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(54) **LESION TREATMENT DEVICE AND METHODS FOR TREATING LESIONS**

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(73) Assignee: **ASYMMETRIC MEDICAL LTD.**, Shdema (IL)

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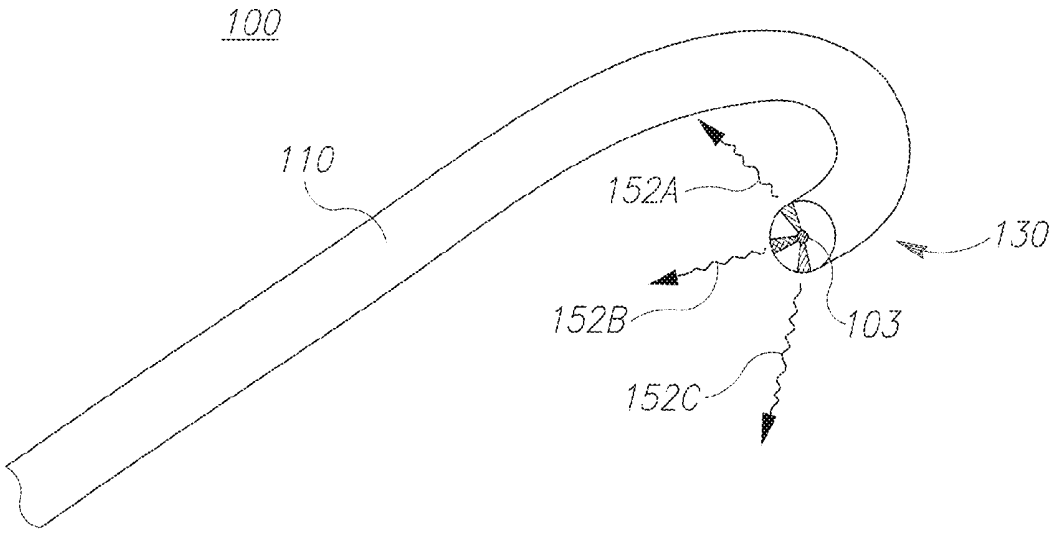
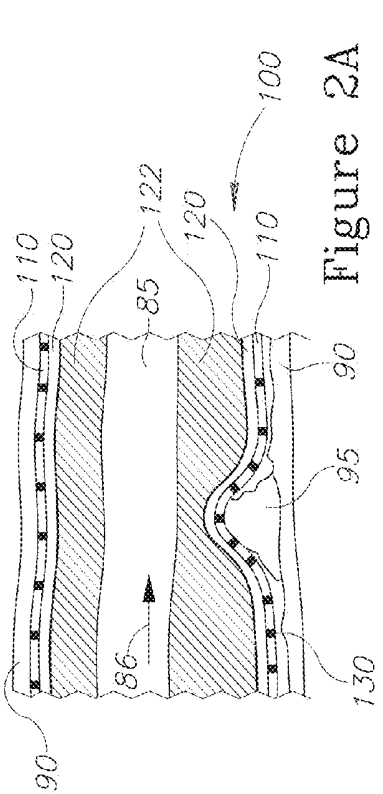
CPC ***A61B 18/245*** (2013.01); ***G06F 17/50*** (2013.01); *A61B 2018/00422* (2013.01)

USPC **606/7**; 703/7

(57) **ABSTRACT**

Tissue and vessel treatment devices and respective methods are provided. Devices comprise a flexible treatment layer that comprises a plurality of operable elements configured to be activated to apply the treatment to the obstruction upon bending of the flexible treatment layer beyond a specified curvature threshold and to be de-activated upon a specified decrease of the bending. The treatment layer may comprise optical fiber(s) with the operable elements as emission regions that emit electromagnetic radiation from the core upon bending the optical fiber beyond a specified bending threshold. Devices may be configured as vessel sealing tips for surgical forceps, in which the treatment layer is configured to yield vessel welding and vessel cutting effects.





