(12) STANDARD PATENT (11) Application No. **AU 2018247062 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Chronic total occlusion crossing devices and methods

(51) International Patent Classification(s)
A61B 17/32 (2006.01)

(21) Application No: **2018247062** (22) Date of Filing: **2018.04.02**

(87) WIPO No: **WO18/184017**

(30) Priority Data

(31) Number	(32) Date	(33) Country
15/666,279	**2017.08.01**	**US**
62/500,303	**2017.05.02**	**US**
62/479,646	**2017.03.31**	**US**

(43) Publication Date: **2018.10.04**
(44) Accepted Journal Date: **2023.01.19**

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(56) Related Art
US 2009/0093829 A1
WO 2009/082228 A1
US 2013/0018384 A1
US 8574253 B2

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
04 October 2018 (04.10.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/184017 A1

(51) International Patent Classification:
A61B 17/32 (2006.01)

(21) International Application Number:
PCT/US2018/025722

(22) International Filing Date:
02 April 2018 (02.04.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/479,646	31 March 2017 (31.03.2017)	US
62/500,303	02 May 2017 (02.05.2017)	US
15/666,279	01 August 2017 (01.08.2017)	US

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(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
— *of inventorship (Rule 4.17(iv))*

(54) **Title:** CHRONIC TOTAL OCCLUSION CROSSING DEVICES AND METHODS

(57) **Abstract:** A device for crossing a lesion in a tissue lumen includes a crossing wire configured to pass through a lumen of a catheter, the crossing wire including a loop at a distal end of the crossing wire. The loop can have a configuration that prevents a width of the loop from exceeding a width of the tissue lumen, and the loop having a pair of lateral opposing portions configured for alignment with a wall of the tissue lumen and a leading portion interconnecting the pair of lateral opposing portions, the leading portion being configured to interrogate the lesion. The loop has a length in an axial direction of the crossing wire extending from the leading portion to proximal ends of the pair of lateral opposing portions, the length being perpendicular to the width, and the length of the loop is at least twice the width of the loop.

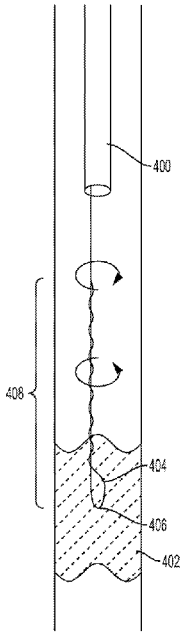


FIG. 4

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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))*

CHRONIC TOTAL OCCLUSION CROSSING DEVICES AND METHODS

[0001] This application claims priority to U.S. Non-Provisional Patent Application No. 15/666,279 filed August 1, 2017, which claims priority to U.S. Provisional Application No. 62/479,646 filed March 31, 2017 and U.S. Provisional Application No. 62/500,303 filed May 2, 2017, the entire contents of each of which are hereby incorporated by reference.

BACKGROUND

1. Technical Field

[0002] The field generally relates to crossing lesions in the vasculature, especially those referred to as a chronic total occlusions (CTO), and, more particularly crossing devices and methods utilizing a loop feature.

2. Discussion of Related Art

[0003] Vascular occlusions and, especially, CTOs can have a severe impact on a patient's health and lifestyle. CTOs are frequently encountered during endovascular interventions. CTOs exist in many patients with symptomatic peripheral arterial disease. In the lower extremities, CTOs are commonly encountered in the superficial femoral artery (SFA). Crossing these lesions may be challenging and may lead to prolonged procedure time, increased operator and patient radiation exposure, high contrast load, and peri-procedural complications including perforation, dissection, loss of collaterals, and creation of an arteriovenous fistula.

[0004] Revascularization of CTOs is usually hindered by failure to cross the lesion due to a variety of factors, so attempts to revascularize heavily calcified CTOs still can meet with failure. Existing CTO crossing devices still have a higher failure rate than desirable. Further, existing devices are too large to use in the vasculature below the waist. There remains an unmet need for devices and methods that can reliably and effectively cross lesions.

[0005] There further remains a need for devices and methods that can be used below the waist, including in the legs, such as the legs of diabetic patients that experience particularly difficult blockages, including peripheral artery disease (PAD). Such devices and methods would allow physicians to reliably and effectively cross the CTO without consequences such as perforating the vessel wall while attempting to cross the CTO. There remains an unmet need for effective and reliable treatment options for crossing CTOs.

SUMMARY

[0006] A device for crossing a lesion in a tissue lumen includes a crossing wire configured to pass through a lumen of a catheter, the crossing wire including a loop at a distal end of the crossing wire, the loop having a configuration that prevents a width of the loop from exceeding a width of the tissue lumen, and the loop having a pair of lateral opposing portions configured for alignment with a wall of the tissue lumen and a leading portion interconnecting the pair of lateral opposing portions, the leading portion being configured to interrogate the lesion. The loop has a length in an axial direction of the crossing wire extending from the leading portion to proximal ends of the pair of lateral opposing portions, the length being perpendicular to the width, and the length of the loop is at least twice the width of the loop.

[0007] According to one aspect, the loop has a rectangular cross-section, wherein the pair of lateral opposing portions are configured such that a long edge of the rectangular cross-section contacts the wall of the tissue lumen for alignment with the wall of the tissue lumen.

[0008] According to one aspect, the loop has a rectangular cross-section comprising two opposing long edges and two opposing short edges, wherein the pair of lateral opposing portions and the leading portion of the loop form a plane, and wherein the two long edges are perpendicular to the plane of the loop.

[0009] According to one aspect, a proximal end of the crossing wire has a first stiffness, and the leading portion of the loop has a second stiffness, wherein the first stiffness is greater than the second stiffness.

[0010] According to one aspect, the proximal end of the crossing wire forms a portion of a primary shaft of the crossing wire, wherein one of the pair of lateral opposing portions of the loop is directly connected to the primary shaft, and wherein another of the pair of lateral opposing portions is directly connected to a secondary shaft of the crossing wire, the secondary shaft being configured to wrap around the primary shaft.

[0011] According to one aspect, the crossing wire is twistable to form primary and secondary shafts that are intertwined. According to one aspect, the crossing wire has a rectangular cross-section, wherein the crossing wire forming the loop is not twisted, and wherein the crossing wire proximal to the loop is twisted.

[0012] According to one aspect, the crossing wire is configured to be rotatable back and forth through an angle less than 360 degrees while maintaining contact with the lesion to erode the lesion.

[0013] According to one aspect, wherein the crossing wire is configured to be twisted through an angle greater than 360 such that lateral opposing portions of the crossing wire become entwined beyond the distal end of the catheter.

[0014] According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 90 degrees. According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 60 degrees. According to one aspect, the leading portion of the loop is flat. According to one aspect, the leading portion of the loop is pointed. According to one aspect, the crossing wire is integrally formed.

[0015] According to one aspect, the leading portion of the loop has a concave configuration such that the pair of lateral opposing portions extend distal to a center of the leading portion of the loop.

[0016] According to one aspect, the crossing wire has a variable stiffness along its length. According to one aspect, wherein the loop includes a material that is radiopaque.

[0017] A device for crossing a lesion in a tissue lumen includes a catheter; a crossing wire configured to pass through a lumen of the catheter, the crossing wire including a loop at a distal end of the crossing wire, the loop having a configuration that prevents a width of the

loop from exceeding a width of the tissue lumen, and the loop having a pair of lateral opposing portions configured for alignment with a wall of the tissue lumen and a leading portion interconnecting the pair of lateral opposing portions, the leading portion being configured to interrogate the lesion; and a stationary inner catheter disposed within the catheter, the stationary inner catheter including a second lumen therein. An outer surface of the stationary inner catheter is fixed to an inner surface of the catheter.

[0018] According to one aspect, the device further includes a mobile inner catheter disposed within the lumen of the catheter eccentric to the stationary inner catheter, the mobile inner catheter forming a third lumen therein, the mobile inner catheter configured to move axially and radially with respect to the stationary inner catheter.

[0019] According to one aspect, a first proximal side of the loop is configured to be disposed within the second lumen, and wherein a second proximal side of the loop is configured to be disposed within the third lumen.

[0020] A device for crossing a lesion in a tissue lumen includes a catheter forming a lumen; and a crossing wire configured to pass through the lumen of the catheter, the crossing wire including a primary shaft and a loop at a distal end of the primary shaft, the loop having a configuration that prevents a width of the loop from exceeding a width of the tissue lumen, and the loop having a leading portion configured to interrogate the lesion. The crossing wire has a first configuration in which opposing lateral sides of the loop are not twisted or are twisted by a first amount, and a second configuration wherein the opposing lateral sides of the loop are twisted by a second amount that is different from the first amount. The crossing wire can be changed from the first configuration to the second configuration by twisting the primary shaft at a position proximal to the catheter.

[0021] According to one aspect, a first side of the opposing lateral sides of the loop is directly connected to the primary shaft, a second side of the opposing lateral sides of the loop is directly connected to a secondary shaft of the crossing wire, and the primary shaft and the secondary shaft are disposed inside the lumen of the catheter.

[0022] According to one aspect, in the second configuration, the opposing lateral sides of the crossing wire twist about each other a plurality of times. According to one aspect,

a shape of the loop at a position distal to the catheter is configured to change when a rotational force is applied to the primary shaft at a position proximal to the catheter.

[0023] A method for crossing a chronic total occlusion (CTO) includes inserting a catheter having a looped wire with a rectangular cross-section disposed in a lumen of the catheter into an occluded vessel; extending a distal end of the looped wire beyond a distal end of the catheter to contact an occlusion, the looped wire being positioned such that a long edge of the rectangular cross-section contacts a wall of the occluded vessel; grasping the looped wire at a position proximal to a proximal end of the catheter; and rotating the grasped looped wire back and forth through an angle less than 360 degrees while maintaining the distal end of the looped wire in contact with the occlusion to erode the occlusion.

[0024] According to one aspect, the method further includes twisting the grasped looped wire through an angle greater than 360 degrees while pressing the distal end of the looped wire against the occlusion such that sides of the looped wire become entwined beyond the distal end of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Further objectives and advantages will become apparent from a consideration of the description, drawings, and examples.

[0026] Figure 1A shows a portion of a device for crossing a lesion according to one aspect of the invention.

[0027] Figure 1B shows a crossing wire in a relaxed state.

[0028] Figure 2 shows a device according to one aspect of the invention inside a vessel lumen with a CTO.

[0029] Figure 3A shows a first example of a looped wire.

[0030] Figure 3B shows a second example of a looped wire.

[0031] Figure 3C shows a third example of a looped wire.

[0032] Figure 3D shows a fourth example of a looped wire.

[0033] Figure 3E shows a fifth example of a looped wire.

[0034] Figure 3F shows a fifth example of a looped wire.

[0035] Figure 3G shows a fifth example of a looped wire.

[0036] Figure 4 shows a device according to one aspect of the invention inside a vessel lumen with a CTO where the device has begun to pass into the CTO lesion.

[0037] Figure 5A shows a device according to one aspect of the invention where the loop is shown in a relaxed state.

[0038] Figure 5B shows the device of Figure 5A, but in another configuration.

[0039] Figure 5C shows the device of Figures 5A, but in another configuration in a sequence of changing configurations from Figures 5A to 5B to 5C.

[0040] Figure 5D shows the device of Figure 5A, but in another configuration in a sequence of changing configuration from Figures 5A to 5B to 5C to 5D.

[0041] Figure 6A shows a device in one aspect of the invention positioned in the vasculature with a CTO, and the crossing wire is shown extended from the catheter proximate the CTO cap.

[0042] Figure 6B shows the device in Figure 6A penetrating the CTO.

[0043] Figure 6C shows the device of Figures 6A and 6B penetrating further into the CTO.

[0044] Figure 6D shows the device of Figures 6A, 6B and 6C penetrating further into the CTO and crossing the CTO.

[0045] Figure 7A shows a crossing wire configured in one aspect of the invention.

[0046] Figure 7B shows a crossing wire configured in another aspect of the invention.

[0047] Figure 7C shows a crossing wire configured in another aspect of the invention.

[0048] Figure 7D shows a crossing wire configured in another aspect of the invention.

[0049] Figure 8A shows a catheter with a side opening and a crossing wire configured in one aspect of the invention.

[0050] Figure 8B shows a catheter with a side opening and a crossing wire configured in another aspect of the invention.

[0051] Figure 8C shows a catheter with a side opening and a crossing wire configured in another aspect of the invention.

[0052] Figure 8D shows a catheter with a side opening and a crossing wire configured in another aspect of the invention.

[0053] Figure 8E shows a catheter and crossing wire with an inverted loop configuration according to some embodiments of the invention.

[0054] Figure 9A shows a configuration of a looped crossing wire configured in one aspect of the invention.

[0055] Figure 9B shows another configuration of a looped crossing wire configured in one aspect of the invention.

[0056] Figure 9C shows another configuration of a looped crossing wire configured in one aspect of the invention.

[0057] Figure 10 shows a device configured in one aspect of the invention, in which two additional inner catheters are disposed within the outer catheter.

[0058] Figure 11A shows another configuration of a device with two additional inner catheters disposed within the outer catheter.

[0059] Figure 11B shows a configuration of a device with three additional inner catheters disposed within the outer catheter.

[0060] Figure 11C shows an end of an outer catheter with three catheters disposed therein.

[0061] Figure 12 shows a configuration of a device wherein at least one inner catheter is mobile with respect to the outer catheter.

[0062] Figure 13A shows a configuration of a device having a wheel to facilitate twisting of the crossing wire.

[0063] Figure 13B shows an enlarged image of the wheel of Figure 13A.

[0064] Figure 14 shows a configuration of a device in which a plurality of catheters are disposed within the outer catheter, and the outer catheter includes a hole in a side surface.

[0065] Figure 15A shows a configuration of a cross-section of a crossing wire.

[0066] Figure 15B shows another configuration of a cross-section of a crossing wire.

[0067] Figure 15C shows another configuration of a cross-section of a crossing wire.

[0068] Figure 15D shows another configuration of a cross-section of a crossing wire.

[0069] Figure 15E shows another configuration of a cross-section of a crossing wire.

[0070] Figure 16 shows an example of a loop having a rectangular cross-section.

[0071] Figure 17 shows arteries below the knee as an example vasculature in which the device can be used.

[0072] Figure 18 shows a crossing wire in a twisted configuration.

[0073] Figure 19A shows a crossing wire before it has been bent and cured or preformed into a looped configuration.

[0074] Figure 19B shows a crossing wire in another twisted configuration.

[0075] Figure 20A shows a crossing wire in a loosely twisted configuration.

[0076] Figure 20B shows a crossing wire in a moderately twisted configuration.

[0077] Figure 20C shows a crossing wire in a stiff configuration.

[0078] Figure 21A shows a crossing wire with a secondary shaft that is not connected to the primary shaft at the proximal tip of the secondary shaft.

[0079] Figure 21B shows a crossing wire with a secondary shaft that is connected to the primary shaft at the proximal tip of the secondary shaft.

[0080] Figure 22 shows a configuration of a twisted wire forming a loop.

[0081] Figure 23 shows another configuration of a twisted wire forming a loop.

[0082] Figure 24 shows another configuration of a twisted wire forming a loop.

[0083] Figure 25 shows another configuration of a twisted wire forming a loop.

[0084] Figure 26 shows another configuration of a twisted wire forming a loop.

[0085] Figure 27 shows another configuration of a twisted wire forming a loop.

[0086] Figure 28A shows another configuration of a twisted wire forming a loop.

[0087] Figure 28B shows another configuration of a twisted wire forming a loop.

[0088] Figure 29 shows another configuration of a twisted wire forming a loop.

[0089] Figure 30A shows a configuration of a crossing wire encased in an outer shell.

[0090] Figure 30B shows another configuration of a crossing wire encased in an outer shell.

[0091] Figure 30C shows a configuration of a crossing wire that is not encased in an outer shell.

[0092] Figure 31A shows a configuration of a crossing wire wherein the secondary shaft has a length that can be varied.

[0093] Figure 31B shows a configuration of a crossing wire wherein the secondary shaft is not bonded to the primary shaft.

[0094] Figure 31C shows a configuration of a crossing wire wherein the secondary shaft is bonded to the primary shaft.

[0095] Figure 32A shows a configuration of an outer shell of a crossing wire with an open distal end.

[0096] Figure 32B shows a configuration of an outer shell of a crossing wire with a closed distal end.

[0097] Figure 32C shows a configuration of a crossing wire extending beyond an open distal end of an outer shell.

[0098] Figure 33A shows a crossing wire having a first stiffness and an outer shell.

[0099] Figure 33B shows a crossing wire having a second stiffness and an outer shell.

[00100] Figure 33C shows a crossing wire having a third stiffness and an outer shell.

[00101] Figure 33D shows a crossing wire having a fourth stiffness and an outer shell.

[00102] Figure 34A shows a crossing wire having a circumferential configuration.

[00103] Figure 34B shows a crossing wire having another circumferential configuration.

[00104] Figure 34C shows a crossing wire having another circumferential configuration.

[00105] Figure 35A shows a crossing wire having a circumferential configuration and two secondary shafts.

[00106] Figure 35B shows a top-down view of the crossing wire shown in Figure 35A.

[00107] Figure 36 shows another configuration of a crossing wire having a primary shaft and two secondary shafts.

[00108] Figure 37A shows a configuration of a crossing wire having a primary shaft and a secondary shaft.

[00109] Figure 37B shows an enlarged view of a portion of Figure 37B.

[00110] Figure 37C shows another configuration of a crossing wire having a primary shaft and a secondary shaft.

[00111] Figure 38A shows a crossing wires having a dual longitudinal helical wire configuration.

[00112] Figure 38B shows a crossing wires having another dual longitudinal helical wire configuration.

[00113] Figure 39A shows a crossing wire having a circular cross-section at the loop.

[00114] Figure 39B shows an enlarged image of the shaft in Figure 39A.

[00115] Figure 39C shows an enlarged image of the loop in Figure 39A.

[00116] Figure 39D shows a crossing wire having a rectangular cross-section at the loop.

[00117] Figure 39E shows cross-section of a crossing wire having a rectangular cross-section at the loop.

[00118] Figure 40 shows a configuration of a crossing wire that has a primary shaft and a secondary shaft that are flat.

[00119] Figure 41 shows another configuration of a crossing wire that has a primary shaft and a secondary shaft that are flat.

[00120] Figure 42 shows another configuration of a crossing wire that has a primary shaft and a secondary shaft that are flat.

[00121] Figure 43A shows a configuration of a crossing wire shaft.

[00122] Figure 43B shows another configuration of a crossing wire shaft.

[00123] Figure 43C shows another configuration of a crossing wire shaft.

[00124] Figure 43D shows another configuration of a crossing wire shaft.

[00125] Figure 44A shows a configuration of a crossing wire loop.

[00126] Figure 44B shows another configuration of a crossing wire loop.

[00127] Figure 45A shows another configuration of a crossing wire loop.

[00128] Figure 45B shows another configuration of a crossing wire loop.

[00129] Figure 46 shows a process for creating a wire having a non-circular cross-section in the loop portion from a wire having a circular cross-section.

[00130] Figure 47A shows a configuration of a crossing wire having a non-circular cross-section.

[00131] Figure 47B shows another configuration of a crossing wire having a non-circular cross-section.

[00132] Figure 47C shows another configuration of a crossing wire having a non-circular cross-section.

[00133] Figure 47D shows another configuration of a crossing wire having a non-circular cross-section.

[00134] Figure 48A shows the crossing wire having a shaved cross-section at the distal portion of the loop.

[00135] Figure 48B shows a crossing wire having a shaved cross-section throughout the loop.

[00136] Figure 48C shows a crossing wire having a loop that is not shaved.

[00137] Figure 48D shows a distal end of a crossing wire that is formed from four sub-wires.

[00138] Figure 49A shows a crossing wire in a loosely wound formation with abrasive elements on the loop.

[00139] Figure 49B shows a crossing wire in a more tightly wound formation with abrasive elements on the loop.

[00140] Figure 50A shows a configuration of a crossing wire having a welded loop.

[00141] Figure 50B shows another configuration of a crossing wire having a welded loop.

[00142] Figure 51 shows a configuration of a crossing wire having a primary shaft and a secondary shaft.

DETAILED DESCRIPTION

[00143] Some embodiments of the current invention are discussed in detail below. In describing embodiments, specific terminology is employed for the sake of clarity. However, the invention is not intended to be limited to the specific terminology so selected. A person skilled in the relevant art will recognize that other equivalent components can be employed and other methods developed without departing from the broad concepts of the current invention. All references cited anywhere in this specification, including the Background and Detailed Description sections, are incorporated by reference as if each had been individually incorporated.

[00144] The devices and methods contemplated are configured to reliably and effectively cross lesions in the vasculature, especially, lesions of the type where the accumulation of plaque is so severe that it results in a complete or nearly complete blockage of the vessel. The devices and methods in accordance with the principles of the invention are configured and adapted to cross an occlusion in order that interventional treatments can follow. The devices and methods described can include a crossing wire, a crossing catheter, and/or a combination of both utilized separately and/or in combination with each other and/or in combination with conventional wires and/or catheters.

[00145] The CTO crossing devices and methods can include a guidewire having a distal end configured for more reliably crossing a CTO. In one aspect this configured distal end can be referred to as a loop, as discussed in more detail below. This loop-ended crossing wire is configured to present a more reliable device for interaction and engagement with the CTO, and, more particularly, a cap of the CTO that can have varying geometries and complexities. The loop-ended crossing wire is also configured to present a more reliable device for advancing through the occlusion to successfully cross the lesion.

[00146] The configuration at the end of the guide wire, referred to as a loop, can include various geometries, shapes, sizes and material properties and can be configured by way of the contemplated methods alone and/or in combination with guidewires and/or catheters. The loop feature, and the associated methods and/or devices, can be configured to present an interrogation conducive distal leading end that balances loop resiliency with stiffness so as to present itself optimally to the lesion yet also allow the loop to pass through the lesion. The loop configuration can be achieved by shape-memory and/or arrangements of

the wire alone, in combination with a catheter, and/or in combination with methods of use. For example, the guidewire loop can include a loop shape prior to use and/or a loop configuration that is formed in whole or in part in-situ, alone and/or in combination with a catheter.

[00147] A device for crossing a lesion in a tissue lumen includes a crossing wire configured to pass through a lumen of a catheter, the crossing wire including a loop at a distal end of the crossing wire, the loop having a configuration that prevents a width of the loop from exceeding a width of the tissue lumen, and the loop having a leading portion configured to interrogate the lesion.

[00148] According to one aspect, the device further includes the catheter, wherein the catheter has a proximal end and a distal end. According to one aspect, a first proximal side of the loop is configured to be disposed within the lumen of the catheter, and a second proximal side of the loop is configured to be disposed outside of the lumen of the catheter. According to one aspect, a first proximal side of the loop and a second proximal side of the loop are configured to be disposed within the lumen of the catheter.

[00149] According to one aspect, the catheter further includes a hole in a side surface of the catheter, wherein a first proximal side of the loop is configured to be disposed within the lumen of the catheter, and wherein a second proximal side of the loop is configured to enter the lumen of the catheter through the hole in the side surface of the catheter.

[00150] According to one aspect, the crossing wire is twistable to form a loop having opposite sides that are intertwined. According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 90 degrees. According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 60 degrees.

[00151] According to one aspect, the leading portion of the loop is rounded. According to one aspect, the leading portion of the loop is flat. According to one aspect, the leading portion of the loop is pointed.

