



(51) International Patent Classification:

A61M 25/10 (2013.01) A61L 29/04 (2006.01)
A61M 29/02 (2006.01) A61L 29/02 (2006.01)

(21) International Application Number:

PCT/US2014/054802

(22) International Filing Date:

9 September 2014 (09.09.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/875,498 9 September 2013 (09.09.2013) US
62/010,275 10 June 2014 (10.06.2014) US

(71) Applicant: **PRYOR MEDICAL DEVICES, INC.**
[US/US]; 5460 Ward Road, Suite 225, Arvada, CO 80002 (US).

(72) Inventor: **FRANKLIN, Curtis**; 2545 Irving Street, Denver, CO 80211 (US).

(74) Agents: **ROSENBAUM, David, G.** et al.; Rosenbaum IP, 148 Techny Road, Northbrook, IL 60062 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: LOW-PROFILE OCCLUSION CATHETER

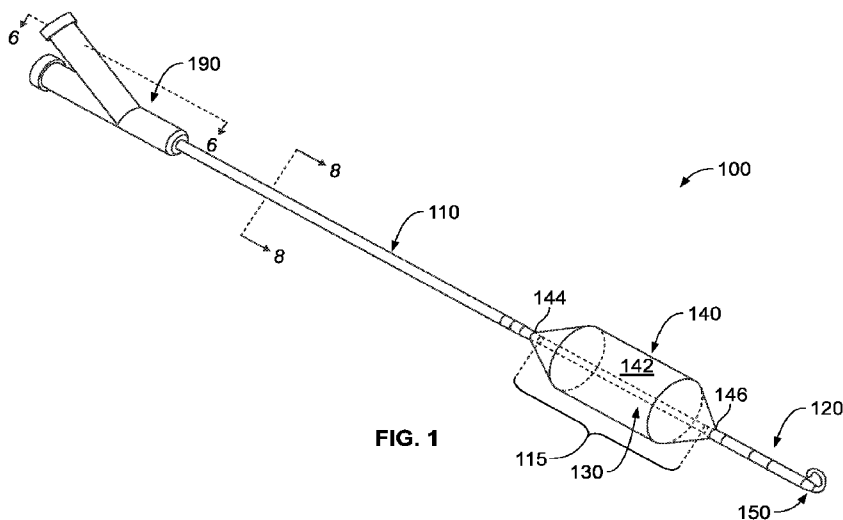


FIG. 1

(57) Abstract: A low profile occlusion catheter having a guiding atraumatic tip that prevents entry of the balloon into collateral vessels. The occlusion catheter system is particularly well suited for use in vascular occlusion and includes a pressure monitoring line to monitor the degree and state of occlusion.



TITLE**LOW-PROFILE OCCLUSION CATHETER****BACKGROUND**

5 [001] The invention generally relates to percutaneously introduced occlusion catheters, and more particularly to an occlusion catheter having an atraumatic guiding tip formed of an elastomeric polymer. More particularly, the present invention pertains to an occlusion catheter in which the atraumatic guiding tip is formed of entirely of polymer, polymer reinforced with a shape memory or superelastic material, or entirely of a shape memory or superelastic material.

10 Still more particularly, the present invention pertains to an occlusion catheter having at least one lumen suitably configured to introduce or withdraw body fluids from a patient into which the catheter is placed, and/or for sensing a condition within the body, such as, for example, pressure or flow rate in the region of the catheter. Yet still more particularly, the present invention pertains to an occlusion catheter having a first catheter member with a first lumen extending

15 longitudinally through the first catheter member and open at a distal end of the first catheter member; a second catheter member having a second lumen extending longitudinally through the second catheter member and open at a distal end of the second catheter member, the second catheter member is positioned over and in spaced apart relationship relative to a proximal section of the first catheter member forming an annular space between the second catheter member and

20 the first catheter member, the proximal section of the first catheter member resides within the second lumen of the second catheter member and the first catheter member extends beyond the distal end of the second catheter member, a third catheter member having a third lumen extending longitudinally through the third catheter member and open at a distal end of the third catheter member; the third catheter member is positioned over a distal section of the first catheter

25 member, the third catheter member having a distal section that extends distally from a distal end of the first catheter member such that the first lumen and the third lumen are in fluid flow communication, whereby the second and third catheter are spaced apart from each other along a longitudinal axis of the first catheter member with the first catheter member extending there between; the atraumatic guiding tip member being joined to a distal end of the third catheter

30 member; and an expandable member, such as a balloon, coupled to the second catheter member

and to the third catheter member, such that the space between the second catheter member member and the third catheter member is within an area bounded by the expandable member.

[002] Balloon catheters generally comprise an elongated catheter shaft with an expandable balloon on the distal end of the shaft, and are used in a number of different medical procedures, including, for example, angioplasty, stent placement, occlusion, drug deliver, etc. The catheter is introduced through a percutaneous introducer sheath and maneuvered into the patient's blood vessels until the balloon is properly positioned within the body, such as at the stenotic site to be dilated or at a site requiring occlusion, drug delivery or other procedure such as stent placement.

[003] It is often desirable for balloon catheters to have very low profiles in order to facilitate passage of the balloon across severe and remote vascular obstructions. High strength materials are commonly required in the design of balloon catheter components to prevent shaft buckling when the balloon is inflated. Additionally, high strength materials are required so that torque applied to the proximal end of the catheter results in rotation of the distal tip of the catheter. High flexibility materials are also commonly required in the design of balloon catheter components to maintain a low-profile and avoid trauma or perforation of the blood vessels while the catheter is maneuvered through the patient's tortuous vasculature.

[004] Conventional balloon catheters, particularly those intended for vascular occlusion, do not adequately balance the need for proximal segment stiffness with the need for low profile, flexible distal segment and trackability through the tortious vascular pathway without entry into collateral vessels. Therefore, a need exists for a low profile occlusion catheter with a high strength and relatively stiff proximal segment and a flexible distal segment with an atraumatic tip having a design that permits tracking along the major vessels while preventing entry into collateral vessels.

SUMMARY OF THE INVENTION

[005] Described herein are systems, methods and compositions for an occlusion catheter system comprising: a first catheter member having a first lumen extending longitudinally through the first catheter member and open at a distal end of the first catheter member; a second catheter member having a second lumen extending longitudinally through the second catheter member and open at a distal end of the second catheter member, the second catheter member is positioned over and in spaced apart relationship relative to a proximal section of the first catheter member

forming an annular space between the second catheter member and the first catheter member, the proximal section of the first catheter member resides within the second lumen of the second catheter member and the first catheter member extends beyond the distal end of the second catheter member, a third catheter member having a third lumen extending longitudinally through
5 the third catheter member and open at a distal end of the third catheter member; the third catheter member is positioned over a distal section of the first catheter member, the third catheter member having a distal section that extends distally from a distal end of the first catheter member such that the first lumen and the third lumen are in fluid flow communication, whereby the second and third catheter are spaced apart from each other along a longitudinal axis of the first catheter
10 member with the first catheter member extending there between; an atraumatic tip member having a proximal section co-axially coupled to a distal end of the third catheter member and terminating the third lumen in the third catheter member; and an expandable occlusion member, such as a balloon, coupled at its proximal end to the second catheter member and at its distal end to the third catheter member and in fluid flow communication with the second lumen of the
15 second catheter member, the expandable occlusion member being positioned such that the longitudinal space between the second catheter member and the third catheter member is within the expandable occlusion member.

[006] Also disclosed herein are systems, methods and compositions for occlusion occlusion catheter system comprising: a first catheter member having a first and second lumens extending
20 along a longitudinal axis thereof that forms a proximal section of the catheter system, a second catheter member having a third lumen forming a distal section of the catheter system and coupled to a distal end of the first catheter member, an expandable occlusion balloon coupled at its proximal end to a distal end of the first catheter member and at its distal end to a proximal end of the second catheter member, a first lumen of the first catheter member terminating within the
25 expandable occlusion balloon to communicate an inflation fluid to an area within the expandable occlusion balloon and a second lumen of the first catheter member being in fluid flow communication with the third lumen of the second catheter member, an atraumatic guiding tip coupled to a distal end of the third lumen of the second catheter member;; and a third catheter member having at least one lumen passing longitudinally there through, the third catheter
30 member being disposed within each of the second lumen of the first catheter member and the third lumen of the second catheter member and passing there through.

[007] The methods, systems, and apparatuses are set forth in part in the description which follows, and in part will be apparent from the description, or can be learned by practice of the methods, apparatuses, and systems. The advantages of the methods, apparatuses, and systems will be realized and attained by means of the elements and combinations particularly pointed out
5 in the appended claims. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the methods, apparatuses, and systems, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[001] In the accompanying figures, like elements are identified by like reference numerals
10 among the several preferred embodiments of the present invention.

[002] FIG. 1 is a perspective view of an embodiment of a occlusion catheter described herein.

[003] FIG. 2 is an enlarged perspective view of the first part of the inventive occlusion catheter depicted in FIG. 1.

[004] FIG. 3 is a longitudinal cross-sectional view of FIG. 2.

15 [005] FIG. 4 is a perspective view of a distal section of the inventive occlusion catheter depicted in FIG. 1

[006] FIG. 5 is a perspective longitudinal cross-sectional view taken along line 5-5 of FIG 4.

[007] FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 1.

20 [008] FIG. 7 is a partial cross-sectional end view of a proximal hub of the occlusion catheter of the present invention.

[009] FIG. 8 is a transverse cross-sectional view taken along line 8-8 of Fig 1 and line 8-8 of Fig. 6.

[010] FIG. 9 is a perspective view of an alternative embodiment of the inventive occlusion catheter.

25 [011] FIG. 9A is a cross-sectional view taken along line 9A-9A of FIG. 9.

[012] FIG. 9B is a partial cross-sectional end view of FIG. 9.

[013] FIG. 9C is a cross-sectional view taken along line 9C-9C of FIG. 9

[014] FIG. 9D is a cross-sectional view taken along line 9D-9D of Fig. 9.

30 [015] FIG. 10 is a perspective view of another alternative embodiment of the inventive occlusion catheter depicting an alternative embodiment of a guiding atraumatic tip.

[016] FIG 11 is an enlarged perspective view of the alternative embodiment of the guiding alternative tip of FIG. 10.

[017] FIG. 12 is a perspective view of another embodiment of a occlusion catheter described herein.

5 [018] FIG. 13 is an enlarged perspective view of the first part of the inventive occlusion catheter depicted in FIG. 12.

[019] FIG. 14 is a longitudinal cross-sectional view of FIG. 13.

[020] FIG. 15 is a perspective view of a distal section of the inventive occlusion catheter depicted in FIG. 12

10 [021] FIG. 16 is a perspective longitudinal cross-sectional view taken along line 16-16 of FIG 15.

[022] FIG. 17 is a cross-sectional view taken along line 17-17 of FIG. 12.

[023] FIG. 18 is a transverse cross-sectional view taken along line 18-18 of Fig. 1 and line 18-18 of Fig. 6.

DETAILED DESCRIPTION OF THE INVENTION

15 [008] The foregoing and other features and advantages of the invention will become more apparent from the following detailed description of exemplary embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

20 [009] While the invention has been described in connection with various embodiments, it will be understood that the invention is capable of further modifications. This application is intended to cover any variations, uses or adaptations of the invention following, in general, the principles of the invention, and including such departures from the present disclosure as, within the known and customary practice within the art to which the invention pertains.

25 [010] Furthermore, while the invention is described as an occlusion catheter system, it will be understood that the inventive occlusion catheter system may be used clinically for a variety of different therapeutic or diagnostic indications involving vascular interventions, including, for example and without limitation, vascular occlusion, angioplasty, stent delivery, artherectomy, drug delivery, imaging or the like. In accordance with an exemplary and preferred embodiment,
30 the inventive occlusion catheter system is well suited for use as a vascular occlusion occlusion catheter, and in particular an aortic occlusion balloon catheter. Applications making

advantageous use of embodiments of the invention may use any suitable access site for vascular intervention. For example, applications of the catheter system may involve access at the femoral artery, the brachial artery, the subclavian artery, or any other blood vessel suitable for use as an access site for catheterization, including venous vessels.

5 [011] In the following description, when reference is made to the terms “proximal” or “proximally” it is intended to mean a portion or component of the inventive occlusion catheter system that is oriented away from the body into which the system is or is intended to be placed. Conversely, when reference is made to the terms “distal” or “distally” it is intended to mean a portion or component of the inventive occlusion catheter system that is oriented toward the body
10 into which the system is or is intended to be placed. Thus, for example, the guiding atraumatic tip described hereinafter is located at a distal end of the occlusion catheter system, while the proximal hub is located at a proximal end of the occlusion catheter system.

