough portions at their proximal and distal limits.

Physicians have attempted to cross or recanalize chronically totally occluded blood vessels such as arteries using a variety of devices and techniques. Unfortunately, many of these devices and techniques have relatively low rates of success and relatively high rates of complications. A particular issue is penetrating a
25 proximal cap of an occlusion without damaging the surrounding blood vessel, as proximal caps can have a curved or angled configuration that guides devices into the vessel wall or perhaps into a branch vessel.

Therefore, a need remains for a safe and effective way to penetrate and traverse occlusions such as chronic total occlusions. A need remains for a safe and
30 effective way to penetrate and traverse difficult portions of an occlusion such as a proximal cap, which then allows traversing of the remainder of the occlusion with a conventional guidewire, catheter or other device.

Summary

The invention is directed to apparatus and methods for recanalizing occluded vasculature such as occluded arterial vasculature. The invention provides a device that includes structure that is configured to penetrate an occlusion while limiting a distance that the penetration structure can extend in order to limit inadvertent vascular damage. Further, a preferred embodiment of the device provides means for centering the penetration into the proximal cap or other difficult portion of an occlusion. In preferred embodiments, the device provides means for advancement through the center of the occlusion.

Accordingly, an example embodiment of the invention can be found in an apparatus that includes an elongate sheath having a distal region, a proximal region and an inner surface defining a lumen extending therebetween. A stylet is disposed within the elongate sheath. The stylet includes a lumen extending from a distal region to a proximal region of the stylet. The elongate sheath and the stylet include, in combination, an engagement section that is configured to limit relative axial movement between the elongate sheath and the stylet.

Another example embodiment of the invention can be found in a recanalization assembly that includes a catheter having a distal region, a proximal region and a lumen extending therebetween. An elongate sheath is disposed within the catheter lumen and has a distal region, a proximal region and an inner surface defining a lumen extending therebetween. A stylet is disposed within the elongate sheath and has a distal region comprising a cutting surface, a proximal region and a lumen extending therebetween. The elongate sheath and the stylet include, in combination, an engagement section that is configured to limit relative axial movement between the elongate sheath and the stylet.

Another example embodiment of the invention can be found in an assembly that is configured for traversing a chronic total occlusion. The assembly includes an elongate shaft that has a distal region, a proximal region and a lumen extending therebetween. The assembly also includes a penetrating structure that is disposed within the elongate shaft lumen. The penetrating structure is disposed within the lumen such that relative axial movement between the elongate shaft and the penetrating structure is limited.

Another example embodiment of the invention can be found in a method of traversing a vascular occlusion. An apparatus including an elongate shaft and a stylet

disposed within the elongate shaft is positioned such that a distal region of the apparatus is proximate an occlusion. The stylet is advanced distally such that a distal region of the stylet that includes a cutting surface extends distally beyond a distal region of the elongate shaft and contacts a surface of the occlusion. The stylet is moved such that its cutting surface contacts and penetrates the occlusion. Provision is also made for injecting contrast media to aid in visualization. Additional medical devices may be advanced over the elongate shaft during a medical procedure.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIG. 1 is a perspective view of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 2 is a plan view of a catheter in accordance with an embodiment of the invention;

FIG. 3 is a cross-sectional view of the catheter of FIG. 1 taken along 3-3 line;

FIG. 4 is a plan view of a balloon catheter in accordance with an embodiment of the invention;

FIG. 5 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 6 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 7 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 8 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 9 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 10 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

5 FIG. 11 is a partially sectioned view of the distal portion of a recanalization apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIG. 12 is a partially sectioned view of the distal portion of an apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

10 FIG. 13 is a partially sectioned view of the distal portion of an apparatus for penetrating a vascular occlusion in accordance with an embodiment of the invention;

FIGS. 14-21 illustrate a particular use of the apparatus for penetrating a vascular occlusion;

FIGS. 22A and 22B are cross-sectional views illustrating another exemplary apparatus for penetrating a vascular occlusion;

15 FIGS. 23A and 23B are cross-sectional views illustrating another exemplary apparatus for penetrating a vascular occlusion; and

FIGS. 24A and 24B are cross-sectional views illustrating another exemplary apparatus for penetrating a vascular occlusion.

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Detailed Description

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

25 All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms “about” may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

30 As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The drawings, which are not necessarily to scale, depict illustrative embodiments of the claimed invention.

5 FIG. 1 is a perspective view of a recanalization assembly 10 in accordance with an embodiment of the present invention. The recanalization assembly 10 includes an elongate shaft 12 that has a distal region 14 defining a distal end 16. An inner surface 18 defines a shaft lumen 20. A sheath 22 is at least partially disposed within the shaft lumen 20. The sheath 22 includes a distal region 24 defining a distal end 26. An inner surface 28 defines a sheath lumen 30. A stylet 32 is at least partially disposed within the sheath lumen 30. The stylet 32 includes a distal region 34 defining a distal end 36. The distal end 36 includes an aperture 38 suitable to accommodate a guidewire as will be discussed in greater detail hereinafter. In the illustrated embodiment, the distal region 34 is defined at least in part by a needle tip 15 40 that can be configured for penetration into an occlusion.

In use, as will be discussed in greater detail hereinafter, the sheath 22 can be moved axially with respect to the elongate shaft 12. In some embodiments, the elongate shaft 12 can be advanced through a patient's vasculature before the sheath 22 has been deployed within the shaft lumen 20. Once the elongate shaft 12 has reached 20 an appropriate position, the sheath 22 can be advanced distally through the shaft lumen 20. In other embodiments, the elongate shaft 12 can be advanced through the patient's vasculature with the sheath 22 already positioned within the shaft lumen 20.

The sheath 22 can be advanced distally so that its distal end 26 extends distally beyond the distal end 16 of the elongate shaft 12. The stylet 32 can move with respect 25 to the sheath 22. In some embodiments, the stylet 32 can be moved axially such that its distal end 36 extends distally beyond the distal end 26 of the sheath 22. In some embodiments, the stylet 32 can undergo reciprocal motion so that the needle tip 40 can penetrate into an occlusion. In some embodiments, the stylet 32 can also rotate to aid in occlusion penetration. The stylet 32 can be made to move axially and/or 30 rotationally using any known technique or method, both manual and mechanical means included.

FIG. 2 is a plan view of a catheter 42 in accordance with an embodiment of the invention. In some embodiments, the shaft 44 can be any of a variety of different catheters, but is preferably an intravascular catheter and will be discussed with respect

to a catheter 42. Examples of intravascular catheters include balloon catheters, atherectomy catheters, drug delivery catheters, diagnostic catheters and guide catheters. Except as described herein, the catheter 42 can be manufactured using conventional techniques and materials.

5 The catheter 42 can be sized in accordance with its intended use. The catheter 42 can have a length that is in the range of about 50 centimeters to about 100 centimeters and can have a diameter that is in the range of about 4F (French) to about 9F.

10 In the illustrated embodiment, the catheter 42 includes an elongate shaft 44 that has a proximal region 46, a distal region 48 and a distal end 50. A hub and strain relief assembly 52 can be connected to the proximal region 46 of the elongate shaft 44. The hub and strain relief assembly 52 includes a main body portion 54, a pair of flanges 56 designed to improve gripping, and a strain relief 58 that is intended to reduce kinking. The hub and strain relief assembly 52 can be of conventional design
15 and can be attached using conventional techniques.

 FIG. 3 is a cross-sectional view of one example of the elongate shaft 44 taken along line 3-3 of FIG. 2. The elongate shaft 44 includes an outer layer 60 and an inner layer 62. Each of the outer layer 60 and the inner layer 62 can extend from the proximal region 46 of the elongate shaft 44 to the distal region 48 of the elongate
20 shaft 44. The inner layer 62 defines a lumen 64 that extends through the elongate shaft 44.

 In some embodiments, the elongate shaft 44 can include a reinforcing braid or ribbon layer 66 to increase particular properties such as kink resistance. The reinforcing braid or ribbon layer 66 can be positioned between the outer layer 60 and
25 the inner layer 62 and can provide adequate kink resistance without substantially increasing the overall profile of the elongate shaft 44. Alternatively, a single layer shaft can be utilized. An inflation lumen can also be provided, whether coaxial or in a multi-lumen co-extrusion, for example.

 In some embodiments (not illustrated), the elongate shaft 44 can include one
30 or more shaft segments having varying degrees of flexibility. For example, the elongate shaft 44 can include a proximal segment, an intermediate segment and a distal segment. In some embodiments, the elongate shaft 44 can also include a distal tip segment that can be formed from a softer, more flexible polymer. The elongate

shaft 44 can include more than three segments, or the elongate shaft 44 can include fewer than three segments.

If the elongate shaft 44 has, for example, three segments such as a proximal segment, an intermediate segment and a distal segment, each segment can include an inner layer 62 that is the same for each segment and an outer layer that becomes
5 increasingly more flexible with proximity to the distal end 50 of the elongate shaft 44. For example, the proximal segment can have an outer layer that is formed from a polymer having a hardness of 72D (Durometer), the intermediate segment can have an outer layer that is formed from a polymer having a hardness of 68D and the distal
10 segment can be formed from a polymer having a hardness of 46D.

If the elongate shaft 44 has three segments, each of the segments can be sized in accordance with the intended function of the resulting catheter 42. For example, the proximal segment can have a length of about 35 inches, the intermediate segment can have a length that is in the range of about 2 inches to about 3 inches, and the distal
15 segment can have a length that is in the range of about 1 inch to about 1.25 inches.

The inner layer 62 can be a uniform material and can define a lumen 64 that can run the entire length of the elongate shaft 44 and that is in fluid communication with a lumen (not illustrated) extending through the hub assembly 52. The lumen 64 defined by the inner layer 62 can provide passage to a variety of different medical
20 devices such as the sheath 22 (see FIG. 1), and thus the inner layer 62 can include, be formed from or coated with a lubricious material to reduce friction within the lumen 64. An exemplary material is polytetrafluoroethylene (PTFE), better known as TEFLON®. The inner layer 62 can be dimensioned to define a lumen 64 having an appropriate inner diameter to accommodate its intended use. In some embodiments,
25 the inner layer 62 can define a lumen 64 having a diameter of about 0.040 inches to about 0.058 inches, and the inner layer 62 can have a wall thickness of about 0.001 inches.

The outer layer 60 can be formed from any suitable polymer that will provide the desired strength, flexibility or other desired characteristics. Polymers with low
30 durometer or hardness can provide increased flexibility, while polymers with high durometer or hardness can provide increased stiffness. In some embodiments, the polymer material used is a thermoplastic polymer material. Some examples of some suitable materials include polyurethane, elastomeric polyamides, block polyamide/ethers (such as PEBAX®), silicones, and co-polymers. The outer layer 60

can be a single polymer, multiple layers, or a blend of polymers. By employing careful selection of materials and processing techniques, thermoplastic, solvent soluble, and thermosetting variants of these materials can be employed to achieve the desired results.

5 In particular embodiments, a thermoplastic polymer such as a co-polyester thermoplastic elastomer such as that available commercially under the ARNITEL® name can be used. The outer layer 60 can have an inner diameter that is about equal to the outer diameter of the inner layer 62.

10 In some embodiments, the outer layer 60 can have an inner diameter in the range of about 0.014 inches to about 0.060 inches and an outer diameter in the range of about 0.018 inches to about 0.0690 inches. Part or all of the outer layer 60 can include materials added to increase the radiopacity of the outer layer 60, such as 50% bismuth subcarbonate.

15 In particular embodiments, the catheter 44 can be a balloon catheter such as the balloon catheter 68 illustrated in FIG. 4. FIG. 4 is a plan view of a balloon catheter 68 that is similar in construction to the catheter 42, but includes a balloon 70 and an inflation lumen. As illustrated, the balloon 70 has a proximal waist 72, a distal waist 74 and an intermediate portion 76. The balloon 70 is seen in an expanded or inflated configuration. Construction of the balloon catheter 68 is conventional. Use
20 of the balloon catheter 68 as the shaft 14 can have advantages that will be discussed in greater detail hereinafter.

FIGS. 5 through 11 illustrate particular embodiments of recanalization assemblies employing a balloon catheter 68 (see FIG. 4) in accordance with the invention. Turning to FIG. 5, a distal portion of a recanalization assembly 78 is
25 illustrated. The balloon catheter 68 defines a lumen 80 that is sized to accept an elongate sheath 82 that has a proximal region 84, a distal region 86 and a distal end 88. The lumen 80 can have an inner diameter that is in the range of about 0.014 to about 0.035 inches, which corresponds to typical guidewire dimensions.

30 The sheath 82 has an inner surface 90 defining a sheath lumen 92. The sheath 82 can be formed of any suitable polymeric material such as those discussed above with respect to the catheter 42 (see FIG. 2). The sheath 82 can also be formed of a suitable metallic material, such as nitinol, stainless steel, Elgiloy® and other alloys, that has been slit or otherwise processed to provide suitable flexibility and other desired characteristics. The sheath 82 can have an outer diameter of about 0.010

inches to about 0.035 inches, preferably about 0.014 inches to about 0.020 inches and an inner diameter of about 0.006 inches to about 0.030 inches, preferably about 0.008 inches to about 0.014 inches. The sheath 82 can have a length that is in the range of about 80 cm to about 150 cm, preferably about 135 cm.

5 A stylet 94 is disposed within the sheath lumen 92. The stylet 94 has a proximal region 96, a distal region 98 and a distal end 100. The distal region 98 can have an outer diameter that is in the range of about 0.004 to about 0.014 inches in order to minimize inadvertent tissue damage. The stylet 94 can have a length that is in the range of about 80 cm to about 150 cm. The distal region 98 includes a cutting
10 surface 102 that as illustrated can be a needle tip. The stylet 94 can be formed of any suitable material. Exemplary materials include metals such as stainless steel, nitinol, Elgiloy®, titanium or other alloys. Although not shown in FIG. 5, the stylet can include a lumen therethrough in some preferred embodiments, as shown in FIG. 1. The lumen allows passage of a guidewire after the occlusion is penetrated.

15 As can be seen, the stylet 94 can be moved axially within the sheath 82, and the sheath 82 can be moved axially within the balloon catheter 68. In other embodiments, the recanalization assembly 78 can include structure that limits relative axial travel between the sheath 82 and the stylet 94. The stylet in FIGS. 5-11 can pierce the proximal or distal cap of the occlusion via application of a forward pushing
20 force, alone or in combination with a turning action imparted to the stylet. The turning action can be applied to the stylet as shown in FIG. 1 by digital manipulation or mechanical means (not shown). These embodiments are shown, for example, in FIGS. 6-11.

Turning now to FIG. 6, a recanalization assembly 104 is illustrated as
25 including the balloon catheter 68. A sheath 106 having a proximal region 108, a distal region 110 and a distal end 112 is disposed within the lumen 80. The sheath 106 includes an inner surface 114 defining a sheath lumen 116. A stylet 118 having a proximal region 120, a distal region 122 and a distal end 124 is disposed within the sheath lumen 116. The distal region 122 can define a cutting surface 126. The sheath
30 106 and the stylet 118 can be formed of any suitable materials and have any suitable dimensions as discussed with respect to FIG. 5.

The recanalization assembly 104 includes an engagement section 128 that is configured to limit relative axial movement between the sheath 106 and the stylet 118. The engagement section 128 can be positioned anywhere along the sheath 106 and the

stylet 118. In some embodiments, as illustrated, the engagement section 128 can be positioned proximate the distal region of the sheath 106 and the stylet 118 for greater control and accuracy.

In the illustrated embodiment, the sheath 106 includes a stop 130 that can be a cylindrical stop having an inner diameter that is less than an inner diameter of the sheath 106 on either side of the stop 130. The stop 130 can be integrally formed with the sheath 106 or can be independently formed and subsequently secured using any suitable technique. In some embodiments, the stop 130 can continue for an entire circumference (360 degrees) of the sheath 106. In other embodiments, the stop 130 can include one or more distinct sections spaced apart along the circumference of the sheath 106.

The stylet 118 includes an engagement portion 132 that has a proximal end 134 and a distal end 136. The engagement portion 132 can have an outer diameter that is reduced with respect to an outer diameter of the stylet 118 on either side of the engagement portion 132. As can be seen, distal movement of the stylet 118 is limited by the stop 130 contacting the proximal end 134 of the engagement portion 132. Similarly, proximal movement of the stylet 118 is limited by the stop 130 contacting the distal end 136 of the engagement portion.

In some embodiments, the stylet 118 can be withdrawn proximally such that the cutting surface 126 is completely within the sheath lumen 116. This permits extending the sheath 106 distally through the balloon catheter lumen 80 without contacting the vasculature distal of the balloon catheter 68. In some embodiments, the distal end 124 of the stylet 118 can extend beyond the distal end 112 of the sheath 106 even when withdrawn.

Turning now to FIG. 7, a recanalization assembly 138 is illustrated as once again including the balloon catheter 68. A sheath 140 having a proximal region 142, a distal region 144 and a distal end 146 is disposed within balloon catheter lumen 80. The sheath 140 includes an inner surface 148 that defines a sheath lumen 150. A stylet 152 having a proximal region 154, a distal region 156 and a distal end 158 is disposed within the sheath lumen 150. The distal region 158 includes a cutting surface 160 that can in some embodiments be a needle tip. The sheath 140 and the stylet 152 can be formed of any suitable materials and have any suitable dimensions as discussed with respect to FIG. 5. As with prior embodiments, the stylet 152 can include a lumen therethrough (now shown) for passage of a guidewire.

The recanalization assembly 138 includes an engagement section 162 that is configured to limit relative axial movement between the sheath 140 and the stylet 152. The sheath 140 includes an engagement portion 164 having a proximal end 166 and a distal end 168. The engagement portion 164 has an inner diameter that is greater than an inner diameter of the sheath 140 on either side of the engagement portion 164. The engagement portion 164 can be integrally formed with the sheath 140, or the sheath 140 can be formed and material can subsequently be removed using any suitable technique to form the increased inner diameter engagement portion 164.