[00152] According to one aspect, the crossing wire is integrally formed. According to one aspect, the crossing wire has a single stiffness along its length. According to one aspect,

the crossing wire has a variable stiffness along its length. According to one aspect, the crossing wire has a cross-section that is rectangular.

[00153] According to one aspect, the device further includes a stationary inner catheter disposed within the catheter, the stationary inner catheter including a second lumen therein. An outer surface of the stationary inner catheter is fixed to an inner surface of the catheter. According to one aspect, the device further includes a mobile inner catheter disposed within the lumen of the catheter eccentric to the stationary inner catheter, the mobile inner catheter forming a third lumen therein, the mobile inner catheter configured to move axially and radially with respect to the stationary inner catheter. According to one aspect, a first proximal side of the loop is configured to be disposed within the second lumen, and a second proximal side of the loop is configured to be disposed within the third lumen.

[00154] According to one aspect, the crossing wire is an elongated wire. The crossing wire has a proximal end controllable by a user, wherein the distal end of the crossing wire is configured for positioning in the tissue lumen for crossing a chronic total occlusion, the distal end including the loop, the loop having a pair of lateral opposing portions configured for alignment with a wall of the tissue lumen and the leading portion interconnecting the pair of lateral opposing portions, wherein the loop is configured for crossing the chronic total occlusion.

[00155] According to one aspect, the proximal end of the crossing wire has a first stiffness, and wherein the leading portion of the loop has a second stiffness, wherein the first stiffness is greater than the second stiffness. According to one aspect, the loop includes a material that is radiopaque. According to one aspect, the proximal end of the crossing wire forms a portion of a primary shaft of the crossing wire, wherein one of the pair of lateral opposing portions of the loop is directly connected to the primary shaft, and wherein another of the pair of lateral opposing portions is directly connected to a secondary shaft of the crossing wire, the secondary shaft being configured to wrap around the primary shaft.

[00156] According to one aspect, the crossing wire is configured to be rotatable back and forth through an angle less than 360 degrees while maintaining contact with the lesion to erode the lesion. According to one aspect, the crossing wire is configured to be twisted through an angle greater than 360 such that lateral opposing portions of the crossing wire become entwined beyond the distal end of the catheter.

[00157] A method for crossing a chronic total occlusion (CTO) includes inserting a catheter having a looped wire disposed in a lumen of the catheter into an occluded vessel; extending a distal end of the looped wire beyond a distal end of the catheter to contact an occlusion; grasping the looped wire at a position proximal to a proximal end of the catheter; and rotating the grasped looped wire back and forth through an angle less than 360 degrees while maintaining the distal end of the looped wire in contact with the occlusion to erode the occlusion.

[00158] According to one aspect, the method further includes twisting the grasped looped wire through an angle greater than 360 degrees while pressing the distal end of the looped wire against the occlusion such that sides of the looped wire become entwined beyond the distal end of the catheter.

[00159] A device for crossing a lesion in a tissue lumen includes a catheter forming a lumen; and a crossing wire configured to pass through the lumen of the catheter, the crossing wire including a primary shaft and a loop at a distal end of the primary shaft, the loop having a configuration that prevents a width of the loop from exceeding a width of the tissue lumen, and the loop having a leading portion configured to interrogate the lesion. The crossing wire has a first configuration in which opposing lateral sides of the loop are not twisted or are twisted by a first amount, and a second configuration wherein the opposing lateral sides of the loop are twisted by a second amount that is different from the first amount. The crossing wire can be changed from the first configuration to the second configuration by twisting the primary shaft at a position proximal to the catheter.

[00160] According to one aspect, a first side of the opposing lateral sides of the loop is directly connected to the primary shaft, a second side of the opposing lateral sides of the loop is directly connected to a secondary shaft of the crossing wire, and the primary shaft and the secondary shaft are disposed inside the lumen of the catheter. According to one aspect, in the second configuration, the opposing lateral sides of the crossing wire twist about each other a plurality of times. According to one aspect, a shape of the loop at a position distal to the catheter is configured to change when a rotational force is applied to the primary shaft at a position proximal to the catheter.

[00161] A device for crossing a lesion includes a catheter including a lumen, the catheter having a proximal end and a distal end, and a crossing wire configured to pass

through lumen, the crossing wire including a loop at a distal end of the crossing wire, the loop having a relaxed state such that opposite sides of the loop form an angle that is less than 180 degrees, and the loop having a leading portion configured to interrogate the lesion.

[00162] According to one aspect, a first proximal side of the loop is configured to be disposed within lumen of the catheter, and a second proximal side of the loop is configured to be disposed outside of the lumen of the catheter. According to one aspect, a first proximal side of the loop and a second proximal side of the loop are configured to be disposed within lumen of the catheter. According to one aspect, the catheter further includes a hole in a side surface of the catheter, wherein a first proximal side of the loop is configured to be disposed within the lumen of the catheter, and wherein a second proximal side of the loop is configured to enter the lumen of the catheter through the hole in the side surface of the catheter.

[00163] According to one aspect, the crossing wire is twistable to form a loop having opposite sides that are intertwined. According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 90 degrees. According to one aspect, a first proximal side and a second proximal side of the loop are configured to be disposed within lumen of the catheter. According to one aspect, the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 60 degrees. According to one aspect, the leading portion of the loop is rounded. According to one aspect, the leading portion of the loop is flat. According to one aspect, the leading portion of the loop is pointed.

[00164] According to one aspect, the crossing wire is integrally formed. According to one aspect, the crossing wire has a single stiffness along its length. According to one aspect, the crossing wire has a variable stiffness along its length. According to one aspect, the wire has a cross-section that is rectangular.

[00165] According to one aspect, the device further includes a stationary inner catheter disposed within the support catheter, the stationary inner catheter including a second lumen therein. An outer surface of the stationary inner catheter is fixed to an inner surface of the support catheter.

[00166] According to one aspect, the device further includes a mobile inner catheter disposed within the lumen of the support catheter eccentric to the stationary inner catheter,

the mobile inner catheter forming a third lumen therein, the mobile inner catheter configured to move axially and radially with respect to the stationary inner catheter.

[00167] According to one aspect, a first proximal side of the loop is configured to be disposed within the second lumen, and a second proximal side of the loop is configured to be disposed within the third lumen.

[00168] A device for crossing a lesion includes a catheter including a lumen, the catheter having a proximal end and a distal end, and a crossing wire configured to pass through lumen, the crossing wire including a loop at a distal end of the crossing wire, the loop having opposite sides that are disposed within the lumen, and the loop having a leading portion configured to interrogate the lesion.

[00169] A chronic total occlusion crossing wire includes an elongated wire configured to pass through a catheter lumen, the elongated wire having a proximal end controllable by a user and a distal end configured for positioning in a vessel for crossing the chronic total occlusion, the distal end including a loop having a pair of lateral opposing portions configured for alignment with a wall of the vessel and a leading portion interconnecting the pair of lateral opposing portions, wherein the loop is configured for crossing the chronic total occlusion.

[00170] According to one aspect, the proximal end of the elongated wire has a first stiffness, and the leading portion of the loop has a second stiffness, wherein the first stiffness is greater than the second stiffness. According to one aspect, the loop includes a material that is radiopaque. According to one aspect, the proximal end of the elongated wire forms a portion of a primary shaft of the elongated wire, wherein one of the lateral opposing portions of the loop is directly connected to the primary shaft, and wherein another of the lateral opposing portions is directly connected to secondary shaft of the elongated wire, the secondary shaft being configured to wrap around the primary shaft.

[00171] A method for crossing a chronic total occlusion (CTO) includes inserting a catheter having a looped wire disposed in a lumen of the catheter into an occluded vessel, and extending a distal end of the looped wire beyond a distal end of the catheter to contact an occlusion. The method further includes grasping the looped wire at a position proximal to a proximal end of the catheter, and rotating the grasped looped wire back and forth through an

angle less than 360 degrees while maintaining the distal end of the looped wire in contact with the occlusion to erode the occlusion.

[00172] In one aspect, the method further includes twisting the grasped looped wire through an angle greater than 360 degrees while pressing the distal end of the wire against the occlusion such that sides of the looped wire become entwined beyond the distal end of the catheter.

[00173] A CTO crossing device according to some embodiments of the invention is directed to the concept of a loop at the distal end of the system, in particular, a guidewire loop. With this loop, the physician has the ability to use the leading distal end of the loop to interrogate the lesion and ultimately cross the lesion. The term "interrogate" as used herein can mean to contact, prod, probe, chip away at, break apart, dissect, and/or drill into a lesion. While interrogating a lesion may lead to crossing the lesion, the term "interrogating" is generally used to mean physically interacting with the lesion. The loop at the distal end of the system provides a stiffer surface for interrogating the lesion compared to, for example, using the floppy distal wire tip of a conventional guidewire.

[00174] Various aspects of the loop configuration can be considered. One aspect of the configuration is a dimensional configuration, such as the width of the loop. The width of the loop can be generally considered a lateral dimension. The width dimension of the loop can be configured based on the width or transverse dimension of the vessel in which the lesion is located. For example, the width may be configured to be half of the cross-sectional diameter of the vessel.

[00175] The loop can be configured to maintain geometries and/or configurations in use that allow crossing of the lesion without the loop collapsing and/or puncturing unintended areas of the vasculature. If the width of the loop exceeds the width of the vessel, or if the loop collapses, the vessel can rupture. The loop width can be selected to allow the loop to move along the vessel wall gently, without exerting point-like pressure on the vessel wall, and/or without exerting forces perpendicular to the vessel wall. According to one aspect, the width of the loop is between about .05 mm and about 6 mm. According to one aspect, the width of the loop is between about 1.5 mm and about 2.5 mm. According to one aspect, the width of the loop is between about 2.5 mm and about 6 mm.

[00176] In one aspect, the device can be configured to limit the width of the loop to be about half the width of the vessel. For example, for a 5 or 6 mm vessel, the width of the loop will less than about 2.5 or 3 mm. A narrow loop can move along the vessel wall without exerting point-like pressure on the vessel wall, and without exerting forces perpendicular to the vessel wall. If the width of the loop were allowed to expand such that it significantly exceeded the diameter of the vessel, the sides of the loop may exert forces perpendicular to the surface of the vessel wall that could puncture the vessel wall.

[00177] The loop can have a configuration that prevents a width of the loop from exceeding a width of the tissue lumen. The configuration may prevent the width of the loop from exceeding the width of the tissue lumen to the point of rupture, risk of rupture, undesirable stress and/or strain on the vessel, or beyond the vessel's elastic limits. In one aspect, the loop configuration may prevent the width of the loop from exceeding a width that is slightly greater than the diameter of the tissue lumen when no forces are being applied, because the shape of the lumen may change when an expanding force is applied by the loop, increasing the width of the lumen. In one aspect, the configuration may prevent the width of the loop from exceeding the width of the tissue lumen to the point of injury. In one aspect, the configuration may provide a loop that is not damaging to the healthy lumen size and/or shape of the lumen. In one aspect, the configuration controls the width of the loop to be about half the diameter of the tissue lumen or less. In one aspect, the configuration controls the width of the loop relative to the lumen diameter. In one aspect, the configuration controls the width of the loop relative to the lesion.

[00178] The distal-most portion of the loop is referred to herein as the leading distal end, or leading portion. The leading distal end of the loop can be configured in accordance with the principles of the invention to have a size and shape that are optimized for a particular application. For example, the leading distal end can be pointed, rounded, convex, or concave depending on the shape and hardness of the lesion to be interrogated.

[00179] The leading distal end of the loop can be configured to come into contact with the lesion. The distal end of the loop can be generally configured with a curvature of various types, some of which are shown in the drawings and discussed below. In one aspect, the leading distal end can be configured to be pointed, providing a smaller surface area for contacting the occlusion as compared to a loop having a rounded leading end. When the

leading distal end contacts the lesion, the pointed leading distal end concentrates a force applied to the lesion over a smaller area of the lesion than a rounded leading distal end would.

[00180] The loop portion of the crossing wire can be pre-formed such that the leading distal end of the loop has a predetermined configuration. For example, the crossing wire can assume a looped or bent shape even when no external forces are acting on it. When no forces are acting on the loop, the configuration of the loop can be referred to as a "relaxed" or steady-state configuration. The fact that the loop is pre-formed helps maintain the narrow width of the loop, because the crossing wire itself will provide a counter-force when the loop is expanded beyond its pre-formed width. For example, when the leading distal end of the loop is brought into contact with a lesion and additional force is applied to the crossing wire, if the lesion resists the applied forces, the loop may begin to expand. However, the crossing wire itself will provide tensile forces that resist expansion of the loop beyond its preformed width. The widest portions of the loop can contact the vessel wall, and can stabilize the loop with respect to the vessel wall, such as the arterial wall.

[00181] In addition to the loop configuration contemplated in its basic form as discussed above in various aspects and configurations, the loop can further be configured to include more complex loop configurations. The additional loop configurations can have a single loop configuration as the basis of the loop configurations. The loop can be configured to allow for twisting and/or wrapping of the loop during use.

[00182] The loop alone and/or in combination with the catheter can be configured to be adaptable and/or controlled during use by methods and techniques contemplated herein. In one aspect, during use of the CTO crossing device, the operator, such as a physician, can control the crossing wire by displacement, for example, such as by rotation and/or twisting. The operator can twist a portion of the wire proximal to the catheter, causing a portion of the wire extending beyond the distal end of the catheter to become intertwined with itself. This can prevent the loop from becoming too wide, and also provides axial support for the leading portion of the loop.

[00183] The present device enables the physician to control the width of the loop, thereby enhancing the safety and efficacy of the procedure. Some configurations of the invention also include a catheter, into which the looped crossing wire is disposed. By disposing the wire inside the catheter, the amount of bowing that the wire can undergo is

limited. If the wire begins to bow inside the catheter, the catheter wall redirects the lateral forces so that they extend along the length of the catheter, and toward the leading distal end of the loop.

[00184] A device for crossing a lesion according to some embodiments of the invention is shown in Figure 1A. The device 100 includes a catheter 102 including a lumen 104, the catheter 102 having a proximal end 106 and a distal end 108. The device also includes a crossing wire 110 configured to pass through lumen 104, the crossing wire 110 including a loop 112 at a distal end of the crossing wire 110, the loop 112 having a relaxed state such that opposite sides 114, 116 of the loop form an angle that is less than 180 degrees, and the loop 112 having a leading portion 118 configured to interrogate the lesion.

[00185] The term "relaxed state" is intended to mean a state of the crossing wire when no external forces are exerted on it. For example, Figure 1B shows a crossing wire 120 in a relaxed state. The opposite sides 122, 124 of the loop 126 can form an angle 128. The angle can be less than 180 degrees. In one aspect of the invention, the angle is between about 90 and about 45 degrees. In one aspect of the invention, the angle is between about 60 and about 30 degrees. The angle will influence the width of the looped portion of the crossing wire. A crossing wire with opposite sides that form an angle of 90 degrees in a relaxed state will form a wider loop than a crossing wire with opposite sides that form an angle of 45 degrees in a relaxed state. The angle may be chosen based on the diameter of the vessel, with smaller angles corresponding to smaller vessels and larger angles corresponding to larger vessels. Further, loops forming a wider angle may be chosen for navigating the true lumen of a vessel during a CTO crossing procedure, while loops forming a narrower angle may be chosen for navigating the subintimal region of the vessel, if the CTO cannot be crossed with the loop remaining in the true lumen.

[00186] Figure 2 shows a catheter 200 inside a vessel lumen 202. A CTO 204 blocks the lumen 202. A CTO wire 206 is shown extending beyond the distal end of the catheter 200. The CTO wire 206 has a loop 208 that forms the distal end of the CTO wire 208. The loop 208 can come into contact with the CTO 204, and can be used by the physician to perform microdissection of the CTO, opening the vessel and creating a path for a guide wire or other device if further treatment is required. The physician my use multiple looped CTO wires to cross the CTO. For example, the physician may use a first looped CTO wire from an antegrade approach and a second looped CTO wire from a retrograde approach.

[00187] The CTO wire can undergo structural formation such that, when no forces are applied to the wire, the wire assumes the configuration or shape as shown, where a portion of the wire doubles back. For example, in Figure 2, the CTO wire 206 has a main shaft 210, a loop 212, and a second shaft 212 that doubles back toward the catheter 200. The wire including the double-backed portion may form a V-shape, a U-shape, a W-shape, or an M-shape, for example. These shapes are provided as examples, and the embodiments of the invention are not limited to these shapes. The wire including the doubled-back portion may be referred to herein as "looped." Loop 208 can be pre-formed, and can have shape memory characteristics. The shape memory characteristics allow the loop to resist forces that would cause the loop to become wider. For example, if the loop 208 is pre-formed to have a particular width, when a force is exerted on the loop that would cause the width of the loop to increase, tensile forces in the wire will resist the lateral forces, helping maintain the predetermined width of the loop. The loop 208 can be passable through the catheter and can assume its relaxed configuration in whole or in part for use.

[00188] The structural formation of the wire can be accomplished by a variety of method, for example, by forming the wire to have a looped shape during its original manufacture, or by applying heat and shaping forces to the wire after its initial formation. Once the wire has undergone structural formation, the wire maintains its structural formation when it is in a relaxed configuration, meaning that no forces are applied to it. When forces are applied to the wire that would change the configuration of the wire, the tensile forces in the wire resist the change. However, the wire may still flex and bend due to the applied forces.

[00189] Figures 3A-3G show various configuration of looped wires. Each configuration may be a result of the structural formation of the wire, and may be the relaxed configuration of the wire. In Figure 3A, the wire 300 has a broad loop. In Figure 3B, the wire 302 has a broad loop with a flattened tip. In Figure 3C, the wire 304 has a broad loop with a pointed tip. In Figure 3D, the wire 306 has an elongated loop with a narrow tip. In Figure 3E, the wire 308 has a broad loop with one end of the wire located very close to the loop. In Figure 3F, the wire 310 has a peaked loop. This loop may be used to interrogate a concave lesion. In Figure 3G, the wire 312 has an inverted loop 314. The leading portion of the inverted loop 314 has a concave configuration such that the pair of lateral opposing portions 316, 318 extend distal to the center 320 of the leading portion of the loop 314. As shown in

Figure 3G, the loop 314 may form a "W" shape, with the pair of lateral opposing portions 316, 318 extending the farthest distally, then the loop extending proximally a first distance, and then again distally a second distance to the center 320 of the leading portion of the loop 314. The second distance may be less than the first distance, as shown in Figure 3G. The loop 314 may be used to interrogate a convex lesion. The pair of lateral opposing portions 316, 318 can engage the sides of the lesion and the walls of the tissue cavity, thus centering the loop on the lesion. The center 320 of the leading portion of the loop 314 can interrogate the lesion as the physician pushes the wire 312 distally and rotates the wire 312. Thus, a physician may select a particular wire based on the shape and density of the lesion.

[00190] According to one aspect of the invention, the crossing wire has a short side on one side of the loop, and a long side on the other side of the loop. The long side of the loop can be disposed within a catheter, while the short side may be disposed within the catheter, or outside of the catheter. According to one aspect of the invention, the short side has a length between about 10 mm and about 70 mm. According to one aspect of the invention, the short side has a length between about 30 mm and about 50 mm. According to one aspect of the invention, the short side has a length of about 40 mm. According to one aspect of the invention, both sides of the loop are the same length.

[00191] Figure 4 shows how the looped wire can be used to cross a lesion according to one aspect of the invention. A physician guides the catheter 400 through the vessel until it is within a few millimeters of the lesion 402. The catheter 400 has a crossing wire 404 that is at least partially disposed inside the catheter or passed through the catheter. The crossing wire 404 has a length such that it can be grasped by the physician proximal to the catheter 400, and can simultaneously extend beyond the distal end of the catheter 400. Once the catheter 400 is in position, the physician then extends the crossing wire 404 beyond the distal end of the catheter 400, toward the lesion 402. The looped wire in Figure 4 can be representative of any of the configurations and embodiments of looped wires described herein.

[00192] The crossing wire 404 has a pre-formed loop. For example, the pre-formed loop may have a relaxed configuration with a primary shaft, a secondary shaft, and a loop portion between the primary and secondary shafts. The primary and second shafts may be separated by a space, as shown in Figures 3A-3G. The physician extends the crossing wire 404 until the leading distal end 406 contacts the lesion 402. Once the leading distal end 406 contacts the lesion 402, the physician may probe the lesion with the leading distal end 406.

Further, the physician may grasp the crossing wire 404 proximal to the catheter 400, and begin to twist the wire. The two sides of the pre-formed loop begin to twist around themselves, forming a twisted loop 408, as shown in Figure 4. The twisted loop 408 can have a higher resistance to bending than a conventional CTO wire, allowing the physician to exert greater force on the lesion 402 than would be possible with a conventional CTO wire, while maintain a loop whose width does not exceed the width of the vessel. The physician may continue twisting the wire as he or she applies pressure on the lesion 402, thereby entering into the lesion 402, as shown in Figure 4. The device entering into the lesion can be referring to as drilling into the lesion. In this way, the physician may use the wire to perform repetitive microdissection of the lesion 402, creating a clear path.

[00193] Figures 5A-5D show a crossing wire in various configurations. Each of the configurations shown in Figures 5A-5D may be used to interrogate and/or cross a lesion. A particular configuration may be chosen based on a variety of considerations, including the size, shape, and hardness of the lesion, for example. The wire may be preformed to have a loop, as in Figure 5A, that can be twisted to obtain the configurations in Figures 5B-5D. Alternatively, the wire may be preformed to have a twisted configuration, such as the configurations shown in Figures 5B-5D.

[00194] In Figure 5A, the crossing wire 500 has two ends that are side-by-side. This can be the state of the crossing wire before the physician begins to apply a torque, or twisting motion, to the wire. The crossing wire 500 can be used to advance the wire through a vessel or for pedal loop crossing. In Figure 5B, the crossing wire 502 has been twisted slightly such that the two sides of the wire have become intertwined. In Figure 5C, the crossing wire 504 has undergone additional twisting, causing the two sides of the crossing wire to become more tightly intertwined, and causing the loop to become narrower. Intertwining the two sides of the wire increases the stiffness of the wire, providing additional column strength for applying a force on the lesion. The crossing wire 506 in Figure 5D has undergone even more twisting, causing the two sides of the wire to become even more tightly intertwined, and the loop at the end of the wire to become even narrower. Of the wires 500-506 shown in Figures 5A-5D, the tightly intertwined wire 506 will be most resistant to bending, and therefor can be used to apply a strong force to the lesion. Softer lesions may not require such a strong force, and one of the other three wires 500-504 may be sufficient to cross the lesion. The number of rotations and amount of turns or twists in the loop is variable and can be dependent upon the

lesion type/hardness. The operator can control the number of twists. The device can be configured to enable the quantity of twists that the crossing wire is capable of forming.

[00195] Figures 6A-6D show a device in one aspect of the invention positioned in the vasculature with a CTO. The physician begins by obtaining arterial or venous access, and then placing a sheath in the artery or vein. The physician may image the region of interest, for example, using an angiogram, to determine the position of the CTO. As shown in Figure 6A, the physician may then guide the catheter 600 into close proximity of the lesion 602. The physician then extends the crossing wire 604 beyond the distal end of the catheter 600 until a leading portion 606 of the loop 608 at the distal end of the crossing wire 604 engages the lesion 602.

[00196] According to one aspect of the invention, the crossing wire 604 has main shaft 610 on one side of the loop 608 and a secondary shaft 612 on the other side of the loop 608. One or both of the main shaft 610 and the secondary shaft 612 extend back into the catheter 600. At least one of the shafts extends the length of the catheter so that it can be manipulated by the physician. Herein, the shaft that is manipulated is referred to as the "main shaft," though in some configurations of the device the physician may manipulate both shafts. In Figures 6A-6D, the main shaft 610 extends through the catheter 600, while the secondary shaft 612, is shorter, and may not be disposed within the catheter 600 while the physician performs the procedure.