[012] As shown in the accompanying Figures, the occlusion catheter system 100 generally includes a catheter assembly having a first catheter member 130 having a first lumen 230, a
15 second catheter member 110 having a second lumen 210, a third catheter member 120 having a third lumen 220, an expandable occlusion member 140, a proximal hub 190 and a guiding atraumatic tip 150. The first lumen 230 of the first catheter member 130 extends longitudinally through the first catheter member and is coupled at its proximal end to the proximal hub 190 and at its distal end to a proximal section of the third catheter member 120 and in fluid flow
20 communication with the third lumen 220 of the third catheter member 120. The second lumen 210 of the second catheter member 110 also extends longitudinally through the second catheter member 110, and terminates in a first port 160 distal to a proximal end of and within a space 142 defined by the expandable occlusion balloon 140, such that the second lumen 210 is in fluid flow communication with the space 142 within the expandable occlusion member 140 to convey a
25 fluid to and from the expandable occlusion member 140 from a fluid source external the occlusion catheter system 100, coupled to the proximal hub 190 via extension lines (not shown) and in fluid communication with the second lumen 210. The third catheter member 120 is coupled at a proximal end thereof to a distal end of the first catheter member 130 such that the third lumen 220 of the third catheter member 120 is in fluid flow communication with the first
30 lumen 230 of the first catheter member 130. The second catheter member 110 and the third catheter member 120 are positioned in longitudinal co-axial spaced apart relationship from one

and other along a longitudinal axis of the first catheter member 130 thereby defining an intermediate region 115 of the first catheter member 130 within the space 142 within the expandable occlusion balloon 140 that is not covered by either the second catheter member 110 or the third catheter member 120.

5 [013] The expandable member, such as an expandable occlusion balloon, 140 is attached, at its proximal end 144 to a distal end of the second catheter member 110 and at its distal end 146 to a proximal end of the third catheter member 120. Referring to FIGs. 2-5, a proximal radio opaque marker 158 may be affixed to the first catheter member 130 at or near the first port 160, which is near the attachment position of the expandable occlusion balloon at the proximal end 144 of the
10 expandable occlusion balloon 140. A distal radio opaque marker 159 may be affixed to the first catheter member 130 near the attachment position of the expandable occlusion balloon on the distal end 146 of the expandable occlusion balloon 140. The proximal and distal radio opaque markers 158, 159 may be implemented as bands made of a radio opaque material. In one example, the radio opaque material is a metal that is radio opaque such as stainless steel, or an
15 alloy, such as a platinum iridium alloy. In another example, the proximal and distal radio opaque markers 158, 159 may be sections of the catheters that have been impregnated with radio opaque material such as for example stainless steel or a suitable alloy. In another example, the proximal and distal radio opaque markers 158, 159 may be implemented as bands or sections of polymer, such as, for example, polyether block amide copolymer (PEBAX, Arkema, Paris, France) that
20 has been mixed or doped with with a radio opaque substance, such as, for example, barium sulfate. The implementation of the proximal and distal radio opaque markers 158, 159 on the catheter system would aid in visualization of the balloon position within the vasculature using fluoroscopy or x-ray.

[014] When an expandable occlusion balloon 140 is employed, it is inflated by introducing an
25 inflation fluid, such as saline, from an external source, such as a syringe, coupled to the proximal hub 190, into and through the second lumen 210, out of the first port 160 and into the space 142 within the expandable occlusion balloon 140. As is known in the art, the inflation fluid is introduced until the expandable occlusion balloon 140 is inflated to a desired diameter volume, pressure or visual appearance when visualized using imaging modalities such as X-ray or
30 fluoroscopy. Deflation of the expandable occlusion balloon 140 is simply the reverse process of withdrawing the inflation fluid from the space 142 of the inflation balloon 140. In its deflated or

collapsed state, the inflation balloon 140 will be positioned either within or adjacent to the intermediate region 115 of the first catheter member 130, thereby providing a lower profile to the entire occlusion catheter system 100.

5 [015] The third catheter member 130 is depicted more particularly in FIGS. 4-5. Third catheter member 120 is coupled at its proximal end to a distal end of the first catheter member 130. A second port 170 passes through a side wall of the third catheter member and communicates between the third lumen 220 and external the occlusion catheter system 100. The distal end of the first catheter member positioned within the third lumen 220 terminates proximal to the second port 170 such that a continuous fluid flow pathway is formed between the first lumen 10 230, the third lumen 220 and the second port 170 to either introduce fluid or withdraw fluid through the second port 170. It will also be understood by those skilled in the art that maintaining fluid communication between the first lumen 230, the second lumen 220 and the second port 170 also permits introduction of tethered sensors, such as flow sensing wires, pressure sensing wires or the like into and through the first lumen 230 and the third lumen 220 to 15 a position proximate to the second port 170.

[016] Finally, a guiding atraumatic tip 150 is coupled to a distal end section of the third catheter member 120. The guiding atraumatic tip 150 may be made of an elastic, shape memory and/or superelastic material, such as a metal or polymer. A reinforcing member 152 (depicted in phantom) may optionally be included either within the guiding atraumatic tip 150 or wound 20 about an external surface of the guiding atraumatic tip 150 to offer additional reinforcement to the tip 150. A proximal end of the guiding atraumatic tip 150 is coupled to a distal end of the third lumen 220 of the third catheter member 120 and a distal end of the guiding atraumatic tip 150 projects distally from the third catheter member 120 and preferably has a generally circular configuration curving proximally and then toward a central longitudinal axis of the occlusion catheter system 100, but leaving a disconnected end of the distal end of the guiding atraumatic tip 25 150 to permit the tip 150 to assume a linear configuration co-axial with the central longitudinal axis of the occlusion catheter system 100 for delivery.

[017] In a first embodiment of the inventive occlusion catheter system 100 illustrated in FIGS. 1-8, the occlusion catheter system 100, when the expandable member 140 is in an unexpanded 30 condition, is of sufficiently small cross-segmental dimension to pass through a 6 French (2 mm) percutaneous sheath. It will be understood by those skilled in the art that the occlusion catheter

system 100 is not limited to a dimension sufficient to pass through a 2 mm (6 French) percutaneous sheath, but that such lower profile or smaller is generally considered desirable to enable percutaneous introduction of the occlusion catheter system 100 and ease of navigation through tortuous vasculature and to a desired position within the body for purposes of vascular occlusion. The occlusion catheter system 100 is, therefore, not intended to be limited to this dimensional size, but may be made of smaller or larger dimension as desired or needed depending upon the site of required occlusion within the body.

[018] In one embodiment of the invention, the first catheter member 130 is formed of stainless steel metal and is radio opaque. In accordance with another embodiment of the invention, the first catheter member 130 of nitinol. In accordance with yet another embodiment of the invention the first catheter member 130 formed of biocompatible polymers. It still yet another embodiment of the invention the first catheter member 130 is made of a metal reinforced polymer. The first catheter member 130 lends column strength to the occlusion catheter system 100 and provides a functional backbone for carrying the second catheter member 110, the third catheter member 120 and the expandable occlusion balloon.

[019] The outer diameter of the first catheter member 130 is smaller than the inner diameter of the second lumen 210 of the second catheter member 110 thereby forming an annular space 212 between the outer surface of the first catheter member 130 and the inner surface of the second catheter member 110 210 (FIGS. 7-8).

[020] In one embodiment of the invention, the distal end of the second catheter member 110 may have a tapering or narrowing diameter of the outside surface and/or the second lumen 210 diameter. Preferably, there is a minimal amount of narrowing on the second catheter member 110 and the proximal lumen 210 to allow the annular space 212 to remain sufficiently large down the length of the second catheter member 110 to permit adequate flow of the inflation fluid through the annular space 212.

[021] Turning now to FIGS. 4-5, the distal portion of the occlusion catheter system 100 is illustrated. The first lumen 230 of the first catheter member 130 may be used as a pressure monitoring line, such as by using a fluid column therein to sense pressures through the second port 170; alternatively, the first lumen 230 may be used to introduce or withdraw fluids, such as drugs, contrast media or blood through the second port 170. Referring to FIG. 5, the outer surface of the first catheter member 130 is coupled to at least a portion of the inner surface of the

distal lumen 220, such that there is no annular space between the outer surface of the first catheter member 130 and the inner surface of the second lumen 220. In one embodiment, the portion of the inner surface of the distal lumen 220 may be the length of the second lumen 220. Referring now to FIG. 4, the third catheter member 120 may include a plurality of segments of distally decreasing durometer polymer to provide a step-down transition to the guiding atraumatic tip 150. The number of step down durometer segments may be between 1 and 6 and may step down in decreasing fashion by regular or irregular increments, such, for example 75D, 63D, 55D, 40D, etc. Alternatively, the third catheter member 120 may be made of a single durometer polymer, but having distally tapering wall thicknesses to impart a flexibility gradient to the third catheter member 120. The plurality of segments of decreasing durometer plastic may be abutted and be bonded together or may be manufactured from a single extrusion including decreasing durometer strengths. Still further, the third catheter member 120 may be fabricated in such a manner as to have varying hardness of the polymer material along the longitudinal length of the third catheter member 120 in combination with varying wall thickness along its longitudinal length. For example, as the wall thickness along the longitudinal length lessens, the hardness of the polymer material may also decrease. Alternatively, as the wall thickness along the longitudinal length of the third catheter member lessens, the hardness of the polymer material may be selected to increase. Thus, there may be a linear relationship or an inverse relationship between wall thickness of the third catheter member and the hardness of the polymer forming the third catheter member.

[022] As depicted in FIGS. 4-5, the guiding atraumatic tip 150 is shown in its unstrained and undeformed state as it would assume when in the body. The guiding atraumatic tip 150 is used to minimize trauma to or perforation of the vasculature as the occlusion catheter system 100 is advanced through the patient's tortuous anatomy. The size, shape and material of the distal section of the tip 150 are such that it will not pass into collateral vessels during delivery. The guiding atraumatic tip 150 has a constrained state when passing through an introducer sheath in which the distal section of the tip 150 is substantially linear and co-axial with the longitudinal axis of the occlusion catheter system 100, and a relaxed state, as depicted, which is assumed upon exiting the introducer sheath and entering a blood vessel. As also described with reference to an alternative embodiment of the guiding atraumatic tip 450 described with reference to FIGS 10-11, below, in its unstrained and undeformed state, the guiding atraumatic tip 150 consists

generally of a polymeric cylindrical or tubular member that has a distal section that has been formed, such as by molding, into a curved section that forms an incomplete circle that project proximally toward the proximal end of the occlusion catheter system 100. The distal section has a distally extending section that first projects distally and a curved section continuous with the distally extending section that curves away from the central longitudinal axis of the occlusion catheter system 100, then proximally toward the occlusion member and subtends an incomplete generally circular arc toward the central longitudinal axis of the occlusion catheter system 100. The angle of the curve may be between 270 degrees to 1080 degrees, desirably the curve is between about 300 degrees and 350 degrees such that a gap is provided between a terminal end of the distal section and a more proximal portion of the distal section. It will also be understood that the distally extending section and curved section may be formed as a generally in plane circular shape or may be formed as an out-of-plane generally helical shape, where a terminal end of the curved section is laterally displaced from the central longitudinal axis of the occlusion catheter system 100.

[023] The guiding atraumatic tip 150 may be formed of elastomeric, shape memory or superelastic material, including metals and polymer. The guiding atraumatic tip 150 may optionally also have a reinforcing elastic, shape memory or superelastic core 152 which aids in transition between the unstressed state and the stressed state of the guiding atraumatic tip 150. In accordance with an exemplary embodiment of the tip 150, the largest outer diameter of the guiding atraumatic tip 150 may be between 1-7 mm, preferably between 2-6 mm and most preferably between 4-6 mm.

[024] The guiding atraumatic tip 150 is joined to the third catheter member 120 by engaging a proximal section of the atraumatic tip 150 within the third lumen 220 of the third catheter member 120 and creating a bond between the two elements, such as by thermal welding, thermal reflow, adhesive or other biocompatible methods of joining catheter components as is generally known to those skilled in the field to which this invention pertains.