The engagement section 162 also refers to a portion of the stylet 152. The stylet 152 includes a stop 170 that has an outer diameter that is greater than an outer diameter of the stylet 152 on either side of the stop 170. In some embodiments, the stop 170 can continue for an entire circumference (360 degrees) of the stylet 152. In other embodiments, the stop 170 can include one or more distinct sections spaced apart along the circumference of the stylet 152. As can be seen, proximal movement of the stylet 152 is limited by the stop 170 contacting the proximal end 166 of the engagement portion 164. Similarly, distal movement of the stylet 152 is limited by the stop 170 contacting the distal end 168 of the engagement portion 164.

In some embodiments, the distal end 158 of the stylet 152 can remain proximal of the distal end 146 of the sheath 140, while in other embodiments, the distal end 158 of the stylet 152 can extend distally beyond the distal end 146 of the sheath 140 when the stylet 152 is completely retracted.

In comparing FIG. 6 to FIG. 7, it is clear that the stylet 152 of FIG. 7 is narrower than the stylet 118 of FIG. 6. In some embodiments, a thinner stylet can be advantageous as this can provide for additional flexibility. In other embodiments, a stronger or stiffer stylet can permit application of additional force in attempting to break through an occlusion. The sheath 140 of FIG. 7 has thicker walls than the sheath 106 of FIG. 6. In some embodiments, a thicker-walled sheath can be advantageous as this can provide for additional pushability. In other embodiments, a thinner-walled sheath may be more flexible.

Turning now to FIG. 8, a recanalization assembly 172 is illustrated as including the balloon catheter 68. A sheath 174 having a proximal region 176, a distal region 178 and a distal end 180 is disposed within balloon catheter lumen 80. The sheath 174 includes an inner surface 182 that defines a sheath lumen 184. A stylet 186 having a proximal region 188, a distal region 190 and a distal end 192 is

disposed within the sheath lumen 184. The distal region 190 includes a cutting surface 194 that can in some embodiments be a needle tip. The sheath 174 and the stylet 186 can be formed of any suitable materials and have any suitable dimensions as discussed with respect to FIG. 5. Further, the stylet can include a lumen therethrough for guidewire passage.

The recanalization assembly 172 includes an engagement section 196 that is configured to limit distal travel of the stylet 186 with respect to the sheath 174. The sheath 174 includes an engagement portion 198 having an inner diameter that is reduced with respect to an inner diameter of the sheath 174 proximal of the engagement portion 198. The engagement portion 198 terminates at a distal stop 200.

The engagement section 196 also pertains to the distal region 190 of the stylet 186, which terminates at a proximal stop 200. The distal region 190 has a reduced outer diameter with respect to an outer diameter of the stylet 186 proximal of the engagement section 196. As can be seen, distal travel of the stylet 186 is limited by the proximal stop 202 of the stylet 186 contacting the distal stop 200 of the sheath 174. In this embodiment, the stylet 186 can be completely removed proximally from the sheath 174, should there be a need to inject contrast fluid or deploy a different device.

In some embodiments, the distal end 192 of the stylet 186 can remain proximal of the distal end 180 of the sheath 174, while in other embodiments the distal end 192 of the stylet 186 can extend distally beyond the distal end 180 of the sheath 174 when the stylet 186 is completely retracted.

In some embodiments, such as illustrated in FIG. 9, a second sheath 204 can be deployed inside the balloon catheter lumen 80 but exterior to the sheath 174. The second sheath 204 has a proximal region 206, a distal region 208 and a distal end 210. The second sheath 204 can be used in situations in which the sheath 174 has an outer diameter that is somewhat less than an inner diameter of the balloon catheter lumen 80 in order to reduce the size differential between the balloon catheter 68 and the sheath 174 and to provide for easier exchange for other devices. The second sheath 204 can extend across the opening in the distal cap and hold in position to allow the sheath and stylet to be exchanged for a guidewire. In some embodiments, the second sheath 204 can have an inner diameter that is about 0.010 to about 0.014 inches and an outer diameter that is about 0.014 to about 0.018 inches in order to account for

standard guidewire sizes. The second sheath 204 can be formed of any suitable material as discussed with respect to the catheter 42 (see FIG. 2).

In some embodiments, the second sheath 204 can be employed in order to move the sheath 174 and the stylet 186 distally further from the balloon 76. While FIG. 9 shows the second sheath 204 deployed with the recanalization assembly 172
5 illustrated in FIG. 8, it is important to note that the second sheath 204 can also be used with the embodiments illustrated in the previous Figures.

In a similar embodiment, shown in FIG. 10, recanalization assembly 172 includes a balloon catheter 212 having a balloon 214. The balloon 214 has a proximal waist 216, a distal waist 218 and an intermediate portion 220. The balloon catheter
10 212 differs from the balloon catheter 68 previously described herein by virtue of having a shaft 222 that extends distally beyond the balloon 214. The shaft 222 includes a distal region 224 that can function to allow the shaft 222 to extend across the opening that is made in the proximal cap and then allow the shaft and stylet to be
15 withdrawn and replaced by a guidewire suitable for extending further through the occlusion. While FIG. 10 shows the elongated balloon catheter shaft 222 deployed with the recanalization assembly 172, it is important to note that the elongated balloon catheter shaft 222 can be used with the embodiments illustrated in the previous
Figures.

FIG. 11 shows another embodiment related to that of FIG. 6. FIG. 11
20 illustrates a recanalization assembly 226 deployed within the balloon catheter 68 previously described. In this embodiment, however, the engagement section 228 includes biasing structure that can be used to forcibly move the stylet 118 distally with respect to the sheath 106. Any suitable biasing structure, such as a resilient
25 material or spring, can be used.

In the illustrated embodiment, the biasing structure includes one or more proximal springs 230 that are positioned between the stop 130 and the proximal end 134 of the engagement portion 132 and one or more distal springs 232 that are positioned between the stop 130 and the distal end 136 of the engagement portion
30 132. In some embodiments, the biasing structure can include only the proximal springs 230, with the distal springs 232 being absent. In other embodiments, the biasing structure can include only the distal springs 232, with the proximal springs 230 being absent.

In use, the stylet 118 can be moved proximally. In the illustrated embodiment, moving the stylet 118 proximally can compress the proximal springs 230 from their equilibrium length with extending the distal springs 232 from their equilibrium length. Letting go of the stylet 118 will permit the proximal springs 230 and the distal springs
5 232 to release the potential energy stored therein as a result of their displacement from their equilibrium lengths. As a result, the stylet 118 can be driven forcibly in a distal direction such that the cutting surface 126 can contact and penetrate an occlusion.

FIGS. 12 and 13 illustrate other embodiments of the invention that employ a piercing catheter. In particular, FIG. 12 shows a piercing catheter 234 having a
10 proximal region 236, a distal region 238 and a distal end 240. The piercing catheter 234 includes an elongate shaft 242 that has an inner surface 244 defining a shaft lumen 246. A stylet 248 is disposed within the shaft lumen 246. The stylet 248 has a proximal region 250, a distal region 252 and a distal end 254. The stylet 248 has a stylet lumen 259 that extends from the proximal region 250 through the distal region
15 252. The distal region 252 of the stylet 248 includes an angled cutting needle surface 254.

The piercing catheter 234 can be formed of any suitable materials such as those discussed above with respect to the catheter 42 (see FIG. 2). Exemplary materials for forming the shaft 242 include nylon, PEBAX®, polyethylene,
20 polyurethane and copolymers thereof. Further, the shaft can be metallic, with or without slots. The shaft 242 can have a length that is in the range of about 80 cm to about 150 cm. The shaft 242 can have an outer diameter that is in the range of about 0.012 inches to about 0.035 inches and an inner diameter that is in the range of about 0.008 inches to about 0.030 inches. The stylet 248 can be formed of any suitable
25 material including stainless steel, nitinol, Elgiloy®, other alloys or polymers and can have a length that is in the range of about 80 cm to about 150 cm, an outer diameter that is in the range of about 0.007 inches to about 0.031 inches and an inner diameter that is in the range of about 0.005 inches to about 0.027 inches.

The piercing catheter 234 includes an engagement section 257 that is
30 configured to limit relative axial movement between the elongate shaft 242 and the stylet 248. The inner surface 244 of the elongate shaft 242 includes an engagement portion 258 that has an inner diameter that is less than an inner diameter of the elongate shaft 242 on either side of the engagement portion 258. The engagement portion 258 has a proximal end 260 and a distal end 262. The engagement portion

258 can have a length between the proximal end 260 and the distal end 262 that is in the range of about 2 mm to about 10 mm, preferably about 3 mm to about 6 mm.

The engagement section 257 also pertains to the stylet 248. The stylet 248 has a stop 264 that has a larger outer diameter than an outer diameter of the stylet 248 on either side of the stop 264. In some embodiments, the stop 264 can be a cylindrical stop that extends circumferentially all the way around the stylet 248 while in other embodiments the stop 264 can include one or more distinct sections that are circumferentially spaced around the stylet 248. As can be seen, proximal travel of the stylet 248 is limited by the stop 264 contacting the proximal end 260 of the engagement portion 258 while distal travel of the stylet 248 is limited by the stop 264 contacting the distal end 262 of the engagement portion 258.

In some embodiments, the stylet 248 can extend proximally through the elongate shaft 242. In other embodiments, as illustrated, the stylet 248 can be shorter than the elongate shaft 242. A pushing tube 266 can have a proximal region 268, a distal region 270 and a distal end 272. The distal end 272 of the pushing tube 266 can contact a proximal end 274 of the stylet 248. In some embodiments, there may be advantages in having a shortened stylet 248 disposed in the distal region 238 of the piercing catheter 234 while a pushing tube 266 having different strength and flexibility characteristics is disposed proximally thereof. The stylet lumen 259 can, in some embodiments, allow for passage of a guidewire through the surface 254 after the stylet 248 has crossed the proximal cap. The angled cutting surface 254 allows the stylet 248 to be rotated within the sheath and allows the tip 265 of the stylet to be centered on the proximal cap via fluoroscopic imaging techniques.

FIG. 13 shows a similar embodiment in which the distal region 252 of the stylet 248 includes a cylindrical cutting edge 268 rather than the angled cutting needle surface 256 shown in FIG. 12. FIG. 13 shows a stylet 248 that extends proximally and thus inclusion of a pushing tube 266 is not necessary. The embodiment shown in FIG. 13 also adds an optional second sheath 270 to the piercing catheter 234 to function similar to the second sheath 204 shown in FIG. 9. The stylet 248 can be rotated to assist in crossing the proximal cap.

FIGS. 14 through 17 illustrate a possible use of the recanalization assemblies described herein. In FIG. 14, an introducer sheath 276 having a proximal region 278 and a distal region 280 has been introduced through a patient's tissue 282 into the patient's vasculature 284 as is well known in the art. A catheter 286 that in some

embodiments can be a balloon catheter has been inserted into the proximal region 278 of the introducer sheath 276 and has been advanced to a position near a desired treatment site, such as an occlusion 288 having a proximal cap 308, distal cap 290 and side branch 291. The catheter 286 has a proximal region 290 and a distal region 292.

5 Turning now to FIG. 15, a sheath 294 having a proximal region 296 and a distal region 298 can be deployed within the catheter 286. The catheter 286 includes a balloon 314 that can be inflated prior to deploying the sheath 294. The balloon can be a dilating balloon or a gentle elastomeric centering balloon made from, for example, latex or polyurethane. In some embodiments, there may be advantages in
10 deploying the sheath 294 prior to inflating the balloon 314. The balloon 314, once inflated, can aid in centering the sheath 294 and thus can assist the sheath 294 and enclosed stylet 300 in properly contacting the occlusion 288 without damaging the vessel wall. The stylet 300 has a proximal region 302 and a distal region 304. The distal region 304 includes a needle tip 306 that is positioned (as illustrated) proximate
15 the occlusion 288.

As seen in FIG. 16, the stylet 300 can be moved distally such that the distal region 304 of the stylet 300 penetrates at least partially into the occlusion 288. The stylet 300 can be axially moved back and forth to aid in penetrating the occlusion 288. In some embodiments, the stylet 300 can be rotated and in other embodiments the
20 stylet 300 can be both rotated and moved reciprocally. In some embodiments, the occlusion 288 can have a stiff or otherwise tough proximal cap 308 and a relatively softer central portion 310. In some embodiments, forcing the stylet 300 to penetrate the proximal cap 308 of the occlusion 288 is sufficient to permit a guidewire 312 to be extended through the stylet 300, and then into and through the occlusion 288, as
25 illustrated in FIG. 17. After the stylet has extended through the proximal cap 308, a guidewire 312 can cross through the second sheath as in FIG. 18 or the shaft extension 222 as in FIG. 19 or through the hollow stylet 248 as in FIG. 20. The recanalization assembly can be further advanced through occlusion 288 and the balloon 70 placed near the distal cap 290 and the stylet centered and passed across the
30 distal cap 290 as in FIG. 21. Contrast in section can be made either through the dilation catheter, the second sheath, or the hollow stylet to provide visualization.

Referring to FIGS. 22A and 22B, another recanalization assembly, illustrated as a guidewire assembly 400, is disclosed. The guidewire assembly 400 includes an elongate shaft 405 having a proximal end 412, a distal end 414, and a lumen 416

extending therethrough. The guidewire assembly 400 may be sized to allow additional medical devices to be inserted over the guidewire assembly 400 and advanced distally, such that the guidewire assembly may facilitate navigation of additional medical devices within an anatomical region, such as the vasculature of a patient. For example, in some embodiments, the guidewire assembly 400 may have an outer diameter of about 0.20 mm (0.008 inch), about 0.25 mm (0.01 inch), about 0.36 mm (0.014 inch), about 0.46 mm (0.018 inch), about 0.64 mm (0.025 inch), about 0.89 mm (0.035 inch), about 0.97 mm (0.038 inch), or other desired size. In some embodiments the guidewire assembly 400 may have a length of about 50 cm to about 300 cm, or more. Although some suitable dimensions are disclosed, one of skill in the art would understand that the guidewire assembly 400 may have dimensions which deviate from those expressly disclosed.

The elongate shaft 405 may comprise any suitable material. Some examples of suitable materials include metals, metal alloys, polymers, or the like, or combinations, blends, or mixtures thereof. Some examples of suitable metals and metal alloys include, but are not limited to, stainless steel, such as 304V, 304L, and 316L stainless steel; alloys including nickel-titanium alloy such as linear elastic or superelastic (i.e., pseudoelastic) nitinol; nickel-chromium alloy; nickel-chromium-iron alloy; cobalt alloy; tungsten or tungsten alloys; MP35-N (having a composition of about 35% Ni, 35% Co, 20% Cr, 9.75% Mo, a maximum 1% Fe, a maximum 1% Ti, a maximum 0.25% C, a maximum 0.15% Mn, and a maximum 0.15% Si); hastelloy; monel 400; inconel 625; or the like; or other suitable material or combinations or alloys thereof. Some examples of suitable polymeric materials may include, but are not limited to, polyurethane, polyamide, high density polyamide (HDPE), low density polyamide (LDPE), polyether block amide (PEBA), polyethylene, polytetrafluoroethylene (PTFE), and their copolymers, combinations, blends, and mixtures thereof. However, other materials not expressly disclosed may be used in forming the elongate shaft 405, or portions thereof.

As illustrated in FIGS. 22A and 22B, the elongate shaft 405 may comprise a metallic tubular member 410 having a tubular wall 418 including a plurality of apertures 420, such as grooves, cuts, slits, slots, or the like, processed therein. The apertures 420 may be processed in a portion of, or along the entire length of, the metallic tubular member 410. Such a structure may be desirable because it may allow the metallic tubular member 410, or select portions thereof, to have a desired level of

lateral flexibility as well as have the ability to transmit torque and pushing forces through the metallic tubular member 410. The apertures 420 may be formed in essentially any known way. For example, the apertures 420 can be formed by methods such as micro-machining, saw-cutting, laser cutting, grinding, milling, casting, molding, chemically etching or treating, or other known methods, and the like. In some such embodiments, the structure of the metallic tubular member 410 is formed by cutting and/or removing portions of the metallic tubular member 410 to form the apertures 420. Some such metallic tubular members 410 are commonly referred to as hypotubes, and some such apertures can be referred to as slots or openings.

In some embodiments, the apertures 420 can extend entirely through the wall 418 of the metallic tubular member 410, or the apertures 420 can extend only partially into the wall 418 of the metallic tubular member 410. Other embodiments may include combinations of both complete and partial apertures 420 through the wall 418 of the metallic tubular member 410. Additionally, the quantity, size, spacing, distribution, and/or orientation of the apertures 420 can be varied to achieve desired characteristics. For example, the quantity or density of the apertures 420 along the length of the metallic tubular member 410 may be constant or may vary, depending upon desired characteristics. For example, the density of the apertures 420 in the distal portion of the metallic tubular member 410 may be greater than the density of the apertures 420 in the proximal portion of the metallic tubular member 410. In such embodiments, the flexibility of the distal portion of the elongate shaft 405 may be greater than the flexibility of the proximal portion of the elongate shaft 405. One of skill in the art would recognize that other arrangements of the apertures 420 may be imparted in the metallic tubular member 410 to achieve desired characteristics.

Some additional examples of shaft constructions and/or arrangements of cuts or slots formed in a tubular member are disclosed in U.S. Patent Nos. 6,428,489 and 6,579,246, which are each incorporated herein by reference. Additionally, U.S. Publication No. 2004/0193140, which is incorporated herein by reference, illustrates additional arrangements of apertures providing a degree of lateral flexibility formed in a medical device.

In some embodiments, such as illustrated in FIGS. 22A and 22B, the inner surface 424 of the metallic tubular member 410 may also include an inner coating or layer of a lubricious, hydrophilic, hydrophobic, and/or protective material. For

example, lubricious coatings can aid in insertion and steerability of devices within the lumen 416 of the metallic tubular member 410. One suitable lubricious coating is polytetrafluoroethylene (PTFE). However, one of skill in the art would recognize other materials having desirable characteristics.