[00197] Once the leading portion 606 of the crossing wire 604 contacts the lesion 602, the physician begins twisting the main shaft 610 of the crossing wire 604, as shown in Figure 6B. The secondary shaft 612 becomes intertwined with the main shaft 610, providing column strength to the crossing wire 604, and causing the loop 608 to become narrower. The physician continues twisting the main shaft 610 and applying pressure until the loop 608 crosses the lesion 602, as shown in Figures 6C and 6D.

[00198] While the physician is applying pressure to main shaft 610, the lesion 602 may resist the force of the distal portion 606 of the loop 608. The axial forces applied by the physician may then be redirected laterally, causing the loop 608 to flex. However, because the loop 608 is formed to have a predetermined width in its relaxed configuration, the loop 608 will resist axial forces that would cause it to become wider than the width of the vessel. Further, by twisting the main shaft 610 and thereby intertwining the main shaft 610 with the

secondary shaft 612, the physician maintains the width of the loop to be narrower than the width of the vessel.

[00199] The physician may twist the main shaft 610 in a single direction, or may rotate the wire back and forth to erode the lesion 602. According to one aspect of the invention, the physician twists the main shaft 610 until the crossing wire 604 has about three or four nodes, or crossing points, in the loop 608. Additional nodes may decrease the resistance of the wire to lateral forces. If the nodes do not remain in a straight line when lateral forces are applied, the loop 608 may collapse, and the wall of the vessel could rupture.

[00200] Figures 20A-20C show wires in three twisted configurations. In Figure 20A, the secondary shaft 2000 is loosely twisted around the primary shaft 2002. The primary shaft 2000 can be alternately twisted clockwise and counter-clockwise to maintain the loosely twisted configuration as the distal tip 2004 contacts and crosses the CTO. The left and right rotations can be a point of variation between 0° and 360°. If the primary shaft 2002 is initially twisted in a clockwise direction to obtain the loosely twisted configuration, additional clockwise rotation will tighten the wire and increase the crossing force applied by the distal tip 2004 of the CTO crossing wire on a lesion.

[00201] The 0°-360° rotation can be used as a back and forth motion or a continuous clockwise (or counter-clockwise) rotation. The rotation of the wire is at the discretion of the user and may depend on the force required to cross the CTO. If a greater force is required, the user may twist the primary shaft in one direction more than in the other direction to increase the stiffness of the wire, thereby increasing the force that can be applied to the CTO by the distal tip.

[00202] In Figure 20B, the secondary shaft 2006 is moderately twisted around the primary shaft 2008 to form a configuration with moderate stiffness. The CTO wire is kept in moderate configuration by rotating the primary shaft 2008 more in one direction than the other direction. The user can rotate clockwise and counter-clockwise as many times as desired as long as there is a surplus of rotations in one of the directions to maintain a moderate or higher stiffness. The user can continuously rotate the primary shaft 2008 until the desired target goal of the wire tip crossing force is achieved.

[00203] In Figure 20C, the secondary shaft 2010 is tightly twisted around the primary shaft 2012 to form a configuration with high stiffness. The CTO crossing wire configuration is kept stiff by increasing the rotations in favor of one direction over the other. If the primary shaft 2012 is initially twisted in the clockwise direction, additional clockwise rotations will increase the stiffness, while counter-clockwise rotations will decrease the stiffness. Additional clockwise rotation of the primary shaft 2012 leads to an incremental increase in the amount of force that the distal tip 2014 of the wire is able to exert on a lesion. Continuous clockwise rotation leads to a tight bond between the primary shaft 2012 and the secondary shaft 2010, providing additional support for the distal tip 2014. Once the primary shaft 2012 is sufficiently twisted such that the wire has the stiff configuration, the user may rotate the primary shaft 2012 clockwise and counter-clockwise. The user may maintain the stiff configuration during these rotations as long as the counter-clockwise rotations do not exceed the clockwise rotations. The increased stiffness is not permanent. It can be reversed, or the force applied by the distil tip 2014 on the lesion can be changed, by rotating the primary shaft 2012 counter-clockwise.

[00204] The distal tip 2014 can have a shape that is influenced by the twisting of the primary shaft 2012 and secondary shaft 2010. Rotating the primary shaft 2012 to obtain a stiff configuration may also narrow the loop and reduce the angle formed by the two sides of the loop. Rotating the primary shaft 2012 in the opposite direction will cause the loop to become broader, increasing the angle between the two sides of the loop. The loop can thus have any configuration desired by the user.

[00205] The secondary shaft 2010 may have different configurations, such as a free tip, or a welded or connected tip. Figure 21A shows a wire having a primary shaft 2100 and a secondary shaft 2102, where the proximal tip 2104 of the secondary shaft 2012 is free, i.e., not welded to the primary shaft 2100. Figure 21B shows a wire having a primary shaft 2106 and a secondary shaft 2108, where the proximal tip 2110 of the secondary shaft 2008 is welded or connected to the primary shaft 2106. The secondary shaft 2108 in the welded configuration may be twisted around the primary shaft 2106 prior to welding, or may be substantially parallel to the primary shaft 2106 when the proximal tip 2110 is welded to the primary shaft 2106. Both free and welded tips can have a similar secondary shaft configuration.

[00206] The configuration is not affected by the length of the secondary shaft, which can have a variety of lengths. The length 2112 of the secondary shaft 2108 is indicated in Figure 21B. The length of the secondary shaft 2108 can be configured based on the required stiffness of the wire. The length of the secondary shaft 2108 can therefore vary from just a looped tip to extending the entire length of the primary shaft 2106. The wire can have a pre-formed loop at the distal tip, and the secondary shaft 2108 may or may not be twisted around the primary shaft 2110 while the CTO crossing wire is in a relaxed state, i.e., before the user has begun to rotate the primary shaft 2106. The variations in the wire provide the variations in the force and support needed to cross a lesion in the coronaries or peripheral arteries and veins.

[00207] Figures 7A-7D show various configurations of a crossing wire. Figures 7A-7D demonstrate how the characteristics of the crossing wire can be varied, depending on the desired application. For example, crossing wire 700 in Figure 7A has a narrower loop 702 than the loop 706 of the crossing wire 704 in Figure 7B. The secondary shaft 708 of wire 700 is shorter than the secondary shaft 710 of the crossing wire 704. A longer secondary shaft can provide more support to the main shaft, enabling a higher force to be applied on a lesion by the loop without the wire bending or buckling. The crossing wire can be configured to bend at a particular point, which can influence the width of the loop. For example, crossing wire 712 in Figure 7C can be configured to bend at one of a variety of points 714-722. Positioning the bending point farther from the leading portion 724 of the loop can result in a wider, longer loop, while positioning the bending point closer to the leading portion of the loop can result in a narrower, shorter loop. The position of the bending point can be determined by the structure of the wire, for example, by having different thicknesses along the length of the wire or by having parts of the wire made from different materials to make some portions of the wire more flexible than others. In one aspect of the invention, the distance from the leading portion 724 of the loop to the first node 734 is between about 1 mm and about 40 mm. In one aspect of the invention, the distance from the leading portion 738 of the loop to the distal end of the catheter is between about 3 mm and about 40 mm.

[00208] As shown in Figure 7A, the wire in some configurations can have a first loop portion 736 that increases in width from the leading distal end 738 to a maximum width 740. The wire includes a second loop portion 742 the decreases in width from the maximum width

740 to a first node 744. The wire includes a tail portion 746 distal to the first node 744. The primary shaft 700 and secondary shaft 708 may form additional nodes in the tail portion 746.

[00209] The crossing wire can have varying stiffness along its length. A particular stiffness is chosen based on the application. The crossing wire can include markers that indicate the proper position of the wire for a particular stiffness. Occlusions providing mild resistance can be crossed with a less stiff portion of the wire, while severe occlusions can be crossed with the stiffest portion of the wire. According to one configuration, the crossing wire has three different stiffness values along its length.

[00210] The crossing wire 726 in Figure 7D has a wider loop 728 with a more blunt leading portion 730 than the crossing wires illustrated in Figures 7A-7C. The crossing wires illustrated in Figures 7A-7D are provided to highlight various characteristics of the crossing wire that can be altered or manipulated to create different configurations of the crossing wire. Some characteristics of the crossing wires shown in Figures 7A-7D may be interchanged and/or combined, and the aspects of the invention are in no way limited to the configurations shown in Figures 7A-7D.

[00211] Figure 18 shows a crossing wire in a twisted configuration. The crossing wire has a shape similar to that of a sperm, with a head 1800 and a tail 1802. The primary shaft 1804 is bent at the base 1806 of the head 1800, and the first head portion 1808 forms an angle α with respect to the axis 1810 of the primary shaft 1804. The first head portion 1808 may be substantially straight until the first transition point 1812. The wire then bends back toward the axis 1810, forming second head portion 1814. Second head portion 1814 may be substantially straight, or may gradually bend. The second head portion 1814 transitions to a third head portion 1816 at a leading distal end 1818 of the wire. The second head portion 1814 and third head portion 1816 may form a rounded leading distal end, a pointed leading distal end, or any other leading distal end configuration. The third head portion 1816 extends from the leading distal end 1818 back toward the proximal end of the wire. The third head portion extends to the second transition point 1820. The first transition point 1812 and the second transition point 1820 may be the locations where the wire forming the head 1800 is farthest from the axis 1810 of the primary shaft 1804. After the second transition point 1820, the wire has a fourth head portion 1822 that extends back toward the base 1806 of the head 1800. The fourth head portion 1822 may form an angle β with respect to the axis 1810 of the primary shaft 1804. The wire then has a secondary shaft 1824 that wraps around the primary shaft

1804. The secondary shaft 1824 wrapped around the primary shaft 1804 forms the tail portion 1802. According to one configuration, the first head portion 1808 and fourth head portion 1822 are substantially symmetrical. According to one configuration, α and β are substantially equal. In one aspect of the invention, the first head portion 1808 and fourth head portion 1822 form a V-shape (sideways in Figure 18).

[00212] Figure 19A shows a crossing wire before it has been bent and cured or preformed into a looped configuration. In one embodiment, the wire has two portions, a first portion 1900 and a second portion 1902, and the two portions do not have the same stiffness. In one configuration, the first portion 1900 is less stiff and more flexible than the second portion 1902. The first portion 1900 can be bent and cured to form the leading distal end of the wire. The first portion 1900 may form a flexible portion of the wire, and can be radiopaque for better visualization under fluoroscopy. The length of first portion 1900 may be between 1 mm and 100 mm. The stiffness of the first portion 1900 may be constant throughout the first portion 1900, or may gradually increase from the tip 1904 of the first portion 1900 to the junction 1906 with the second portion 1902.

[00213] The second portion 1902 forms the primary shaft of the crossing wire. The second portion 1902 may also form a portion of the loop when the crossing wire is bent into a looped configuration. The second portion 1902 of the CTO wire may not be radiopaque, and may be stiffer than the first portion 1900. The second portion 1902 can allow the first portion 1900 to loop around the second portion 1902 with added stability and push ability due to the double wire support.

[00214] Figure 19B shows a crossing wire in a twisted configuration. The primary shaft 1908 and first head portion 1910 are formed from the second portion 1902 in Figure 19A, while the remaining head portions 1912-1916 and the secondary shaft 1918 are formed from the first portion 1900 in Figure 19A. The wire may transition from the stiffer second portion 1902 to the more flexible first portion 1900 at the transition point 1918. Alternatively, the wire may transition from the stiffer second portion 1902 to the more flexible first portion 1900 at other positions in the loop 1920.

[00215] The second head portion 1912 and third head portion 1914 form the leading distal end 1922 of the crossing wire, and can form a variety of angles and have a variety of configurations. The leading distal end 1922 can have the flexibility to conform to a CTO cap.

The wire forming the leading distal end 1922 can also have micro-skives in it to help weaken the CTO cap without impacting the vessel wall.

[00216] The secondary shaft 1918 can wrap around the primary shaft 1908, forming a tail that adds propulsion value and stiffness to the leading distal end 1922 of the crossing wire. As the tail becomes more tightly wrapped around the primary shaft 1908, for example, by twisting the primary shaft 1908, the gram weight on the CTO wire and/or crossing device increases along with its ability to penetrate resistant material such as a CTO cap. The primary shaft 1908 can have any diameter deemed fit for a particular CTO crossing. In one aspect, the diameter of the primary shaft 1908 is between 0.09" and 0.40". In one aspect, the diameter of the primary shaft 1908 is one or more of 0.09", 0.14", 0.18", 0.21", 0.24", 0.27", 0.28", 0.30", 0.33", 0.35", and 0.40". The loop may have the same diameter as the primary shaft, or a greater or lesser diameter.

[00217] The primary shaft and secondary shaft may have the same diameter along their entire length. Alternatively, the primary shaft may have a first diameter along a proximal portion of the shaft, and a second diameter at the distal portion of the shaft. Figure 22 shows an example configuration in which the primary shaft 2200 has proximal portion 2202 having a first diameter, for example, 0.35". The primary shaft 2200 has a distal portion 2204 having a second diameter, for example, 0.175". The secondary shaft 2206 may also have the second diameter, for example, 0.175". The combined width 2208 of the loop formed by the distal portion 2204 of the primary shaft 2200 and the secondary shaft 2206 may equal the diameter of the proximal portion 2202 of the primary shaft 2200, for example, 0.35". The diameter values provided herein are solely examples, and the embodiments of the invention are not limited to these values.

[00218] The secondary shaft 2206 may be bonded to the distal portion 2204 of the primary shaft 2200. For example, the secondary shaft may be bonded to the primary shaft at the proximal end 2210 of the secondary shaft 2206. The secondary shaft 2206 may be bonded to the distal portion 2204 of the primary shaft 2200 at a plurality of other locations. Alternatively, the secondary shaft 2206 may not be bonded to the distal portion 2204 of the primary shaft 2200. The examples below may also have one or more points at which the secondary shaft is bonded to the primary shaft, or the secondary shaft and primary shaft may not be bonded.

[00219] Figure 23 shows a configuration in which the diameter of the primary shaft 2300 is constant along the length of the primary shaft 2300, and is equal to the diameter of the secondary shaft 2302. For example, the primary shaft and the secondary shaft may each have a diameter of 0.35", while the width 2304 of the loop formed by the primary shaft 2300 and secondary shaft 2302 is twice the diameter of each shaft, for example, 0.70".

[00220] Figure 24 shows an example configuration in which the primary shaft 2400 has a proximal portion 2402 having a first diameter, for example, 0.18". The primary shaft 2400 has a distal portion 2404 having a second diameter, for example, 0.09". The secondary shaft 2406 may also have the second diameter, for example, 0.09". The combined width 2408 of the loop formed by the distal portion 2404 of the primary shaft 2400 and the secondary shaft 2406 may equal the diameter of the proximal portion 2402 of the primary shaft 2400, for example, 0.18".

[00221] Figure 25 shows a configuration in which the primary shaft 2500 and the secondary shaft 2502 each have the same diameter, for example, 0.18", while the width 2504 of the loop formed by the primary shaft 2500 and secondary shaft 2502 is twice the diameter of each shaft, for example, 0.36". A user may stiffen the wire by rotating the primary shaft 2500 clockwise, for example, and loosen the wire by performing a counter-clockwise rotation, for example, of the primary shaft 2500.

[00222] Figure 26 shows an example configuration in which the primary shaft 2600 has proximal portion 2602 having a moderately stiff body and a first diameter, for example, 0.14". The primary shaft 2600 has a distal portion 2604 having a second diameter, for example, 0.07". The secondary shaft 2606 may also have the second diameter, for example, 0.07". The combined width 2608 of the loop formed by the distal portion 2604 of the primary shaft 2600 and the secondary shaft 2606 may equal the diameter of the proximal portion 2602 of the primary shaft 2600, for example, 0.14".

[00223] Figure 27 shows a configuration in which the primary shaft 2700 and the secondary shaft 2702 may each have a diameter of 0.14", while the width 2704 of the loop formed by the primary shaft 2700 and secondary shaft 2702 is twice the diameter of each shaft, for example, 0.28". The 0.28" loop may be stiffened by tightening the helical distal portion of the primary shaft 2700 and/or the helical secondary shaft 2702 by rotating the primary shaft 2700 clockwise, for example. The stiffness of the 0.28" loop may be reduced

by rotating the primary shaft 2700 in the opposite direction, for example, counter-clockwise. The loop in the configuration of Figure 27 may be stiffer than the loop in the configuration of Figure 24, because the primary and secondary helical wires forming the loop are thicker relative to the diameter of the proximal portion of the primary shaft than in Figure 24.

[00224] As described above, the primary shaft and the secondary shaft of the wire may or may not be bonded to one another. Figure 28A shows a configuration in which the primary shaft 2800 is a straight shaft, and the secondary shaft 2802 is a helical shaft that winds around the straight shaft 2800. The proximal end 2804 of the helical secondary shaft 2802 may be independent of, i.e. not bonded to, the primary shaft 2800. Figure 28B shows a configuration in which the primary shaft 2806 is straight shaft, and the secondary shaft 2808 is a helical shaft. The proximal end 2810 of the helical secondary shaft 2808 is bonded to the primary shaft 2806. The secondary shaft 2808 may be additionally or alternatively bonded to the primary shaft at other points, for example, on or more of the crossing points 2812, 2814, 2816 shown in Figure 28B. Bonding the primary shaft 2806 to the secondary shaft 2808 increases the stiffness of the wire and the loop 2818 at the distal end of the wire. The helical secondary shaft 2808 may be integrally formed with the primary shaft 2806, or may be separately formed and then bonded to the primary shaft to form a continuous wire, for example, at or near the loop 2818. The helical secondary shaft 2808 may have the same diameter as the primary shaft 2806, or a different diameter. The primary shaft 2806 may also have varying diameters along its length.

[00225] Figure 29 shows a configuration in which both the distal portion 2902 of the primary shaft 2900 and the secondary shaft 2904 have a helical configuration. The secondary shaft 2904 can be bonded to the primary shaft 2900 at the proximal end 2906 of the secondary shaft 2904, and at other points, for example, points 2908, 2910 along the length of the secondary shaft. The distal tip 2912 may have a shape that can be adjusted by the user, for example by twisting the primary shaft 2900 clockwise or counter-clockwise. The proximal portion of the primary shaft 2900 may be integrally formed with the distal portion 2902 of the primary shaft 2900 and the secondary shaft 2904. Alternatively, the distal portion 2902 of the primary shaft 2900 and the secondary shaft 2904 may be integrally formed, and may be bonded to the proximal portion of the primary shaft 2900 to form a continuous wire. This configuration may be useful when the proximal portion of the primary shaft 2900 has a different diameter than the distal portion 2902 of the primary shaft 2900 and the secondary

shaft 2904. The wire may be preformed to have the twisted shape shown in Figures 22-29, or the twisted shape may be obtained in situ, for example, by rotating the primary shaft.

[00226] According to some aspects of the invention, the wire can be adapted for use in all arteries and veins. The gram tip stiffness of the wire can start at 1-3 grams. The wire can be made from a hydrophilic or non-hydrophilic material, and the choice of the material may be based on the lesion. The crossing wire can be encased in an outer shell. The outer shell can prevent the proximal end of the secondary shaft from inadvertently catching on tissue. The outer shell may be useful when navigating the crossing wire through particular veins and arteries, for example, the aortic junction.

[00227] Figure 30A shows a crossing wire 3000 encased in an outer shell 3002. The outer shell may be designed to have 1:1 torque and 1:1 pushability and tracability. The proximal two-thirds of the crossing wire 3000 can be stiff. The distal third of the wire 3000 has a pre-shaped loop. The stiffness of the distal third can be increased or decreased by rotating the primary shaft. For example, if the primary shaft is initially rotated clockwise, additional clockwise rotations will increase the stiffness of the distal end, while counter-clockwise rotations will decrease the stiffness of the distal end. The stiffness and force by gram is transmitted to the outer shell 3002, making the combination of the crossing wire 3000 and outer shell 3002 equally stiff. The stiffness can be reduced by counter-clockwise rotation, for example, reducing the force and inner gram weight therefore the entire device including the crossing wire 3000 and outer shell 3002 can become soft or floppy based on the number of counter-clockwise rotations. Figure 30B shows another example of a wire 3004 encased in an outer shell 3006. Figure 30C shows a crossing wire 3008 that is not encased in an outer shell.

[00228] There is a direct force communication between the crossing wire and the outer shell. The wire, either encase in an outer shell or not encased, can have a configuration that is pre-set before the wire is introduced into the body. The wire can have an angled or straight configuration. Each configuration can have a similar force transmission without losing the pre-shaped configuration.

[00229] The crossing wire encased in the outer shell can have different sizes, for example, the combined device may have a cross-section between 0.09” – 0.35”. For example,

the cross-section may be 0.09", 0.14", 0.21", 0.28", or 0.35". The variety in sizes allows for the wires to accommodate a wide range of veinal size spectrums.

[00230] Figures 31A-31C show crossing wires according to some aspects of the invention. Figure 31A shows the length "L" of the secondary shaft 3101. The length L of the secondary shaft 3101 can vary depending on the size and type of the crossing wire. Further, as the distal tip of the wire is used to interrogate a lesion, the primary shaft 3100 may be pushed toward the lesion, causing the length L of the secondary shaft 3101 to become longer. The primary shaft 3100 may have varying stiffness along its length. For example, the portion of the wire that initially forms the loop may have a first stiffness. As the primary shaft 3100 is pushed toward the lesion, the secondary shaft 3101 may become longer, and the loop may be formed from a portion of the primary shaft 3100 having a greater stiffness than the original stiffness of the loop.

[00231] Figure 31B shows a crossing wire wherein the secondary shaft 3102 is not bonded to the primary shaft 3104. Figure 31C shows a crossing wire wherein the proximal end 3106 of the secondary shaft 3108 is bonded to the primary shaft 3110.

[00232] Figures 32A-32C show some aspects of the outer shell. As shown in Figures 32A and 32B, the distal end of the outer shell may be open (Figure 32A) or closed (Figure 32B). In the configuration of Figure 32A, the outer shell keeps the loop at the distal end of the crossing wire narrow and provides support. The outer shell functions as the primary leading wire despite the amount of force generated from the loop. The crossing wire can be modulated to have variable degrees of stiffness, and can be used from within the outer shell. Alternatively, as shown in Figure 32C, the distal end of the crossing wire 3200 can exit distal end of the outer shell 3202, and can work independently of the outer shell 3202. The distal end of the crossing wire 3200 can advance past the distal end of the outer shell 3202, and can become the leading wire, as shown in Figure 32C.

[00233] Figure 32B shows the outer shell having a closed distal end. The action of the crossing wire is translated and transmitted by the outer shell to the obstruction or lesion in the patient's body. The stiffness of the crossing wire inside the outer shell can be varied from floppy to very stiff by rotating the primary shaft of the crossing wire.

[00234] The force generation and stiffness of the crossing wire can be based on a mechanical configuration change, and hence the stiffness can be variable. However, the wire can also have a configuration in which the distal end of the wire applies a specific force that is constant. For example, the crossing wire can be formed to have a closed loop, meaning that the primary and secondary shafts are bonded or welded such that the loop has a predetermined stiffness.