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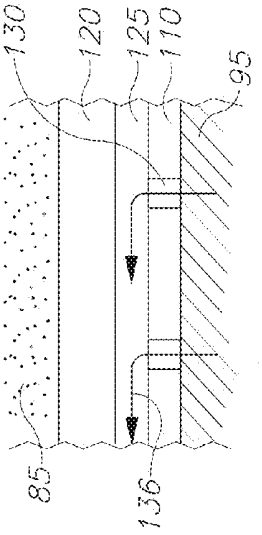
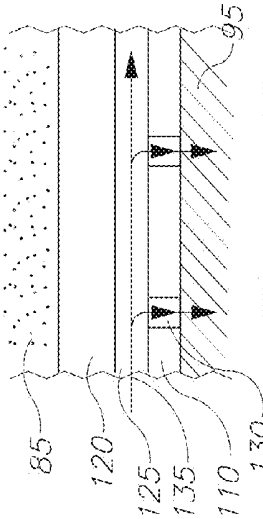


Figure 2C



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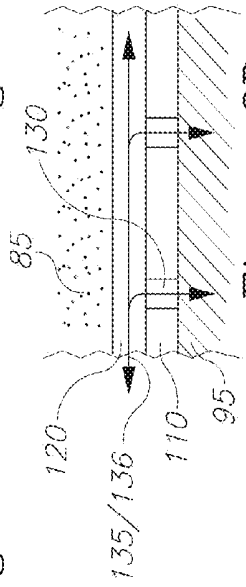
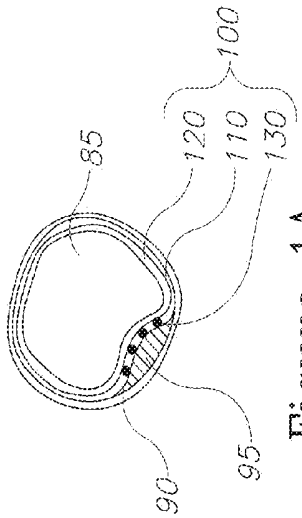


Figure 2D



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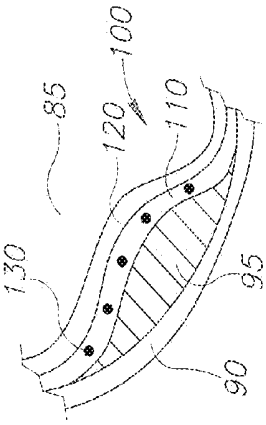

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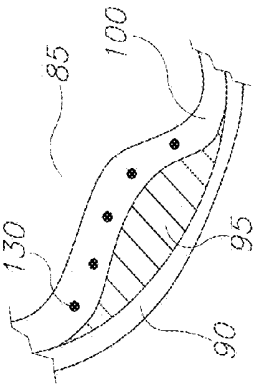

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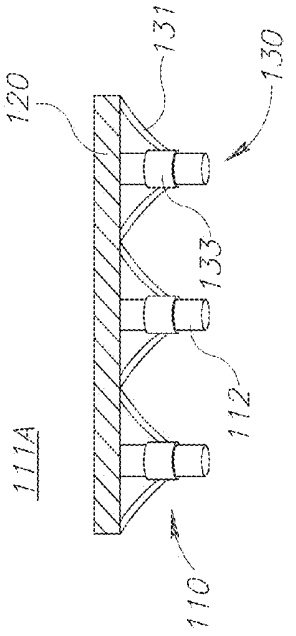
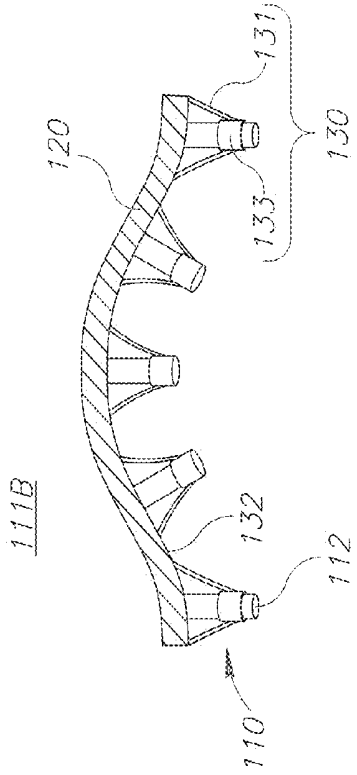