5 The distal end 414 of the elongate shaft 405 may include an atraumatic tip 428. The atraumatic tip 428 may be adapted to reduce or prevent damage to a vessel wall during insertion and/or manipulation of the elongate shaft 405 within a vasculature. For example, the atraumatic tip 428 may include a polymer material having a relatively small durometer of hardness. However, other suitable materials
10 may be used to form the atraumatic tip 428.

 A stylet 450 is disposed within the lumen 416 of the metallic tubular member 410. The stylet 450 has a proximal end 452 and a distal end 454. The distal end 454 of the stylet 450 includes a cutting surface 456 illustrated as a needle tip. However, in
15 other embodiments, the distal end 454 may include other suitable cutting and/or penetrating means. For example, in some embodiments, the distal end 454 of the stylet 450 may include a tapered, beveled, pointed, rounded, or flat tip. In other
 embodiments, the distal end 454 of the stylet 450 may include a machining element, such as an end mill, a spade mill, a fluted drill, a drill point, hard grit, grinding
20 surfaces, or the like. The stylet 450 and/or the cutting surface 456 may comprise any suitable material. Some examples include metal or metal alloys, glass, ceramic
 material, or polymeric materials, including those materials disclosed elsewhere herein.

 The proximal end of the guidewire assembly 400 may include a control means for selectively controlling the position of the stylet 450 within the lumen 416 of the
 elongate shaft 405. For example, the proximal end of the guidewire assembly 400
25 may include a hub assembly 460 configured to limit axial movement of the stylet 450 within the elongate shaft 405. The hub assembly 460, as shown in FIGS. 22A and
 22B includes a hub element 462 coupled to the proximal end 452 of the stylet 450. The hub element 462 may be coupled to the proximal end 452 of the stylet 450 in any
 known way. For example, the hub element 462 may be removably coupled to the
30 stylet 450, or the hub element 462 may be permanently coupled to the stylet 450. As shown in the illustrative embodiment, the hub element 462 may include a threaded
 portion configured for mating engagement with a complementary threaded portion of the proximal end 452 of the stylet 450. Thus, the hub element 462 may be variably
 positioned at one of multiple longitudinal positions of the stylet 450. However, in

other embodiments, the hub element 462 may be coupled to the stylet 450 with mechanical fasteners, crimping, adhesive or other bonding material, welding, thermal bonding, chemical bonding, an interference or frictional fit, an interlocking or snap fit, or the like. Movement of the stylet 450 with respect to the metallic tubular member 5
410 can be controlled or limited in a manner that is similar to that shown in Figures 6-8.

The hub element 462 may be configured to have radial extents greater than the lumen 416 of the elongate shaft 405 such that the hub element 462 may limit longitudinal movement of the stylet 450 within the lumen 416. For instance abutment
10 of the hub element 462 against the proximal end 412 of the elongate shaft 405, as shown in FIG. 22B, prevents further longitudinal movement of the stylet 450 in the distal direction.

Actuation of the stylet 450 may be accomplished by relative longitudinal movement between the stylet 450 and the elongate shaft 405 and/or rotational
15 movement of the stylet 450 within the elongate shaft 405. For example, the stylet 450 may be slidably actuated between a first, or retracted, position shown in FIG. 22A and a second, or extended, position shown in FIG. 22B. In the second or extended position of FIG. 22B, the cutting surface 456 of the stylet 450 is extended distally of the distal end 414 of the elongate shaft 405. In the first or retracted position, the
20 cutting surface 456 of the stylet 450 is retracted within the lumen 416 of the elongate shaft 405. Thus, the hub assembly 460 may be manipulated in order to selectively extend the stylet 450 distal of the distal end 414 of the elongate shaft 405 and retract the stylet 450 within the elongate shaft 405. However, in some embodiments, the distal end 454 of the stylet 450 can extend beyond the distal end 414 of the elongate
25 shaft 405 even in the retracted position.

Referring to FIGS. 23A and 23B, another recanalization assembly, illustrated as a guidewire assembly 500, is disclosed. The guidewire assembly 500 includes an elongate shaft 505 having a proximal end 512, a distal end 514, and a lumen 516 extending therethrough. The guidewire assembly 500 may be sized to allow
30 additional medical devices to be inserted over the guidewire assembly 500 and advanced distally, such that the guidewire assembly 500 may facilitate navigation of additional medical devices within an anatomical region, such as the vasculature of a patient. For example, in some embodiments, the guidewire assembly 500 may have an outer diameter of about 0.20 mm (0.008 inch), about 0.25 mm (0.01 inch), about

0.36 mm (0.014 inch), about 0.46 mm (0.018 inch), about 0.64 mm (0.025 inch), about 0.89 mm (0.035 inch), about 0.97 mm (0.038 inch), or other desired size. In some embodiments the guidewire assembly 500 may have a length of about 50 cm to about 300 cm, or more. Although some suitable dimensions are disclosed, one of skill
5 in the art would understand that the guidewire assembly 500 may have dimensions which deviate from those expressly disclosed.

The elongate shaft 505 may be substantially similar to the elongate shaft 405 of FIGS. 22A and 22B, thus for the sake of repetitiveness, similarities of the elongate shaft 505 with the elongate shaft 405 will not be repeated. For example, the elongate
10 shaft 505 may be formed of any suitable material, such as those disclosed above regarding the elongate shaft 405. For example, the elongate shaft 505 may include a metallic tubular member 510 having a tubular wall 518 including a plurality of apertures 520, such as grooves, cuts, slits, slots, or the like, processed therein. The apertures 520 may be desirable as the apertures 520 may impart a desired level of
15 lateral flexibility to the metallic tubular member 510, or select portions thereof. The apertures 520 may be formed in essentially any known way.

Additionally, an inner tubular member, such as a polymeric tubular member 525 may be positioned within the metallic tubular member 510. The inner tubular member 525 may provide a fluid passageway and/or reduce frictional forces within
20 the elongate shaft 505. In some embodiments, the inner surface 524 of the metallic tubular member 510 may additionally or alternatively include an inner coating or layer of a lubricious, hydrophilic, hydrophobic, and/or protective material, such as a polytetrafluoroethylene (PTFE) coating, or the like. However, one of skill in the art would recognize that the metallic tubular member 510 may be coated or combined
25 with other materials to impart desired characteristics to the elongate shaft 505.

The distal end 514 of the elongate shaft 505 may include an atraumatic tip 528. The atraumatic tip 528 may be adapted to reduce or prevent damage to a vessel wall during insertion and/or manipulation of the elongate shaft 505 within a vasculature. For example, the atraumatic tip 528 may include a polymer material
30 having a relatively small durometer of hardness. However, other suitable materials may be used to form the atraumatic tip 528.

A stylet 550 is disposed within the lumen 516 of the metallic tubular member 510. The stylet 550 has a proximal end 552 and a distal end 554. The distal end 554 of the stylet 550 includes a cutting surface 556 illustrated as a needle tip. However, in

other embodiments, the distal end 554 may include other suitable cutting and/or penetrating means. For example, in some embodiments the distal end 554 of the stylet 550 may include a tapered, beveled, pointed, rounded, or flat tip. In other embodiments, the distal end 554 of the stylet 550 may include a machining element, such as an end mill, a spade mill, a fluted drill, a drill point, hard grit, grinding surfaces, or the like. The stylet 550 and/or the cutting surface 556 may comprise any suitable material. Some examples include metal or metal alloys, glass, ceramic material, or polymeric materials, including those materials disclosed elsewhere herein.

The stylet 550, as illustrated in FIGS. 23A and 23B, may include a plurality of apertures 555, such as grooves, cuts, slits, slots, or the like, processed therein. The apertures 555 may be substantially similar to the apertures 520 processed in the metallic tubular member 510. The apertures 555 may be desirable as the apertures 555 may impart a desired level of lateral flexibility to the stylet 550, or select portions thereof, yet retain sufficient rigidity to the stylet 550 to permit longitudinal actuation of the stylet 550 through the elongate shaft 505. The apertures 520 may be formed in essentially any known way.

The proximal end of the guidewire assembly 500 may include a control means for selectively controlling the position of the stylet 550 within the lumen 516 of the elongate shaft 505. For example, the proximal end of the guidewire assembly 500 may include a hub assembly 560 configured to limit axial movement of the stylet 550 within the elongate shaft 505. The hub assembly 560, as shown in FIGS. 23A and 23B includes a hub element 564 coupled to the proximal end 512 of the elongate shaft 505. The hub element 564 may be coupled to the proximal end 512 of the elongate shaft 505 in any known way. For example, the hub element 564 may be removably coupled to the elongate shaft 505, or the hub element 564 may be permanently coupled to the elongate shaft 505. In some embodiments, the hub element 564 may be coupled to the elongate shaft 505 with mechanical fasteners, a threaded connection, crimping, adhesive or other bonding material, welding, thermal bonding, chemical bonding, an interference or frictional fit, an interlocking or snap fit, or the like.

The hub assembly 560 includes an engagement section 566 providing selective engagement between the stylet 550 and the elongate shaft 505. The engagement section 566 includes an engagement portion 568 of the hub element 564. In the illustrative embodiment, the engagement portion 568 is a portion of the hub element 564 having greater inner dimensions from an adjacent portion of the hub element 564.

For example, the engagement portion 568 may be a recessed area, such as a cavity, groove, bore, slot, or the like. The engagement portion 568 includes a proximal end 571 and a distal end 572.

The engagement section 566 of the hub assembly 560 also refers to a portion
5 of the stylet 550. The stylet 550 includes a stop 558 that has an outer periphery that is greater than the outer periphery of the stylet 550 on either side of the stop 558. For example, in some embodiments, the stop 558 may be an annular ring extending around the circumference of the stylet 550. In other embodiments, the stop 558 may include one or more distinct sections extending from the periphery of the stylet 550.
10 As shown in FIG. 23A, proximal movement of the stylet 550 is limited by the stop 558 contacting the proximal end 571 of the engagement portion 568. Similarly, distal movement of the stylet 550 is limited by the stop 558 contacting the distal end 572 of the engagement portion 568.

Additionally, the hub assembly 560 may include a biasing structure, such as a
15 helical spring 563. In the illustrated embodiment, the helical spring 563 is positioned between the distal end 572 of the engagement portion 568 of the hub element 564 and the stop 558. Thus, the helical spring 563 may bias the stop 558, and thus the stylet 550 proximally. In other words, the helical spring 563 may bias the stylet 550 in a first, or retracted position shown in FIG. 23A. Thus, an actuation force greater than
20 the biasing force of the helical spring 563 is necessary to actuate the stylet 550 to an extended position. However, in other embodiments, the helical spring 563, or another biasing structure, may be positioned between the stop 558 and the proximal end 571 of the engagement portion 568 of the hub element 564, biasing the stylet 550 in a second, or extended position shown in FIG. 23B.

25 Actuation of the stylet 550 may be accomplished by relative longitudinal movement between the stylet 550 and the elongate shaft 505 and/or rotational movement of the stylet 550 within the elongate shaft 505. The stylet 550 may be actuated by manipulating the proximal end 552 of the stylet 550 extending proximal of the hub assembly 560. For example, the stylet 550 may be slidably actuated
30 between a first, or retracted, position shown in FIG. 23A and a second, or extended, position shown in FIG. 23B. In the second or extended position of FIG. 23B, the cutting surface 556 of the stylet 550 is extended distally of the distal end 514 of the elongate shaft 505. In the first or retracted position, the cutting surface 556 of the stylet 550 is retracted within the lumen 516 of the elongate shaft 505. Thus, the hub

assembly 560 may be manipulated in order to selectively extend the stylet 550 distal of the distal end 514 of the elongate shaft 505 and retract the stylet 550 within the elongate shaft 505. However, in some embodiments, the distal end 554 of the stylet 550 can extend beyond the distal end 514 of the elongate shaft 505 even in the retracted position.

Referring now to FIGS. 24A and 24B, another recanalization assembly, illustrated as a guidewire assembly 600, is disclosed. The guidewire assembly 600 includes an elongate shaft 605, having a proximal end 612, a distal end 614, and a lumen 616 extending therethrough. The guidewire assembly 600 may be sized to allow additional medical devices to be inserted over the guidewire assembly 600 and advanced distally, such that the guidewire assembly 600 may facilitate navigation of additional medical devices within an anatomical region, such as the vasculature of a patient. For example, in some embodiments, the guidewire assembly 600 may have an outer diameter of about 0.20 mm (0.008 inch), about 0.25 mm (0.01 inch), about 0.36 mm (0.014 inch), about 0.46 mm (0.018 inch), about 0.64 mm (0.025 inch), about 0.89 mm (0.035 inch), about 0.97 mm (0.038 inch), or other desired size. In some embodiments the guidewire assembly 600 may have a length of about 50 cm to about 300 cm, or more. Although some suitable dimensions are disclosed, one of skill in the art would understand that the guidewire assembly 600 may have dimensions which deviate from those expressly disclosed.

The elongate shaft 605 may include a single-layer or multi-layer tubular member. For example, the elongate shaft 605 may include an inner tubular member 606, an outer tubular member 607 and a reinforcement layer 608 interposed between the inner tubular member 606 and the outer tubular member 607. The inner tubular member 606 and the outer tubular member 607 may be formed of any suitable material including, but not limited to, those materials disclosed elsewhere herein. For instance, the inner tubular member 606 and the outer tubular member 607 may each include a polymeric material, such as, but not limited to, any of the polymer materials described herein. For example, in some embodiments the inner tubular member 606 may include a lubricious polymeric material, such as high density polyethylene (HDPE) or polytetrafluoroethylene (PTFE), thus imparting lubricity to the inner surface 624 of the elongate shaft 605. In some embodiments, the outer tubular member 607 may include a polyamide, or a polyether block amide (PEBA). Different portions or segments of the elongate shaft 605 may include dissimilar materials and/or

materials having different durometers and/or flexibilities, thus imparting a plurality of regions having dissimilar flexibilities along the length of the elongate shaft 605. For example, in some embodiments, the outer tubular member 607 may include multiple tubular segments, having dissimilar flexibility and/or hardness properties.

5 In some embodiments, the reinforcement layer 608 may include one or more filaments, such as ribbon members, helically wound or coiled around the inner tubular member 606. In other embodiments, the reinforcement layer 608 may include one or more braid members, such as one or more braids having interwoven opposingly helically wound filaments disposed on the inner tubular member 606. The
10 reinforcement layer 608 may provide the elongate shaft 605 with a desired degree of kink resistance, yet provide sufficient flexibility for navigation through a tortuous anatomy.

The distal end 614 of the elongate shaft 605 may include an atraumatic tip 628. The atraumatic tip 628 may be adapted to reduce or prevent damage to a vessel
15 wall during insertion and/or manipulation of the elongate shaft 605 within a vasculature. For example, the atraumatic tip 628 may include a polymer material having a relatively small durometer of hardness. However, other suitable materials may be used to form the atraumatic tip 628.

A stylet 650 is disposed within the lumen 616 of the elongate shaft 605. The
20 stylet 650 has a proximal end 652 and a distal end 654. The distal end 654 of the stylet 650 includes a cutting surface 656 illustrated as a needle tip. However, in other embodiments, the distal end 654 may include other suitable cutting and/or penetrating means. For example, in some embodiments the distal end 654 of the stylet 650 may include a tapered, beveled, pointed, rounded, or flat tip. In other embodiments, the
25 distal end 654 of the stylet 650 may include a machining element, such as an end mill, a spade mill, a fluted drill, a drill point, hard grit, grinding surfaces, or the like. The stylet 650 and/or the cutting surface 656 may comprise any suitable material. Some examples include metal or metal alloys, glass, ceramic material, or polymeric materials, including those materials disclosed elsewhere herein.

30 The stylet 650 may include a radiopaque marker 659 imparting a degree of radiopacity to the stylet 650. In other embodiments, all or portions of the elongate shaft 605 and/or the stylet 650 may be made of, impregnated with, plated or clad with, or otherwise include a radiopaque material and/or structure to facilitate radiographic visualization. Radiopaque materials are understood to be materials capable of

producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with radiopaque filler, and the like.

5 The proximal end of the guidewire assembly 600 may include a control means for selectively controlling the position of the stylet 650 within the lumen 616 of the elongate shaft 605. For example, the proximal end of the guidewire assembly 600 may include a hub assembly 660 configured to limit axial movement of the stylet 650 within the elongate shaft 605. The hub assembly 660, as shown in FIGS. 24A and
10 24B includes a hub element 664 coupled to the proximal end 612 of the elongate shaft 605. The hub element 664 may be coupled to the proximal end 612 of the elongate shaft 605 in any known way. For example, the hub element 664 may be removably coupled to the elongate shaft 605, or the hub element 664 may be permanently coupled to the elongate shaft 605. In some embodiments, the hub element 664 may
15 be coupled to the elongate shaft 605 with mechanical fasteners, a threaded connection, crimping, adhesive or other bonding material, welding, thermal bonding, chemical bonding, an interference or frictional fit, an interlocking or snap fit, or the like. In the illustrative embodiment, the hub element 664 includes an annular projection 667 extending into the proximal end 612 of the elongate shaft 605. Thus, the annular
20 projection 667 may be coupled to the proximal end 612 of the elongate shaft 605. For example, the annular projection 667 may be bonded to the elongate shaft 605 with adhesive, UV bonding, thermal bonding, chemical bonding, RF welding, laser welding, or the like.

As shown in the illustrative embodiment, the outer extents of the hub element
25 664 may be substantially similar to the outer diameter of the proximal end 612 of the elongate shaft 605. Thus, the inclusion of the hub element 664 at the proximal end 612 of the elongate shaft 605 does not significantly hinder the ability of other medical devices of conventional sizes of being disposed about the guidewire assembly 600 and advanced distally over the elongate shaft 605 through a tortuous vasculature.
30 However, in other embodiments, the hub element 664, and/or other portions of the hub assembly 660, may be removed from the elongate shaft 605 prior to disposing and advancing additional medical devices over the guidewire assembly 600.

The hub assembly 660 includes an engagement section 666 providing selective engagement between the stylet 650 and the elongate shaft 605. The engagement

section 666 includes an engagement portion of the hub element 664. In the illustrative embodiment, the engagement portion of the hub element 664 is an opening 668, or a plurality of openings 668 extending through the wall of the hub element 664. For example, the opening 668 may be a slot, gap, or the like, allowing access to the interior of the hub element 664. The opening 668 includes a proximal end 671 and a distal end 672. In some embodiments, the opening 668 may be a portion of a bayonet style coupling mechanism for coupling the stylet 650 with the elongate shaft 605. Thus, the stylet 650 may be selectively retained with the opening 668.