[025] Turning now to FIGS. 6-8, a proximal portion of the occlusion catheter system 100 and the proximal hub 190 are illustrated. The second catheter member 110 is coupled to the proximal hub 190 and the distal end of the first catheter member 130 may be operably coupled to the proximal hub 190 at a proximal bonding site using an adhesive 180 to bond an inner wall surface of the proximal hub 190 to an outer wall surface of the first catheter member 130. As illustrated,

the proximal hub 190 has two fluid pathways 192 and 194. A first fluid pathway 192 communicates with the first lumen 230 of the first catheter member and a second fluid pathway 194 communicates with the second lumen 210 of the second catheter member 120. It will be understood that the proximal hub 190 may be configured to have more than two fluid pathways, with each fluid pathway communicating with a different lumen in the occlusion catheter system 100. The first fluid pathway 192 of the proximal hub 190 may be connected to an external pressure sensor, which would transduce pressure from a fluid column within the first lumen 230 and through the second port 170 (FIG. 5).

[026] Turning now to FIGS. 9 and 9A-9D, an alternative embodiment of the occlusion catheter system 300 is illustrated. Like the occlusion catheter system 100, occlusion catheter system 300 generally includes a catheter assembly including a first catheter member 310 having at least two lumens 210, 330 passing longitudinally through the first catheter member 310, a second catheter member 320 having a single lumen 230 passing longitudinally through the second catheter member 320 and an expandable occlusion member 140. Expandable occlusion member 140 may be an inflatable balloon or may be another expandable member capable of occluding a vessel. The first catheter member 310 is coupled at its proximal end to a proximal hub 190 (not shown) and at a distal end thereof to a proximal end of the expandable occlusion member 140. The second catheter member 320 is coupled at its distal end to a proximal end of the first catheter member 310 such that one of the first lumen 210 or the second lumen 330 is in fluid flow communication with the second catheter member 320. The other of the first lumen 210 or the second lumen 230 terminates at the distal end of the first catheter member 310. For purposes of illustration only and for clarity in the following description, it will be assumed that second lumen 330 terminates at the distal end of the first catheter member 310 and has a distal port opening 160, it will also be assumed that the first lumen 210 is in fluid flow communication with the second catheter member 320. As with the first embodiment of the occlusion catheter system 100 described above, the second embodiment of the occlusion catheter system 300, when the occlusion member 140 is in an contracted state, it is of a sufficiently small cross-sectional diameter to pass through a 6 French (2 mm) percutaneous sheath. It will be understood by those skilled in the art that the occlusion catheter system 300 is not limited to a dimension sufficient to pass through a 2 mm (6 French) percutaneous sheath, but that such lower profile or smaller is generally considered desirable to enable percutaneous insertion and removal and passage through

tortuous vasculature and to a desired position within the body for purposes of vascular occlusion. The occlusion catheter system 300 is, therefore, not intended to be limited to this dimensional size, but may be made of smaller or larger dimension as desired or needed.

[027] Referring now to FIG. 9A, the first catheter member 310 includes first lumen 330 and a
5 second lumen 210. The second catheter member 320 includes a first lumen 220. The first catheter member 310 terminates at its distal end within the space defined under the balloon 140, where it is both coupled to the second catheter member 320 and terminates with an open port 160 in fluid communication with lumen 330, permitting fluid to be delivered to and from the balloon 140 for inflation and/or deflation. In accordance with an alternative embodiment, the distal end
10 of the first catheter member 310 may, optionally, be tapered, such as by narrowing the wall thickness of the catheter member 310 or by crimping the first catheter member 310 to a smaller diameter, thereby compressing and reducing the open area of the first lumen 330 and the second lumen 210. If the first catheter member 310 is crimped to a tapered diameter, it is preferable that the extent of the crimping does not compress the open area of the first lumen 330 and the second
15 lumen 210 in a manner that significantly reduces fluid flow there through of fluid flow pressures therein, particularly with the second lumen 330 when it is used for the inflation fluid for the inflation balloon 140.

[028] The third catheter member 130 is positioned within one of the first lumen 210 or the second lumen 330 of the first catheter member 310. As depicted in the figures this arrangement
20 is illustrated with the third catheter member 130 being positioned within the first lumen 210 of the first catheter member 310 and also within the first lumen 220 of the second catheter member 320. The outer diameter of the third catheter member 130 is less than the inner diameter of the first lumen 210 of the first catheter member 310 as well as smaller than the inner diameter of the first lumen 210 of the second catheter member 320, such that an annular space 212 is formed
25 there between as depicted in Figure 9C. In the more distal region of the first catheter member 310, within the region of the distal taper discussed above, the annular space 212 is compressed and either closes or is substantially closed to fluid flow, thereby effectively sealing the distal end of the first lumen 210 near the transition to the proximal attachment point of the expandable occlusion balloon 140, as depicted in Fig. 9A.

[029] The third catheter member 130 passes longitudinally into the first lumen 230 of the
30 second catheter member 320 and has a first lumen 230 passing longitudinally through the third

catheter member 130. As with the first catheter member 130 of the first alternative embodiment described above, the first lumen 230 of the third catheter member 130 permits monitoring of conditions within the body, such as arterial pressure monitoring by hydrostatic pressure within a fluid column within the first lumen 230, or allows for the introduction of tethered sensors, such as flow sensing wires, pressure sensing wires or the like to the distal end of the occlusion catheter system 300. First lumen 230 may also be used to deliver drugs, contrast media, or permit the introduction or withdrawal of fluids to and from the body.

[030] As with the alternative embodiment discussed above with reference to Figures 1-8, the embodiment depicted in Figures 9 – 9D may, optionally, include the second catheter member 320 being constructed of plural segments having distally increasing flexibility, such as by making the segments of distally decreasing durometer polymer or fashioning the second catheter member 320 to have a distally tapering wall thickness. The second catheter member 320 may be formed of discrete segments abutted and coupled together to form an elongated second catheter member 320 with either distally decreasing durometers or distally tapering wall thicknesses. Alternatively, the second catheter member 320 may be made by extrusion or molding polymers of distally decreasing Durometer, distally tapering wall thicknesses or combinations thereof.

[031] As with the alternative embodiment of the occlusion catheter system 100, the second catheter member 320 includes an open port 170 that is in fluid flow communication with the first lumen 230 of the third catheter member. Similarly, as with the occlusion catheter system 100, occlusion catheter system 300 includes a guiding atraumatic tip (not shown in Figures 9-9D) as described above with reference to guiding atraumatic tip 150, which is joined to a distal end of the second catheter member 320.

[032] With reference to FIGS. 10 and 11, there is depicted an alternative embodiment of the guiding atraumatic tip 450. It will be understood that guiding atraumatic tip 450 may be employed with any of the foregoing embodiments of the inventive occlusion catheter system 100 or of the inventive occlusion catheter system 300. Guiding atraumatic tip 450 consists generally of a polymeric cylindrical or tubular member 452 that has a distal section 454 thereof that has been formed, such as by molding or extrusion, into a generally flattened shape having at least two generally planar opposing surfaces 455, 457. Depending upon the formation process, two generally radiused curved opposing surfaces 458, 459 may also be formed during the formation process. The distal section 454 has a distally extending section 453 that projects distally and a

curved section 456 continuous with the distally extending section that curves away from the central longitudinal axis of the occlusion catheter system 100, 300 then proximally toward the occlusion balloon and subtends a generally circular arc toward the central longitudinal axis of the occlusion catheter system 100, 300. The angle of the curve may be between 270 degrees to 1080
5 degrees, desirably the curve is between about 300 degrees and 350 degrees such that a gap is provided between the terminal end of the generally cylindrical flattened distal section 454 and the more proximal surface of the distal section 454. It will also be understood that the distally extending section 453 and curved section 456 may be formed as a generally in plane circular shape or may be formed as an out-of-plane generally helical shape, where a terminal end of the
10 curved section 456 is laterally displaced from the central longitudinal axis of the occlusion catheter system 100 or occlusion catheter system 300. In this manner, the generally flattened distal section 454 is characterized by a generally circular, proximally oriented bend that operates in a manner similar to the guiding atraumatic tip 150 or guiding atraumatic tip 350, but is made of a polymer material without the need for a reinforcing member 152 as described above.

15 [033] A tapered transition section 451 may, optionally, be provided between the polymeric cylindrical or tubular member 452 and the generally flattened distal section 454. Guiding atraumatic tip 450 may be integral with the third catheter member 120 of occlusion catheter system 100 or the second catheter member 320 of occlusion catheter system 300. Alternatively, guiding atraumatic tip 450 may be fabricated as a discrete member and joined to the third
20 catheter member 120 of occlusion catheter system 100 or the second catheter member 320 of occlusion catheter system 300.

[034] The guiding atraumatic tip 450 may be made of PEBAX having a durometer of 40, or a similar polymer, such polyurethane, that matches the catheter shaft and balloon to make bonding easier and more secure. As discussed above, the longitudinal flexibility of guiding atraumatic tip
25 450 may be manipulated by varying the thickness, the hardness or both properties of the curved distal section of the guiding atraumatic tip 450. Thus the curved distal section 456 may have a hardness of 40 D (Shore Durometer), while the proximal section of the guiding atraumatic tip 450 may have a higher hardness, such as 72 D (Shore Durometer). As discussed above, the guiding atraumatic tip 450 may be either cylindrical or tubular, or have a solid cylindrical section
30 and a tubular section. The curve of the guiding atraumatic tip 450 may be made by any of a wide number of processes, including, for example, injection molding, round extrusion, flattening and

post-processing into the curved distal section 456, a flat extrusion bonded to a round extrusion, or an extrusion that is pressed into a hot die having a shape of the desired curved distal section 450.

5 [035] The atraumatic tip 450 may include a radio opaque tip marker 460. The radio opaque tip marker 460 may be implemented as a band surrounding the tip 450 or as a two-dimensional planar material on one or both of the planar opposing surfaces 455. Alternatively, the radio opaque tip marker 460 may be located at the most distal point of the atraumatic tip 450 indicated at 460' in Fig. 11. The band or the planar material may be composed of any suitable radio opaque material, such as for example, stainless steel or a suitable alloy such as platinum iridium.

10 In another example embodiment, the tip 450 may be made of a plastic or polymer, such as for example, PEBAX that is impregnated or doped with a radio opaque material. In another example embodiment, the plastic or polymer composition forming the tip 450 may be mixed with a radio opaque compound such as, for example, barium sulfate sufficient to permit visualization of the tip 450 using X-ray or fluoroscopy.

15 [036] In an alternative embodiment described herein with reference to FIGs. 12-18, an occlusion catheter system 500 generally includes a catheter assembly having a solid wire 530, an inflation catheter member 510 having an inflation lumen 610, a distal catheter member 520, an expandable occlusion balloon 540, a proximal hub 590 and a guiding atraumatic tip 550. The solid wire 530 extends longitudinally through the inflation catheter member 510, and is coupled

20 at its proximal end to the proximal hub 590 and at its distal end to a proximal section of the distal catheter member 520. The inflation lumen 610 of the inflation catheter member 510 also extends longitudinally through the inflation catheter member 510, and terminates in a first port 560 distal to a proximal end of and within a space 542 defined by the expandable occlusion balloon 540, such that the inflation lumen 610 is in fluid flow communication with the space 542 within the

25 expandable occlusion balloon 540 to convey an inflation fluid to and from the expandable occlusion balloon 540 from a source external the occlusion catheter system 500. The distal catheter member 520 is coupled at a proximal end thereof to a distal end of the solid wire 530. The inflation catheter member 510 and the distal catheter member 520 are positioned in longitudinal co-axial spaced apart relationship from one and other along a longitudinal axis of

30 the solid wire 530 thereby defining an intermediate region of the solid wire 530 within the space

542 within the expandable occlusion balloon 540 that is not covered by either the inflation catheter member 510 or the distal catheter member 520.

[037] In general, the alternative embodiment described herein with reference to FIGs. 12-18 includes a wire 530 instead of a tube with a lumen. The wire 530 may be implemented as a solid
5 flexible wire made of any suitable material that may be formed into a wire-like component, or may be a solid wire reinforced with an outer wire winding or windings. Examples of materials that may be used for the solid flexible wire include nitinol and stainless steel. The wire 530 implementation without a lumen eliminates the fluid communication with a third lumen having sensors thereby removing the elements used to implement the sensing function in the catheter
10 system 100 described above with reference to FIGs. 1-8. The wire 530 does, however, allow for the achieving a lower profile for the catheter system.