[00235] For example, Figures 33A-33D demonstrate how the stiffness of the loops may be varied by varying the configuration of the crossing wire. In Figure 33A, the secondary shaft 3300 is loosely wrapped around or entwined with the primary shaft 3302, resulting in a relatively floppy wire. The secondary shaft 3300 and primary shaft 3302 may be disposed in an outer shell 3304. In Figure 33B, the secondary shaft 3306 is more tightly wrapped around or entwined with the primary shaft 3308, resulting in a wire with mild stiffness. The secondary shaft 3306 and primary shaft 3308 may be disposed in an outer shell 3310. In Figure 33C, the secondary shaft 3312 is even more tightly wrapped around or entwined with the primary shaft 3314, resulting in a wire with moderate stiffness. The secondary shaft 3312 and primary shaft 3314 may be disposed in an outer shell 3316. In Figure 33D, the secondary shaft 3318 is very tightly wrapped around or entwined with the primary shaft 3320, resulting in a wire with maximum stiffness. The secondary shaft 3318 and primary shaft 3320 may be disposed in an outer shell 3322.

[00236] In some aspects, the crossing wire has a spring-like configuration. Figure 34A shows a wire 3400 having a spring-like configuration. The secondary shaft may circumscribe the primary shaft such that there is space between the primary shaft and the secondary shaft. The length "L_1" of the helical portion in Figure 34A may be about 60 mm, for example. Figure 34B shows another crossing wire 3402 having a spring-like configuration. The length "L_1" of the helical portion in Figure 34B may be about 60 mm - 80 mm, for example. The width "W" of the crossing wire proximal to the loop 3404 is wider for the crossing wire 3402 than for a wire having the secondary shaft wound tightly around the primary shaft, such as the crossing wire shown in Figure 33D, for example. Another crossing wire having a spring-like configuration is shown in Figure 34C. The secondary shaft 3406 can be helically wrapped around the primary shaft 3408 without contacting the primary shaft 3408, except at the distal end 3410 of the secondary shaft 3406. The secondary shaft 3406 in this configuration can prevent buckling of the crossing wire, and can act as a support system that

transmits energy from the distal tip of the crossing wire to the lesion to be crossed. In one aspect, the secondary shaft 3406 can be circumferentially wound around the primary shaft 3408 to create the spring-like support feature.

[00237] The helical portion of the wire can be formed from a single wire or multiple wires. For example, Figure 35A shows a side view of a crossing wire having a helical portion formed from two wires 3500, 3502. Figure 35B shows a top-down view of the wire of Figure 35A. The crossing wires in Figures 34A-C, 35A, and 35B may be considered to have a "circumferential" configuration.

[00238] Figure 36 shows a crossing wire having a primary shaft 3600 and two secondary shafts 3602, 3604. The two secondary shafts 3602, 3604 are connected to the distal tip 3606 of the primary shaft 3600. The primary shaft 3600 and two secondary shafts 3602, 3604 form a loop at the distal end of the crossing wire. The two secondary shafts 3602, 3604 can be wound around the primary shaft 3600. The crossing wire in Figure 36 may be considered to have a "longitudinal" configuration. In this configuration, the secondary wire spans a greater longitudinal distance, i.e., distance along the length of the primary shaft, per revolution around the primary shaft than in the circumferential configuration. The secondary shaft in the longitudinal configuration may also be closer to the primary shaft in the longitudinal configuration. The distance between the primary shaft and the secondary shaft is discuss in more detail with respect to Figure 37. The crossing wire can include additional wires, for example, more than two primary or secondary shafts. The number of wires will determine the stiffness of the distal end of the crossing wire, with more wire resulting in increased stiffness.

[00239] In one aspect of the invention, varying the distance between the primary shaft and the secondary shaft can result in a variation in the stiffness of the distal end of the shaft. Figure 37A shows a crossing wire having a primary shaft 3700 and a secondary shaft 3702. Figure 37B shows an enlarged view of the region enclosed by the dashed circle in Figure 37A. The distance "D" between the primary shaft 3700 and the secondary shaft 3702 can be increased or decreased to decrease or increase the stiffness of the crossing wire. Figure 37C shows another configuration of a crossing wire having a gap 3704 between the primary shaft 3706 and the secondary shaft 3708.

[00240] Figures 38A and 38B show crossing wires having a dual longitudinal helical wire configuration. In one aspect, the primary and secondary shafts both have a helical shape.

[00241] Figures 39A-39D show a crossing wire according to one aspect of the invention. Figure 39A shows a crossing wire configured to pass through a lumen of a catheter. The crossing wire includes a loop 3900 at a distal end of the crossing wire. The loop 3900 has a configuration that prevents a width LW of the loop 3900 from exceeding a width of a tissue lumen in which the crossing wire is disposed. The loop 3900 has a pair of lateral opposing portions 3904, 3906 configured for alignment with a wall of the tissue lumen and a leading portion 3908 interconnecting the pair of lateral opposing portions 3904, 3906. The leading portion 3908 is configured to interrogate a lesion in the tissue lumen. The loop 3900 has a length LL in an axial direction of the crossing wire extending from the leading portion 3908 to proximal ends of the pair of lateral opposing portions 3904, 3906, and the length LL is perpendicular to the width LW. The length LL of the loop 3900 is at least twice the width LW of the loop 3900.

[00242] In one aspect, the length LL of the loop 3900 is three, four, or five times the width LW of the loop 3900. In one aspect, the length LL of the loop 3900 is more than five times the width LW of the loop 3900.

[00243] As shown in Figure 39A, the crossing wire may also have a shaft 3902 that is formed from the primary shaft 3904 and secondary shaft 3906, which are intertwined. The pair of lateral opposing portions 3904, 3906 and the leading portion 3908 can have a circular cross section at the loop 3900. Alternatively, as shown in Figure 39D, the pair of lateral opposing portions 3904, 3906 and the leading portion 3908 can have a rectangular cross section at the loop 3900. For example, a wire having a circular cross-section can be ground or shaved to have a rectangular cross-section, or the crossing wire can be formed from a wire that is manufactured to have a non-circular cross-section. Figure 39B shows an enlarged image of the shaft 3902. It is evident from Figure 39B that the shaft is formed from two wires, the primary shaft and the secondary shaft. The primary shaft and the secondary shaft are precisely intertwined along the length of the shaft 3902. Figure 39C shows an enlarged image of the loop 3900.

[00244] Figure 39D shows a crossing wire with a rectangular cross-section. The crossing wire in the loop 3900 is not twisted, while the crossing wire in the shaft 3902 is

twisted. One of the pair of lateral opposing portions 3904, 3906 of the loop 3900 is directly connected to the primary shaft, and the other of the pair of lateral opposing portions 3904, 3906 is directly connected to a secondary shaft of the crossing wire. The secondary shaft is configured to wrap around the primary shaft. The leading portion 3908 of the loop 3900 can be flat, due to the rectangular cross-section of the wire. The flat, wide surface of the wire is perpendicular to the plane of the loop, and faces outward from the center of the loop. Thus, the flat, wide surface of the pair of lateral opposing portions 3904, 3906 contacts the tissue over a larger surface area than if the crossing wire in the loop 3900 were twisted. The large surface area can distribute forces so that the crossing wire is less likely to slice or puncture the wall of the tissue. The flat, wide surface of the pair of lateral opposing portions 3904, 3906 aligns with the wall of the tissue lumen, and can be flush against the wall of the tissue lumen.

[00245] Figure 39E shows a cross-section of the crossing wire in the loop 3900. The cross-section is rectangular, with two short edges 3910, 3912, and two long edges 3914, 3916. The outer-facing side of the crossing wire, which corresponds to the long edge 3914 in Figure 39E, contacts the wall of the tissue, spreading the forces applied to the wall of the tissue over the wide surface of the crossing wire. In one aspect, the pair of lateral opposing portions 3904, 3906 and the leading portion 3908 of the loop 3900 form a plane, and the two long edges 3914, 3916 are perpendicular to the plane of the loop.

[00246] Figures 40-42 show crossing wires according to some additional aspects of the invention. Each of the crossing wires in Figures 40-42 has a primary shaft and a secondary shaft that are flat, i.e., have a rectangular cross-section, at the loop and along the shaft of the crossing wire. In Figures 40-42, the crossing wire is twisted two or more times in the loop portion. However, the twists are located proximal to the widest section of the loop. The wide, flat side of the crossing wire in each of the loops is perpendicular to the plane of the loop at the widest section of the loop. The wide, flat side of the crossing wire provides a stable surface that can be aligned with the wall of the tissue. The wire in the shaft is twisted more tightly than the wire in the loop. While the wire in the loop may be twisted one, two, or three times in each of the pair of lateral opposing portions of the loop, the primary and secondary shafts are much more tightly twisted in the shaft, for example, five, ten, or twenty times in the equivalent distance. The length LL of the loop with respect to the width LW may be shorter, as in Figure 40, or longer as in Figure 42.

[00247] Figures 43A-43D shows crossing wire shafts according to some additional aspects of the invention. The shaft can have a variety of width. The term "width" can refer here to the longest dimension of the cross-section of the shaft. Figures 44A, 44B, 45A, and 45B show crossing wire loops according to some additional aspect of the invention. The looped portion of the crossing wire can have a rectangular cross-section. As shown in Figure 45A, the secondary shaft 4500 may be welded to the primary shaft 4502 without being twisted around the primary shaft 4502. The crossing wires can have variable weights, widths, and stiffnesses of the looped portion and shaft. The length of the loop from the distal tip to the point where the primary shaft meets the secondary shaft may be varied. For example, the crossing wires in Figures 44A and 44B have longer loops than the crossing wires in Figures 45A and 45B. In some embodiments, the loop has a weight between 3 grams and 30 grams.

[00248] Figure 46 demonstrates a process for creating a wire having a non-circular cross-section in the loop portion from a wire having a circular cross-section. In Figure 46, the hashed portion 4600 of the crossing wire 4602 can be shaved off, resulting in the crossing wire 4604. The narrowed portion 4606 of the crossing wire 4604 can be used to form the loop of the crossing wire, by connecting the opposite ends 4608, 4610.

[00249] Figures 47A-47D show additional aspects of formation of a crossing wire having a non-circular cross-section. Figure 47A shows how the crossing wire can be shaved along a first side 4700 and a second side 4702 to create first and second flat edges and first and second round edge. The wire can be used in this formation to cross occlusions. Alternatively, the round portions 4704, 4706 can be shaved, resulting in a wire having a square or rectangular cross-section, as shown in Figure 47B. In one aspect, the shaving is performed on the portion of the wire that is used to create the loop. Figures 47C and 47D further demonstrate how the crossing wire can be shaved to reduce its diameter or cross-section.

[00250] Figures 48A-48C show crossing wires according to some aspects. As shown in Figure 48A, the crossing wire may have a shaved cross-section at the distal portion 4800 of the loop 4802. As shown in Figure 48B, the crossing wire may have a shaved cross-section throughout the loop 4804. As shown in Figure 48C, the crossing wire may have a loop 4806 that is not shaved. The primary shaft and secondary shaft of the crossing wires may be welded or may not be welded to each other.

[00251] As an alternative to shaving, a non-circular cross-section of the wire may be achieved by combining multiple wires together. For example, Figure 48D shows a distal end of a crossing wire that is formed from four sub-wires 4808-4814. The four sub-wires 4808-4814 can be aligned to form a flat surface. The sub-wires can be welded or adhered together to form the crossing wire, and more or fewer than four sub-wires can be used. The individual sub-wires may have circular or non-circular cross-sections.

[00252] In one aspect of the invention, the wire may have abrasive elements at the distal tip of the wire. For example, Figure 49A shows a crossing wire in a loosely wound formation with abrasive elements 4900 on the loop 4902. Figure 49B shows a crossing wire in a more tightly wound formation with abrasive elements 4904 on the loop 4906. The abrasive elements may be adhered to the wire, or the wire may be roughened to create the abrasive elements. The abrasive elements can interrogate a lesion, and can aid a physician in eroding away at and crossing a lesion.

[00253] Figures 50A and 50B show crossing wires having a welded loop according to some aspects. In Figure 50, the loop 5000 can be welded to the shaft 5002. Alternatively, one side of the loop may be formed by the primary shaft, while the other side is formed by the secondary shaft. The proximal end of the secondary shaft may be welded to the primary shaft, for example, at the point 5004 on Figure 50B.

[00254] Figure 51 shows a crossing wire according to one aspect. The width 5100 of the loop 5102 can be between 1 mm – 14 mm. The primary shaft 5104 and secondary shaft 5106 may individually or in combination have a diameter of 0.09" to 0.35", for example.

[00255] In some aspects, the crossing wire is used in conjunction with a catheter. Figure 8A shows a catheter with a side opening and a crossing wire configured in one aspect of the invention. The catheter 800 includes a hole 802 in a side surface of the catheter 800. As shown in Figure 8A, the main shaft 804 of the crossing wire is disposed in the lumen of the catheter 800, while the secondary shaft 806 is at least partially disposed outside the lumen. In Figures 8B and 8D, a portion 808 of the secondary shaft 806 enters the lumen through the hole 802. In Figures 8A and 8C, the secondary shaft 806 wraps around the outside of the catheter 804 without entering the hole 802. The catheter according to one aspect can be prepared with secondary shaft 806 the crossing wire at least partially disposed outside the lumen before the catheter is introduced into the vessel or artery. As show in Figures 8A-8D,

the loop can have various configurations. For example, the loop can be pointed, rounded, or peaked, as in the loop 810. As would be understood by one of ordinary skill in the art from the configuration of the catheter 800 and crossing wire 806 in Figures 8B and 8D, the catheter according to some configurations can be formed without a hole 802, and the secondary shaft 806 can remain outside of the catheter along its length.

[00256] Figure 8E shows a catheter and crossing wire having another configuration. The main shaft 814 of the crossing wire is disposed within the lumen of the catheter 812, while the secondary shaft 818 is disposed outside the lumen. The crossing wire includes an inverted loop 816.

[00257] Figures 9A-9C shows additional configurations of looped crossing wires according to some aspects of the invention. As shown in Figures 9A-9C, the intertwined shafts of the wire may have a variety of shapes, as may the loops.

[00258] Figure 10 shows a device 1000 configured in one aspect of the invention, in which two additional inner catheters 1002, 1004 are disposed within the outer catheter 1002. The inner catheters can be stationary, mobile, or a combination of both. The device 1000 in Figure 10 has one inner catheter 1004 that is stationary, and one inner catheter 1006 that is mobile. The mobile inner catheter 1006 can be moved longitudinally along the length of the outer catheter 1002, and can even be pushed to extend beyond the distal end 1008 of the outer catheter 1002, as shown in Figure 10. The mobile inner catheter 1006 can also be manipulated radially around the inside of the outer catheter 1002. As shown in Figure 10, the crossing wire 1010 passes through the stationary inner catheter 1004 and the mobile inner catheter 1006, and forms a loop, or U-turn, at the distal end of the device 1000. The leading portion 1012 of the loop is brought into contact with the lesion. Figure 10 also shows a torque device 1014 that can be used to grasp the two wires to prevent them from moving with respect to one another. A physician can use the torque device 1014 to manipulate the crossing wire and loop. For example, once the outer catheter has neared the lesion, the loop can be extended beyond the distal end of the catheter to contact the lesion, and then the physician can twist the torque device 1014 to create one or more figure eight-like segments in the distal portion of the wire. The physician can also twist one shaft of the crossing wire 1010 to create a twisted loop at the distal end of the crossing wire 1010. For example, the physician may twist, or rotate, the shaft disposed in the mobile inner catheter 1006, creating a twisted loop distal to the distal end of the mobile inner catheter 1006 and the stationary inner catheter

1004. Alternatively, the physician may twist the shaft disposed in the stationary inner catheter 1004 to create the twisted loop.

[00259] According to one aspect, a method for crossing a lesion involves moving the portion of the crossing wire 1010 in the mobile inner catheter 1006 with respect to the portion of the crossing wire 1010 in the stationary inner wire 1004. This causes the leading portion 1012 of the loop to undergo a fan-like motion. One side of the loop portion is stationary, while the other side moves in an arc around it. The leading portion 1012 of the loop acts like a sweeping blade that shaves into the lesion.

[00260] Figure 11A shows another configuration of a device with two inner catheters disposed within the outer catheter. An additional inner catheter can be provided for a conventional and/or additional guidewire. The additional inner catheter 1100 is shown in Figures 11B and 11C. The additional inner catheter may be mobile, or may be fixed to the outer catheter or one or both of the inner catheters. The inner support catheters support the looped CTO wire and help manage the portions of the wire. The inner support catheters also provide column strength to prevent buckling of the wire. The inner support catheters may have a length that is longer than the length of the outer catheter, so that the physician can push the proximal end of one of the inner support catheters, causing the distal end to extend beyond the distal end of the outer catheter.

[00261] Figure 12 shows a configuration of a device wherein at least one inner catheter 1200 is mobile with respect to the outer catheter. The crossing wire 1202 forms a continuous loop at both the distal end 1204 and proximal end 1206 of the device. The crossing wire 1202 may have a variety of stiffnesses along its length, and the physician may position the wire such that the distal end 1204 has a preferred stiffness. For example, the physician may initially interrogate the lesion with a region of the wire having a first stiffness. If the distal end 1204 of the wire does not have a sufficient stiffness to cross the lesion, the physician may pull one side of the crossing wire 1202 such that a different portion of the wire forms the distal tip. The physician may pull one side of the crossing wire 1202 until a portion of the wire having a greater stiffness than the first stiffness is positioned at the distal end 1204. The physician can then use the new, stiffer distal end 1204 to interrogate the legion. In one aspect, the crossing wire has three or more different stiffnesses along its length.

[00262] Figure 13A shows a configuration of a device having a wheel to facilitate twisting of the crossing wire. The wheel 1300 is disposed within the proximal loop 1302 of the crossing wire. The wheel 1300 can facilitate twisting of the crossing wire. Figure 13B shows an enlarged view of the wheel 1300 of Figure 13A. The wheel 1300 includes an outer circle 1304 that represents an outer grabber that helps rotate the wire. The semicircles 1306 represent an inner grabber that helps adjust the position of the leading distal end of the loop. For example, each space between two adjacent semicircles may correspond to a distal end having a particular stiffness. The physician may interrogate the lesion with the crossing wire aligned at a position indicated by a first semicircle such that the distal end has a first stiffness. If the first stiffness is insufficient to cross the lesion, the physician may rotate the wheel 1300 to a second position indicated by a second semicircle that corresponds to a distal end of the wire having a greater stiffness. The wheel 1300 can aid the physician in adjusting the stiffness of the distal end of the wire while the crossing wire is *in situ*.

[00263] Figure 14 shows a configuration of a device in which a plurality of catheters are disposed within the outer catheter 1400, and the outer catheter 1400 includes a hole 1402 in a side surface. The crossing wire 1404 exits the distal end of the catheter 1400, and then reenters the lumen of the catheter through the side hole 1402.

[00264] In some configurations of the device, the crossing wire has a cross-section that is not circular. Figure 15A shows a crossing wire 1500 having a circular cross-section 1502. However, it may be beneficial to have a cross-section that is not circular, to allow for a smaller surface area of the wire to interrogate the lesion. The cross-section may have a variety of shapes. For example, Figure 15B shows a first rectangular cross-section 1504, and Figure 15C shows a second rectangular cross-section 1506. Figure 15D shows an oval cross-section 1508. Figure 15E shows a cross-section 1510 with a serrated edge. The serrated edge may be applied to any cross-section to aid the physician in interrogating the lesion. In one aspect, the longest dimension of the cross-section of the crossing wire is one or more of 0.09", 0.14", 0.18", 0.21", 0.24", 0.27", 0.28", 0.30", 0.33", 0.35", and 0.40".

[00265] Figure 16 shows an example of a loop having a rectangular cross-section. The pre-formed CTO wires can be produced from a single material, and the two sides of the wire and the looped portion can be integrally formed. Alternatively, the sides of the wire may be made from a first material, and the looped portion made be made of a second material, and the two materials may be welded together to form a continuous wire. This enables the side

portions of the wire to be formed from a material that has properties that are different from the material properties of the looped portion. For example, it may be beneficial to have the looped portion formed from a material that is more resistant to bending than the material from which the side portions are formed. As an additional example, the sides and looped portion of the wire may all be formed from the same material, but may have different properties that change the compliance of the wire. For example, the wire at looped portion may be thicker or thinner than the wire at the side portions, making the looped portion more or less resistant to bending than the side portions.

[00266] Existing CTO crossing devices are too large to be used in the arteries below the knee. The present device can have a size that allows it to be used below the knee, for example, throughout the vasculature illustrated in Figure 17. The device can be used in vessels having a diameter between 1.5 mm and 30 mm, according to some aspects. According to one aspect, the catheter is a .035" catheter. According to one aspect, the crossing wire is a .018" wire. The embodiments of the invention are not limited to these dimensions.

[00267] The CTO specialty wire can have the same or varying degrees and/or combinations of rigidity and/or column strength so that the loop at the end can be moved in and out to the desired portion/rigidity/strength wire for a particular application. The combination(s) of rigidity can be predetermined.

[00268] The embodiments illustrated and discussed in this specification are intended only to teach those skilled in the art how to make and use the invention. In describing embodiments of the invention, specific terminology is employed for the sake of clarity. However, the invention is not intended to be limited to the specific terminology so selected. The above-described embodiments of the invention may be modified or varied, without departing from the invention, as appreciated by those skilled in the art in light of the above teachings. Moreover, features described in connection with one embodiment of the invention may be used in conjunction with other embodiments, even if not explicitly stated above. It is therefore to be understood that, within the scope of the claims and their equivalents, the invention may be practiced otherwise than as specifically described.

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CLAIMS:

1. A device for crossing a lesion in a tissue lumen, comprising:

a crossing wire configured to pass through a lumen of a catheter, the crossing wire including a loop at a distal end of the crossing wire, and the loop having a pair of lateral opposing portions configured for alignment with a wall of the tissue lumen and a leading portion interconnecting the pair of lateral opposing portions, the leading portion being configured to interrogate the lesion,

wherein the loop has a length in an axial direction of the crossing wire extending from the leading portion to proximal ends of the pair of lateral opposing portions, the length being perpendicular to the width,

wherein the length of the loop is at least twice the width of the loop,

wherein the crossing wire forming the loop has a rectangular cross-section comprising two opposing long edges and two opposing short edges, wherein the pair of lateral opposing portions and the leading portion of the loop form a plane, and wherein the two opposing long edges are perpendicular to the plane of the loop, and

wherein the crossing wire forming the loop is not twisted, and wherein the crossing wire proximal to the loop is twisted.

2. The device for crossing a lesion according to claim 1, wherein the pair of lateral opposing portions are configured such that a long edge of the rectangular cross-section contacts the wall of the tissue lumen for alignment with the wall of the tissue lumen.

3. The device for crossing a lesion according to any one of claims 1 or 2, wherein a proximal end of the crossing wire has a first stiffness, and wherein the leading portion of the loop has a second stiffness, wherein the first stiffness is greater than the second stiffness.

4. The device for crossing a lesion according to any one of claims 1 to 3, wherein the proximal end of the crossing wire forms a portion of a primary shaft of the crossing wire, wherein one of the pair of lateral opposing portions of the loop is directly connected to the primary shaft, and wherein another of the pair of lateral opposing portions is directly connected to a secondary shaft of the crossing wire, the secondary shaft being configured to wrap around the primary shaft.

5. The device for crossing a lesion according to claim 4, wherein the crossing wire is twistable to form primary and secondary shafts that are intertwined.

6. The device for crossing a lesion according to any one of claims 1 to 5, wherein the crossing wire is configured to be rotatable back and forth through an angle less than 360 degrees while maintaining contact with the lesion to erode the lesion.