The engagement section 666 of the hub assembly 660 also refers to a portion of the stylet 650. The stylet 650 includes a stop 658 that extends at least partially into the opening 668. For example, in some embodiments, the stop 658 may be a projection extending into or through the opening 668. As shown in FIG. 24A, proximal movement of the stylet 650 is limited by the stop 658 contacting the proximal end 671 of the engagement portion 668. Similarly, distal movement of the stylet 650 is limited by the stop 658 contacting the distal end 672 of the engagement portion 668. In embodiments where the hub assembly 660 includes a bayonet style coupling mechanism, the stop 658 may be passed from the distal end of the hub element 664, rotated, and positioned in the opening 668 of the hub element 664.

Actuation of the stylet 650 may be accomplished by relative longitudinal movement between the stylet 650 and the elongate shaft 605 and/or rotational movement of the stylet 650 within the elongate shaft 605. The stylet 650 may be actuated by moving the stop 658 along the opening 668. For example, the stylet 650 may be slidably actuated between a first, or retracted, position shown in FIG. 24A and a second, or extended, position shown in FIG. 24B. In the second or extended position of FIG. 24B, the cutting surface 656 of the stylet 650 is extended distally of the distal end 614 of the elongate shaft 605. In the first or retracted position, the cutting surface 656 of the stylet 650 is retracted within the lumen 616 of the elongate shaft 605. Thus, the hub assembly 660 may be manipulated in order to selectively extend the stylet 650 distal of the distal end 614 of the elongate shaft 605 and retract the stylet 650 within the elongate shaft 605. However, in some embodiments, the distal end 654 of the stylet 650 can extend beyond the distal end 614 of the elongate shaft 605 even in the retracted position.

In use during a medical procedure, the guidewire assembly 400, 500, 600 may be advanced through a vasculature to a distal location. When the distal end of the

guidewire assembly 400, 500, 600 is proximate an occlusion, such as a chronic total occlusion of the vasculature, the stylet 450, 550, 650 may be actuated from the proximal end of the guidewire assembly 400, 500, 600. For example, the stylet 450, 550, 650 may be actuated by advancing the stylet 450, 550, 650 distally and/or proximally, with a longitudinal back and forth (e.g., reciprocal) motion, a tapping motion, a rotational motion, and the like. Actuation of the stylet 450, 550, 650 may allow the distal end 454, 554, 654 of the stylet 450, 550, 650 to penetrate the occlusion, such as the proximal cap of a chronic total occlusion. Once penetration of the occlusion has occurred, the guidewire assembly 400, 500, 600 may be advanced further distally into or across the occlusion to a desired location in the vasculature. Once properly positioned, additional medical devices, such as a balloon catheter, a cutting device, or the like, may be advanced over the guidewire assembly 400, 500, 600 and navigated through the vasculature to a target location, such as the occlusion and/or a location distal of the occlusion. Thus, the guidewire assembly 400, 500, 600 may facilitate crossing an occlusion, such as a chronic total occlusion, within the vasculature with conventional medical devices. A similar procedure can be followed to allow passage of the guidewire assembly through the entire vessel lesion including passage through the distal cap of a chronic total occlusion. A balloon catheter such as an angioplasty catheter or other diagnostic or therapeutic catheter can be used to help center the guidewire assembly and the stylette in the vessel and allow the stylette to enter more closely to the central region of a proximal cap of a chronic total occlusion, for example, prior to advancing the guidewire assembly across the proximal cap. The stylette can be removed from the tubular member if desired to allow delivery of contrast medium through the tubular member lumen.

As noted, the medical devices in accordance with the present invention can be of conventional materials and construction, except as described herein. The medical devices described herein can be partially or completely coated with a lubricious or other type of coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity that can improve handling and device exchanges. An example of a suitable fluoropolymer is polytetrafluoroethylene (PTFE), better known as TEFLON®.

Lubricious coatings can improve steerability and improve lesion crossing capability. Examples of suitable lubricious polymers include hydrophilic polymers such as polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl celluloses, algin, saccharides, caprolactones, and the like, and mixtures and

combinations thereof. Hydrophilic polymers can be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility. In some embodiments, a distal portion of a composite medical device can be coated with a hydrophilic polymer as discussed above, while the more proximal portions can be coated with a fluoropolymer.

The medical devices described herein can include, or be doped with, radiopaque material to improve visibility when using imaging techniques such as fluoroscopy techniques. Any suitable radiopaque material known in the art can be used. Some examples include precious metals, tungsten, barium subcarbonate powder, and the like, and mixtures thereof. In some embodiments, radiopaque material can be dispersed within the polymers used to form the particular medical device. In some embodiments, the radiopaque materials distinct from the ferromagnetic materials are dispersed.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A guidewire assembly having a proximal end and a distal end, the guidewire assembly configured to penetrate a vascular occlusion, the guidewire assembly comprising:

a metallic tubular member having a proximal end, a distal end, and a lumen extending therethrough, the metallic tubular member including a wall having a plurality of apertures processed therein to provide a degree of flexibility to the metallic tubular member; and

a stylet disposed within the lumen of the metallic tubular member, the stylet having a proximal end and a distal end including a cutting surface adapted to penetrate a vascular occlusion.

2. The guidewire assembly of claim 1, further comprising a hub assembly coupled to the proximal end of the guidewire, wherein the hub assembly limits relative axial movement between the stylet and the metallic tubular member.

3. The guidewire assembly of claim 2, wherein the hub assembly is removably coupled to the proximal end of the guidewire.

4. The guidewire assembly of claim 1, further comprising an inner lubricious liner disposed in the lumen of the metallic tubular member.

5. The guidewire assembly of claim 1, further comprising a hub element coupled to the proximal end of the metallic tubular member, wherein a portion of the stylet extends into the hub element.

6. The guidewire assembly of claim 5, wherein the hub element includes an engagement portion and the stylet includes an engagement member engaged with the engagement portion of the hub element.

7. The guidewire assembly of claim 1, further comprising a hub element coupled to the proximal end of the stylet configured for manipulation of the stylet.

8. The guidewire assembly of claim 7, wherein the hub element is sized larger than the lumen of the metallic tubular member in order to limit distal actuation of the stylet through the metallic tubular member.

9. The guidewire assembly of claim 1, wherein the stylet includes a plurality of slots cut therein to provide a degree of flexibility to the stylet.

10. An elongate medical device having a proximal end and a distal end, the elongate medical device configured to penetrate a vascular occlusion, the elongate medical device comprising:

an elongate shaft having a proximal end, a distal end, and a lumen extending therethrough;

a stylet disposed within the lumen of the elongate shaft, the stylet having a proximal end and a distal end; and

a hub assembly coupled to the proximal end of the elongate medical device, wherein the hub assembly allows for limited axial movement of the stylet within the lumen of the elongate shaft, such that in a first position the stylet extends distally from the distal end of the elongate shaft, and in a second position the stylet is retracted into the lumen of the elongate shaft.

11. The elongate medical device of claim 10, wherein the elongate shaft comprises a metallic tubular member including a wall having a plurality of apertures processed therein to provide a degree of flexibility to the metallic tubular member.

12. The elongate medical device of claim 10, wherein the elongate shaft comprises a polymeric member including an inner layer, an outer layer, and a reinforcement layer interposed between the inner layer and the outer layer.

13. The elongate medical device of claim 12, wherein the reinforcement layer is a braid member.

14. The elongate medical device of claim 12, wherein the reinforcement layer is a ribbon coil.

15. The elongate medical device of claim 10, wherein the stylet includes a plurality of slots cut therein to provide a degree of flexibility to the stylet.

16. The elongate medical device of claim 10, wherein the hub assembly is removably coupled to the proximal end of the elongate medical device.

17. A guidewire assembly having a proximal end and a distal end, the guidewire assembly configured to penetrate a vascular occlusion, the guidewire assembly comprising:

a metallic tubular member having a proximal end, a distal end, and a lumen extending therethrough, the metallic tubular member including a wall having a plurality of slots cut therein to provide a degree of flexibility to the metallic tubular member;

a stylet disposed within the lumen of the metallic tubular member, the stylet having a proximal end and a distal end configured to penetrate a vascular occlusion; and

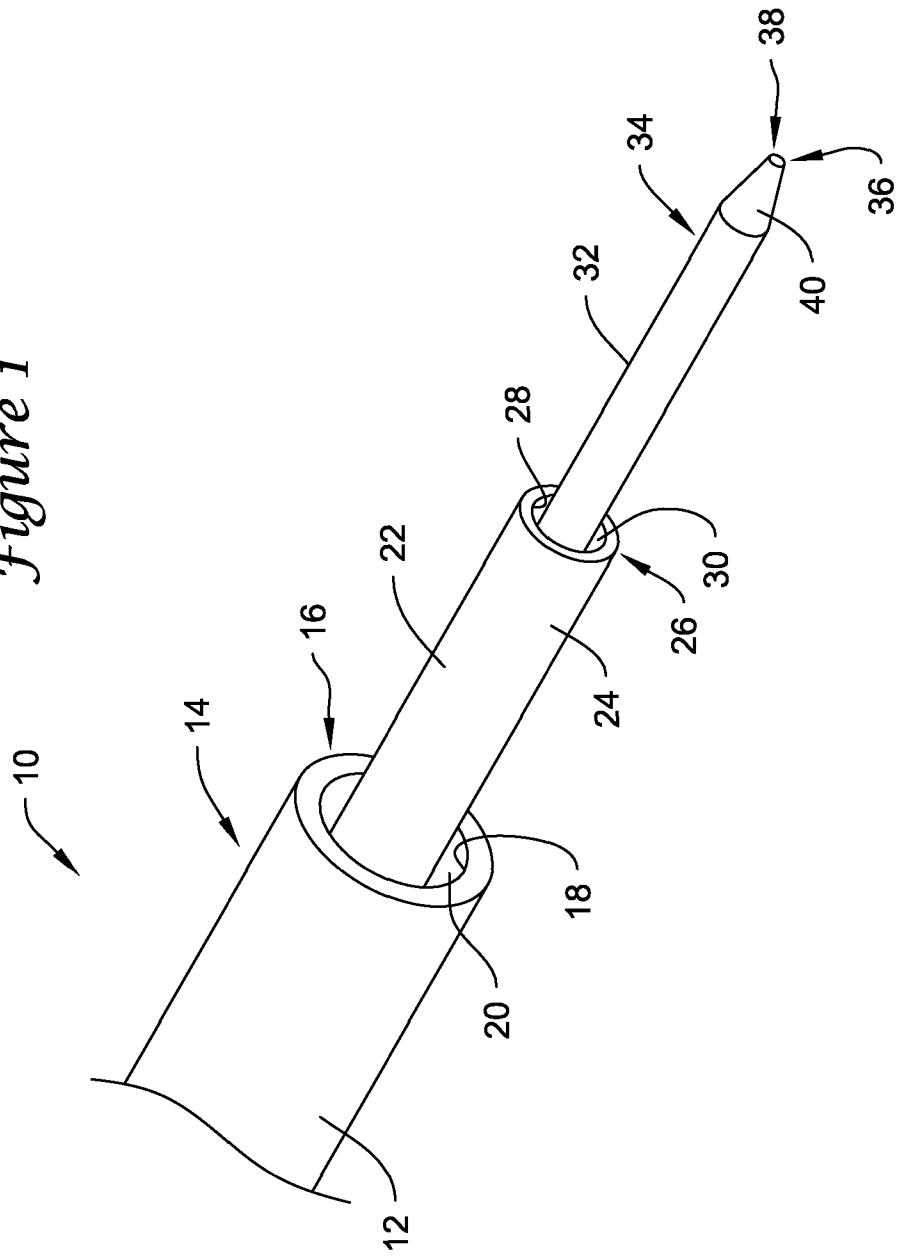
a hub assembly coupled to the proximal end of the guidewire assembly, wherein the hub assembly allows for limited axial movement of the stylet within the lumen of the metallic tubular member, such that in a first position the stylet extends distally from the distal end of the metallic tubular member, and in a second position the stylet is retracted into the lumen of the metallic tubular member.

18. The guidewire assembly of claim 17, wherein the hub assembly is removably coupled to the proximal end of the guidewire assembly.

19. The guidewire assembly of claim 17, wherein the hub assembly includes a hub element coupled to the proximal end of the stylet.

20. The guidewire assembly of claim 17, wherein the hub assembly includes a hub element coupled to the proximal end of the metallic tubular member, the hub element including an engagement portion, wherein a portion of the stylet is engaged with the engagement portion of the hub element.

Figure 1



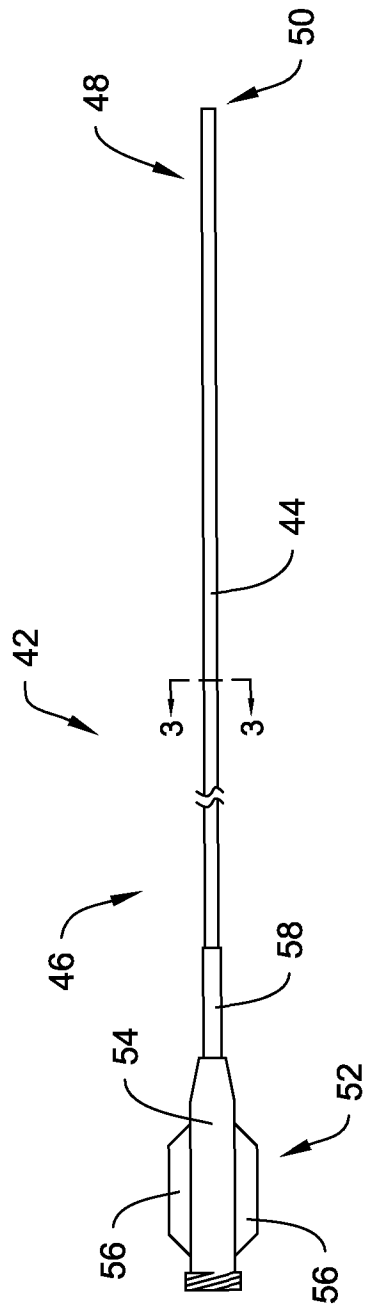
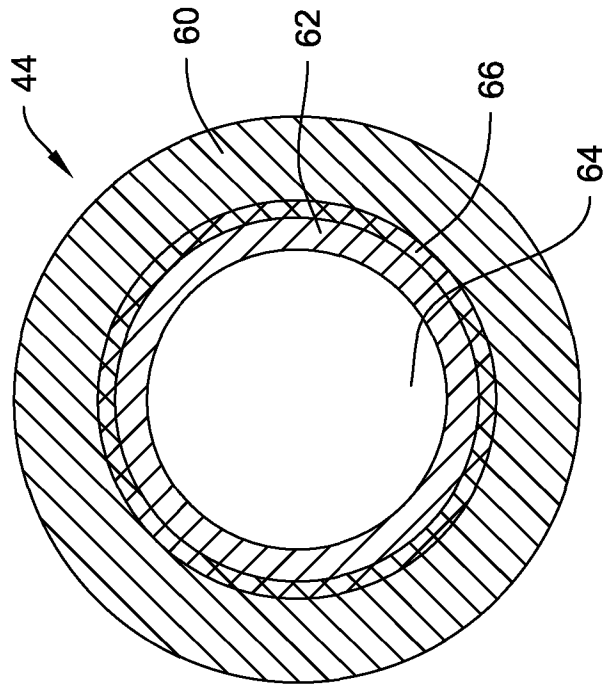