[038] Referring to FIGs. 12-18, the expandable occlusion balloon 540 is attached, at its proximal end 544 to a distal end of the inflation catheter member 510 and at its distal end 546 to a proximal end of the distal catheter member 520. In operation, expandable occlusion balloon
15 540 is inflated by introducing an inflation fluid, such as saline, from an external source, such as a syringe, coupled to the proximal hub 590, into and through the inflation lumen 610, out of the first port 560 and into the space 542 within the expandable occlusion balloon 540. Inflation and deflation of the expandable occlusion balloon 540 in FIGs. 1-8 is performed as described above with reference to FIGs. 1-8.

[039] Referring to FIGs. 15 and 16, the third catheter member 520 is fixedly coupled at its proximal end concentrically about a distal end of the solid wire 530. In the example shown in FIG. 16, the distal catheter member 520 has a lumen 620 extending longitudinally through the distal catheter member and coupled concentrically about a proximal end of the atraumatic tip
20 550. The guiding atraumatic tip 150 may be made of an elastic, shape memory and/or superelastic material, such as a metal or polymer. A reinforcing member 552 (depicted in phantom) may optionally be included either within the guiding atraumatic tip 550 or wound about an external surface of the guiding atraumatic tip 550 to offer additional reinforcement to the tip 550. A distal end of the guiding atraumatic tip 550 projects distally from the distal catheter member 520 and preferably has a generally circular configuration curving proximally
25 and then toward a central longitudinal axis of the occlusion catheter system 500, but leaving a
30 unconnected end of the distal end of the guiding atraumatic tip 550 to permit the tip 550 to

assume a linear configuration co-axial with the central longitudinal axis of the occlusion catheter system 500 for delivery.

[040] As noted above in the description of the first embodiment of the inventive occlusion catheter system 100 illustrated in FIGS. 1-8, the occlusion catheter system 100, when the expandable occlusion member 140 is in an unexpanded state, it is of sufficiently small cross-sectional dimension to pass through a 6 French (2 mm) percutaneous sheath. It will be understood by those skilled in the art that example implementations of the occlusion catheter system 500 described herein with reference to FIGS. 12-18 may have an even smaller cross-sectional dimension due to the use of a solid wire 530 instead of a catheter with a lumen. The diameter of the solid wire 530 is smaller than the inner diameter of the inflation lumen 610 of the inflation catheter member 510 thereby forming an annular space 612 between the outer surface of the solid wire 530 and the inner surface of the inflation catheter member 510. The dimensions of the inner diameter of the inflation lumen 610 and the diameter of the solid wire 530 may be specified in example implementations to provide optimal inflation fluid flow as well as a reduced profile that may further ease deployment.

[041] Turning now to FIGS. 14-16, the distal portion of the occlusion catheter system 500 is illustrated. As shown in FIG. 16, the outer surface of the solid wire 530 is coupled to at least a portion of the inner surface of the second lumen 620, such that there is no annular space between the outer surface of the solid wire 530 and the inner surface of the second lumen 620. Referring now to FIG. 15, the distal catheter member 520 may include a plurality of segments of distally decreasing durometer polymer to provide a step-down transition to the guiding atraumatic tip 150. The number of step down durometer segments may be between 1 and 6 and may step down in decreasing fashion by regular or irregular increments, such, for example 75D, 63D, 55D, 40D, etc. Alternatively, the distal catheter member 520 may be made of a single durometer polymer, but having distally tapering wall thicknesses to impart a flexibility gradient to the third catheter member 520. The plurality of segments of decreasing durometer plastic may be abutted and be bonded together or may be manufactured from a single extrusion including decreasing durometer strengths, wall thicknesses, or combinations thereof.

[042] In an alternative embodiment, the wire 530 extends completely into the space shown for the second lumen 620 such that the distal catheter member 520 completely covers the distal end

of the wire 530. The atraumatic tip 550 may also be formed as an extension of the second catheter body 520 rather than as a separate member joined to the second catheter body 520.

[043] Turning now to FIG. 17, the proximal portion of the occlusion catheter system 500 is illustrated. The inflation catheter member 510 is coupled to the proximal hub 590 and the distal end of the solid wire 530 is fixedly coupled to the proximal hub 590 at a proximal bonding site using an adhesive 580 to bond an inner wall surface of the proximal hub 590 to an outer wall surface of the solid wire 530. The amount of adhesive 580 used should be sufficient to fixedly couple the solid wire 530 to the proximal hub 590. As shown in FIG. 17, the adhesive 580 may fill the entire portion 592 of the proximal hub 590 that holds the solid wire 530. Since the solid wire 530 has no lumen, no fluid pathway is needed in the portion 592 that holds the solid wire 530. As illustrated, the proximal hub 190 has a single fluid pathway 194. The second fluid pathway 194 communicates with the inflation lumen 610 of the inflation catheter member 520. It will be understood that the proximal hub 590 may be configured to have more than a single fluid pathway, with each fluid pathway communicating with a different one of any additional lumens in the occlusion catheter system 500.

[044] It will be understood that when reference is made to coupling two or more component pieces of the occlusion catheter system, that conventional catheter material bonding modalities are intended to be encompassed and employed. For example, a wide variety of biocompatible adhesives useful in catheter manufacture are known, similarly, thermobonding techniques used in catheter manufacture are also known. Thus, for example, where it is described that the guiding atraumatic tip is coupled to the third catheter member or to the distal catheter member, it is contemplated that such coupling may be made using thermobonding, biocompatible adhesives or other methods of fixedly bonding two components in medical devices.

[045] It will also be understood by those skilled in the art that it is well known to manufacture catheters of a variety of medical grade, biocompatible polymers, such as, for example and without limitation, silicone, nylon, polyurethane, PETE, latex, thermoplastic elastomers, polyether block amides (PEBAX, Arkema, Paris, France). Alternatively, it is known to manufacture catheters of metals, such as nitinol or stainless steel. Similarly, it is known to manufacture catheters of metal-reinforced polymer, such as, for example and without limitation, stainless steel braiding over polyurethane, stainless steel helical windings over silicone or nitinol reinforced polymer. Thus, any or all of the first catheter member, the second catheter member,

the inflation catheter member, the distal catheter member, or the third catheter member in any of the foregoing embodiments may be fabricated of biocompatible polymers, biocompatible metals or metal-reinforced polymers, as is known in the art.

[046] It will also be understood by those skilled in the art that while the implementation of radio opaque markers are described in the context of embodiments described with reference to FIGs. 1-8, it may be desirable to include radio opaque marker bands positioned at the proximal and distal ends of the balloon in implementations of embodiments described above with reference to FIGs. 9-11, and embodiments described above with reference to FIGs. 12-18. It is also desirable to include length markers on the outer catheter shaft to indicate to the physician the insertion depth of the occlusion catheter system 100, the occlusion catheter system 300, or the occlusion catheter system 500. The length markers may be printed or laser etched onto the outside of the catheter shaft.

[047] It will also be understood by those skilled in the art that it is well known to coat the catheters and balloons with a variety of coatings, including without limitation, antibacterial, antimicrobial, lubricants, anticoagulant and/or antifouling coatings. Thus, any or all of the first catheter members, the solid wire, the inflation catheter member, the second catheter member, the distal catheter member, the third catheter member, the expandable occlusion balloon or the guiding atraumatic tip may further include one or more coatings as is known in the art.

CLAIMS

What is claimed is:

1. A occlusion catheter system comprising:

5 a first catheter member having a first lumen extending longitudinally through the first catheter member and open at a distal end of the first catheter member;

10 a second catheter member having a second lumen extending longitudinally through the second catheter member and open at a distal end of the second catheter member, the second catheter member is positioned over and in spaced apart relationship relative to a proximal section of the first catheter member forming an annular space between the second catheter member and the first catheter member, the proximal section of the first catheter member resides within the second lumen of the second catheter member and the first catheter member extends beyond the distal end of the second catheter member,

15 a third catheter member having a third lumen extending longitudinally through the third catheter member and open at a distal end of the third catheter member; the third catheter member is positioned over a distal section of the first catheter member, the third catheter member having a distal section that extends distally from a distal end of the first catheter member such that the first lumen and the third lumen are in fluid flow communication, whereby the second and third catheter are spaced apart from each other along a longitudinal axis of the first catheter member with the first catheter member extending there between;

20 an atraumatic tip member having a proximal section co-axially coupled to a distal second of the third catheter member; and

25 an expandable occlusion member coupled at its proximal end to the second catheter member and at its distal end to the third catheter member, the expandable occlusion member being positioned such that the space between the second catheter member and the third catheter member is within the expandable occlusion member.

2. The occlusion catheter system of claim 1, wherein the atraumatic tip further comprises a biocompatible polymer.

3. The occlusion catheter system of claim 2, wherein the atraumatic tip further comprises a distal section formed in an incomplete circular shape.

30

4. The occlusion catheter system of claim 2, wherein the proximal section of the atraumatic tip has a generally circular transverse cross-sectional profile and the atraumatic tip further comprises a distal section having a generally flattened cylindrical shape.

5 5. The occlusion catheter system of claim 3, further comprising a reinforcing member within the atraumatic tip.

6. The occlusion catheter system of claim 5, wherein the reinforcing member is selected from the group consisting of elastic, superelastic or shape memory materials.

10 7. The occlusion catheter system of claim 6, wherein the reinforcing member further comprises nitinol.

8. The occlusion catheter system of claim 1, wherein the atraumatic tip further comprises a biocompatible metal.

9. The occlusion catheter system of claim 1, further comprising a pressure sensor operably associated within the first lumen.

15 10. The occlusion catheter system of claim 9, further comprising a port opening passing through a wall surface of the third catheter member and in fluid flow communication with the third lumen.

20 11. The occlusion catheter system of claim 1, further comprising a proximal hub coupled to and in fluid flow communication with each of the first catheter member and the second catheter member.

12. The occlusion catheter system of claim 11, further comprising a fluid source coupled to the proximal hub and in fluid flow communication with the second catheter member.

13. The occlusion catheter system of claim 12, further comprising a pressure sensor operably coupled to the proximal hub and in communication with the first catheter member.

25 14. The occlusion catheter system of claim 1, wherein the third catheter member has distally increasing flexibility.

15. The occlusion catheter system of claim 14, wherein the third catheter member further comprises plural sections having distally decreasing durometer.

30 16. The occlusion catheter system of claim 14, wherein the third catheter member further comprises distally tapering wall thickness.

17. The occlusion catheter system of claim 1, wherein a greatest outer diameter of the occlusion catheter system is less than 2.3 mm.

18. The occlusion catheter system of claim 1, wherein the expandable occlusion
5 member is a balloon.

19. The occlusion catheter system of claim 18, further comprising:
a radio opaque marker fixed to the catheter system to provide a visual indication of the
location of the catheter system during deployment when the radio opaque marker is irradiated.

20. The occlusion catheter system of claim 19, where the radio opaque marker is a
10 first radio opaque marker affixed near a first attachment point for coupling the proximal end of
the balloon to the second catheter, the system further comprising:

a second radio opaque marker affixed near a second attachment point for coupling the
distal end of ballon to the third catheter.

21. The occlusion catheter system of claim 19, where the radio opaque marker is
15 fixed to the atraumatic tip.

22. The occlusion catheter system of claim 19, where the radio opaque marker is
made of either stainless steel or a suitable radio opaque alloy.

23. The occlusion catheter system of claim 21, where the suitable radio opaque alloy
is platinum iridium.

24. The occlusion catheter system of claim 18, where the radio opaque marker is
20 made of a polymer mixed with a radio opaque material.

25. The occlusion catheter system of claim 23, where the radio opaque material is
barium sulfate.

26. A balloon catheter vascular occlusion system comprising:
25 a catheter assembly comprising a first catheter member having at least two lumens
passing longitudinally through the first catheter member and a second catheter member having at
least one lumen passing longitudinally through the second catheter member, the second catheter
member being joined to the first catheter member such that a first lumen of the second catheter
member is in fluid flow communication and co-axial with one of the at least two lumens of the
30 first catheter member and extends distally therefrom;

a guiding atraumatic tip coupled to the second catheter member and projecting distally

therefrom;

an occlusion balloon in fluid flow communication with a second lumen of the first catheter; and

5 a third catheter member having at least one lumen passing longitudinally there through, disposed within the first lumen of the first catheter member and the at least one lumen of the second catheter.

27. The balloon catheter occlusion system of claim 25, further comprising a port opening passing through a wall surface of the second catheter member and communicating with the at least one lumen of the third catheter.

10 28. The balloon catheter occlusion system of claim 25, wherein the guiding atraumatic tip is formed of an elastomeric polymer.

29. The balloon catheter occlusion system of claim 25, wherein the guiding atraumatic tip is formed of a biocompatible metal.