Figure 4A



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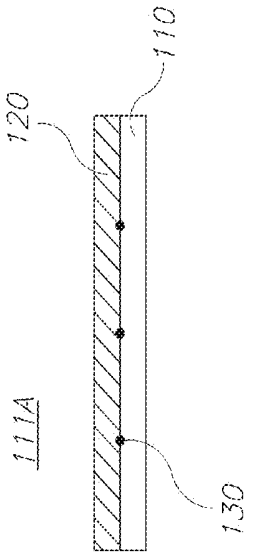

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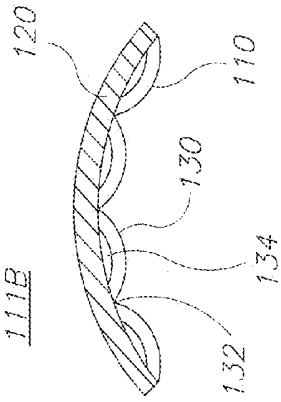

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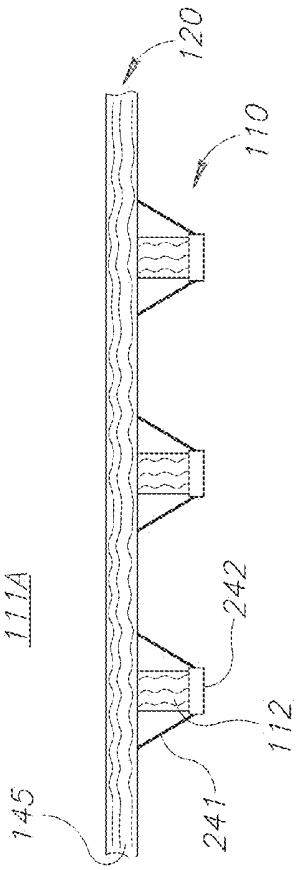

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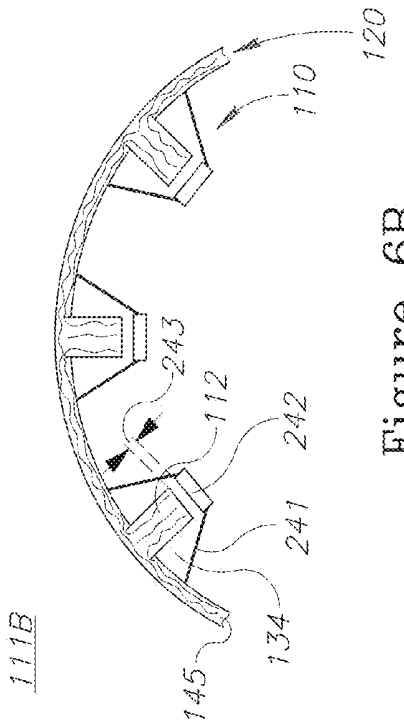

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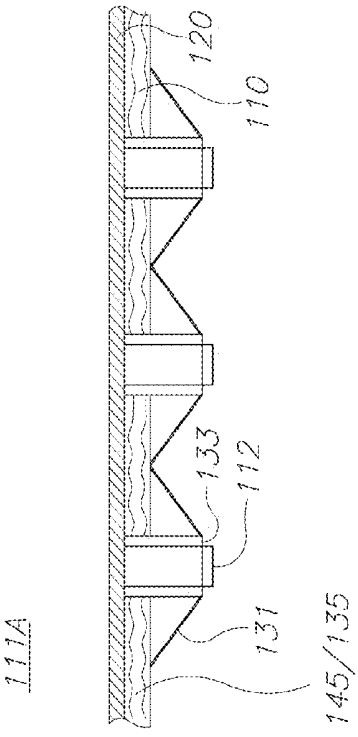

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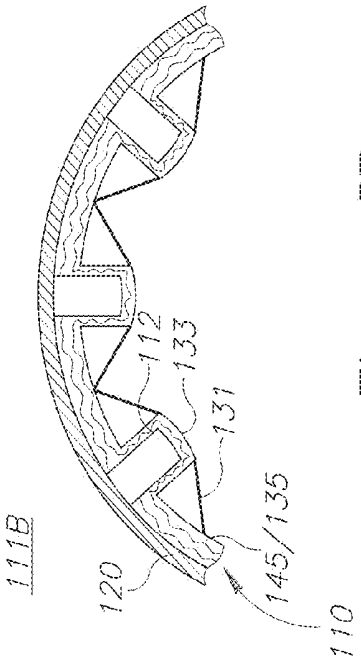