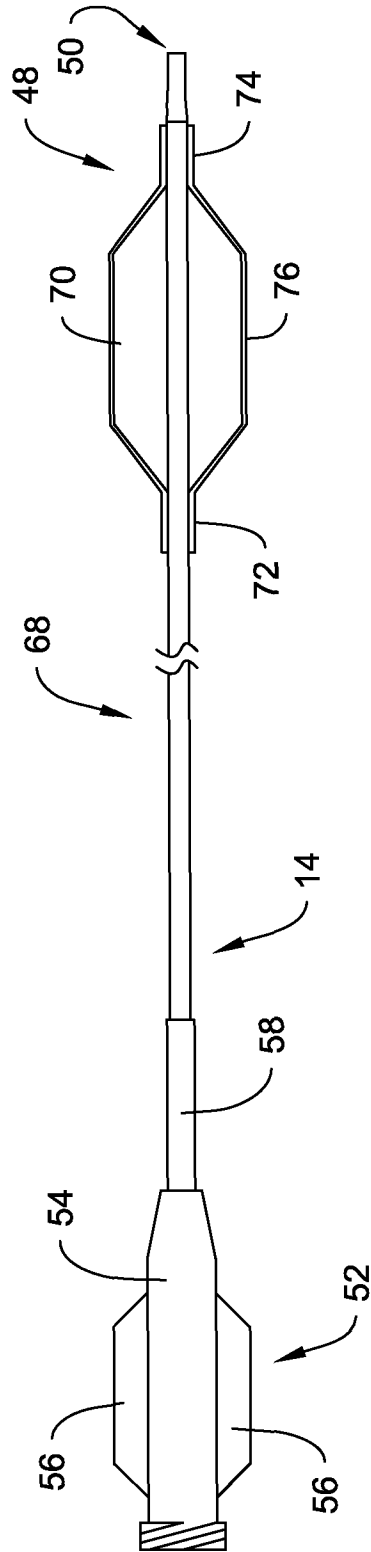
Figure 2

Figure 3



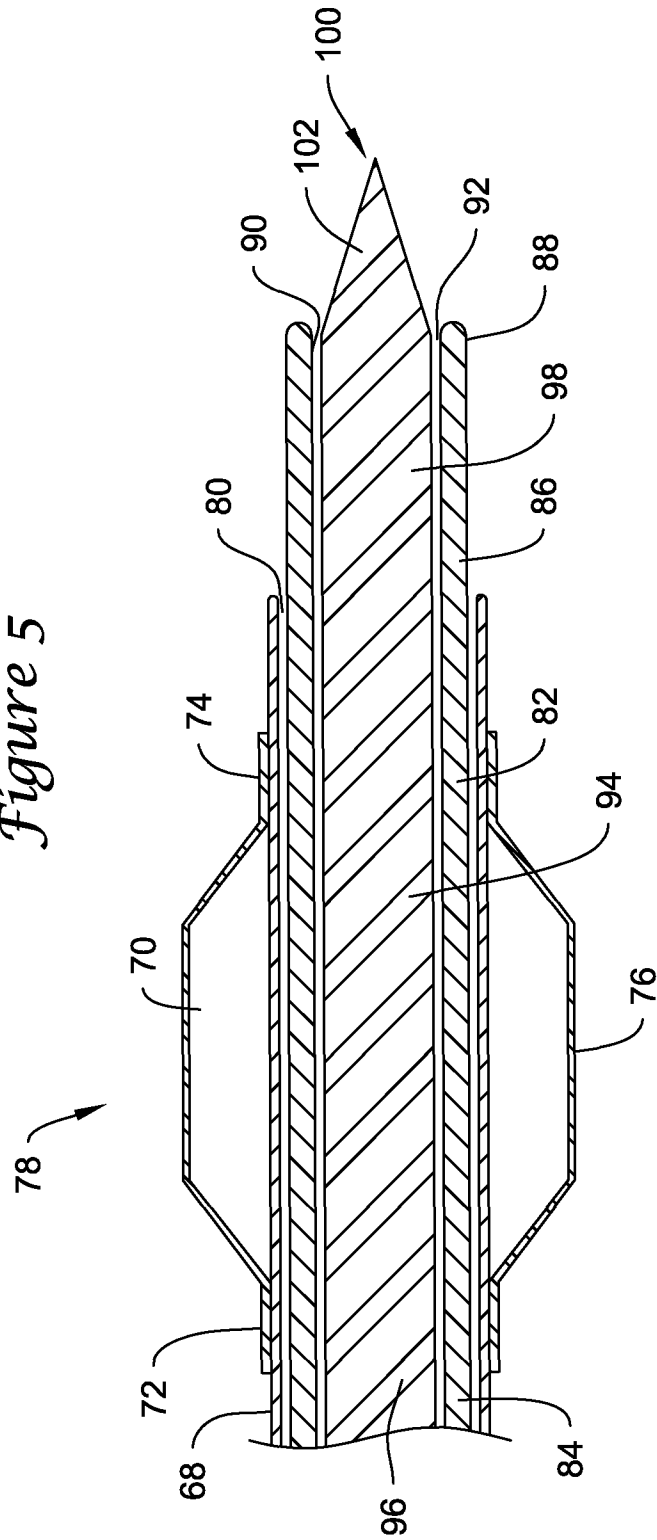
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Figure 4



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Figure 5



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Figure 6

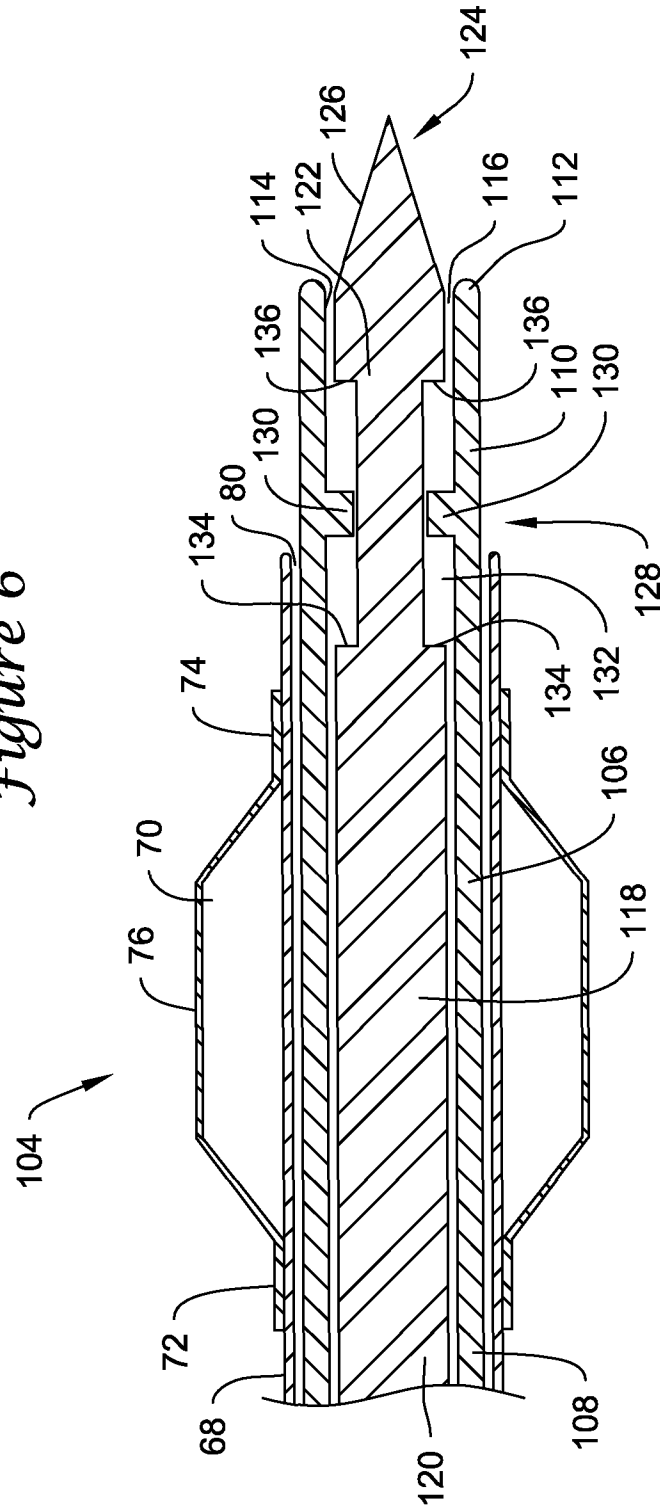
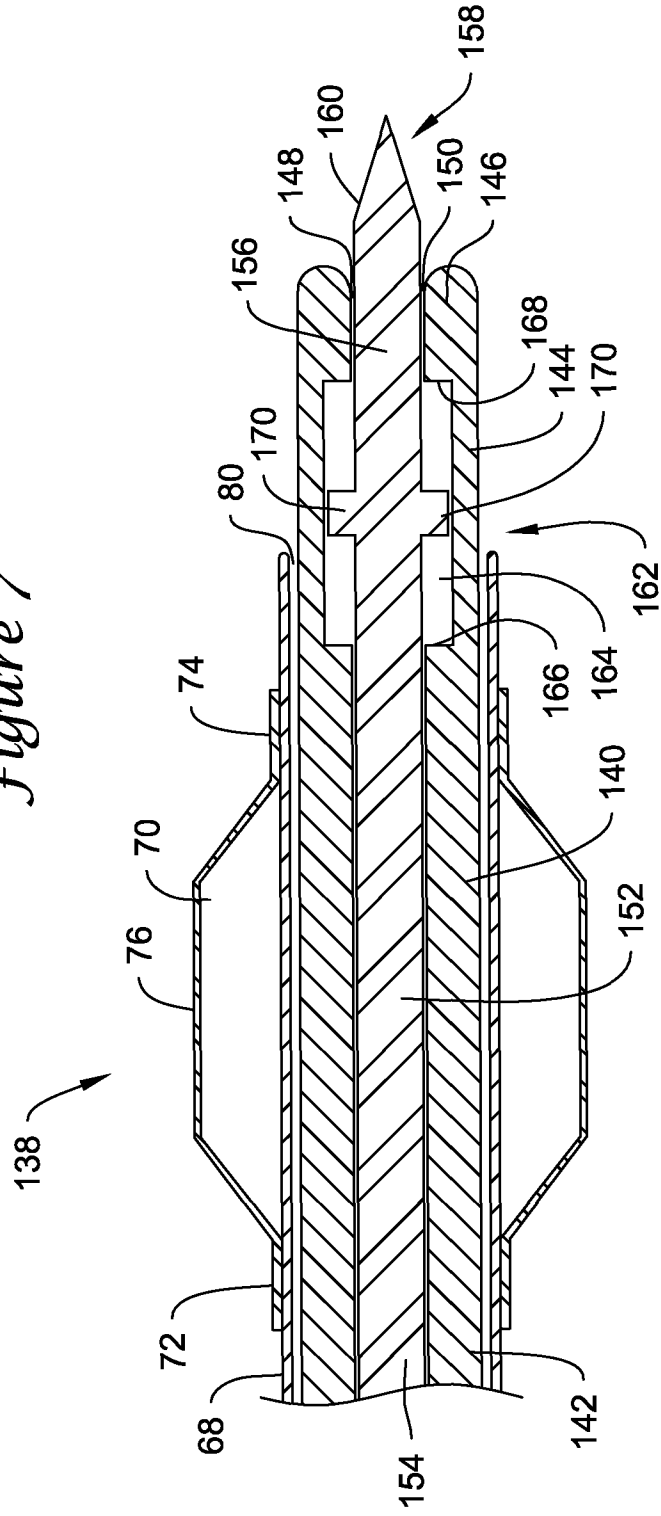
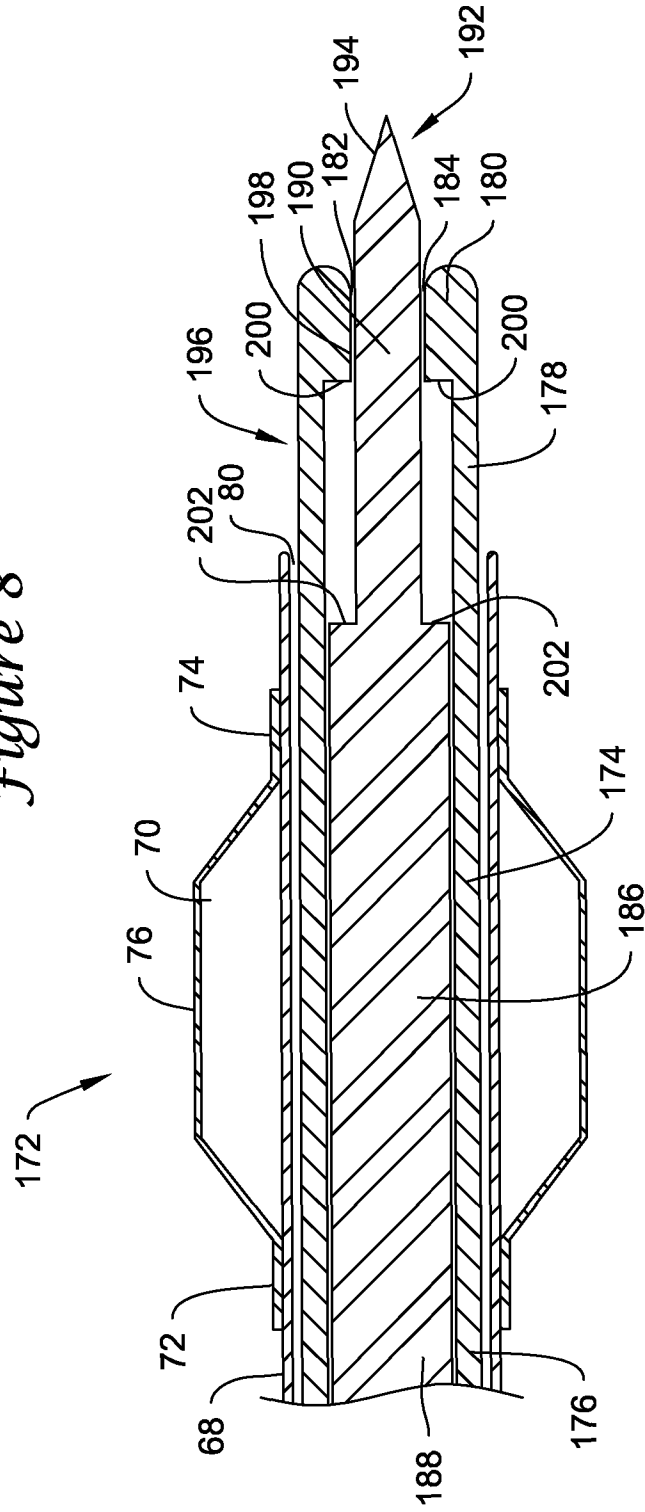


Figure 7



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Figure 8



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Figure 9

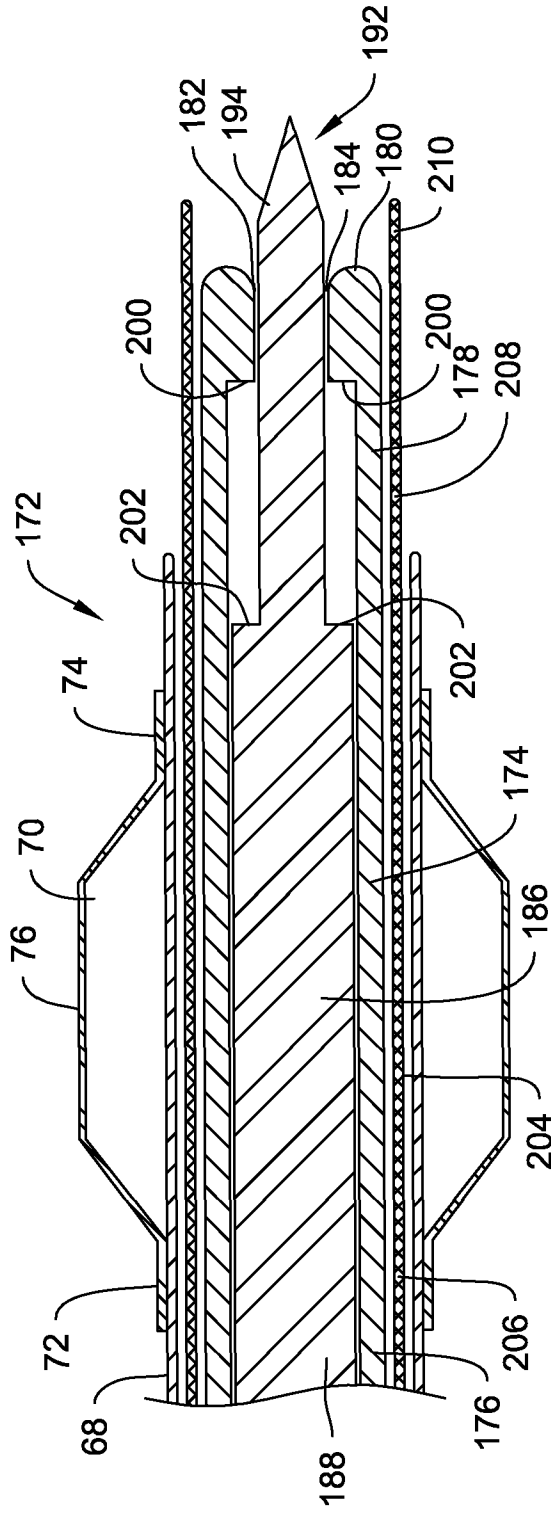
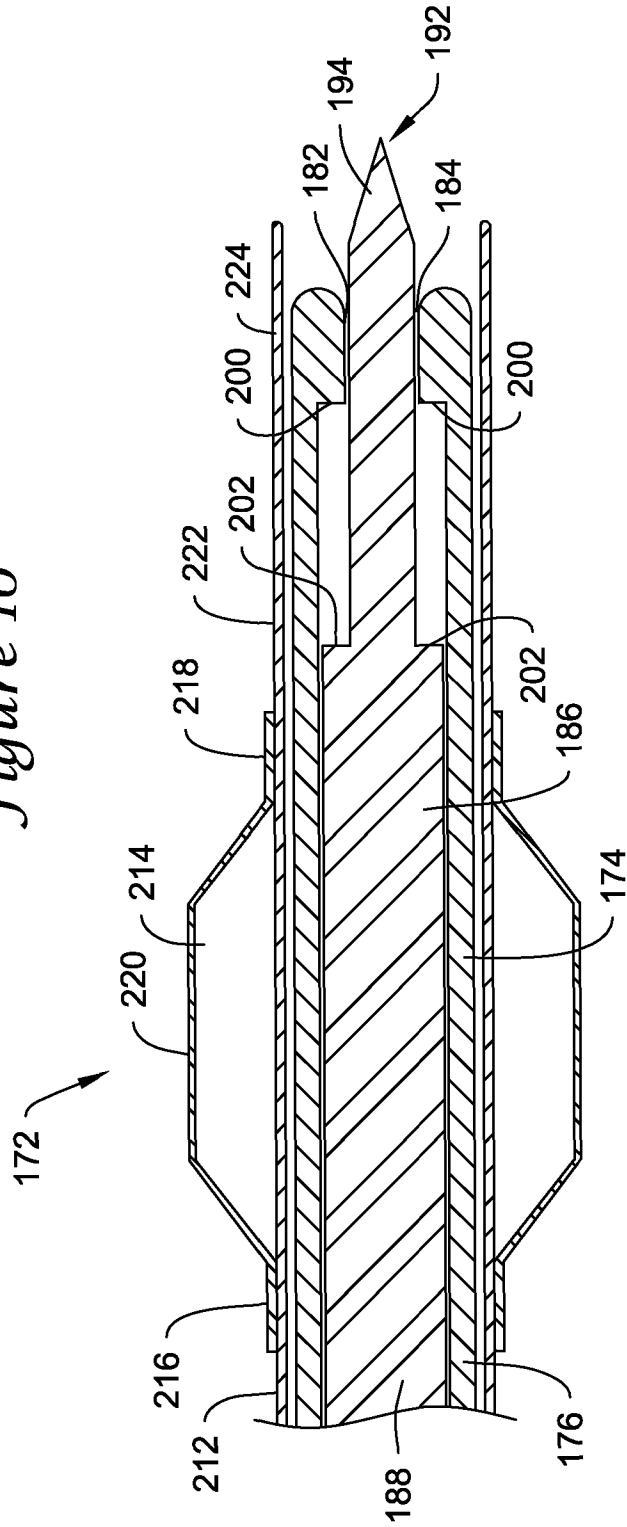