15 30. The balloon catheter occlusion system of claim 27, wherein the guiding atraumatic tip further comprises a reinforcing member.

31. The occlusion catheter system of claim 25, further comprising a proximal hub coupled having a first channel communicating with the first lumen of the first catheter, a second channel communicating with the second lumen of the first catheter and a third channel communicating with the at least one lumen of the third catheter.

20 32. The balloon catheter occlusion system of claim 30, further comprising an external pressure sensor operably coupled to the third channel of the proximal hub.

33. The balloon catheter occlusion system of claim 25, wherein the third catheter member has distally increasing flexibility.

25 34. The balloon catheter occlusion system of claim 25, wherein the second catheter member further comprises plural sections having distally decreasing durometer.

35. The balloon catheter occlusion system of claim 25, wherein the third catheter member further comprises distally tapering wall thickness.

36. The balloon catheter occlusion system of claim 25, wherein a greatest outer diameter of the occlusion catheter system is less than 2.3 mm.

30

37. The occlusion catheter system of claim 25, further comprising a radio opaque marker fixed to the catheter system to provide a visual indication of the location of the catheter system during deployment when the radio opaque marker is irradiated.

5 38. The occlusion catheter system of claim 36 where the radio opaque marker is a first radio opaque marker fixed to the second catheter at or near a first attachment point for coupling the proximal end of the balloon to the second catheter, the system further comprising:

a second radio opaque marker fixed to the third catheter at or near a second attachment point for coupling the distal end of the balloon to the third catheter.

10 39. The occlusion catheter system of claim 36 where the radio opaque marker is fixed to the atraumatic tip.

40. The occlusion catheter system of claim 36 where the radio opaque marker is made of either stainless steel or a suitable radio opaque alloy.

15 41. The occlusion catheter system of claim 39 where the suitable radio opaque alloy is platinum iridium.

42. The occlusion catheter system of claim 36 where the radio opaque marker is made of a polymer mixed with a radio opaque material.

43. The occlusion catheter system of claim 41 where the radio opaque material is barium sulfate.

20 44. A occlusion catheter system comprising:
an elongate wire;

an first catheter member having a first lumen extending longitudinally to open at a distal end of the first catheter member, the first catheter member is positioned over and in spaced apart relationship relative to a proximal section of the elongate wire forming an annular space between the first catheter member and the elongate wire, the proximal section of the wire resides within the first lumen of the first catheter member and the elongate wire extends beyond the distal end of the first catheter member,

25 a second member extending longitudinally and positioned over a distal section of the elongate wire, the second catheter member having a section extending distally from a distal end of the elongate wire, whereby the first catheter member and the second catheter member are spaced apart from each other along a longitudinal axis of the elongate wire with the elongate
30

wire extending there between;

an atraumatic tip member extending from a distal section of the second catheter member;
and

5 an expandable occlusion member coupled at its proximal end to the first catheter member
and at its distal end to the second catheter section and positioned such that the space between the
first catheter member and the second catheter section is within the expandable occlusion
member.

45. The occlusion catheter system of claim 43, wherein the atraumatic tip further
comprises a biocompatible polymer.

10 46. The occlusion catheter system of claim 44, wherein the atraumatic tip further
comprises a distal section formed in an incomplete circular shape.

47. The occlusion catheter system of claim 44, wherein the proximal section of the
atraumatic tip has a generally circular transverse cross-sectional profile and the atraumatic tip
further comprises a distal section having a generally flattened cylindrical shape.

15 48. The occlusion catheter system of claim 45, further comprising a reinforcing
member within the atraumatic tip.

49. The occlusion catheter system of claim 47, wherein the reinforcing member is
selected from the group consisting of elastic, superelastic or shape memory materials.

20 50. The occlusion catheter system of claim 48, wherein the reinforcing member
further comprises nitinol.

51. The occlusion catheter system of claim 43, wherein the atraumatic tip further
comprises a biocompatible metal.

52. The occlusion catheter system of claim 43, further comprising a proximal hub
coupled to and in fluid flow communication with the inflation catheter member.

25 53. The occlusion catheter system of claim 51, further comprising a fluid source
coupled to the proximal hub and in fluid flow communication with the inflation catheter
member.

54. The occlusion catheter system of claim 43, wherein the distal catheter member
has distally increasing flexibility.

30 55. The occlusion catheter system of claim 53, wherein the distal catheter member
further comprises a plurality of sections having distally decreasing durometer.

56. The occlusion catheter system of claim 53, wherein the distal catheter member further comprises distally tapering wall thickness.

57. The occlusion catheter system of claim 43, wherein a the occlusion catheter system fits within a 6 French introducer sheath.