7. The device for crossing a lesion according to any one of claims 1 to 6, wherein the crossing wire is configured to be twisted through an angle greater than 360 such that lateral opposing portions of the crossing wire become entwined beyond the distal end of the catheter.

8. The device for crossing a lesion according to any one of claims 1 to 7, wherein the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 90 degrees.

9. The device for crossing a lesion according to any one of claims 1 to 7, wherein the loop has a relaxed state such that opposite sides of the loop form an angle that is less than 60 degrees.

10. The device for crossing a lesion according to any one of claims 1 to 9, wherein the leading portion of the loop is flat.

11. The device for crossing a lesion according to any one of claims 1 to 9, wherein the leading portion of the loop is pointed.

12. The device for crossing a lesion according to any one of claims 1 to 11, wherein the crossing wire is integrally formed.

13. The device for crossing a lesion according to any one of claims 1 to 7, wherein the leading portion of the loop has a concave configuration such that the pair of lateral opposing portions extend distal to a center of the leading portion of the loop.

14. The device for crossing a lesion according to any one of claims 1 to 13, wherein the crossing wire has a variable stiffness along its length.

15. The device for crossing a lesion according to one of claims 1 to 14, wherein the loop includes a material that is radiopaque.

16. The device for crossing a lesion according to any one of claims 1 to 15, further comprising:

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the catheter forming the lumen.

17. A method for crossing a chronic total occlusion (CTO), comprising:

inserting a catheter having the device according to claim 1 disposed in a lumen of the catheter into an occluded vessel;

extending the distal end of the crossing wire beyond a distal end of the catheter to contact an occlusion;

grasping the crossing wire at a position proximal to a proximal end of the catheter; and

rotating the grasped crossing wire back and forth through an angle less than 360 degrees while maintaining the distal end of the crossing wire in contact with the occlusion to erode the occlusion.

18. The method for crossing a CTO according to claim 17, further comprising:

twisting the grasped crossing wire through an angle greater than 360 degrees while pressing the distal end of the crossing wire against the occlusion such that sides of the crossing wire become entwined beyond the distal end of the catheter.

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Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