Figure 10



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Figure 11

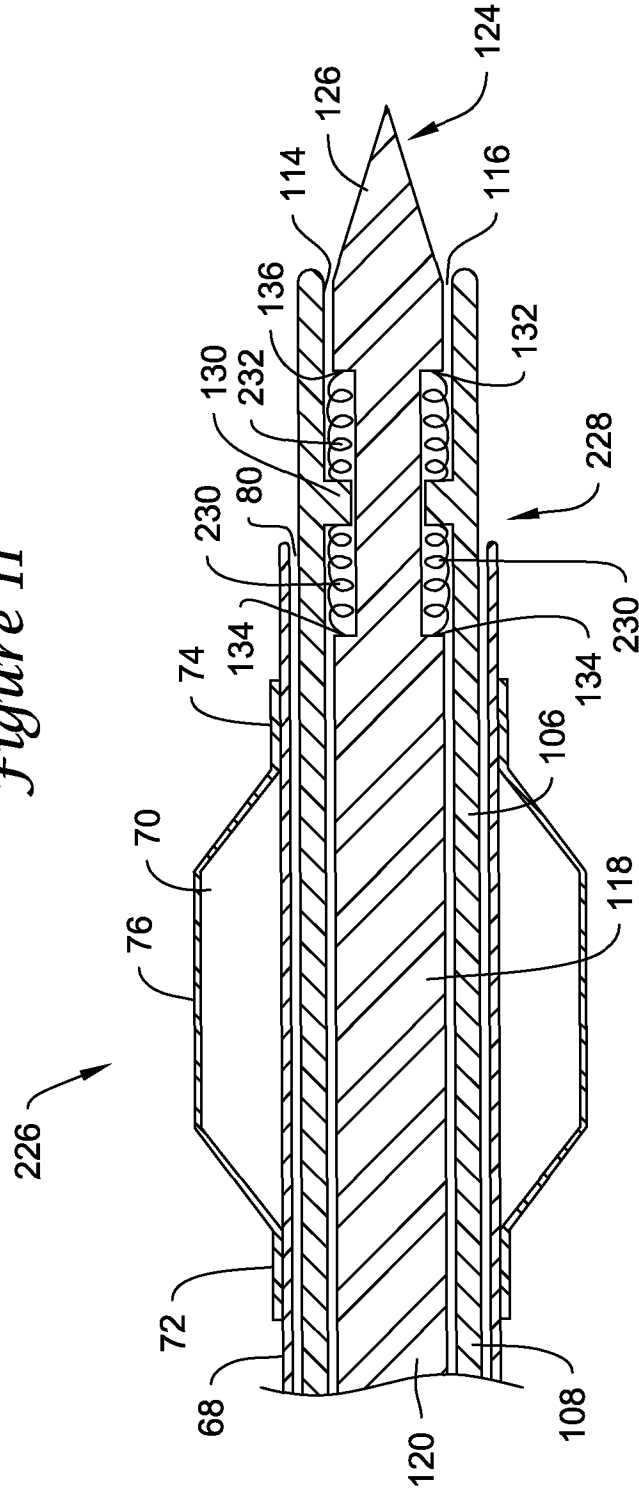


Figure 12

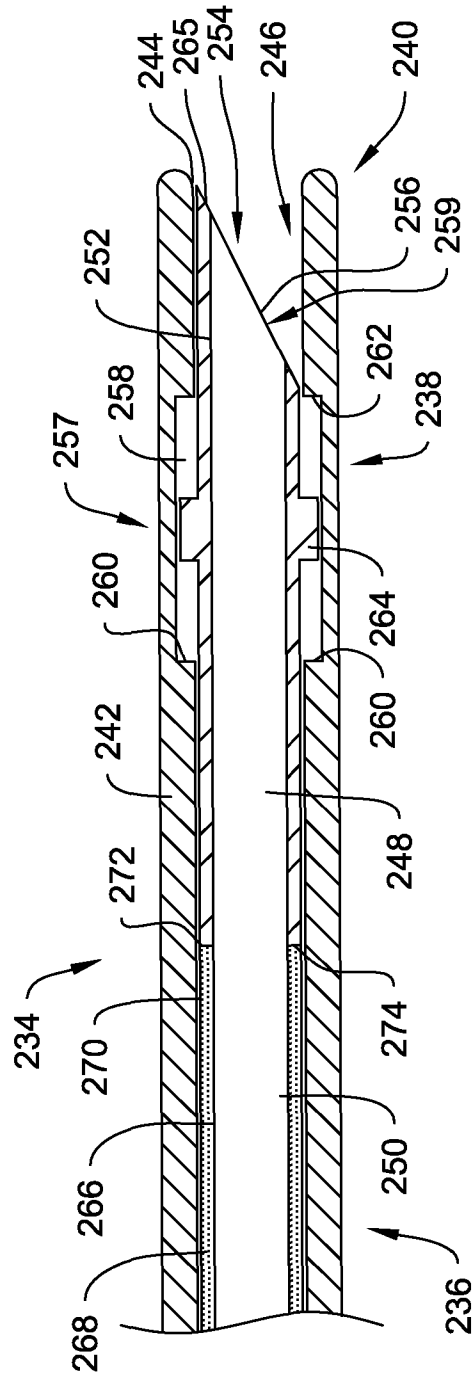
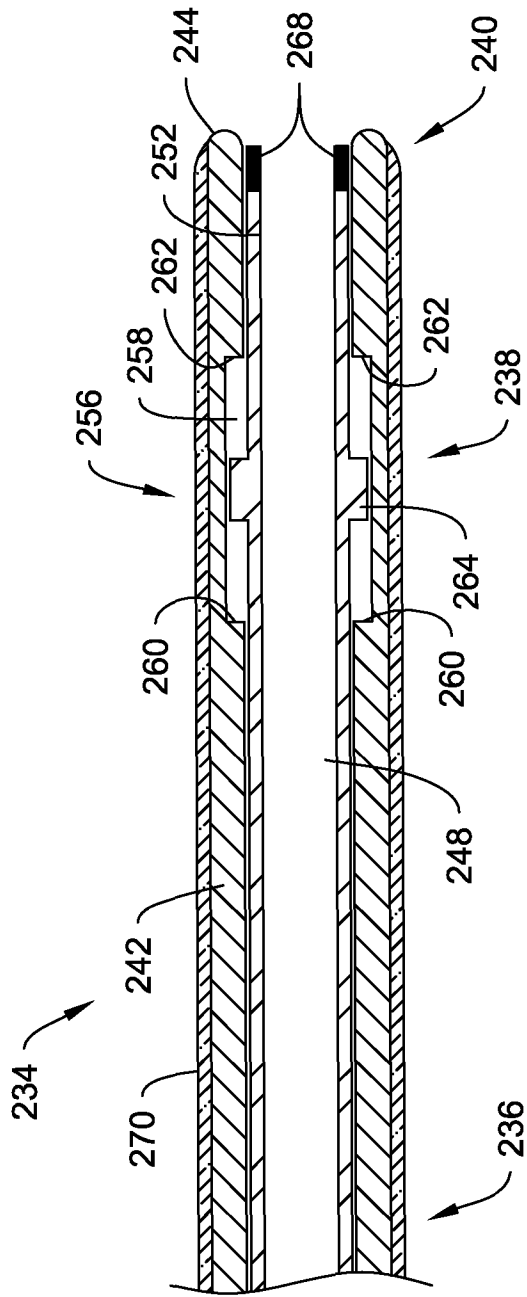


Figure 13



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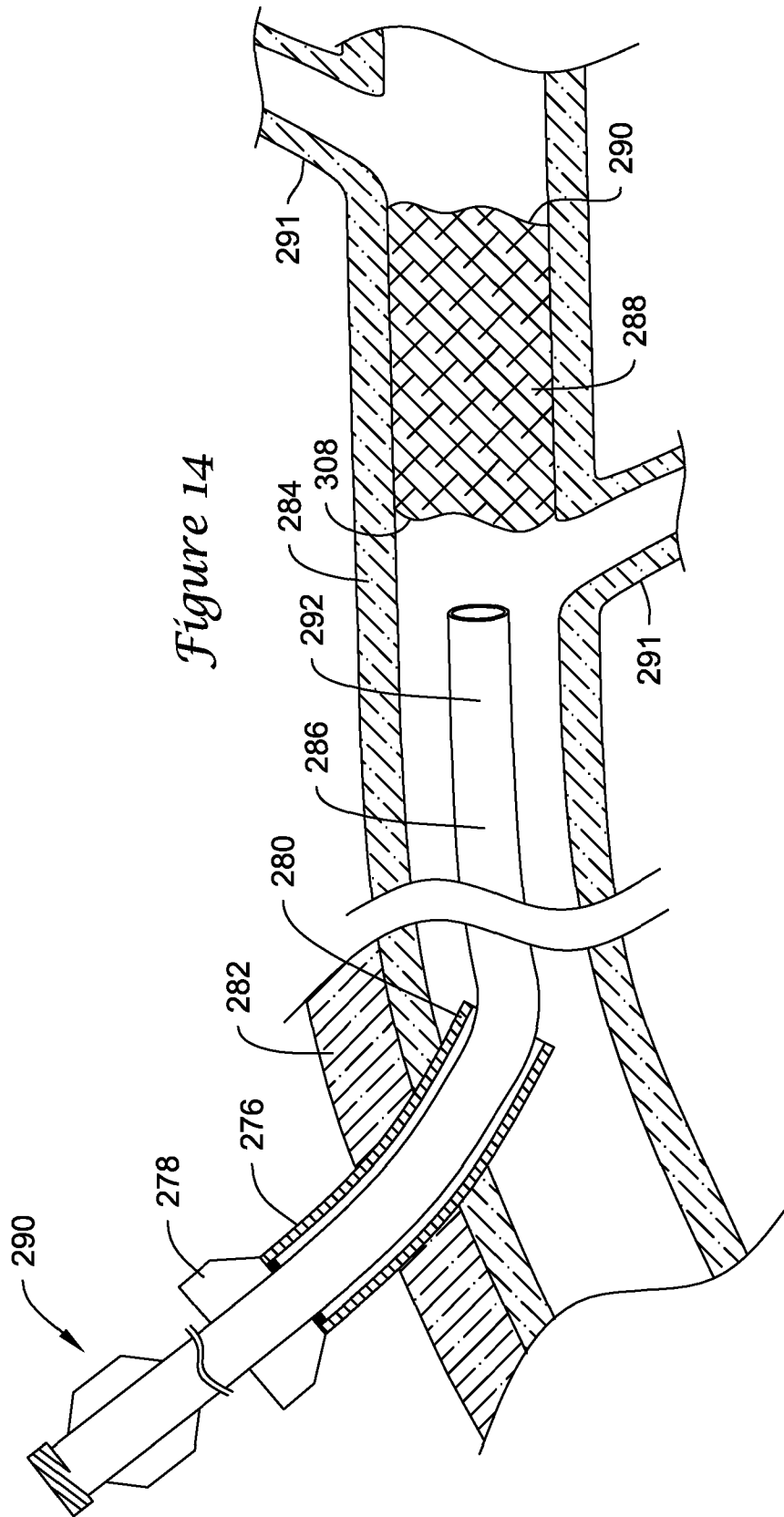


Figure 14

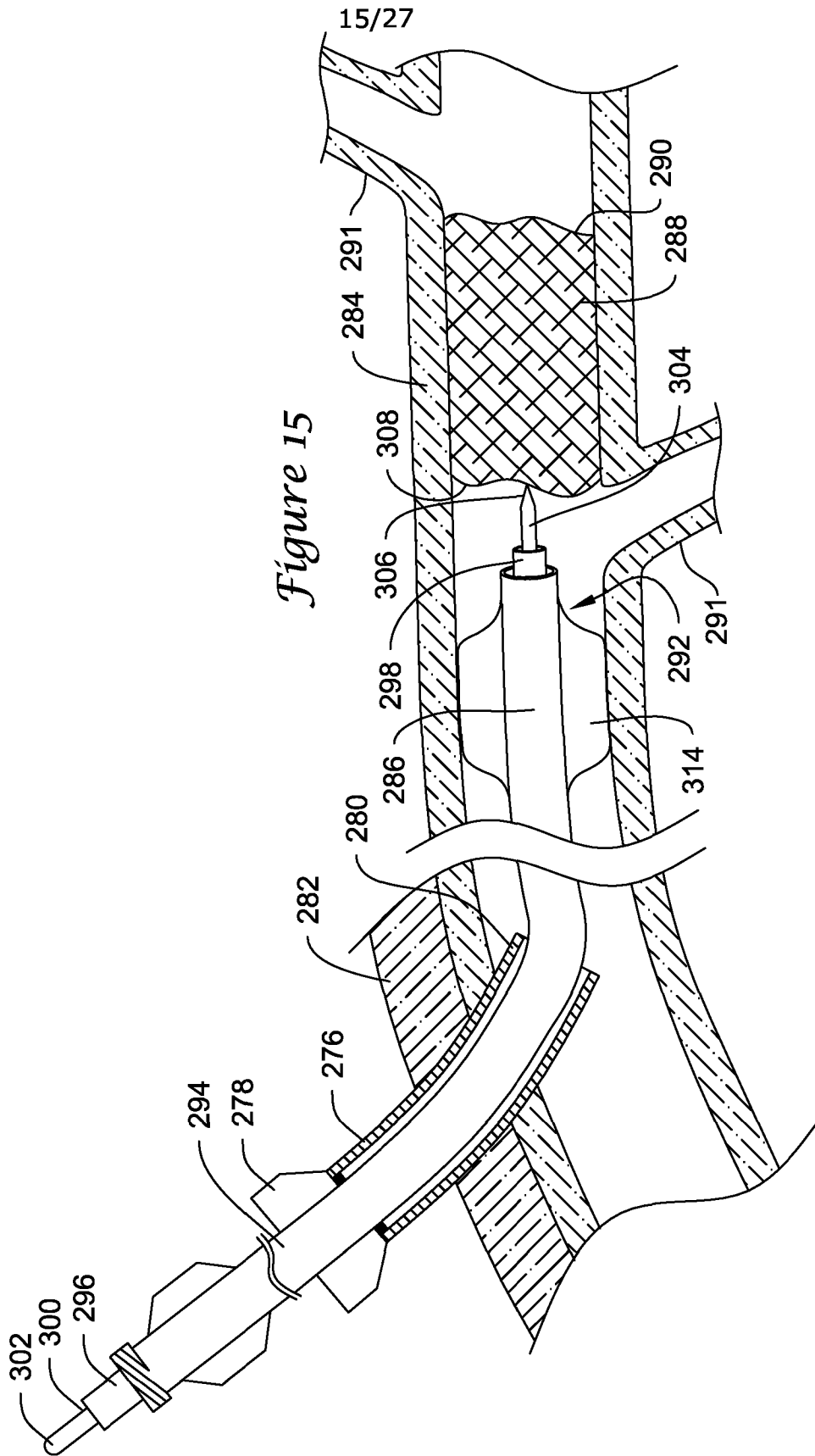
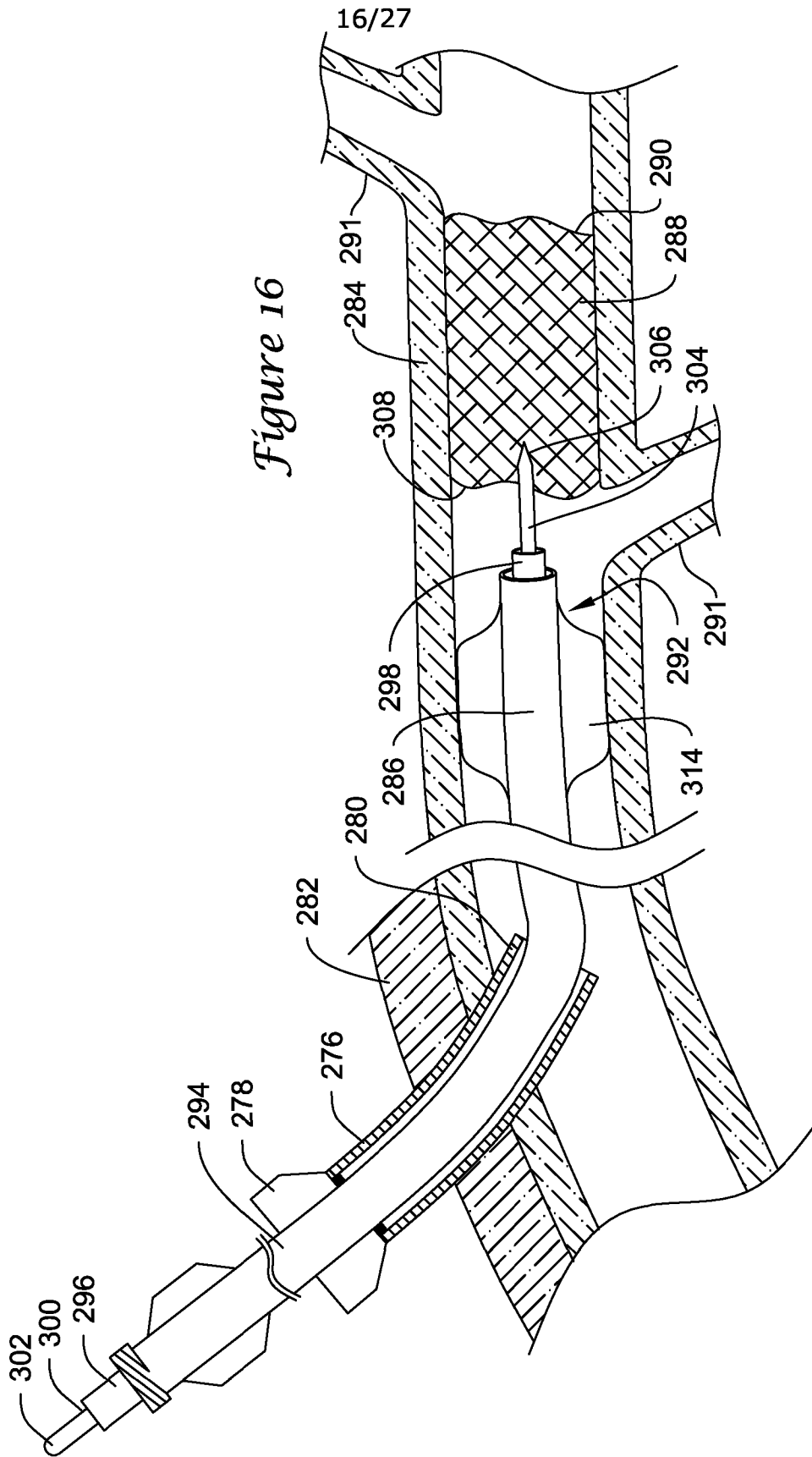