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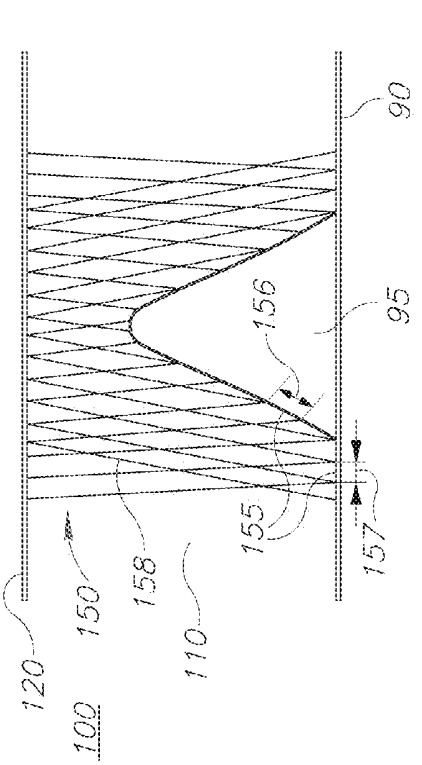

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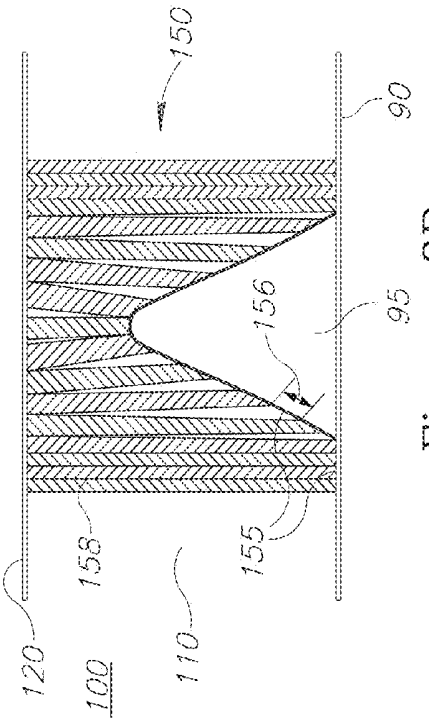

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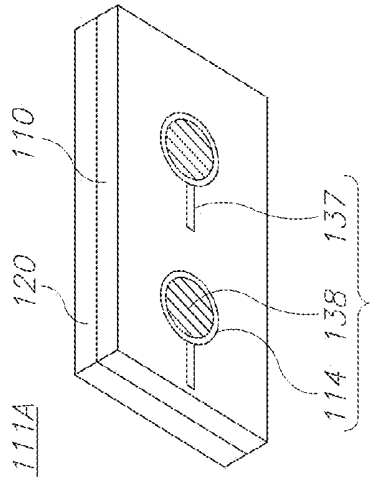

Figure 7A

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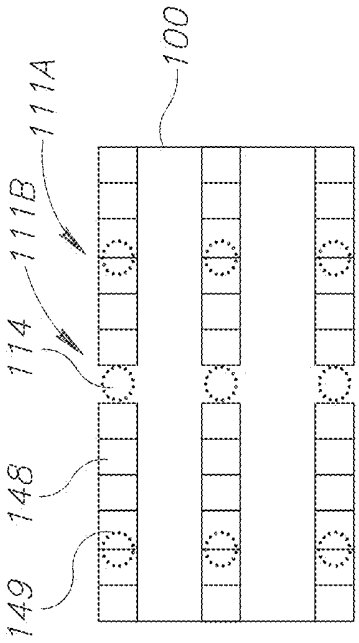