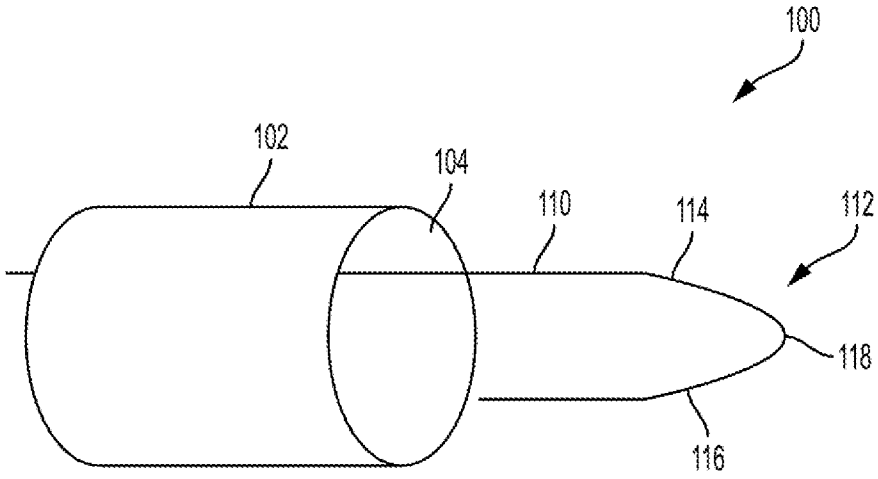


FIG. 1A

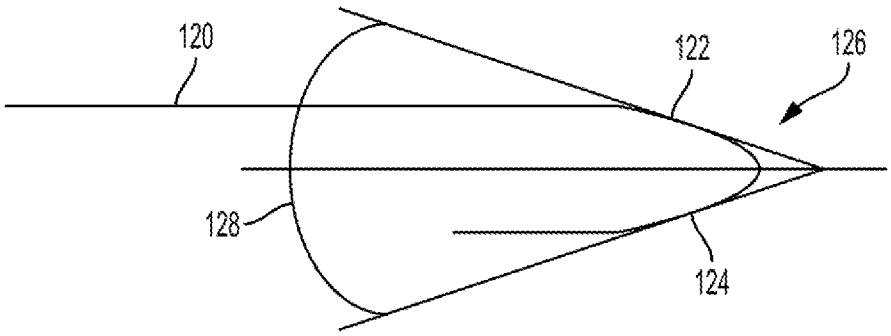


FIG. 1B

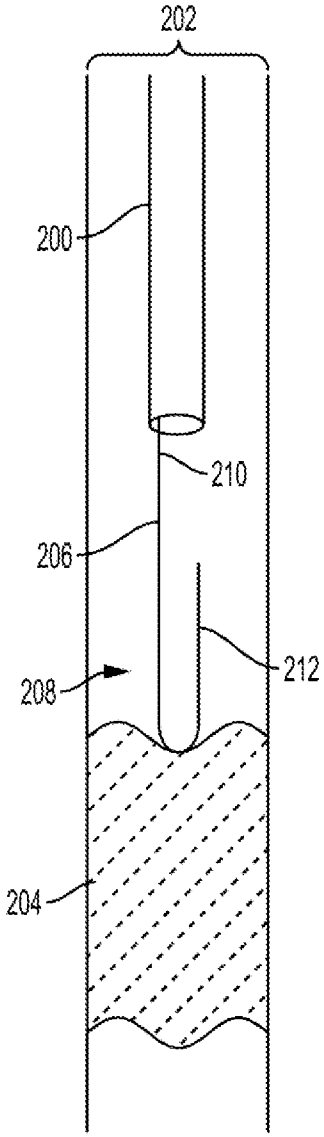


FIG. 2

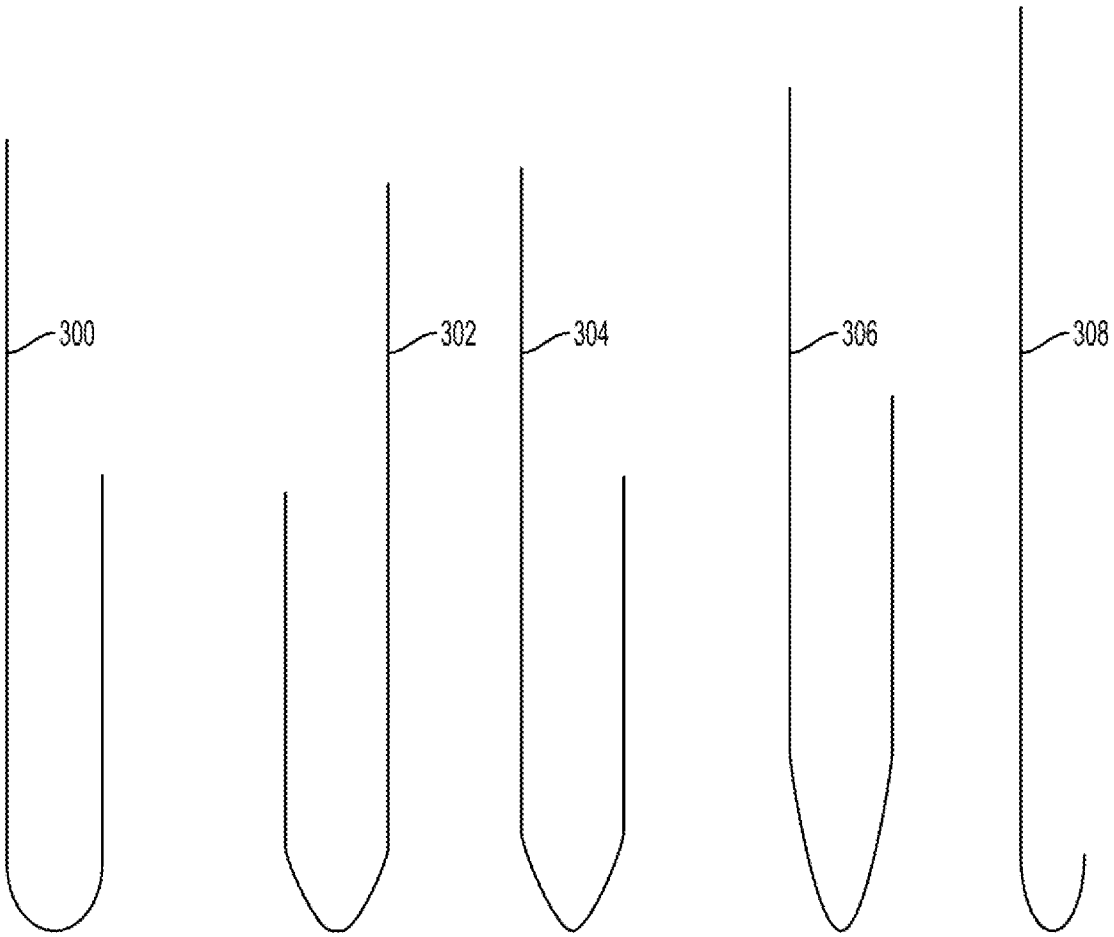


FIG. 3A FIG. 3B FIG. 3C FIG. 3D FIG. 3E

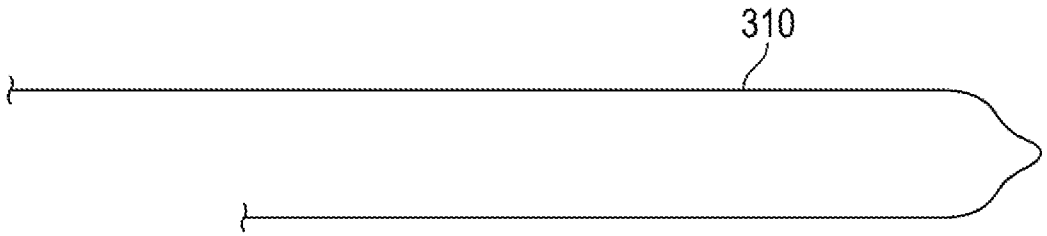


FIG. 3F

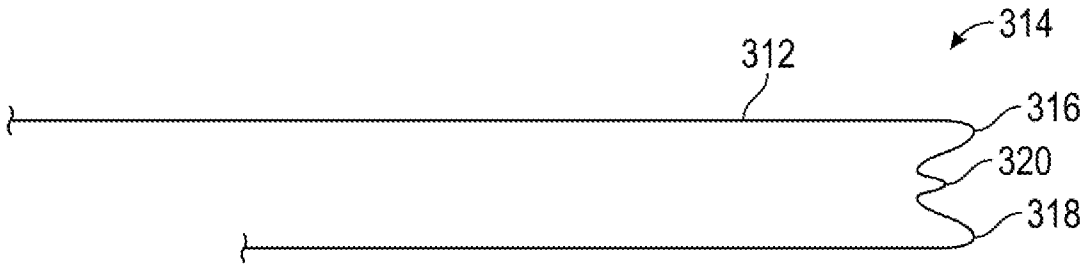


FIG. 3G

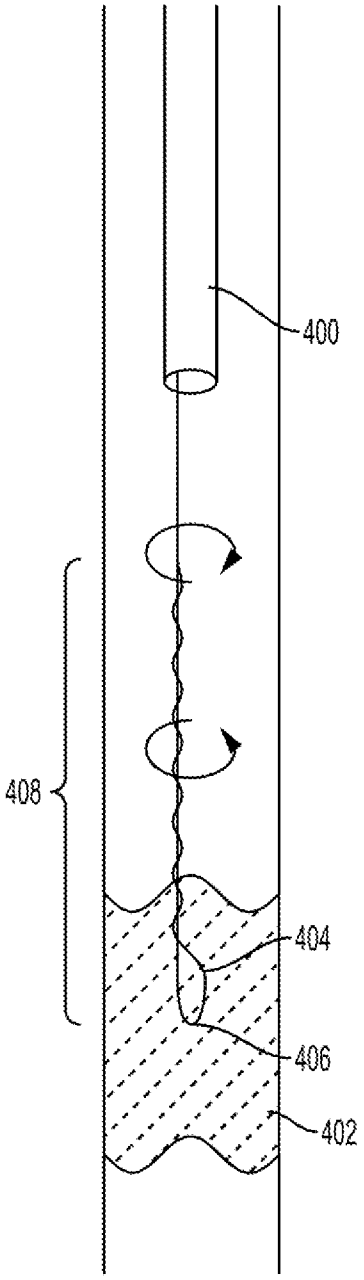


FIG. 4



FIG. 5A

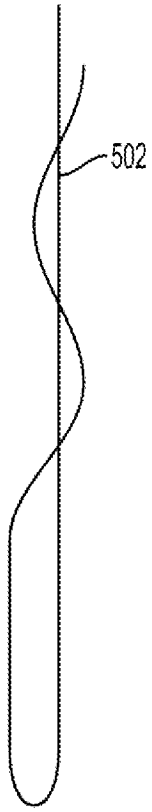


FIG. 5B



FIG. 5C

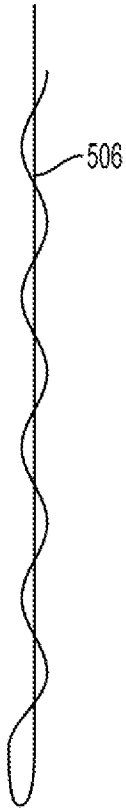


FIG. 5D

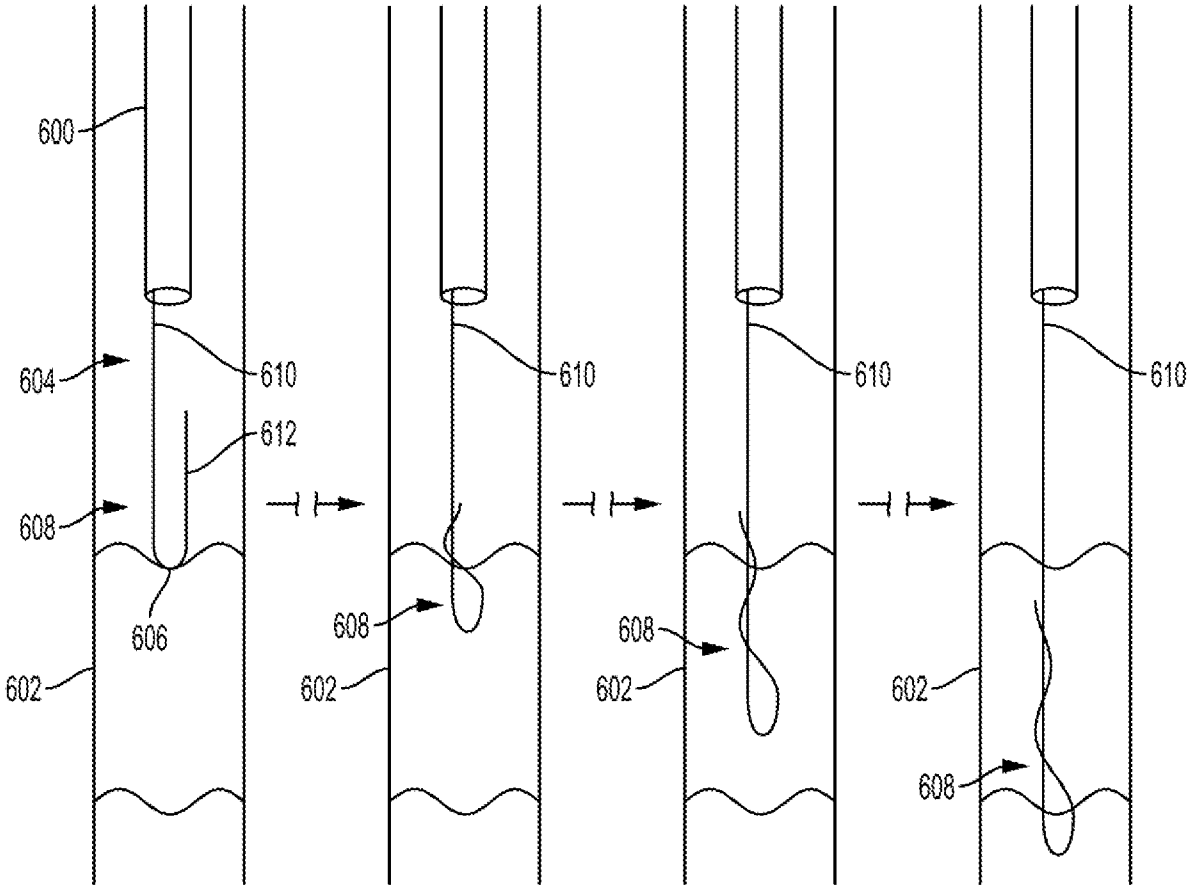


FIG. 6A FIG. 6B FIG. 6C FIG. 6D

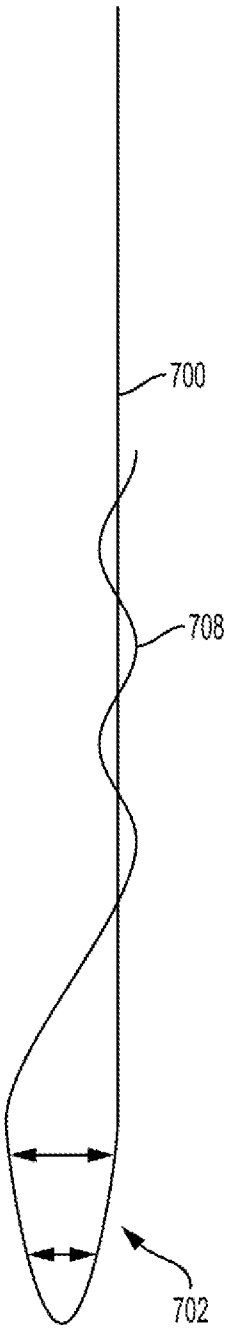


FIG. 7A

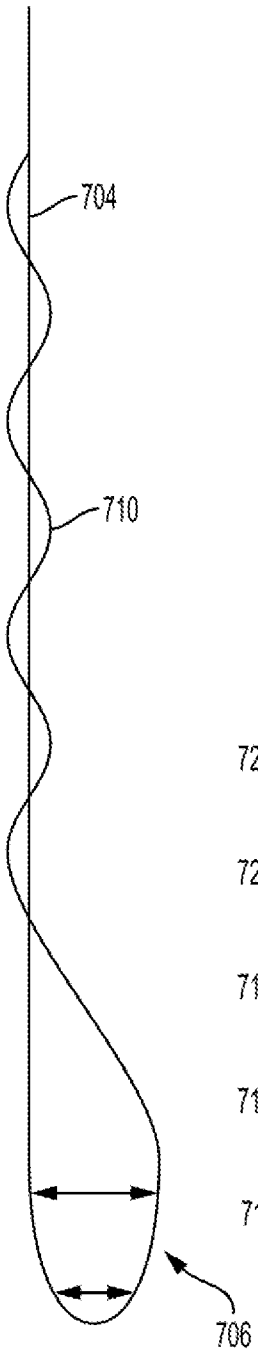


FIG. 7B

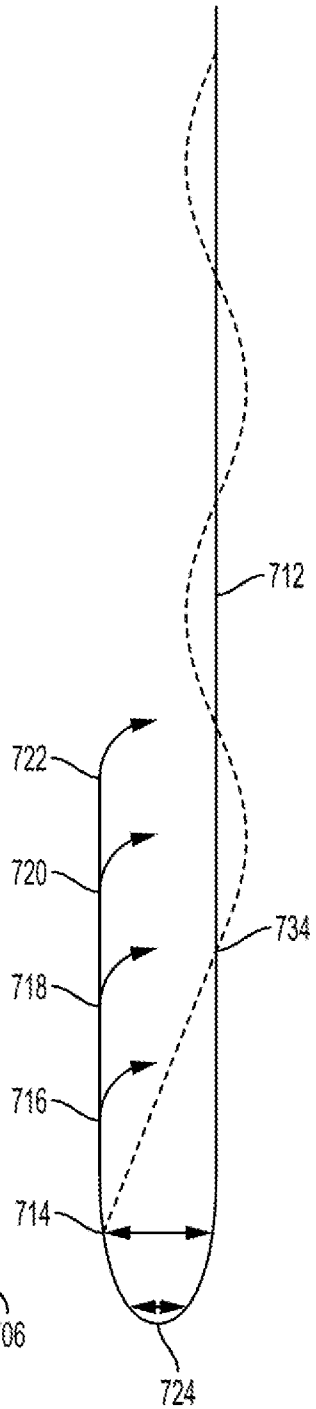


FIG. 7C

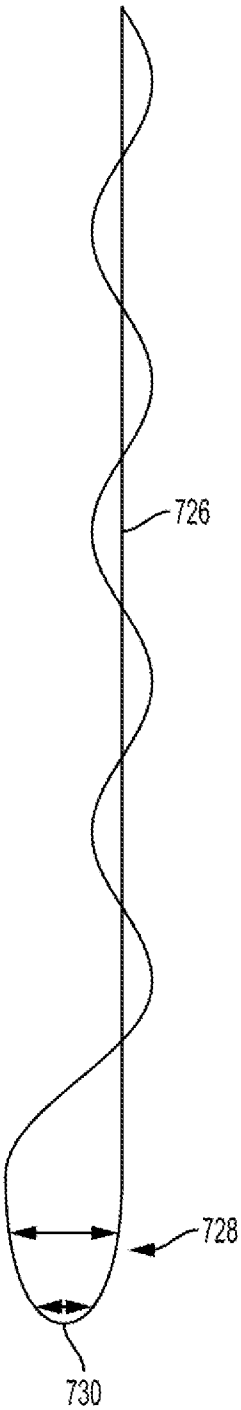


FIG. 7D

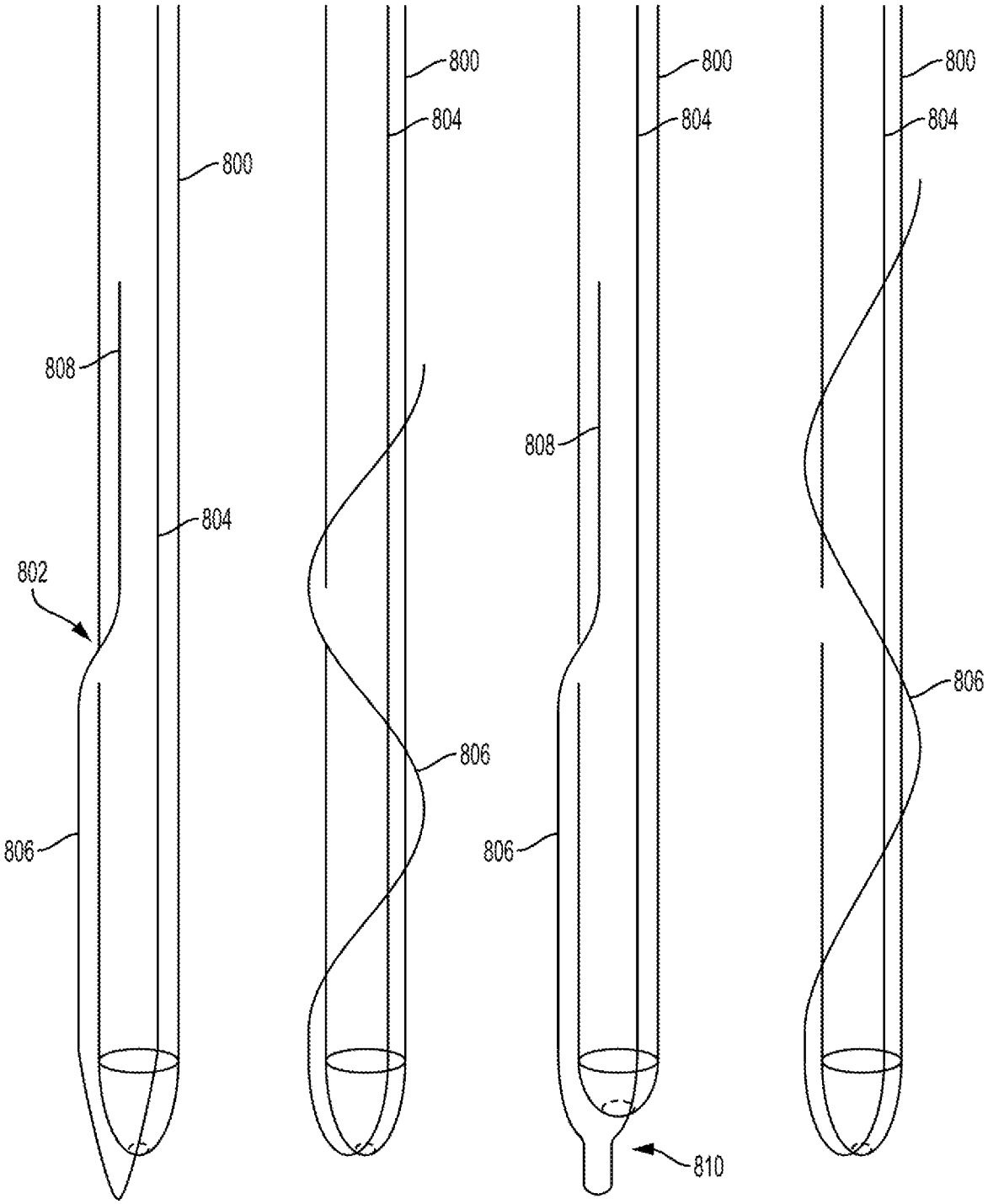


FIG. 8A FIG. 8B FIG. 8C FIG. 8D

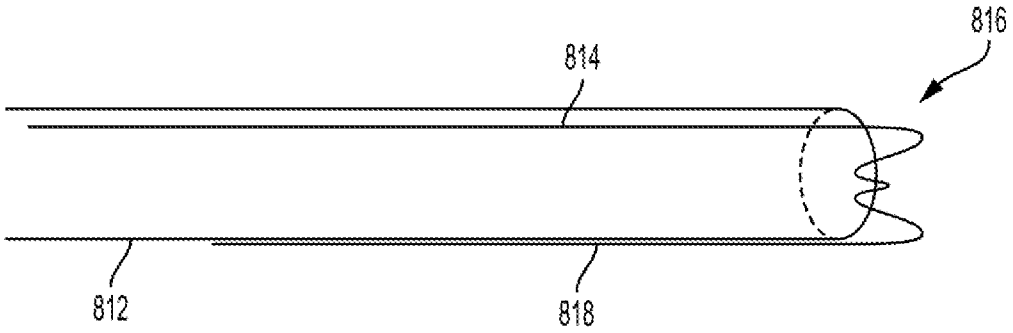


FIG. 8E

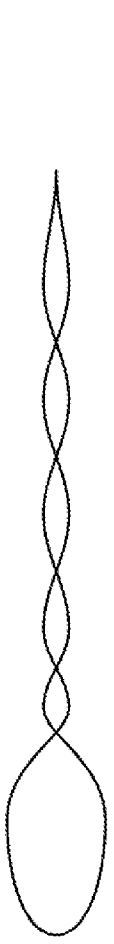


FIG. 9A



FIG. 9B



FIG. 9C

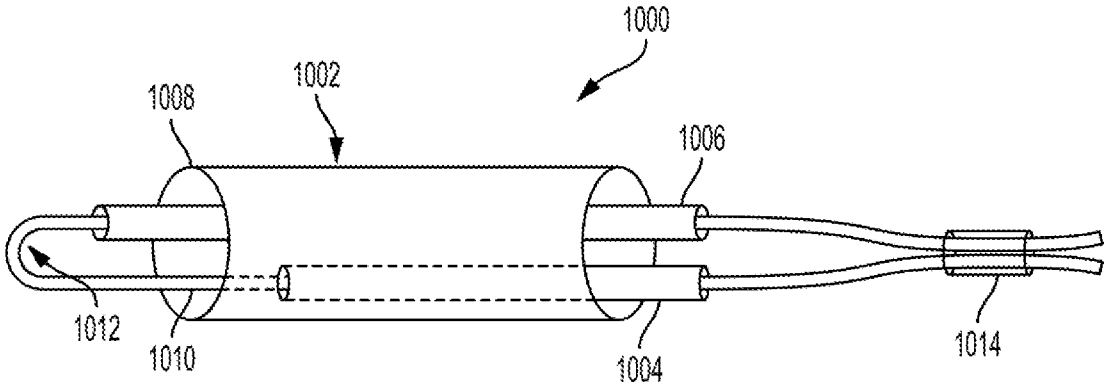


FIG. 10

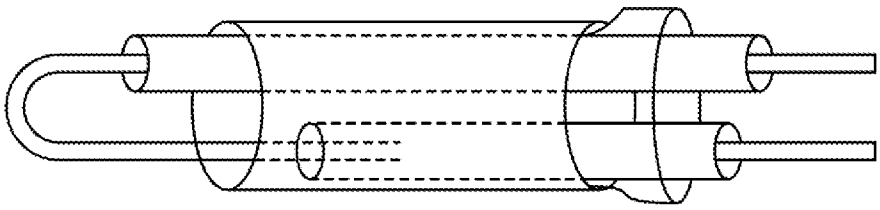


FIG. 11A

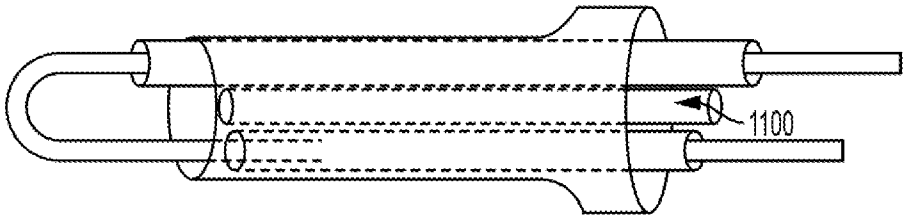


FIG. 11B

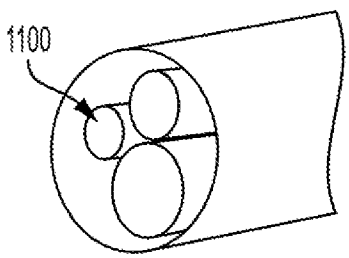


FIG. 11C

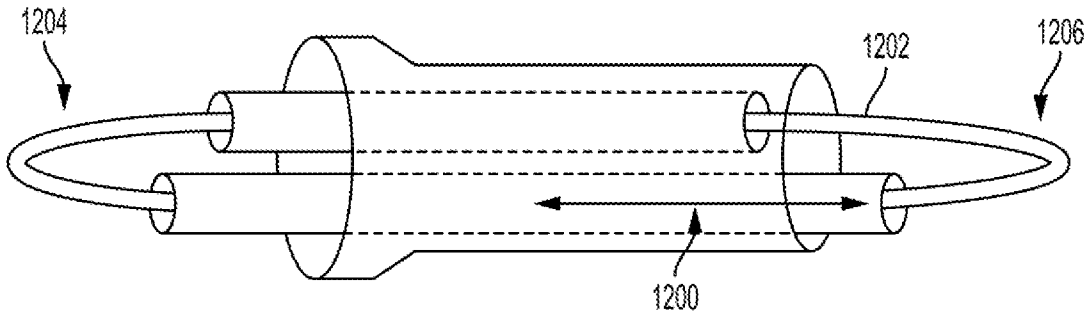


FIG. 12

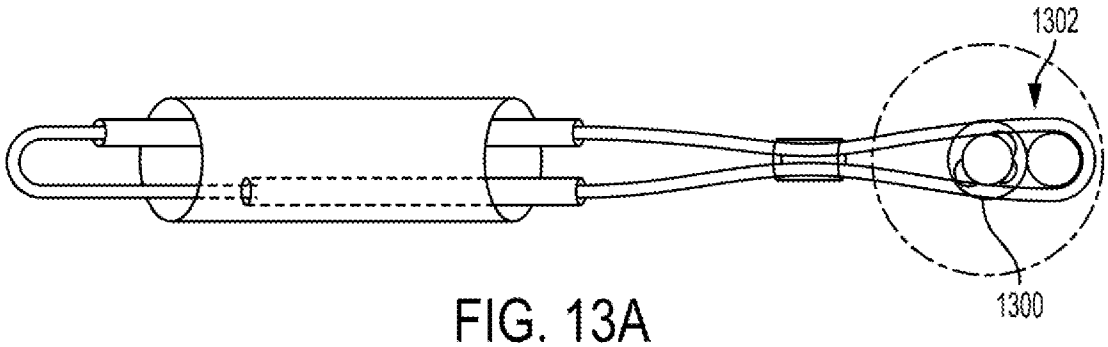


FIG. 13A

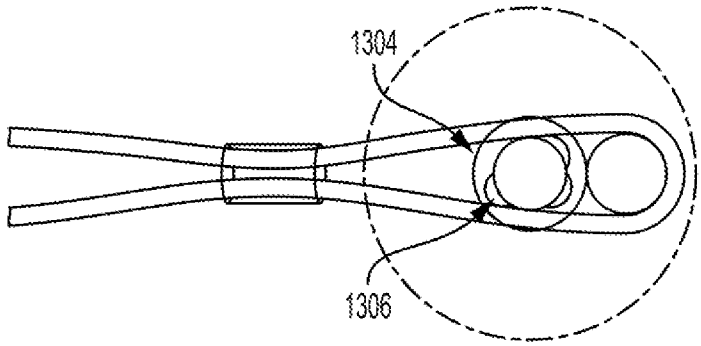


FIG. 13B

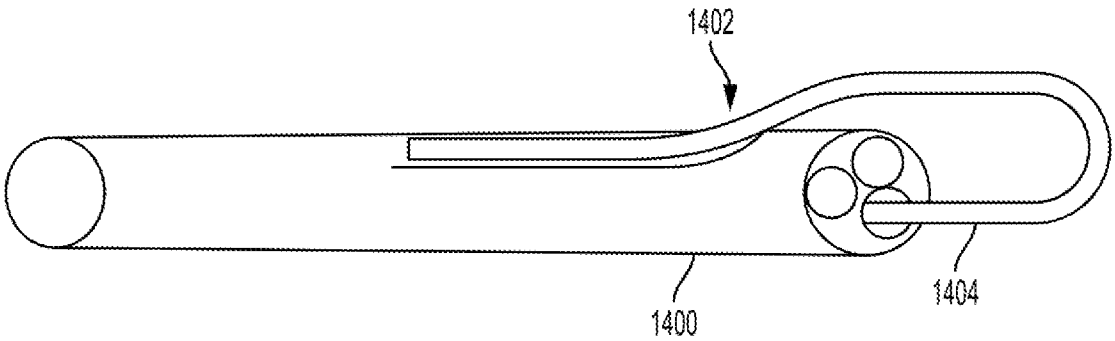


FIG. 14

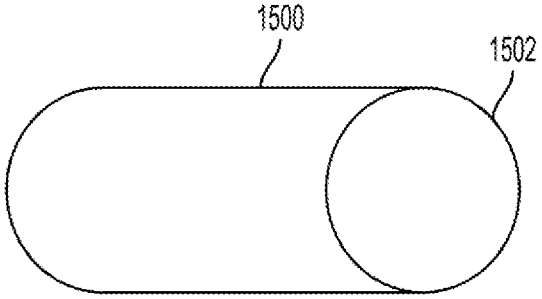


FIG. 15A

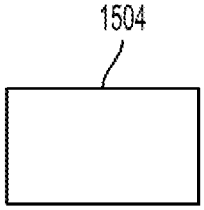


FIG. 15B

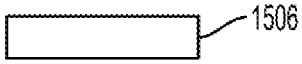


FIG. 15C

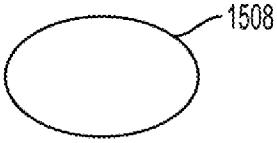


FIG. 15D

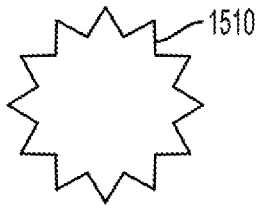


FIG. 15E

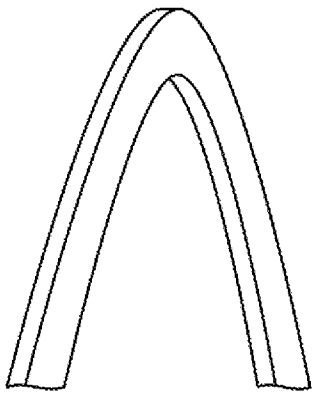