Figure 16



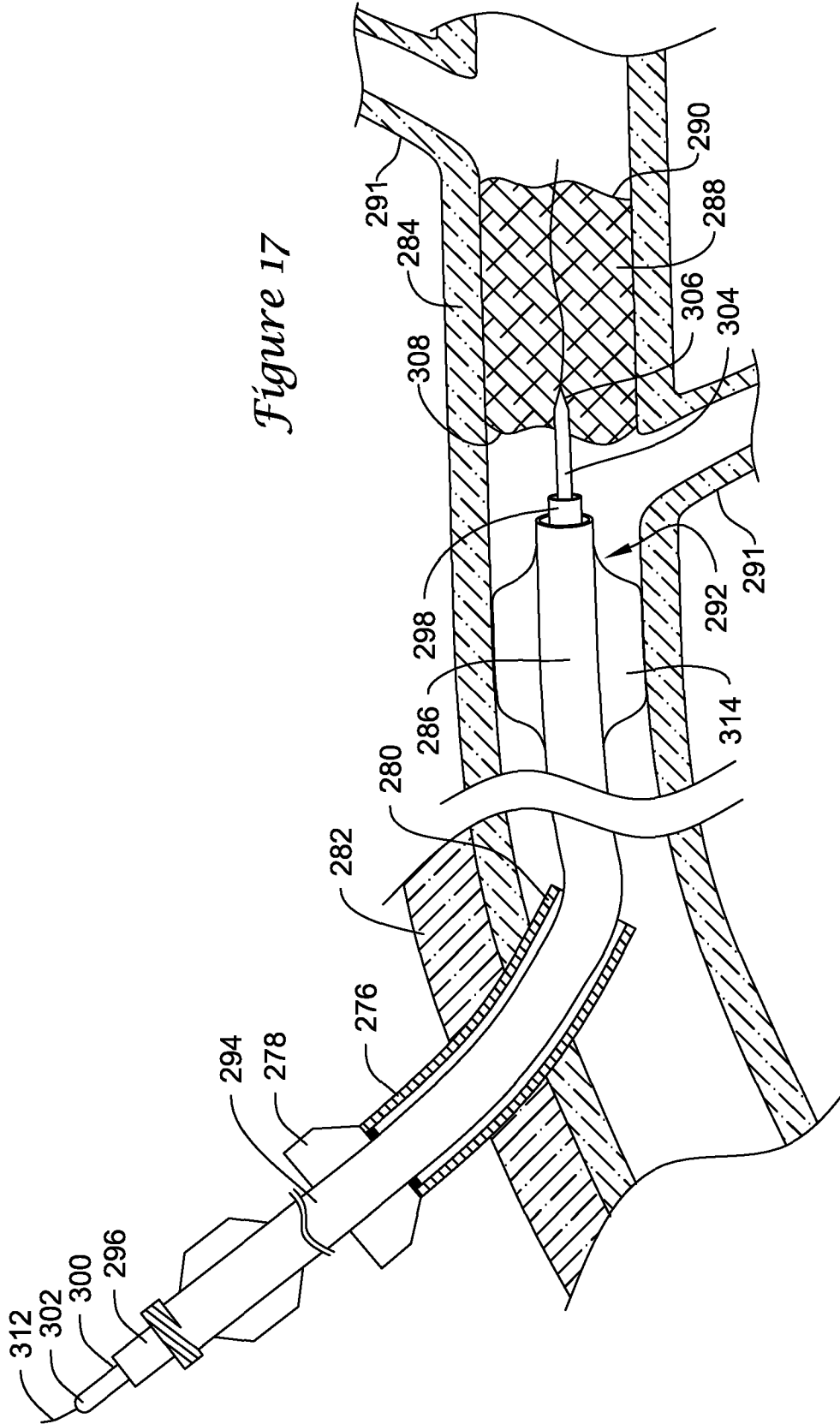
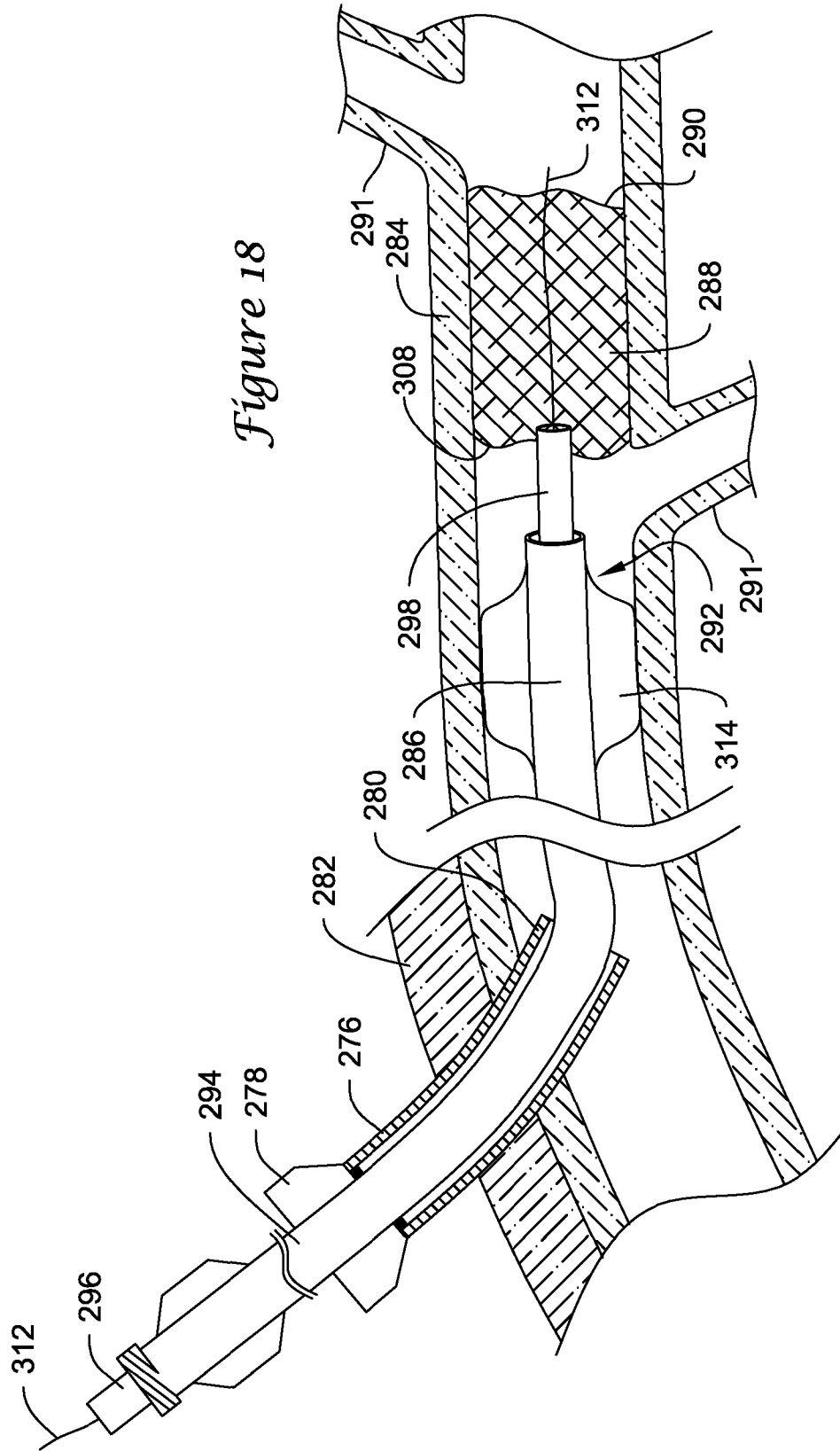
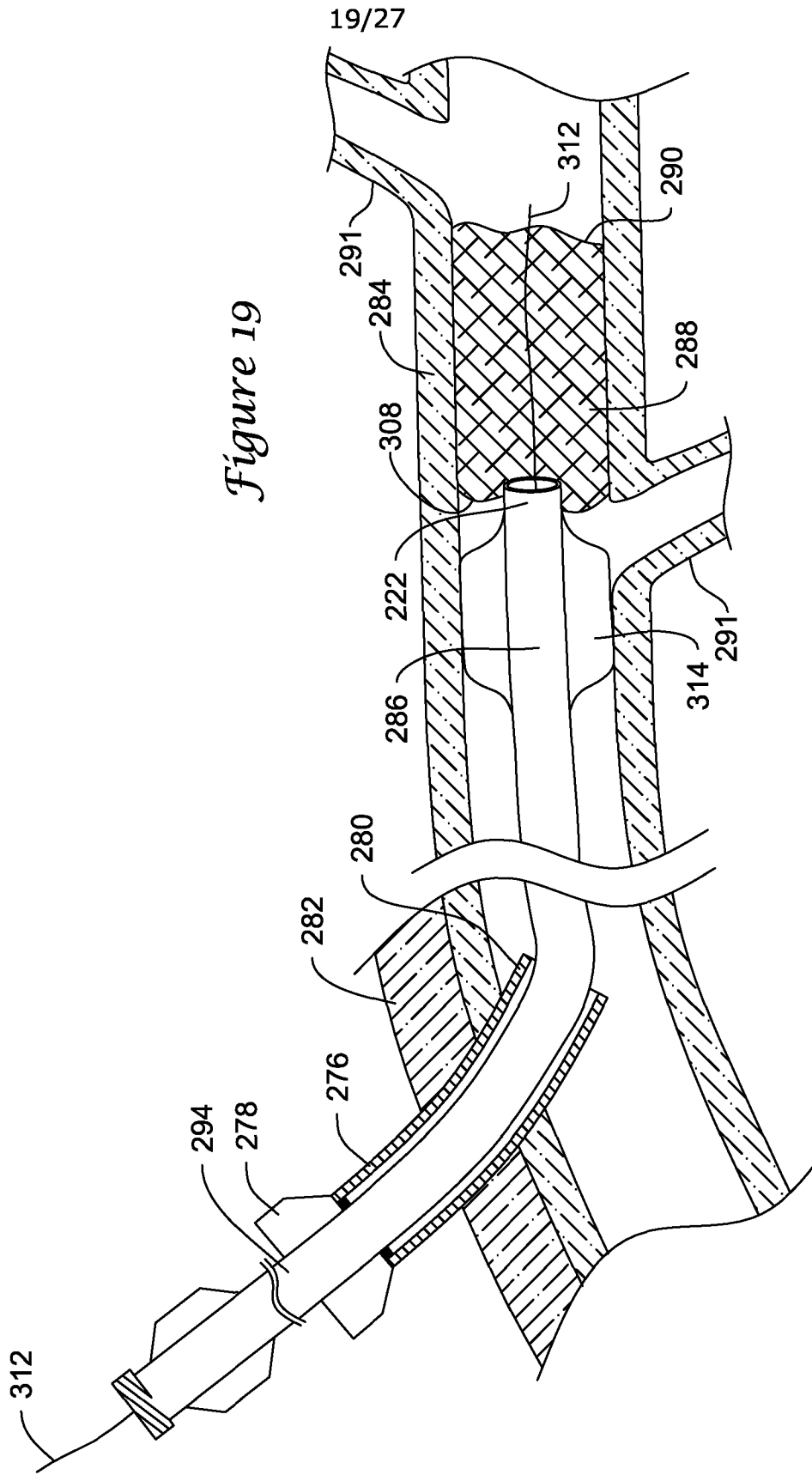
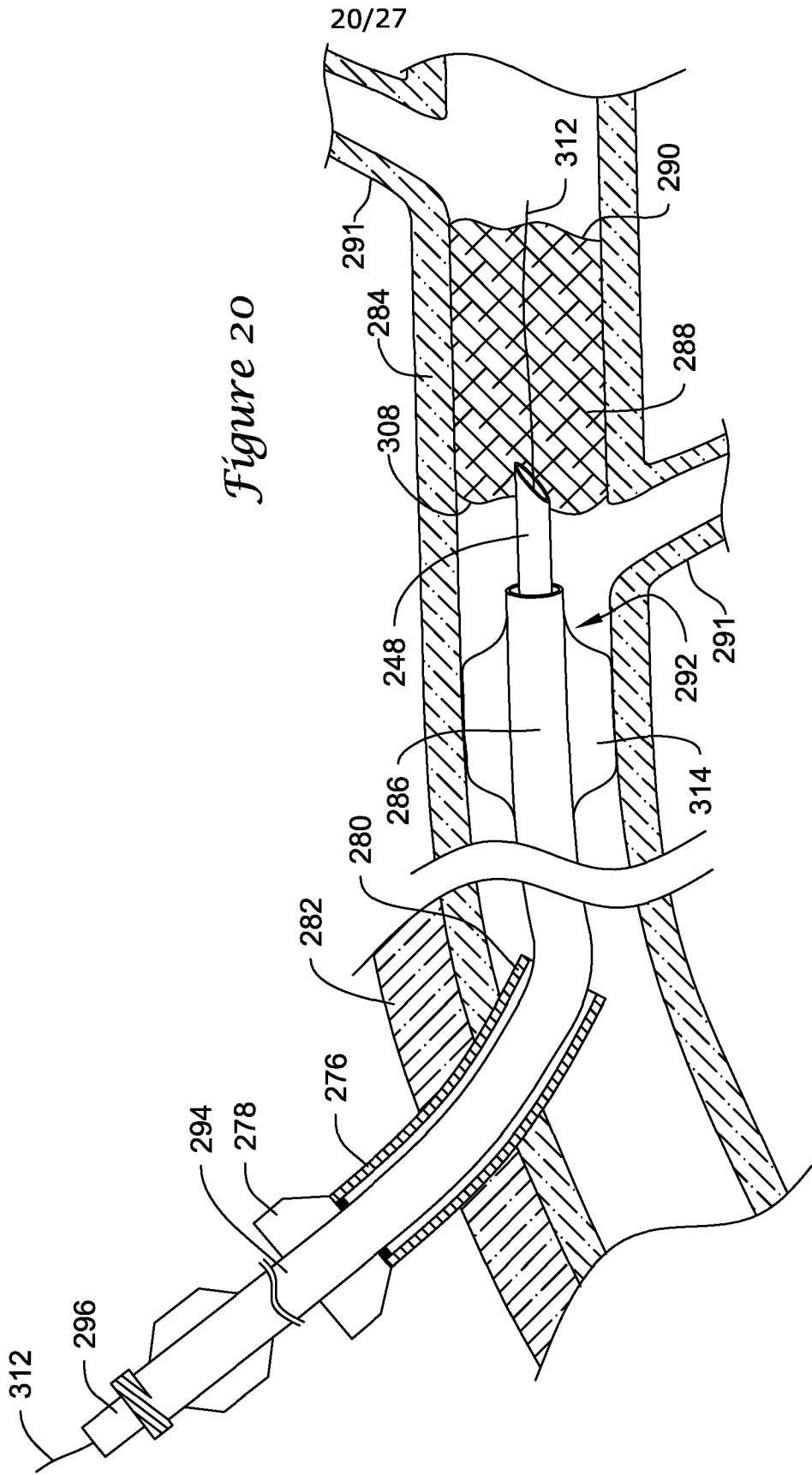