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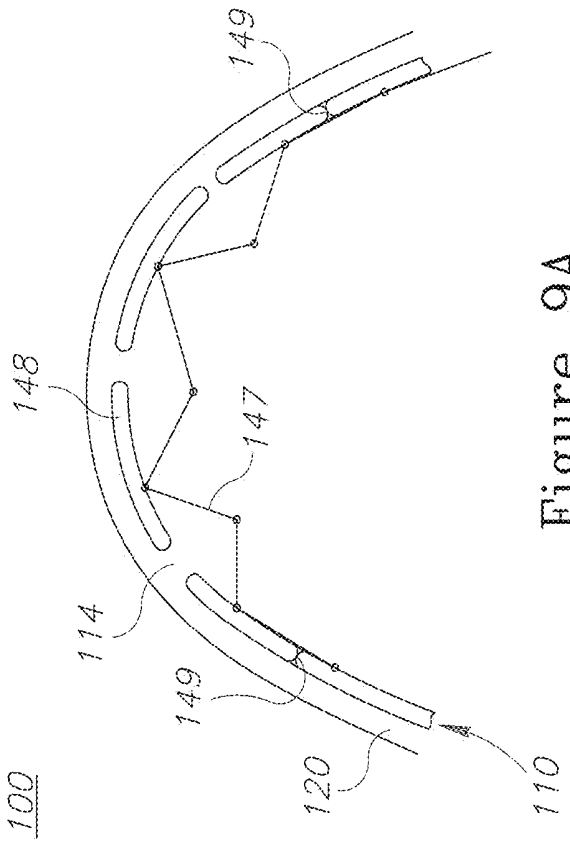

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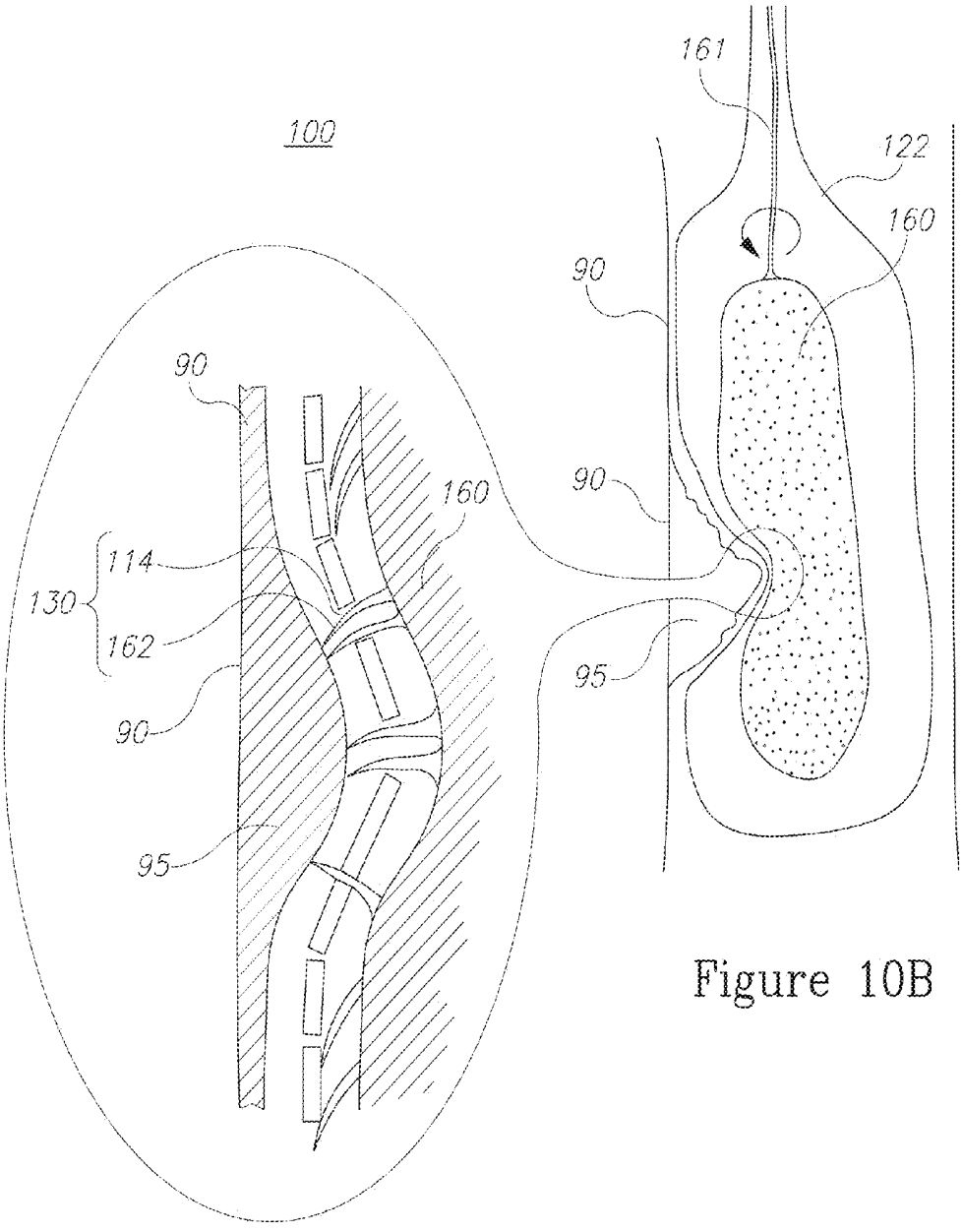