5

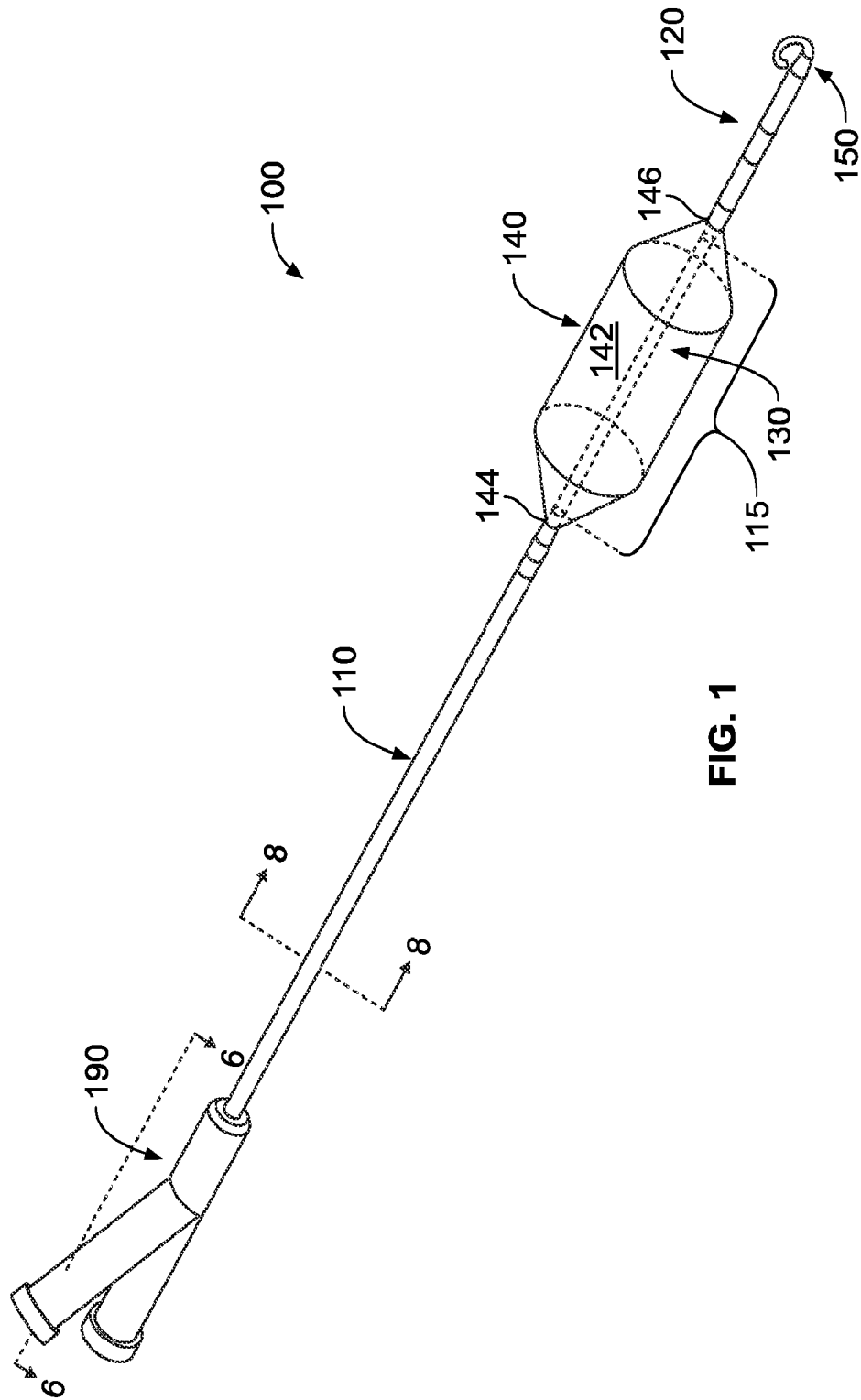


FIG. 1

2/9

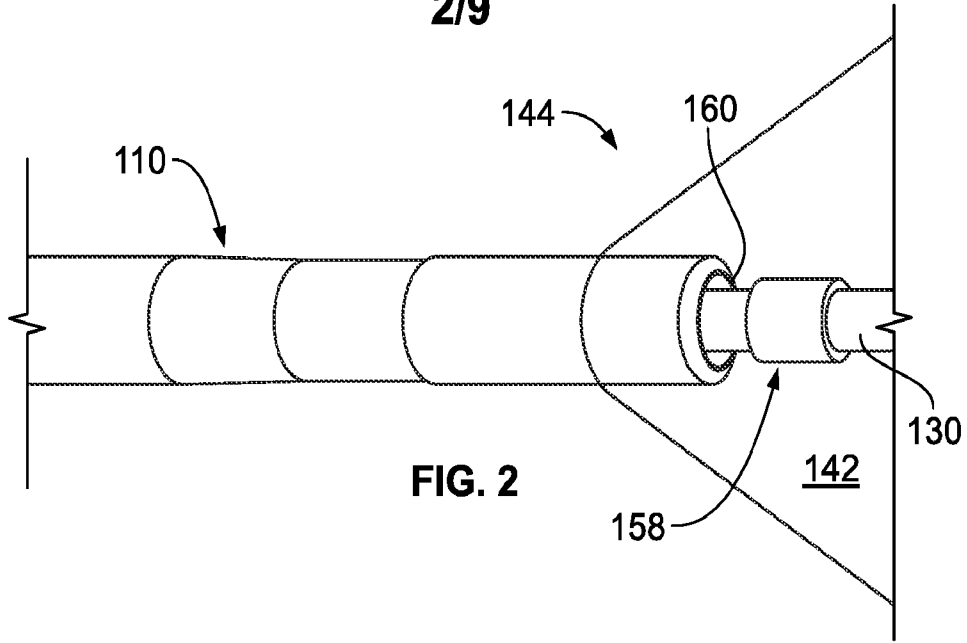


FIG. 2

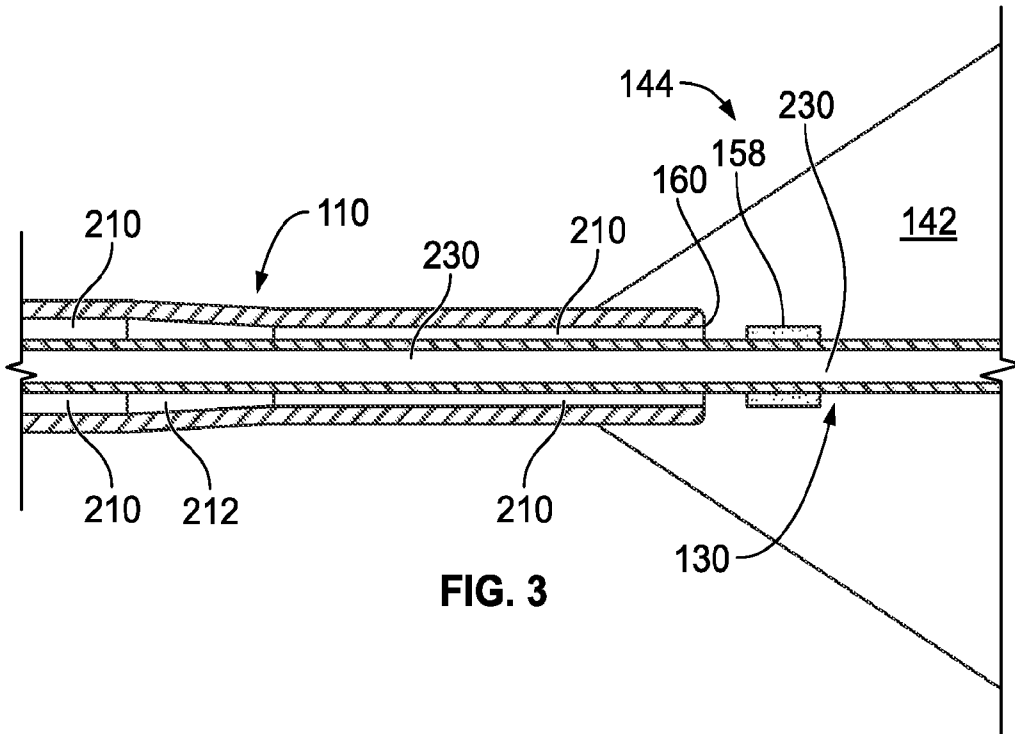


FIG. 3

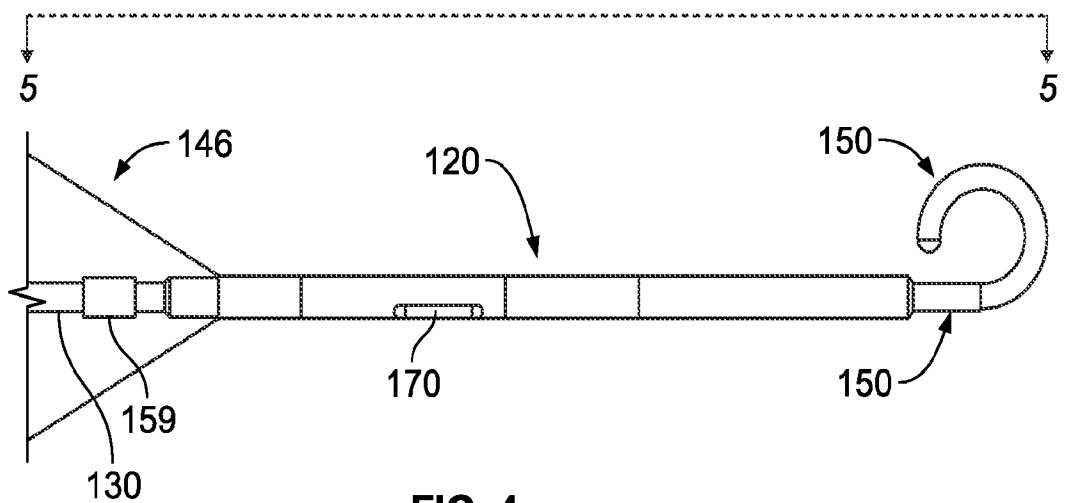
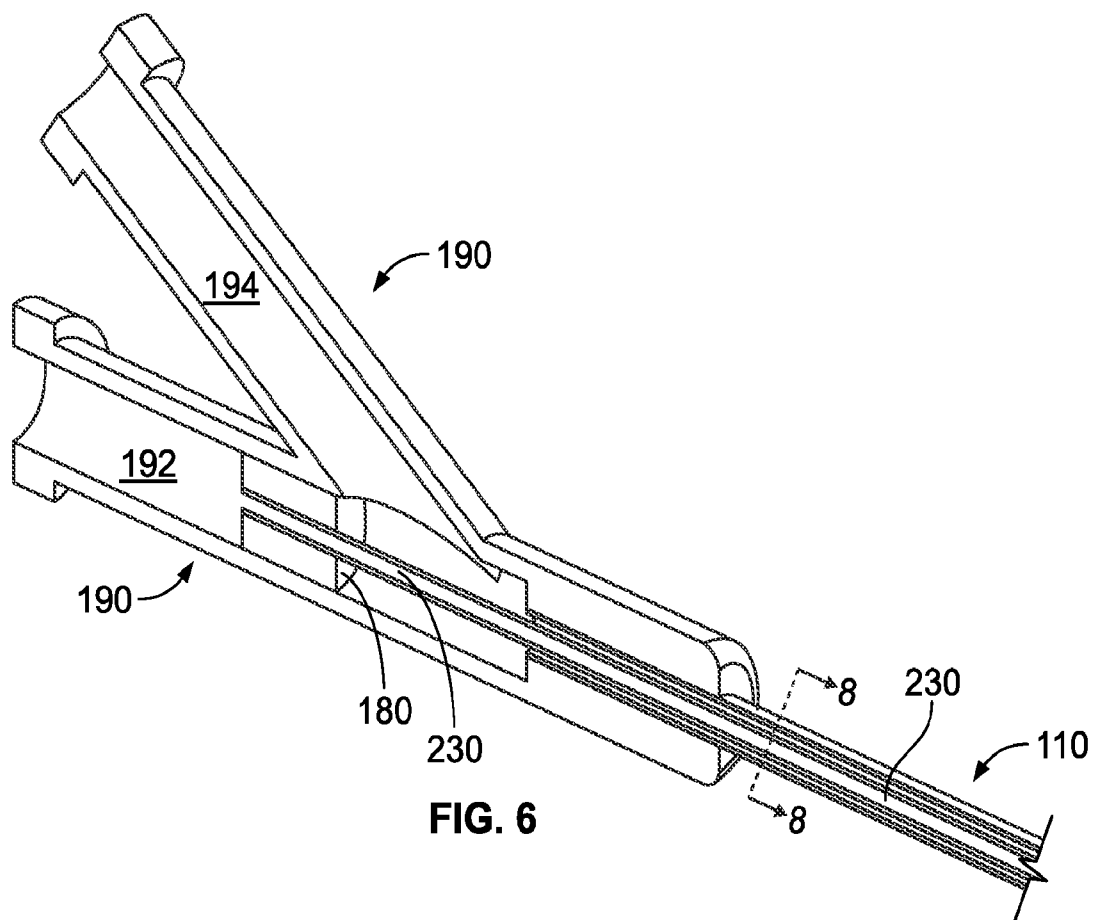
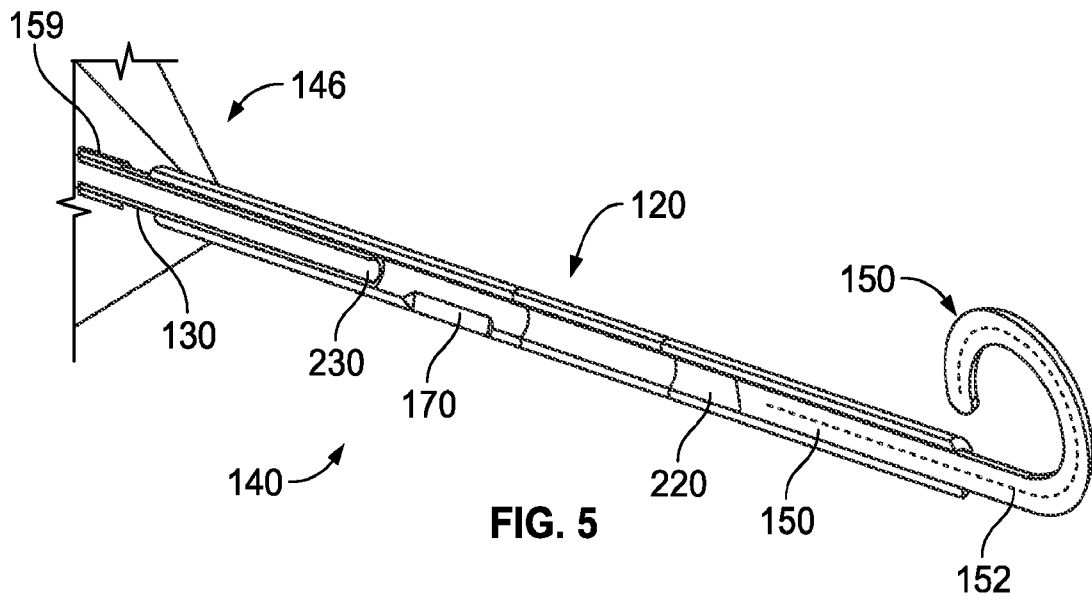