Figure 17

Figure 18







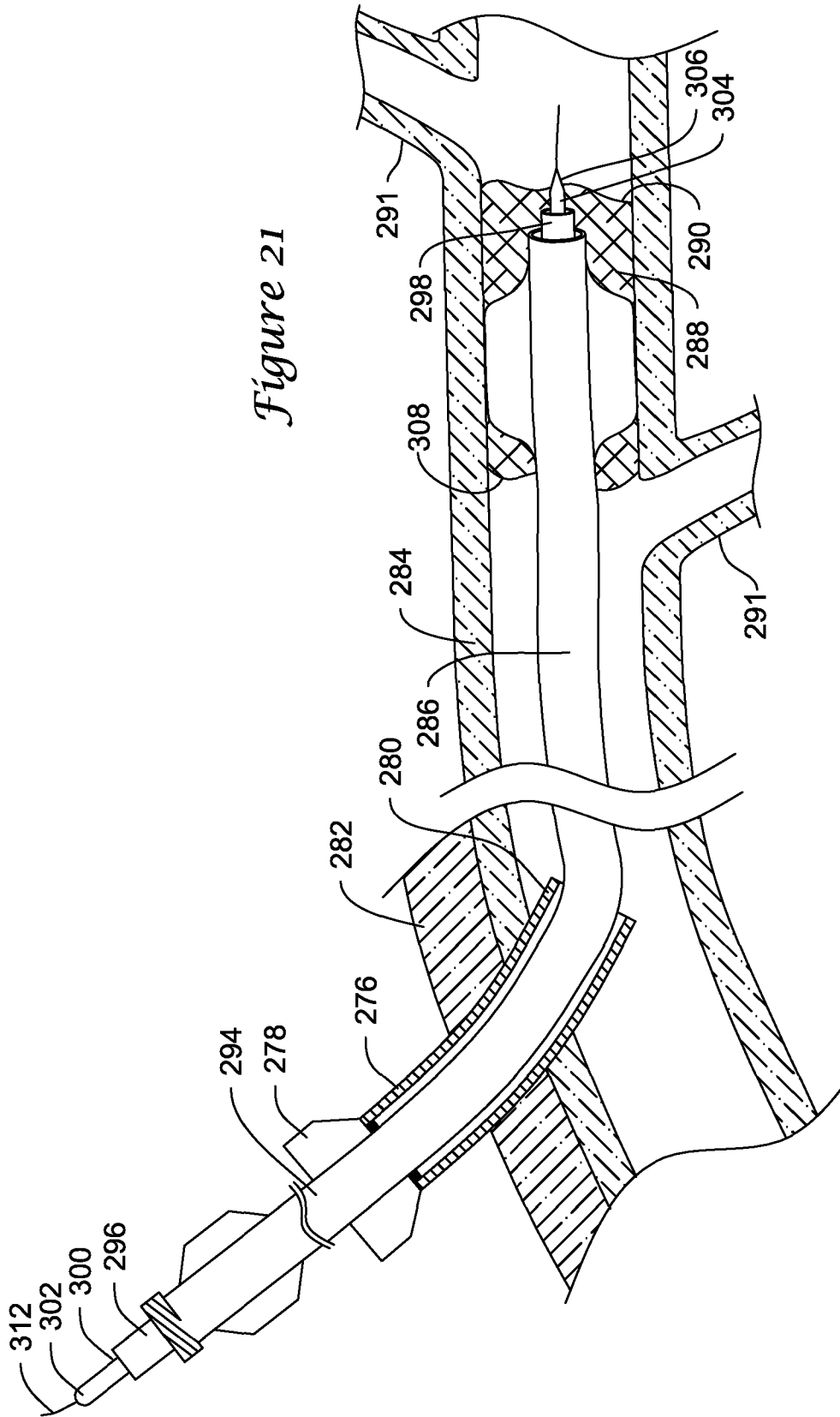
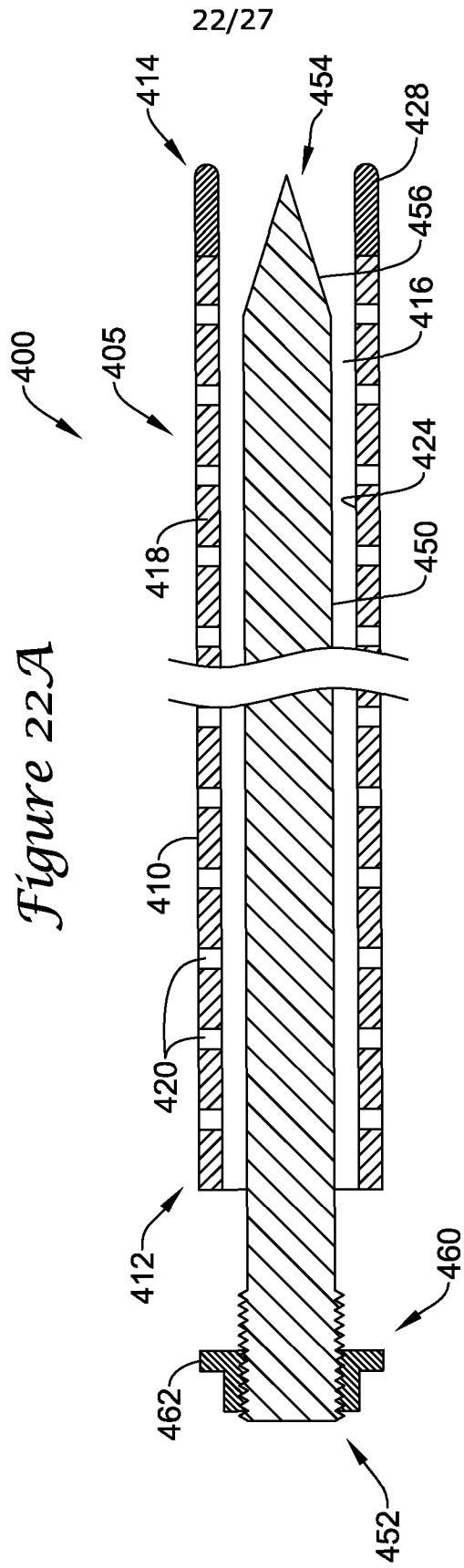
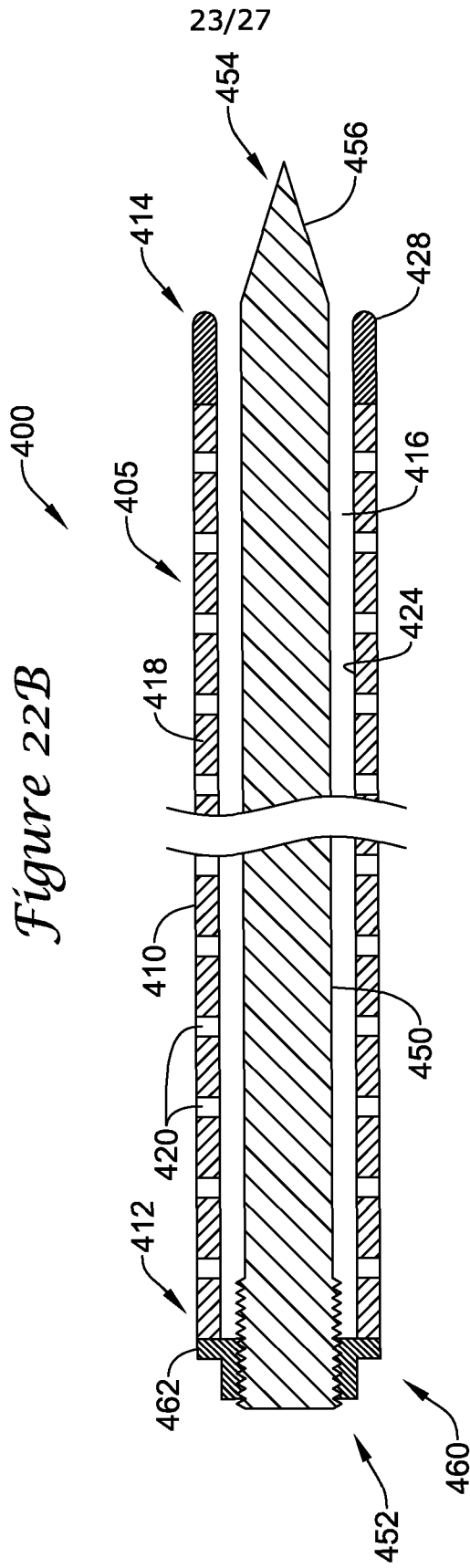
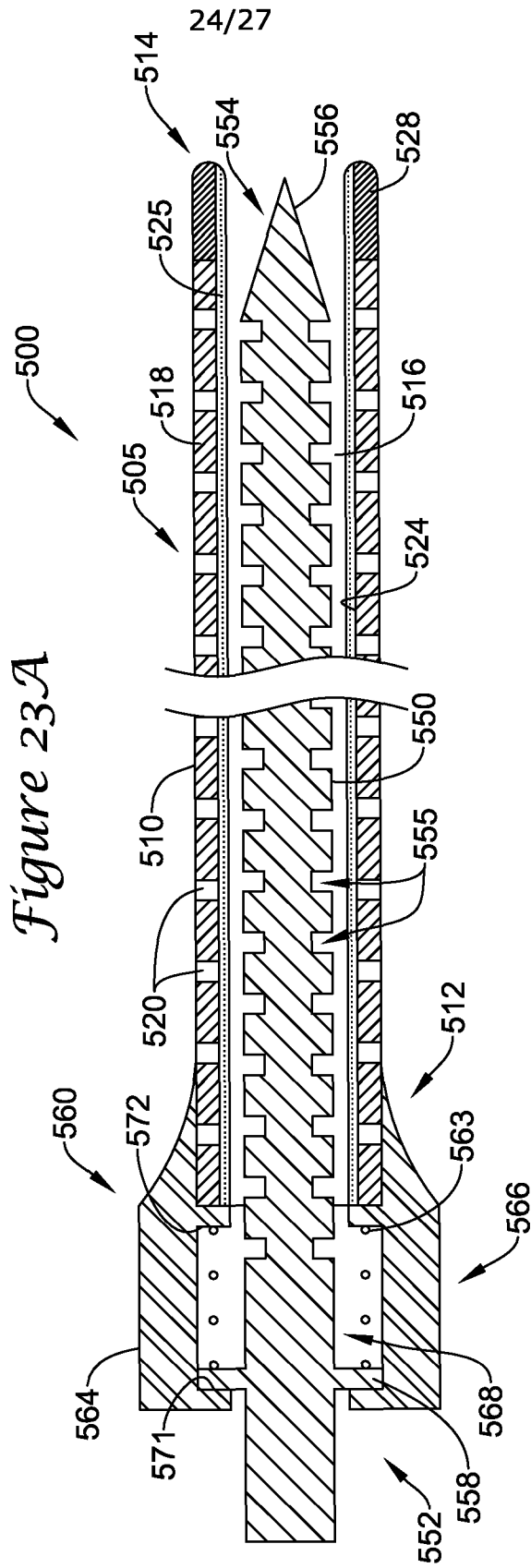


Figure 21







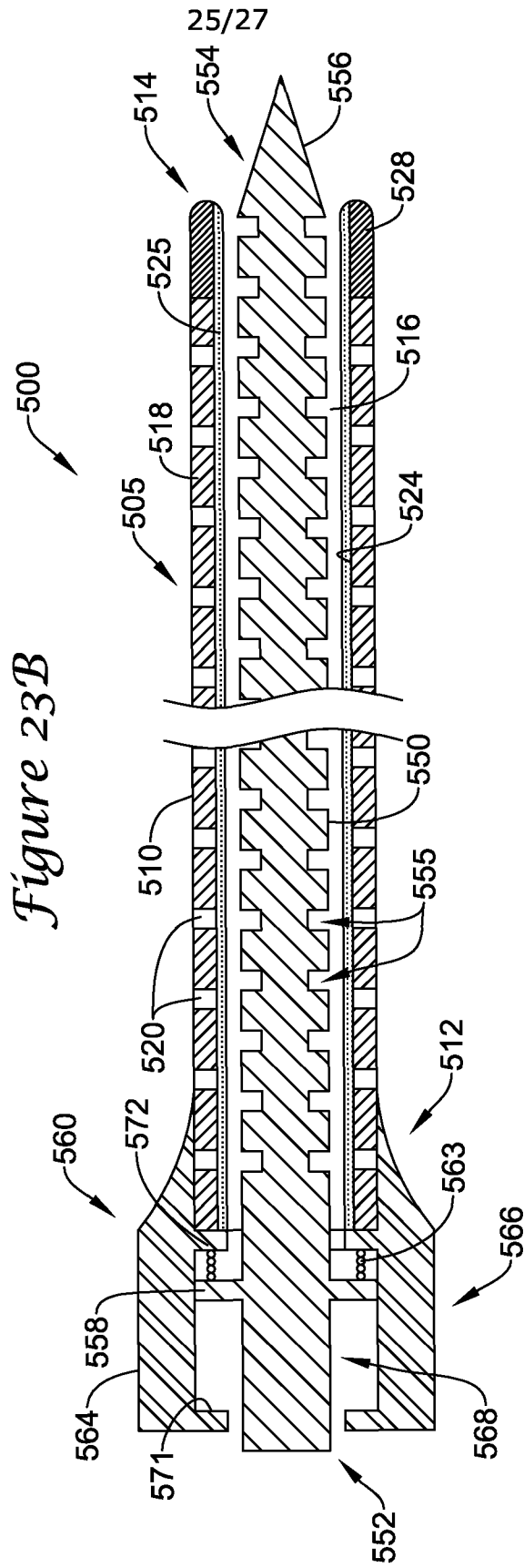
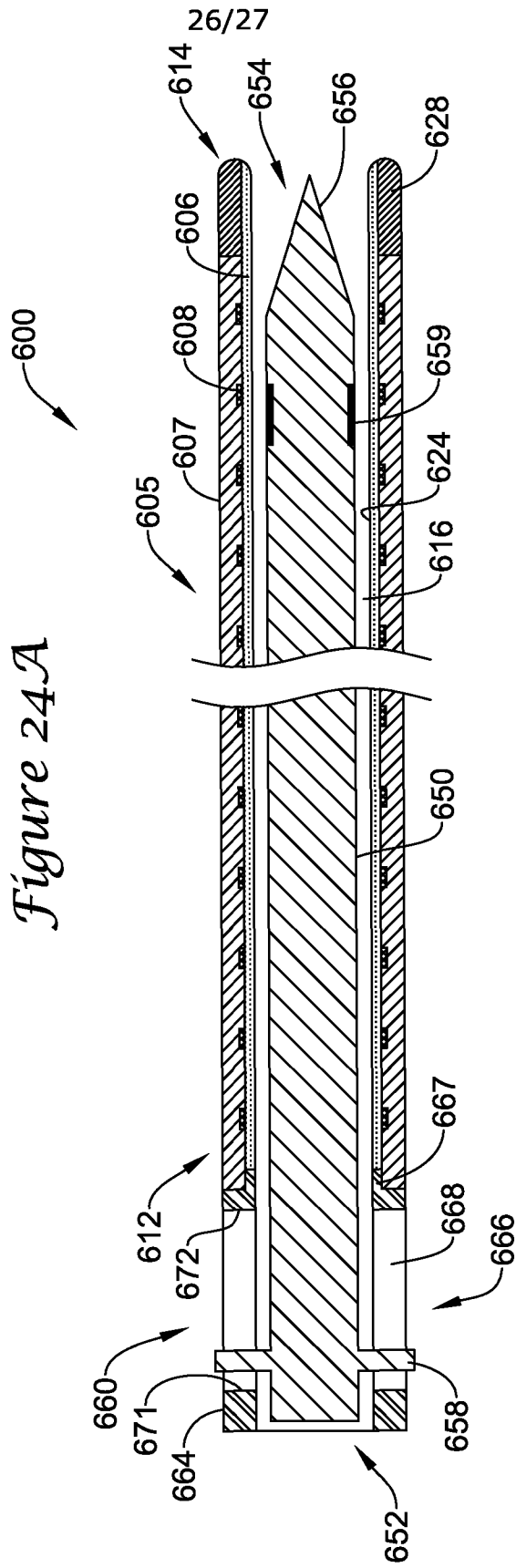
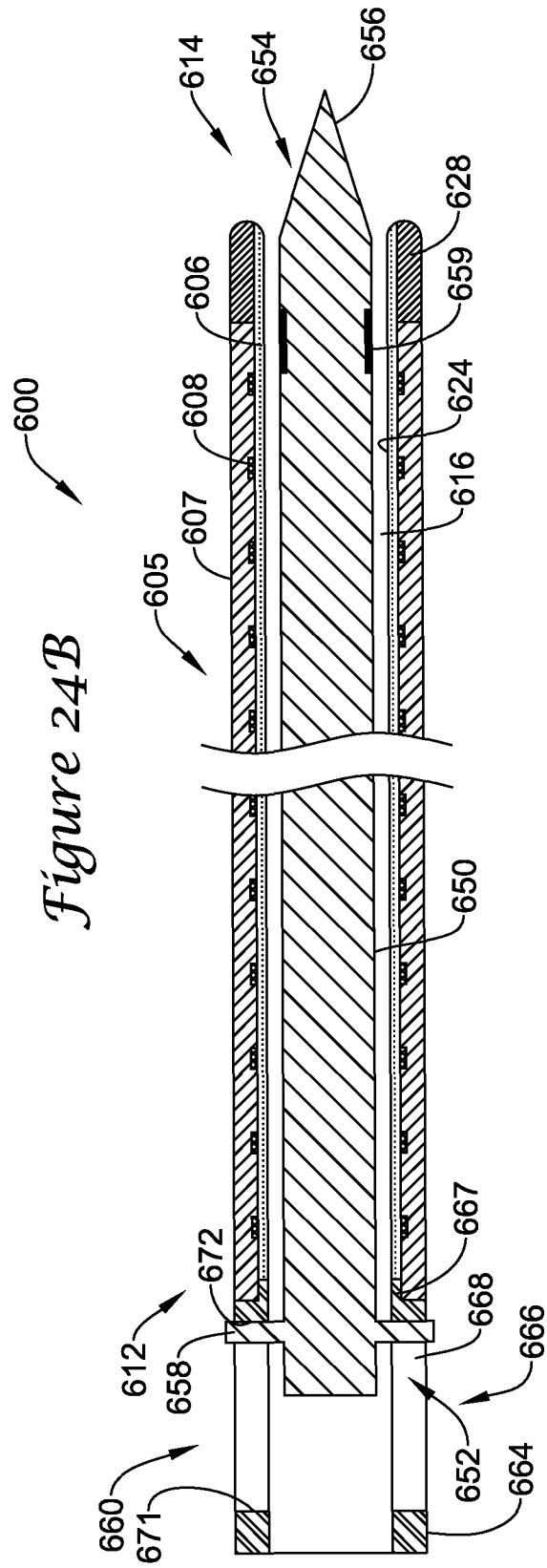


Figure 24A





INTERNATIONAL SEARCH REPORT

International application No PCT/US2007/061995

A. CLASSIFICATION OF SUBJECT MATTER
 INV: A61B17/22 A61M25/00 A61M25/09

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/119615 A1 (NORIEGA GERARDO V [US] ET AL) 2 June 2005 (2005-06-02) claims 1-3,6,7,11,15-18 claims 20-22,25-29,31-33,36,37,40,41; figures 1,3-7C,9,10,12A,12D,15,16-24B paragraphs [0003], [0008] - [0037], [0075] - [0129]	1-20
X	US 2005/288695 A1 (JENSON MARK L [US] ET AL) 29 December 2005 (2005-12-29) figures 1-21 paragraphs [0001], [0005] - [0009], [0030] - [0081]	1,2,4-8, 10-14, 17,19,20
A	----- -/--	3,9,15, 16,18

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

* Special categories of cited documents :

<p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the international filing date</p> <p>*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)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p>	<p>*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</p> <p>*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</p> <p>*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.</p> <p>*&* document member of the same patent family</p>
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Date of the actual completion of the international search 15 June 2007	Date of mailing of the international search report 26/06/2007
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center;">Przykutta, Andreas</p>
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/061995

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/061995

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WO 2006058223 A	01-06-2006	NONE	