FIG. 16

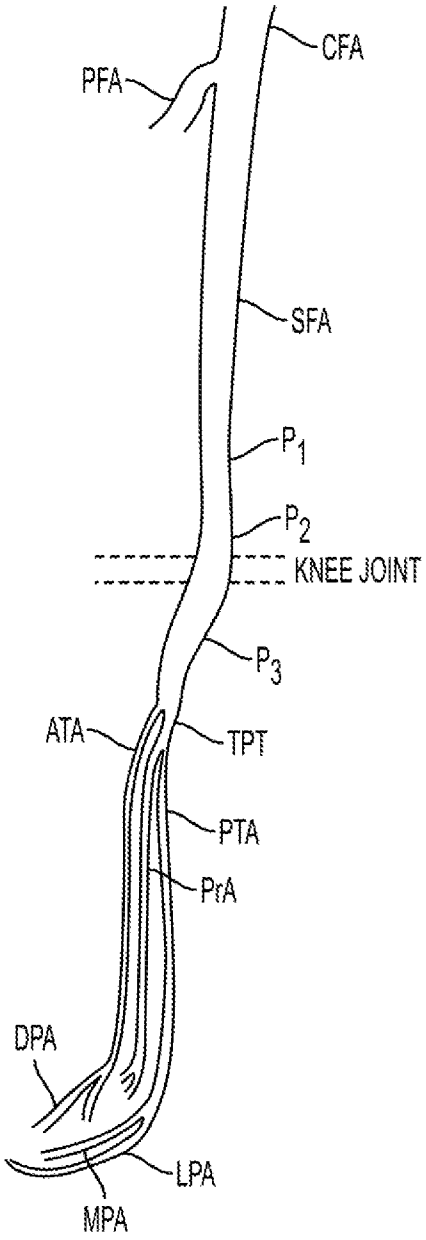


FIG. 17

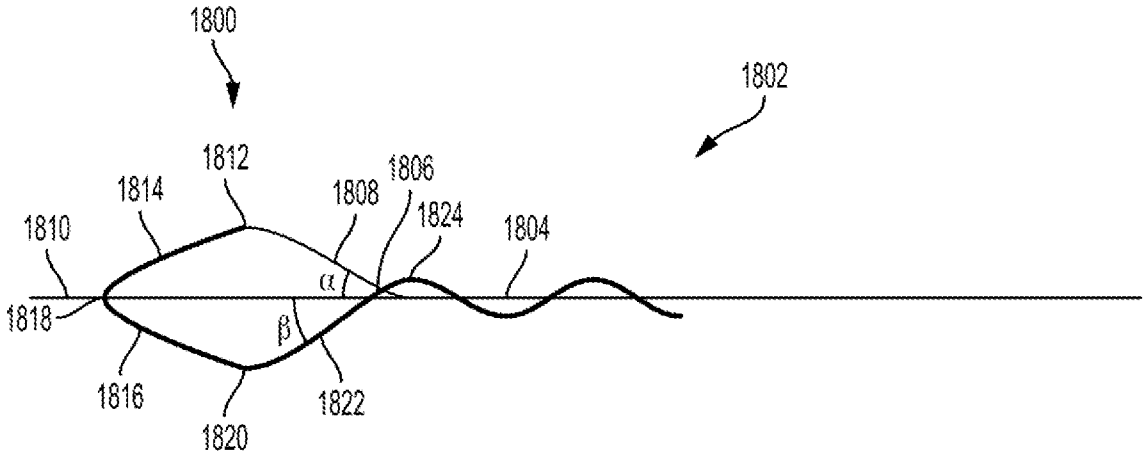


FIG. 18

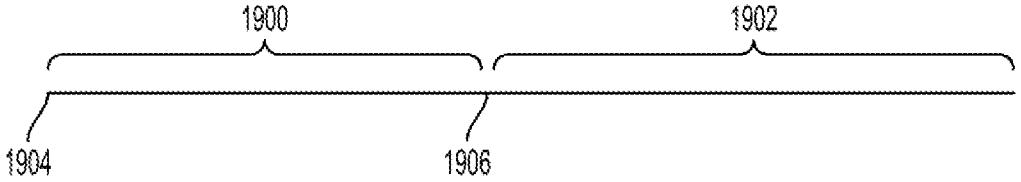


FIG. 19A

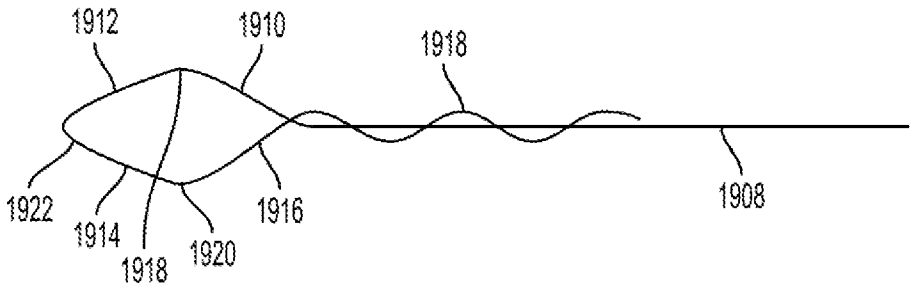


FIG. 19B

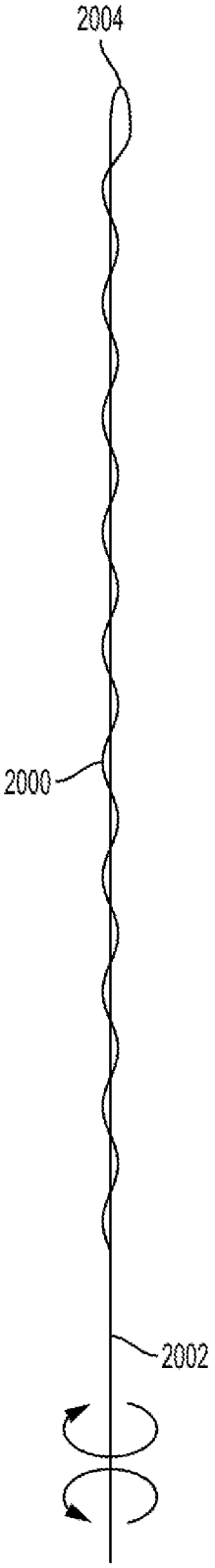


FIG. 20A

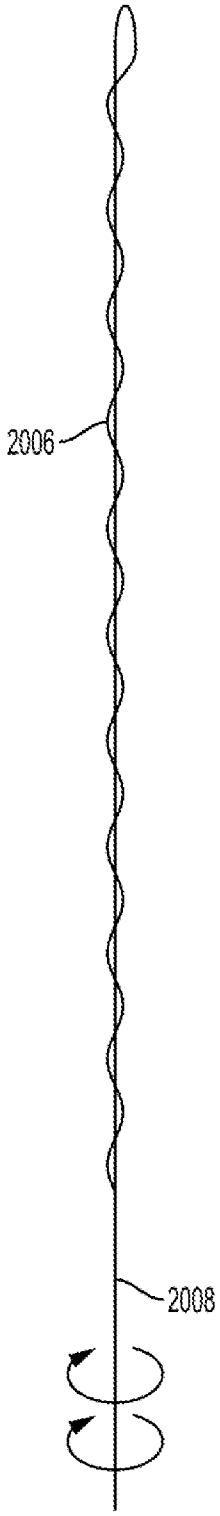


FIG. 20B

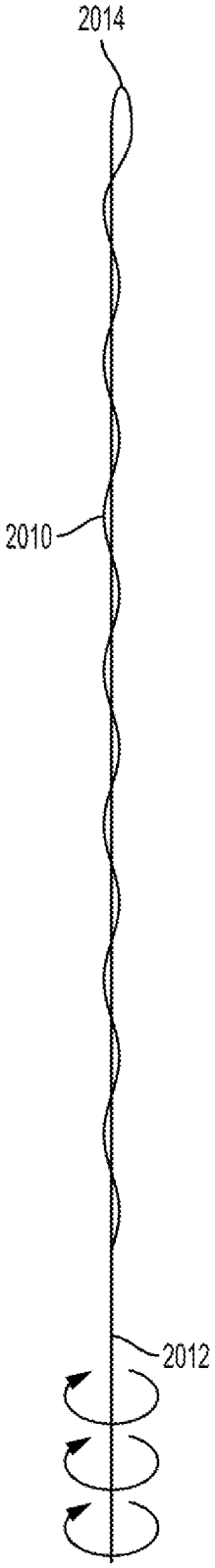


FIG. 20C

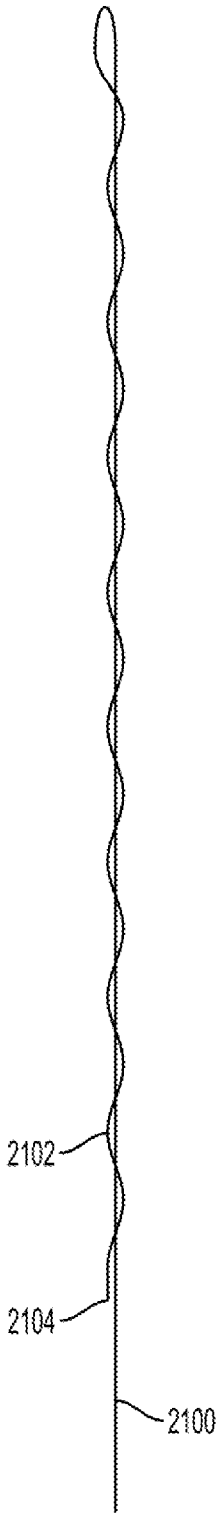


FIG. 21A

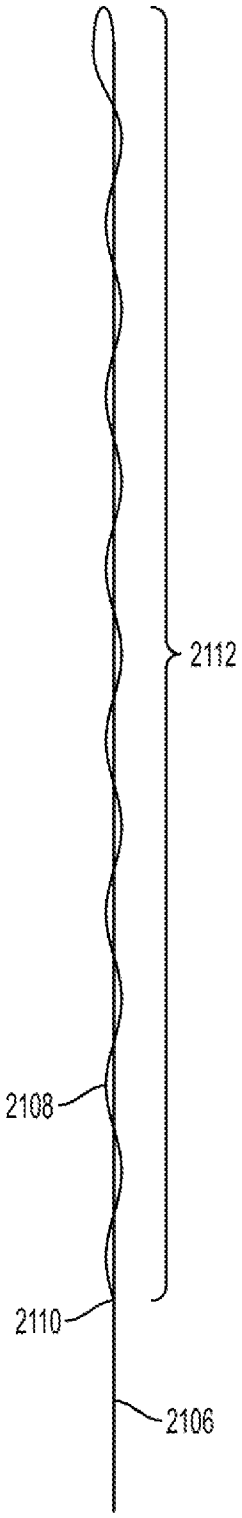


FIG. 21B

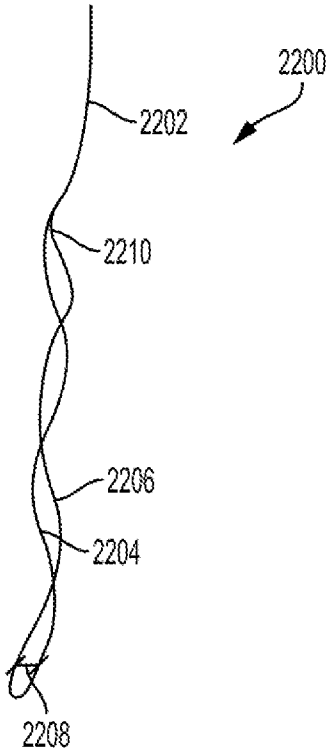


FIG. 22

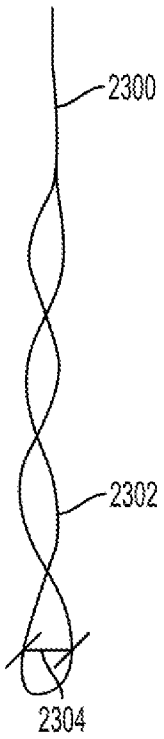


FIG. 23

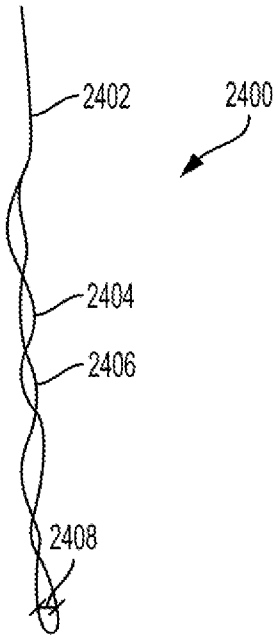


FIG. 24

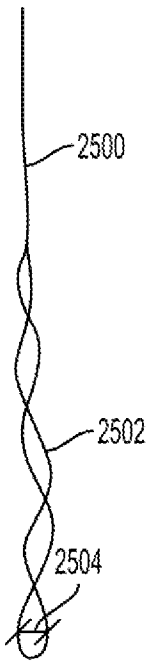


FIG. 25

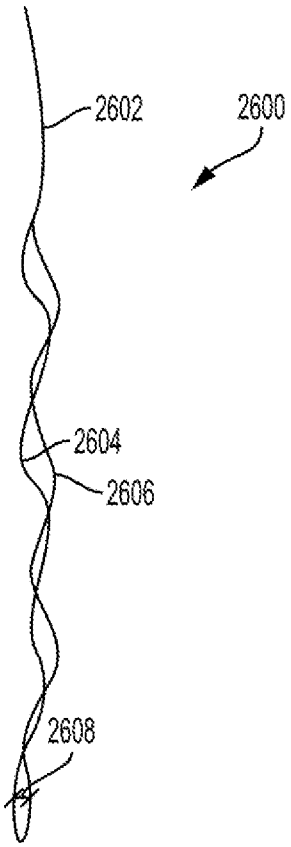


FIG. 26

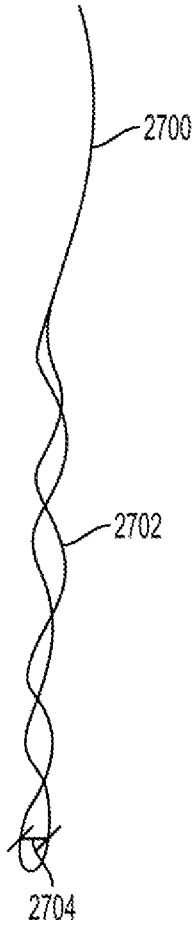


FIG. 27

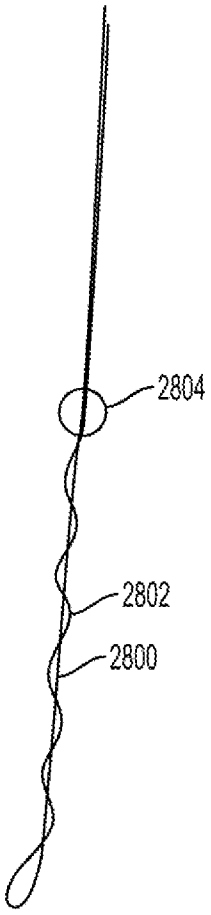


FIG. 28A

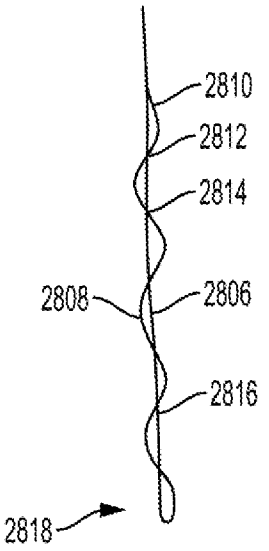


FIG. 28B

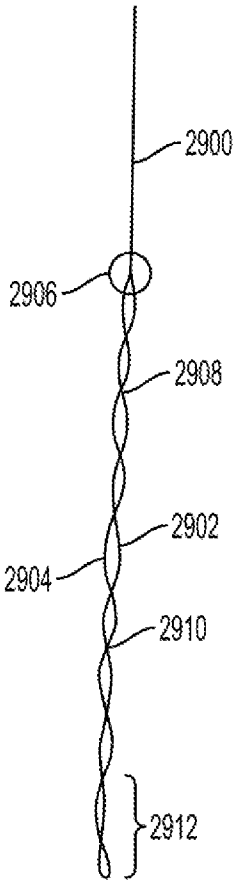


FIG. 29

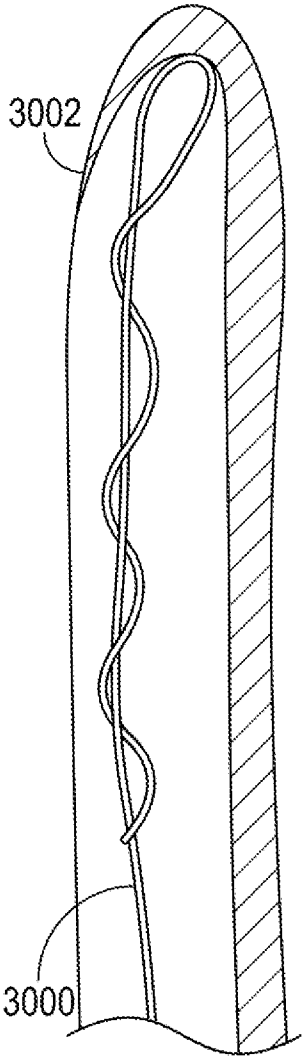


FIG. 30A

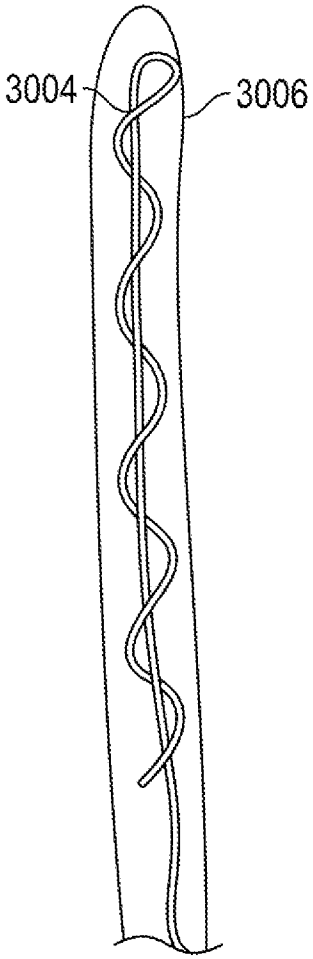


FIG. 30B

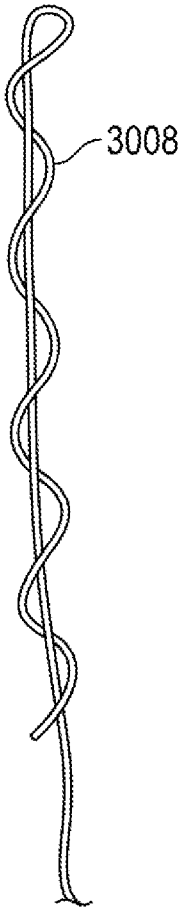


FIG. 30C

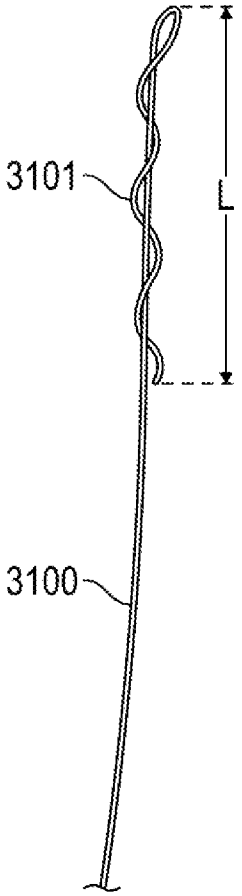


FIG. 31A

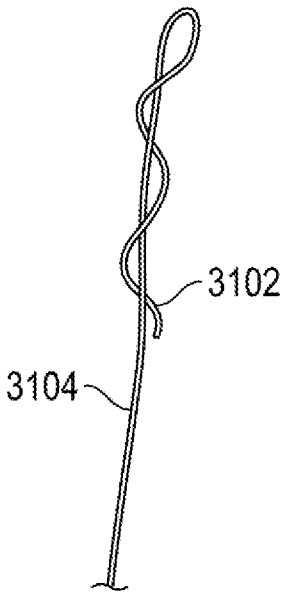


FIG. 31B

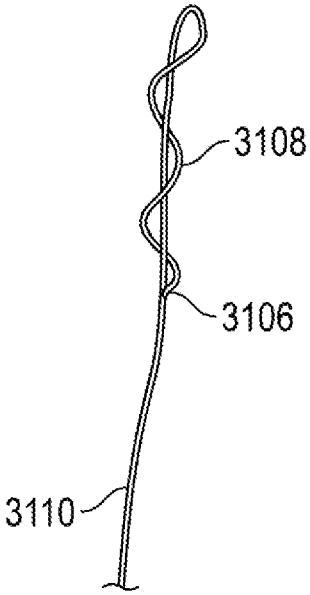


FIG. 31C

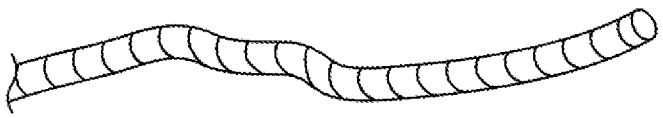


FIG. 32A

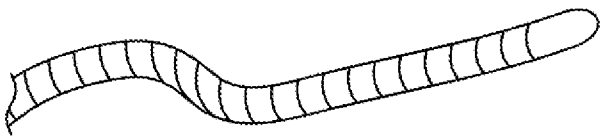


FIG. 32B

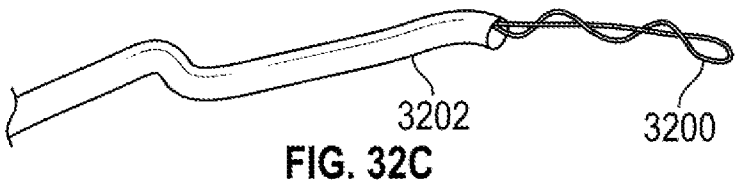
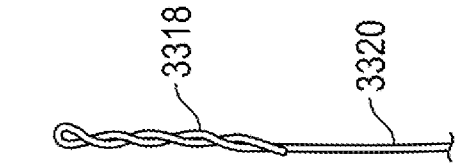


FIG. 32C



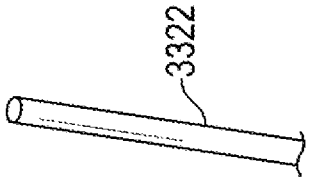


FIG. 33D

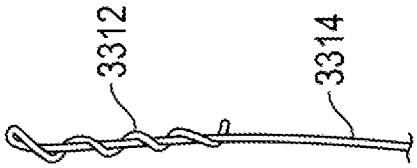
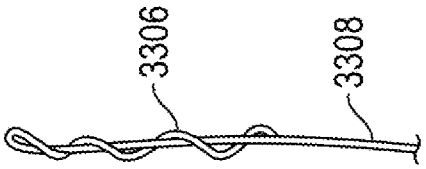




FIG. 33C



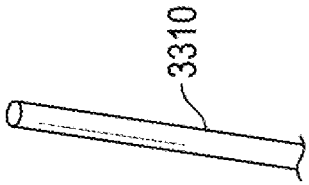
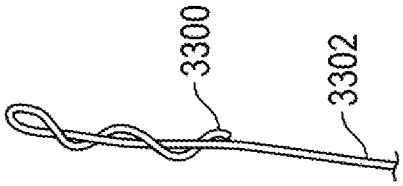