FIG. 4



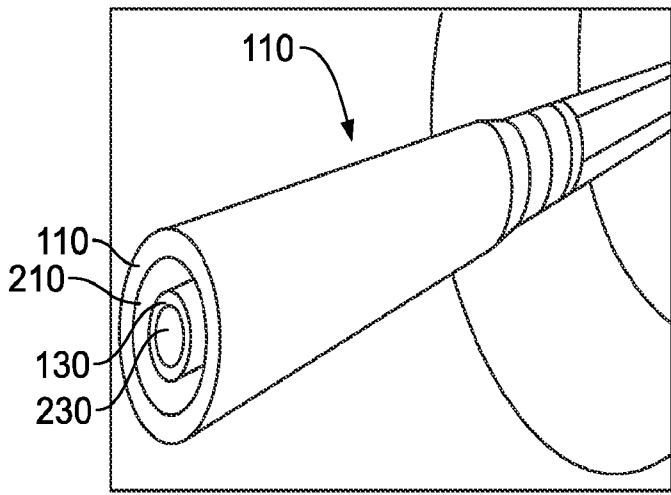


FIG. 7

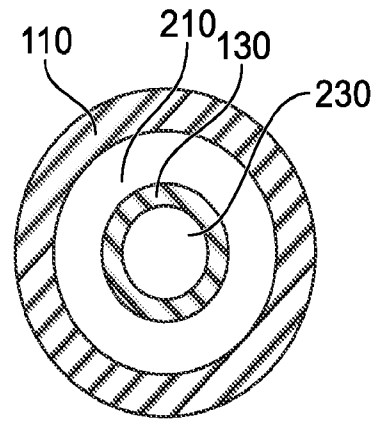


FIG. 8

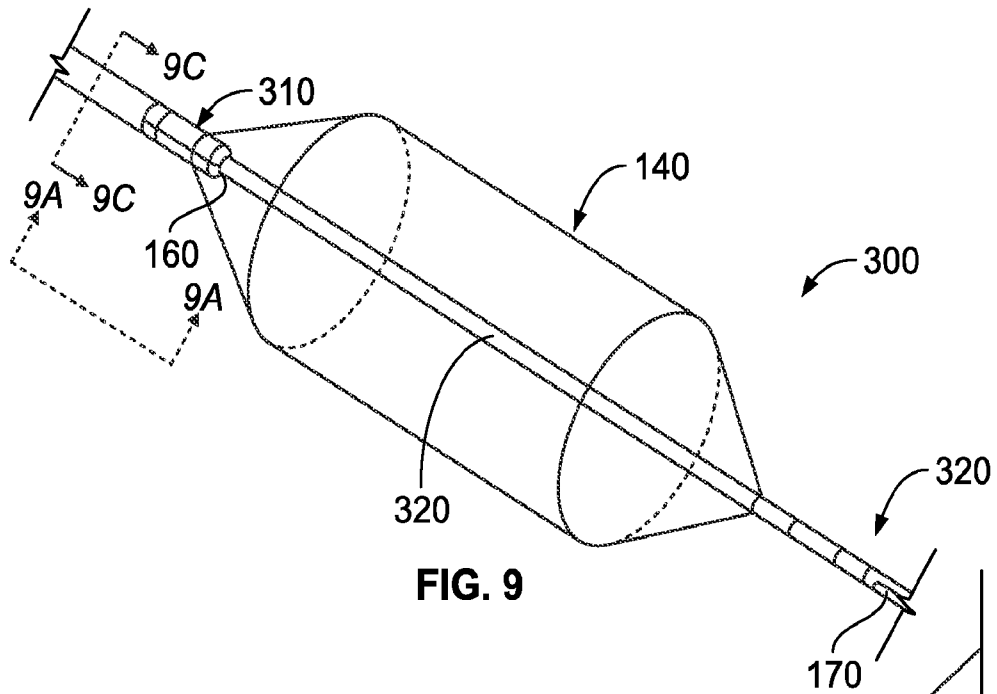


FIG. 9

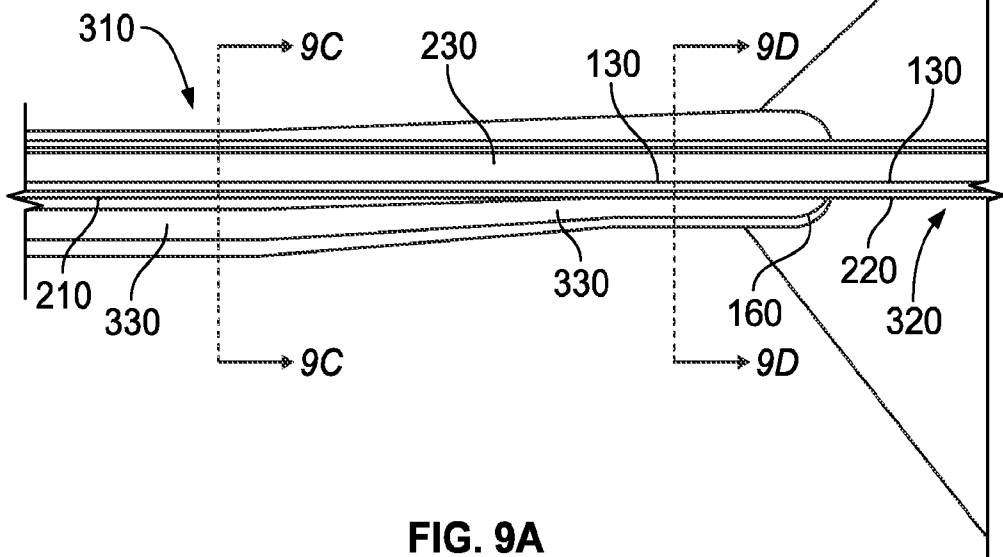


FIG. 9A

5/9

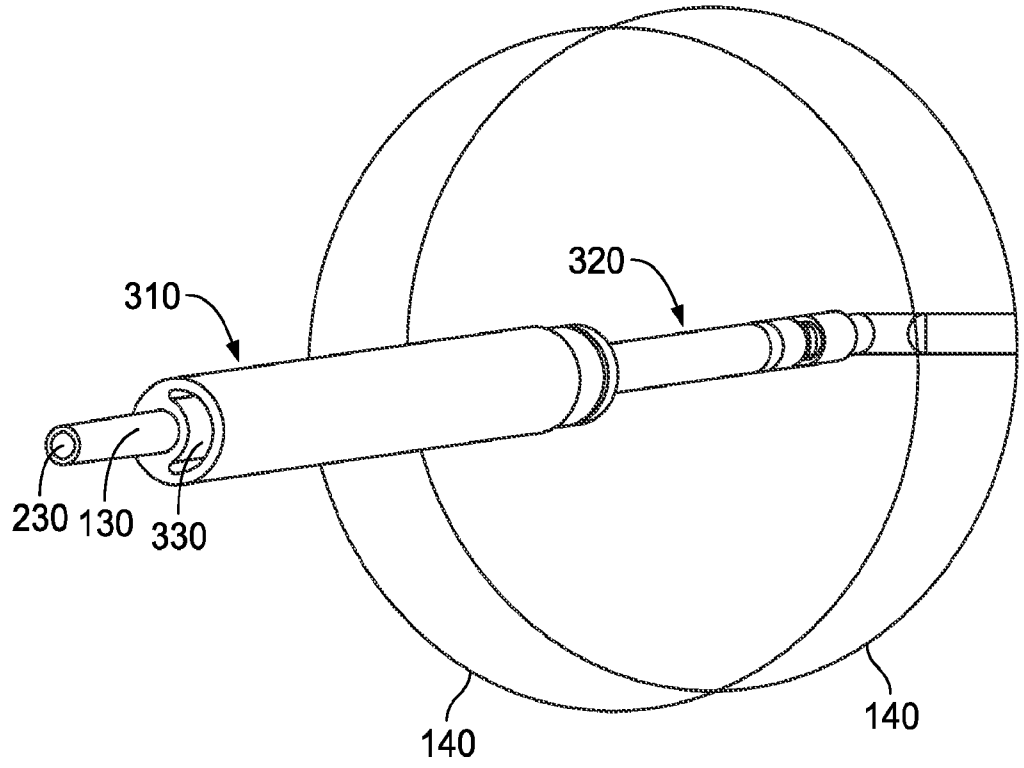


FIG. 9B

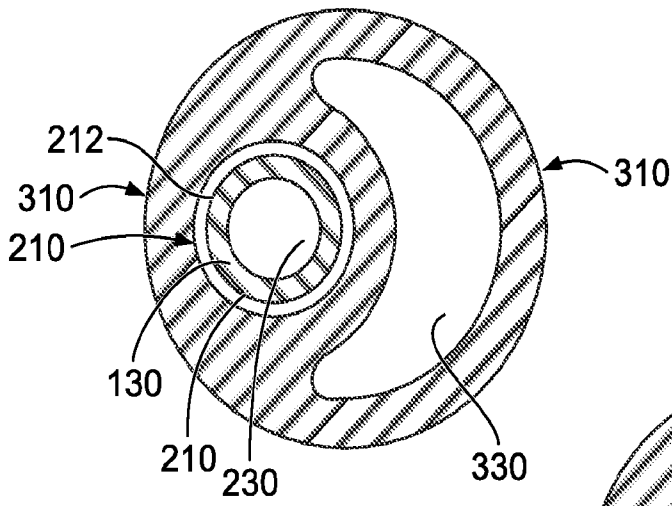


FIG. 9C

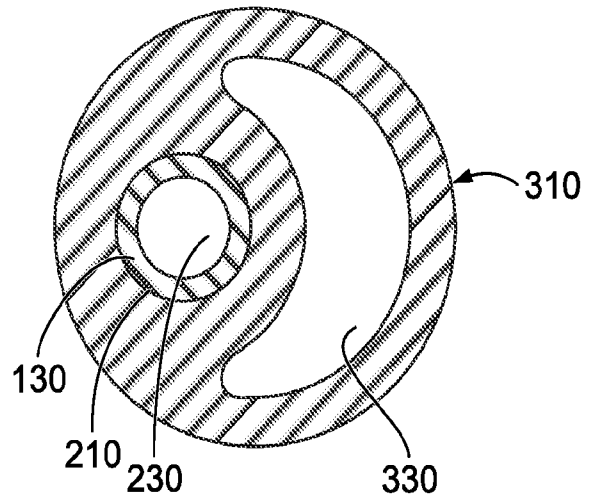
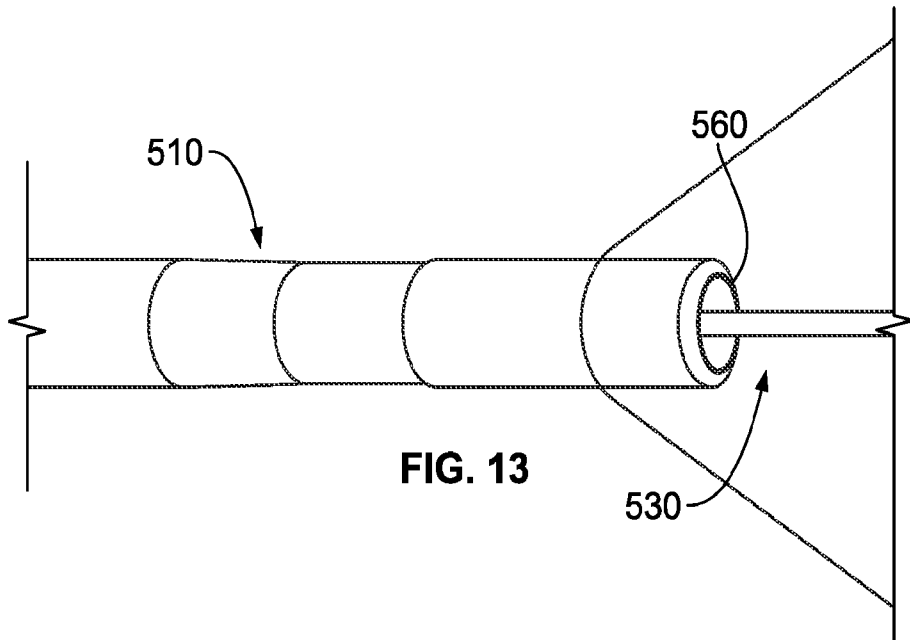
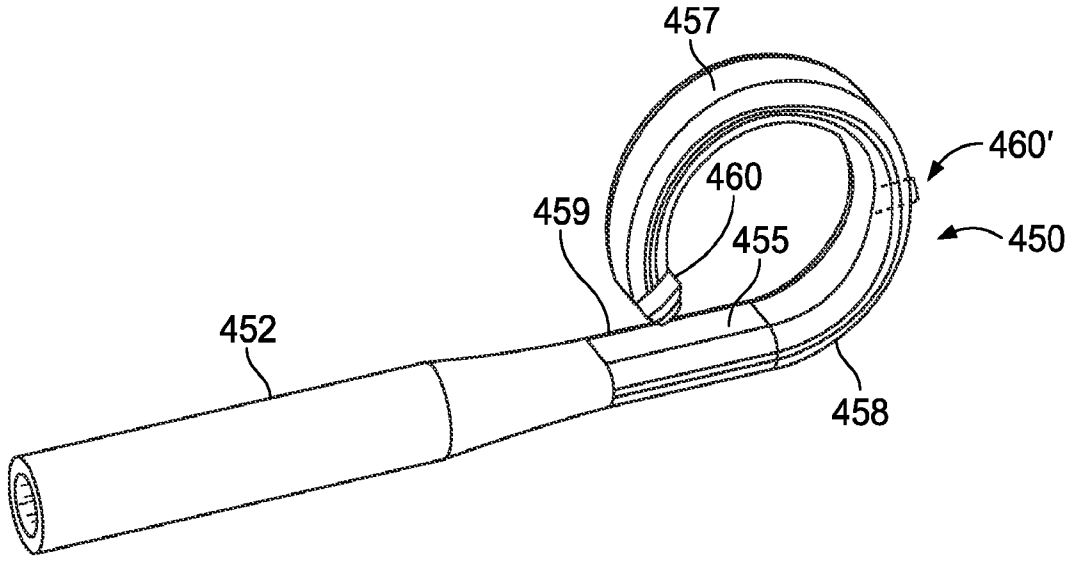
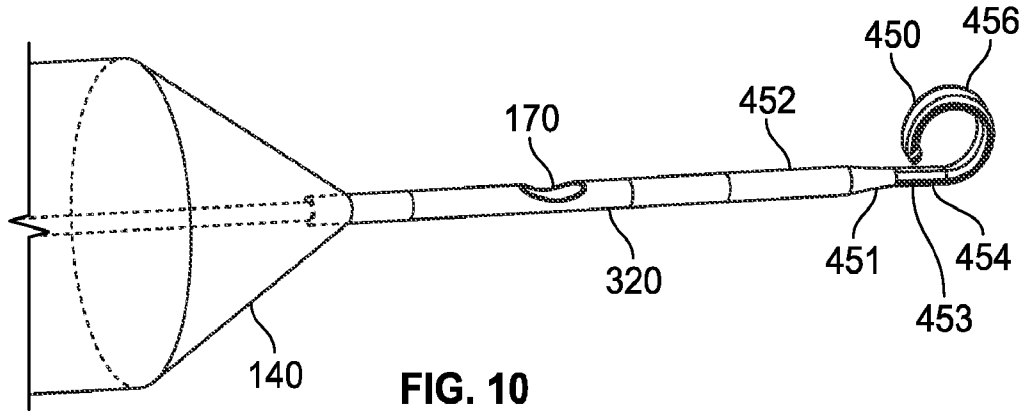