FIG. 33B



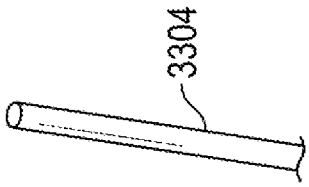


FIG. 33A

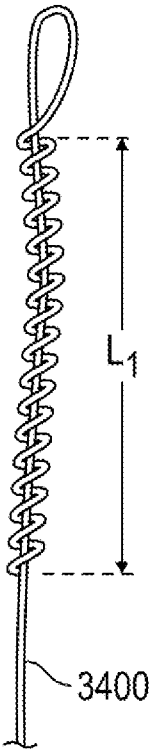


FIG. 34A

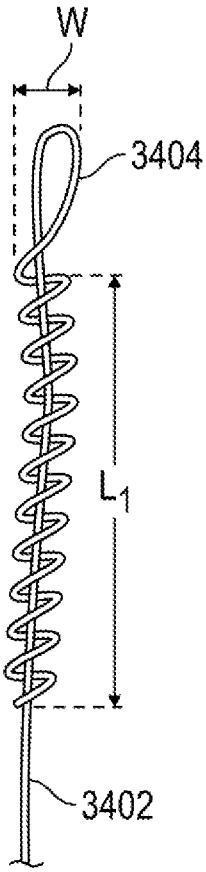


FIG. 34B

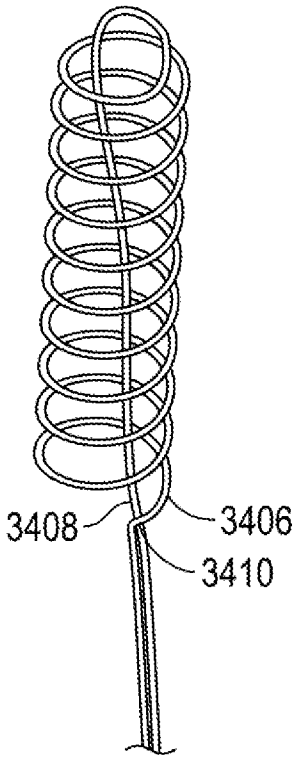


FIG. 34C

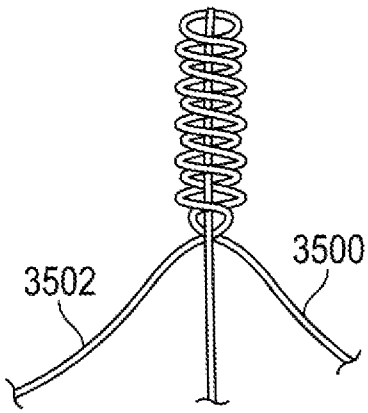


FIG. 35A

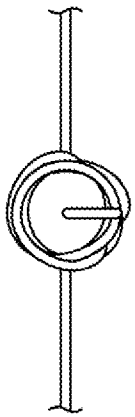


FIG. 35B

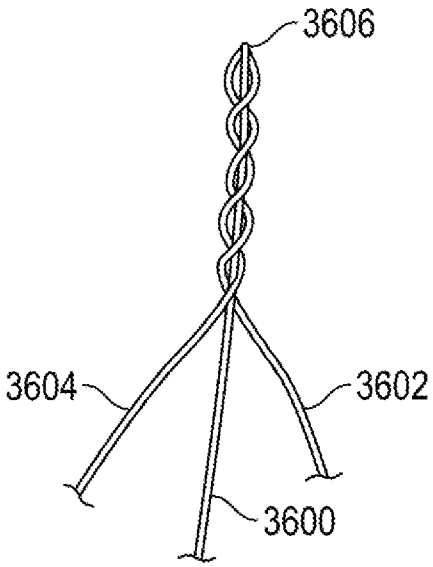


FIG. 36

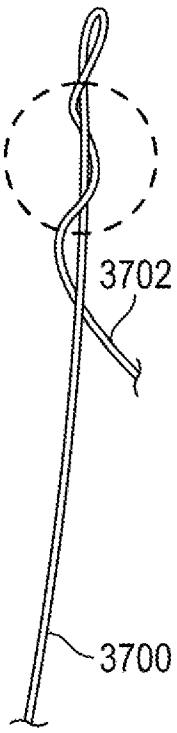


FIG. 37A

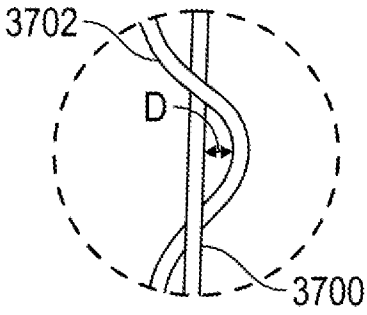


FIG. 37B

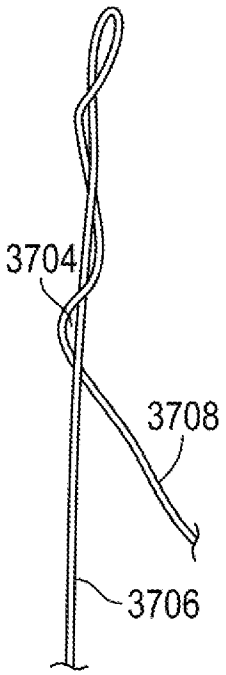


FIG. 37C

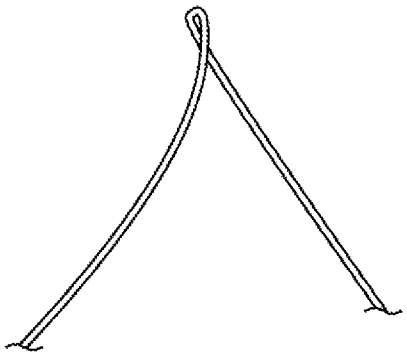


FIG. 38A

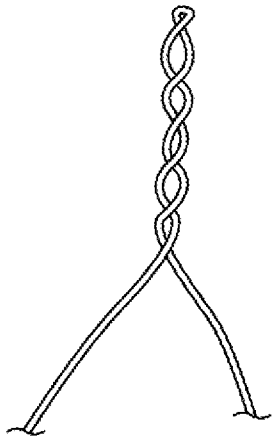


FIG. 38B

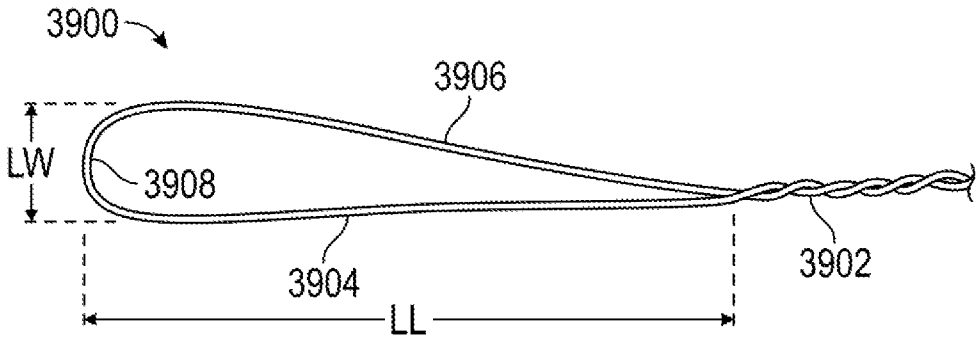


FIG. 39A

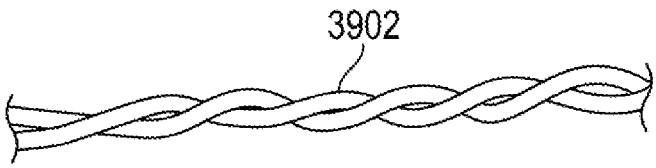


FIG. 39B

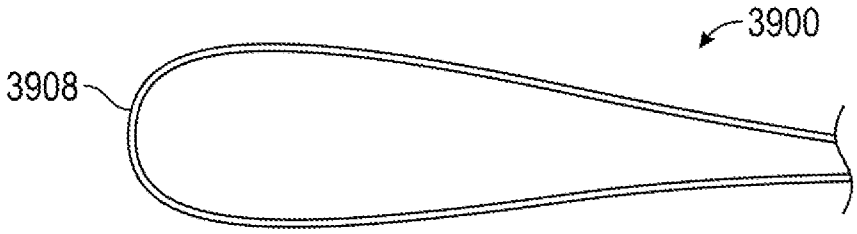


FIG. 39C

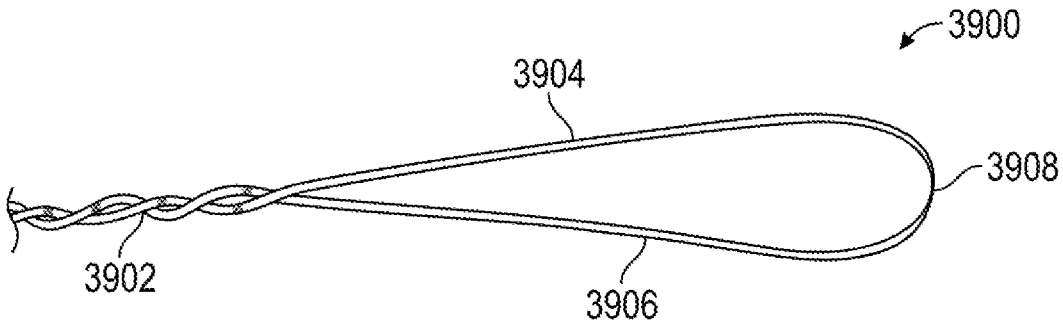


FIG. 39D

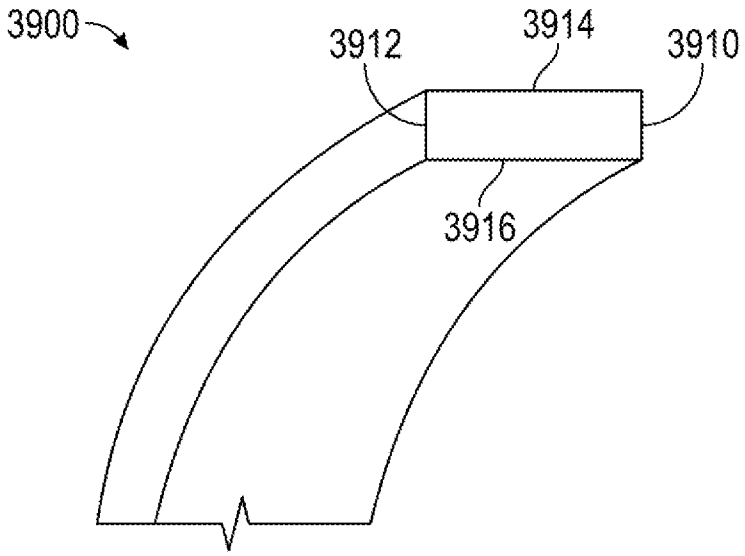


FIG. 39E



FIG. 40

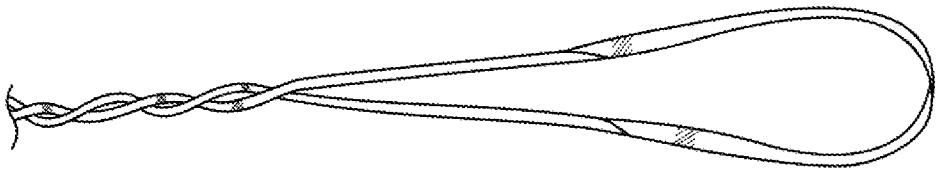


FIG. 41

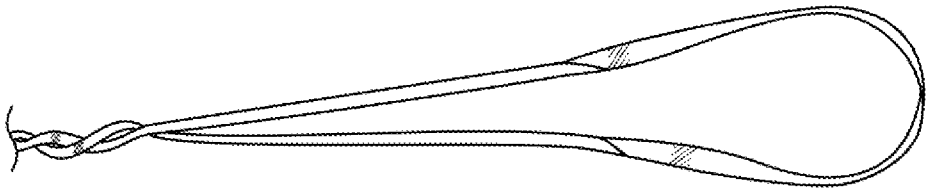


FIG. 42

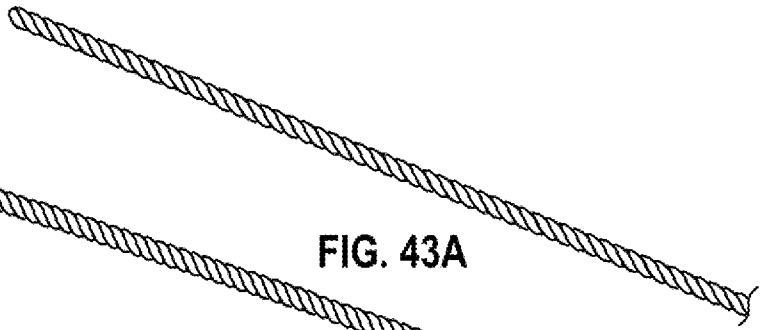


FIG. 43A

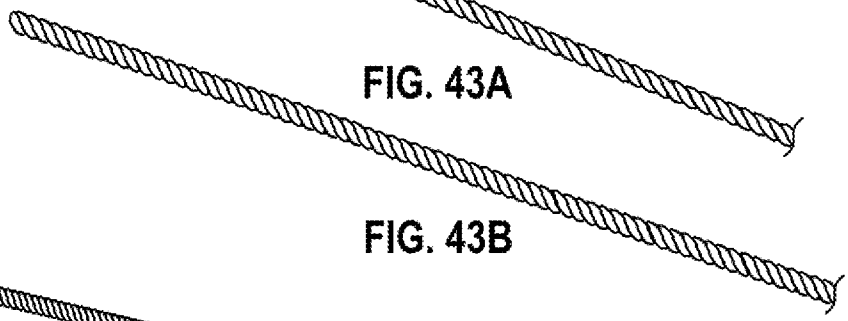


FIG. 43B

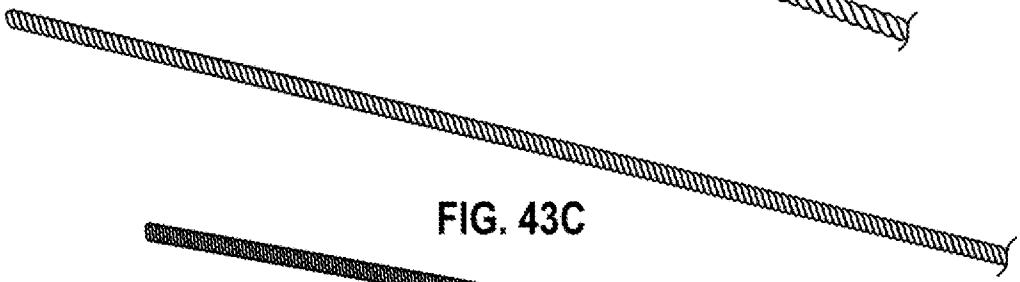


FIG. 43C

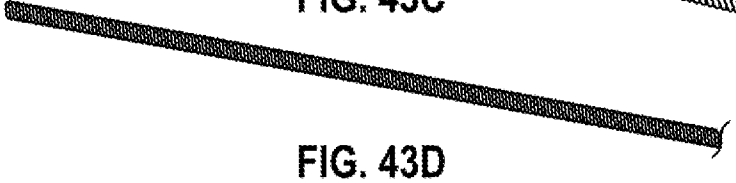


FIG. 43D

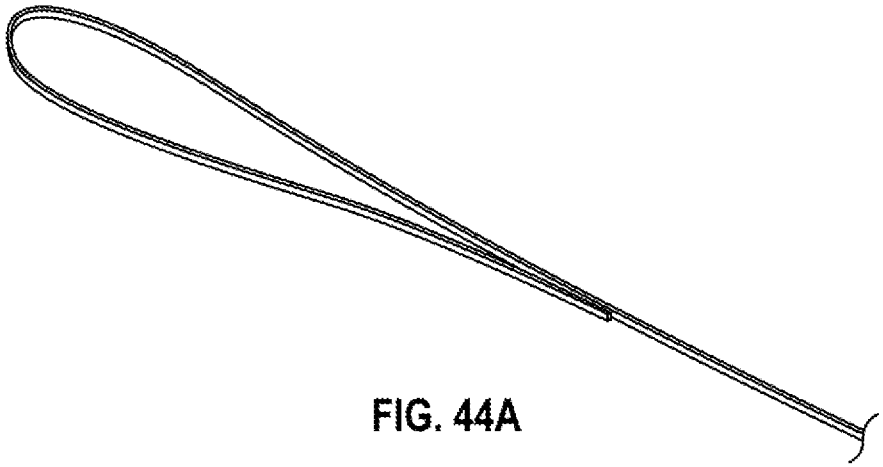


FIG. 44A

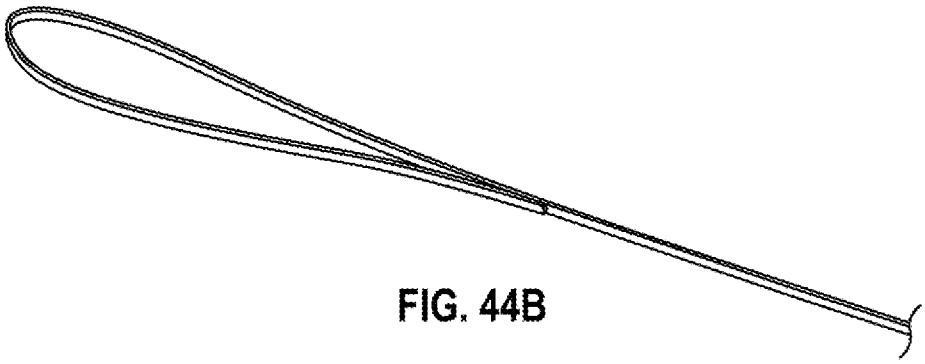


FIG. 44B

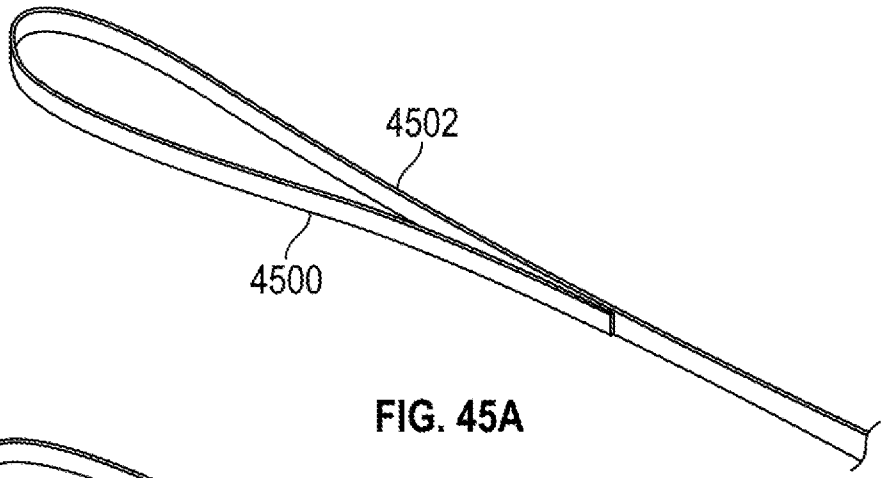


FIG. 45A

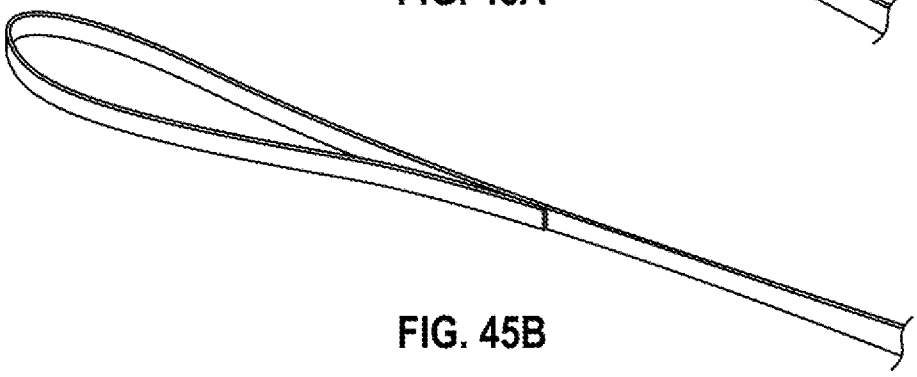


FIG. 45B

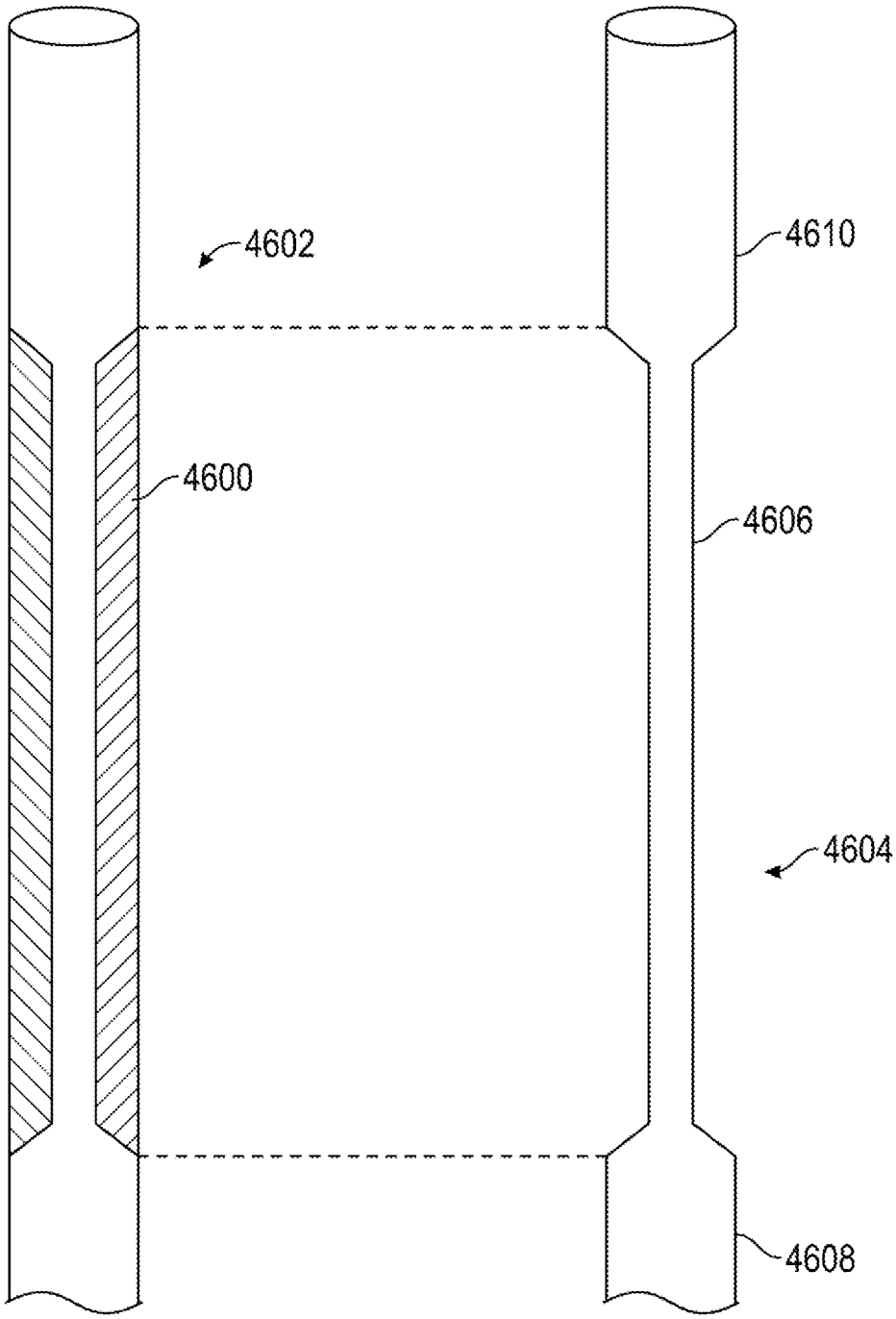


FIG. 46

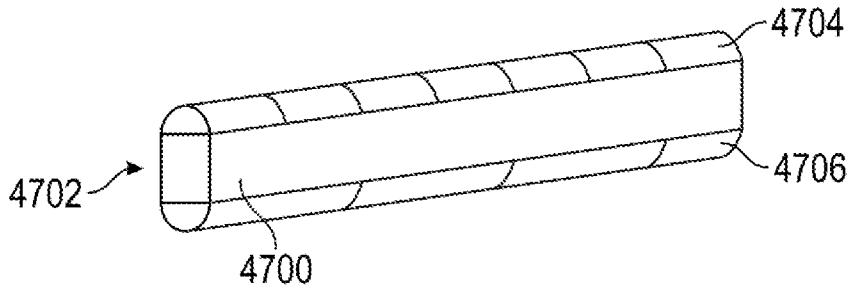


FIG. 47A

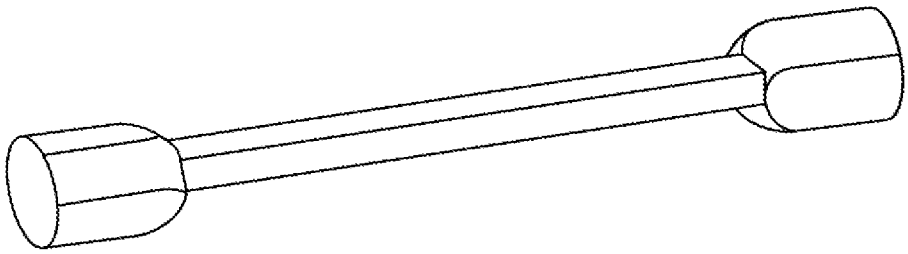


FIG. 47B

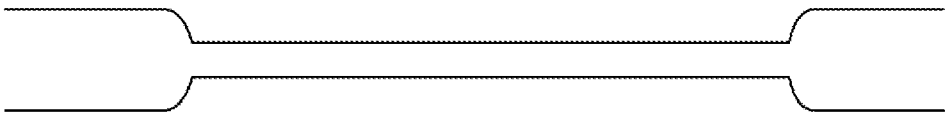


FIG. 47C

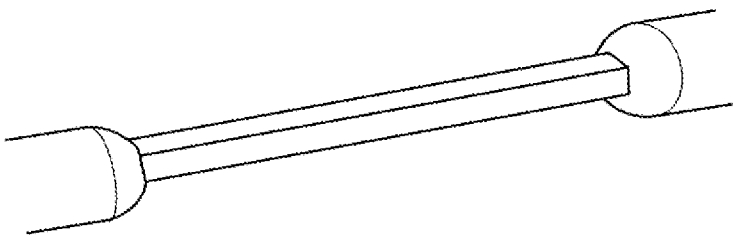


FIG. 47D

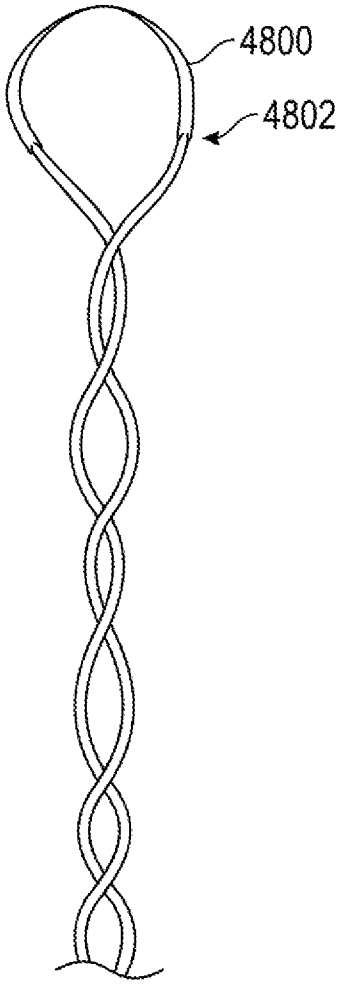


FIG. 48A

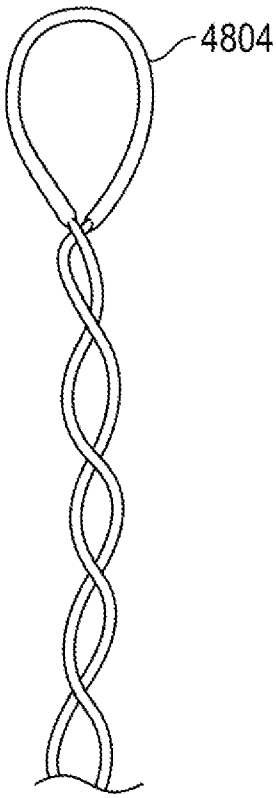


FIG. 48B

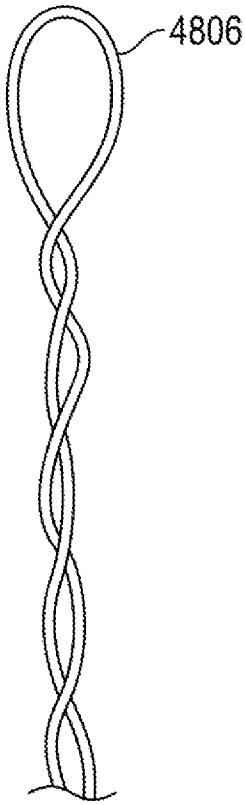


FIG. 48C

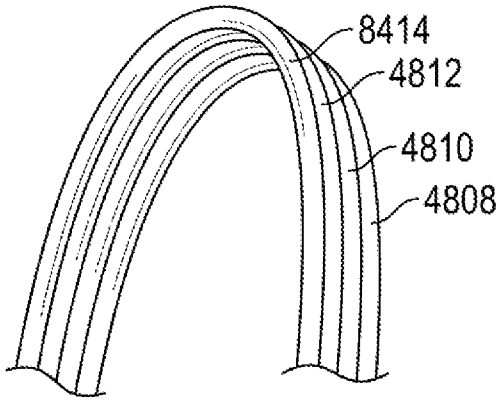


FIG. 48D

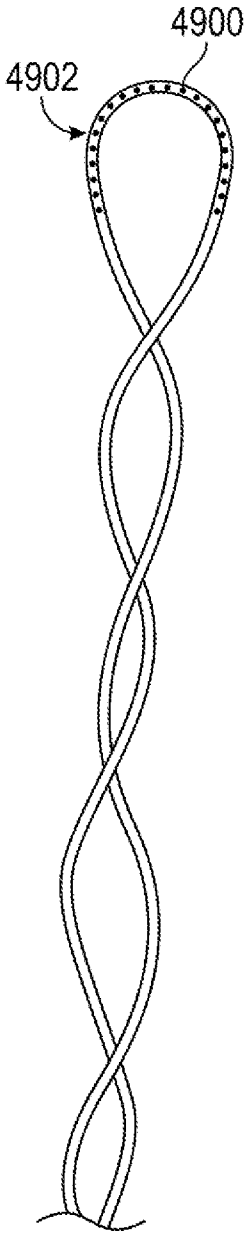


FIG. 49A

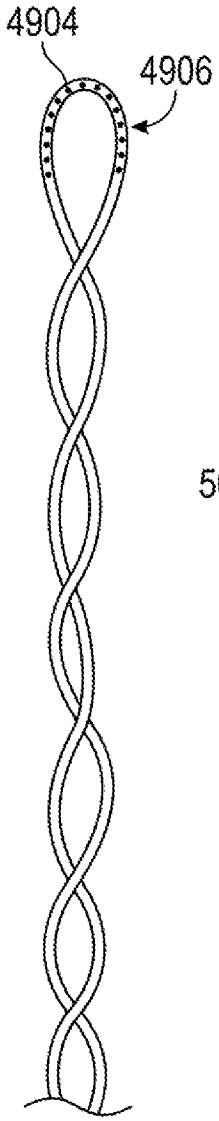


FIG. 49B

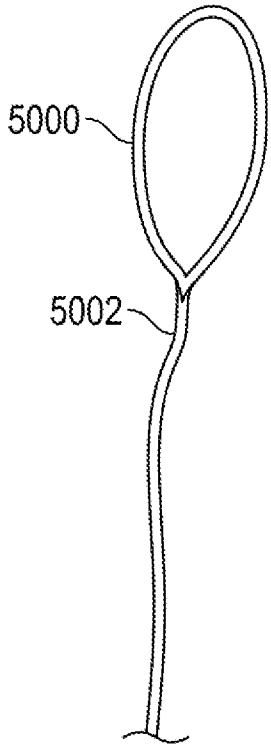


FIG. 50A

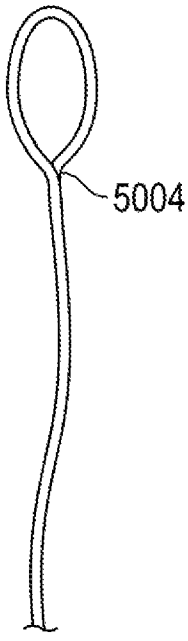


FIG. 50B

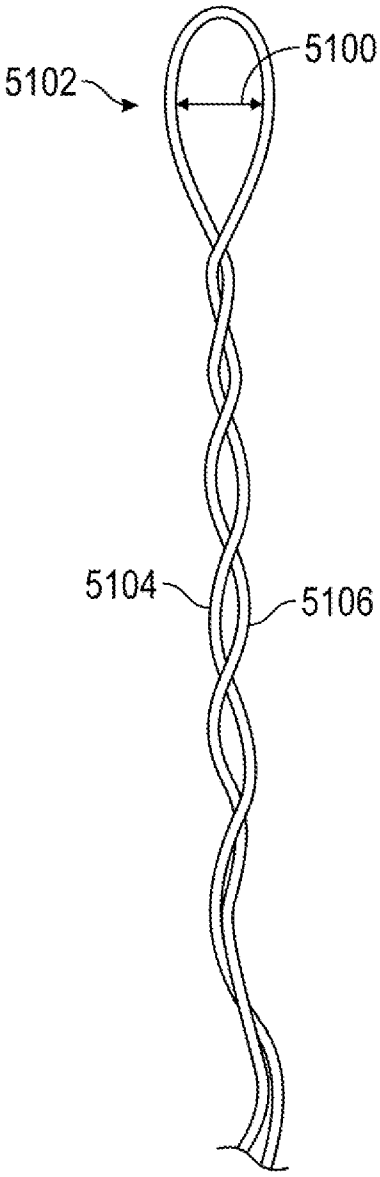


FIG. 51