FIG. 9D



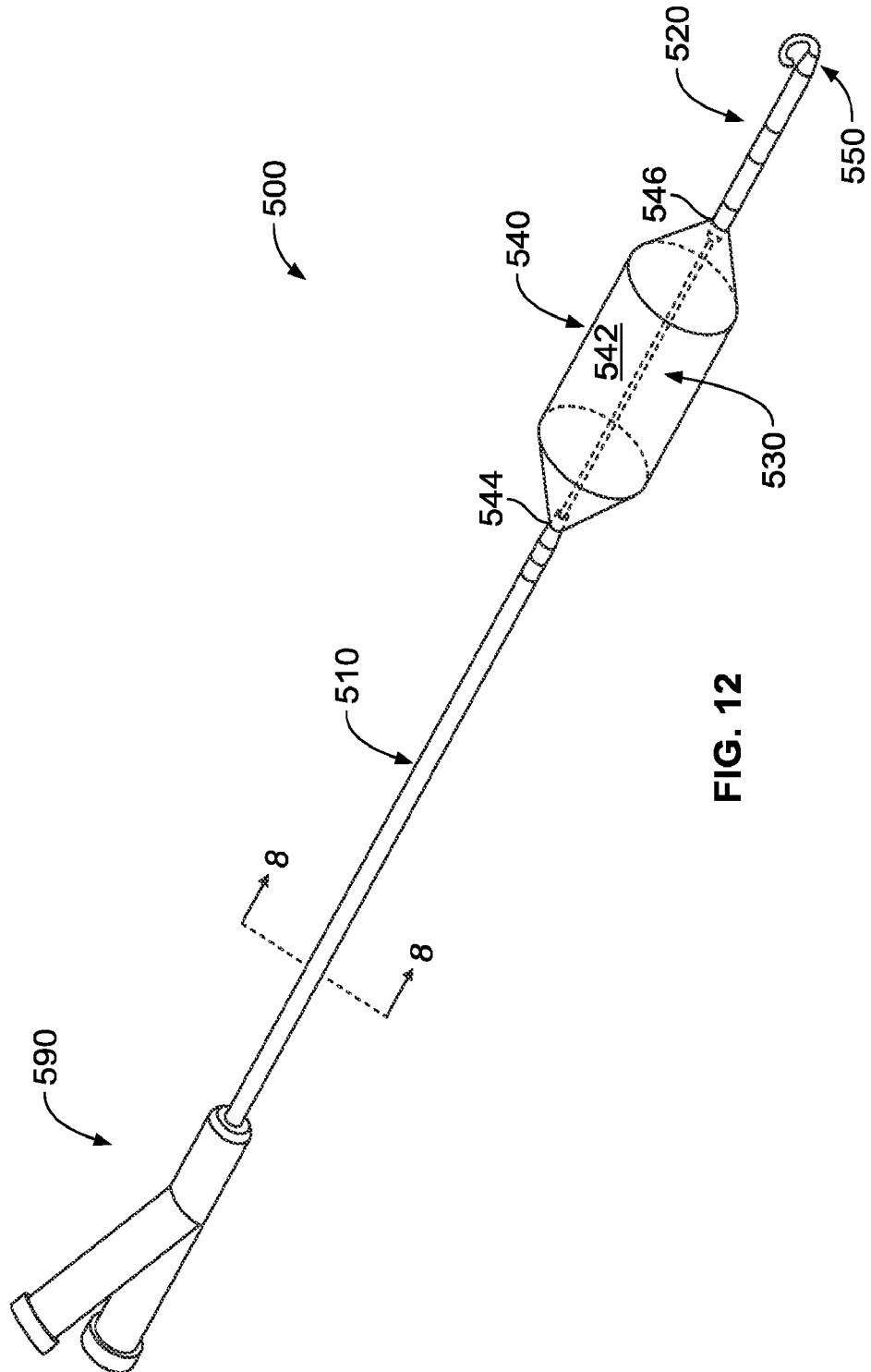


FIG. 12

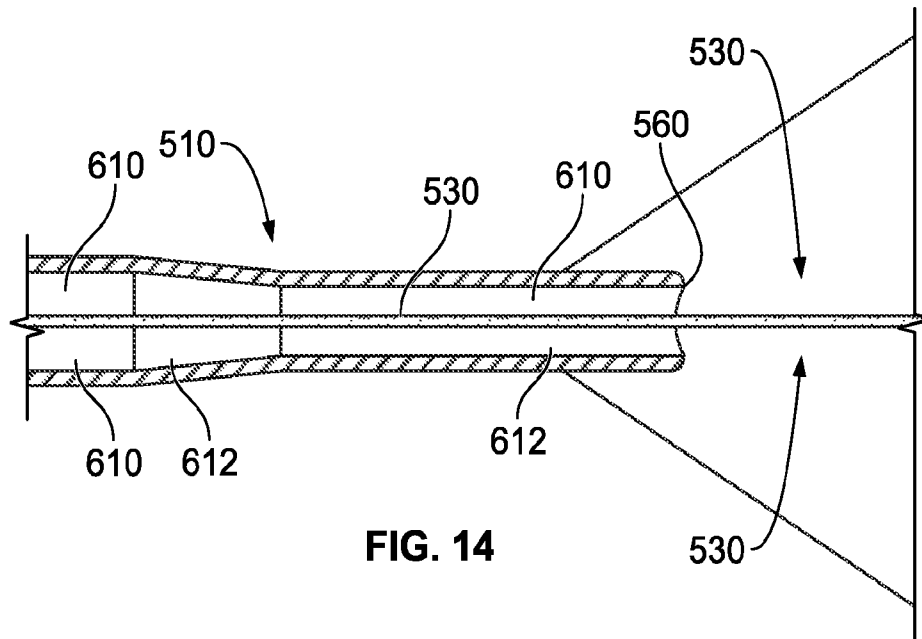


FIG. 14

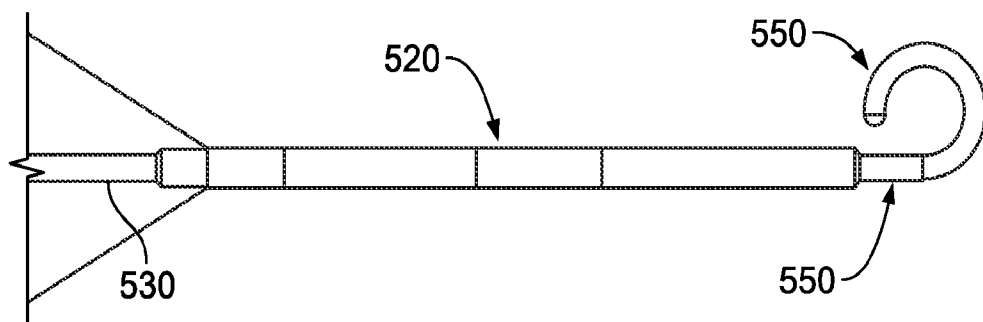


FIG. 15

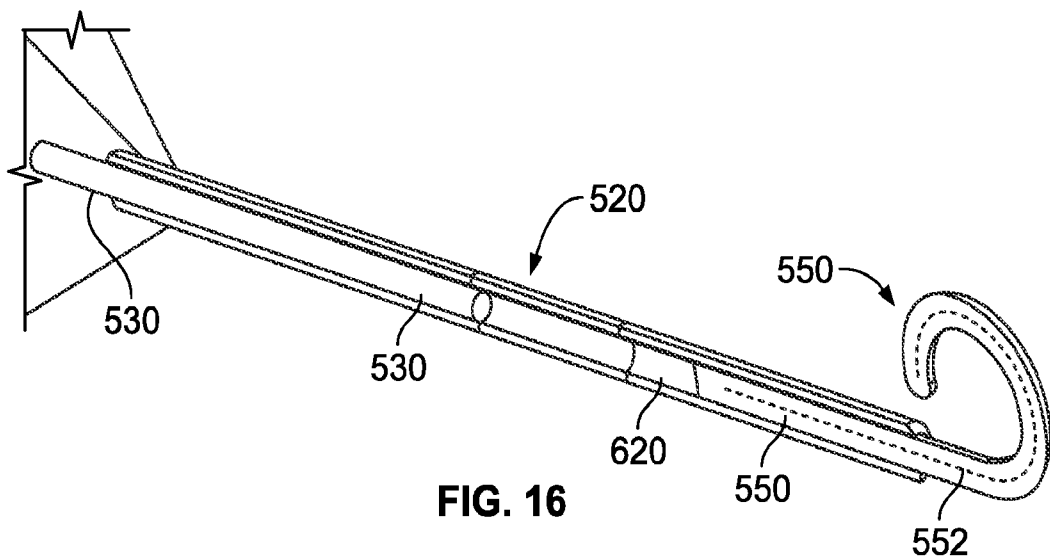
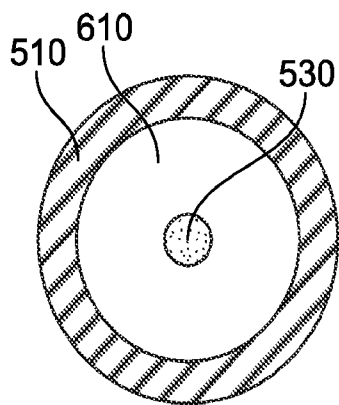
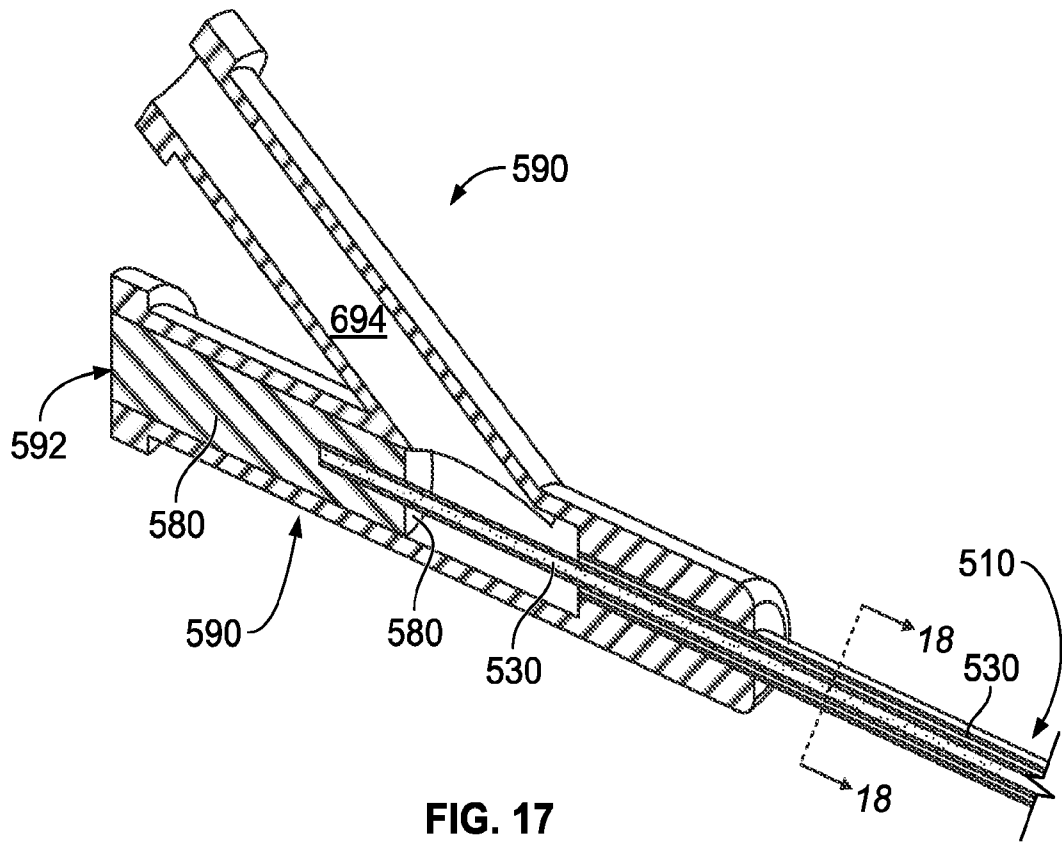


FIG. 16



A. CLASSIFICATION OF SUBJECT MATTER**A61M 25/10(2006.01)i, A61M 29/02(2006.01)i, A61L 29/04(2006.01)i, A61L 29/02(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 25/10; A61M 29/00; A61M 3/00; A61B 6/00; A61M 27/00; A61M 29/02; A61L 29/04; A61L 29/02

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: low profile occlusion catheter, balloon, multi lumen, tip, biocompatible polymer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5718678 A (FLEMING, III, J. A.) 17 February 1998 See abstract; column 4, line 60 - column 6, line 37; column 10, lines 9-16; claims 1-13; and figures 1-4.	1-57
Y	US 7503904 B2 (CHOI, S. B.) 17 March 2009 See abstract; column 3, line 40- column 4, line 47; column 5, lines 30-39, lines 42-43; claims 1, 8, 22; and figures 1, 4-5.	1-57
A	US 2004-0073162 A1 (BLEAM, J. C. et al.) 15 April 2004 See abstract; paragraphs [46], [64]; claims 1, 8; and figures 3A, 3B, 6.	1-57
A	US 2008-0262477 A1 (DJALADAT, H.) 23 October 2008 See abstract; paragraph [21]; claims 1, 2; and figures 1, 2.	1-57
A	WO 92-20398 A1 (LEOCOR, INC.) 26 November 1992 See abstract; claim 1; and figures 1, 3.	1-57

 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

27 January 2015 (27.01.2015)

Date of mailing of the international search report

28 January 2015 (28.01.2015)

Name and mailing address of the ISA/KR

International Application Division
Korean Intellectual Property Office
189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea

Facsimile No. ++82 42 472 3473

Authorized officer

Han, Inho

Telephone No. +82-42-481-3362



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2014/054802

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 05718678 A	17/02/1998	None	
US 7503904 B2	17/03/2009	US 2003-0204138 A1 US 2005-0119567 A1 US 2009-0182271 A1	30/10/2003 02/06/2005 16/07/2009
US 2004-0073162 A1	15/04/2004	WO 03-101523 A1	11/12/2003
US 2008-0262477 A1	23/10/2008	None	
WO 92-20398 A1	26/11/1992	EP 0586371 A1 EP 0586371 A4 JP 03-190332 B2	16/03/1994 27/07/1994 23/07/2001