Figure 10A

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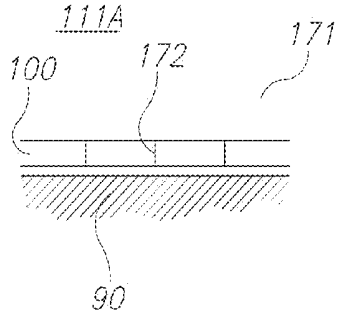

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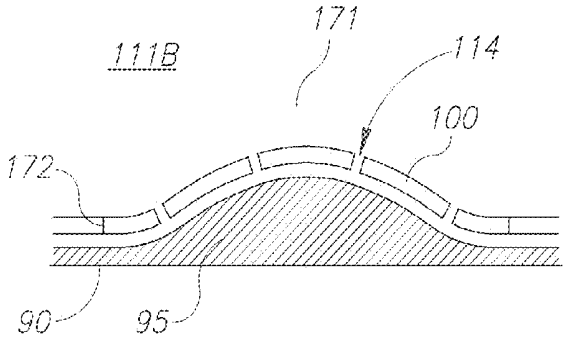

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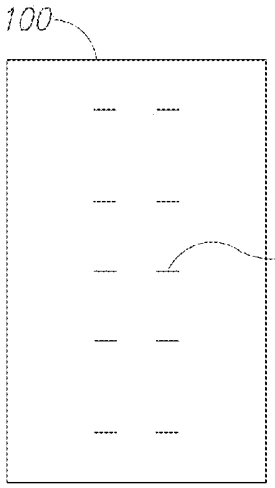

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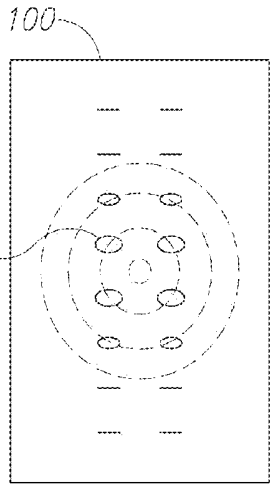

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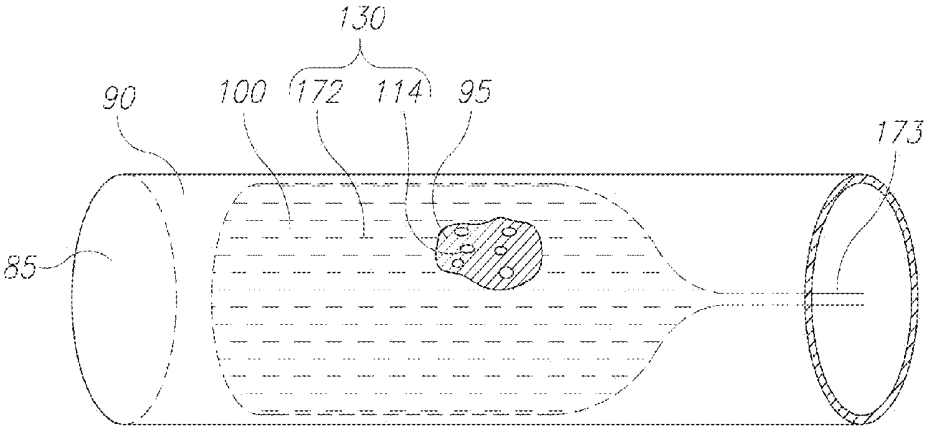

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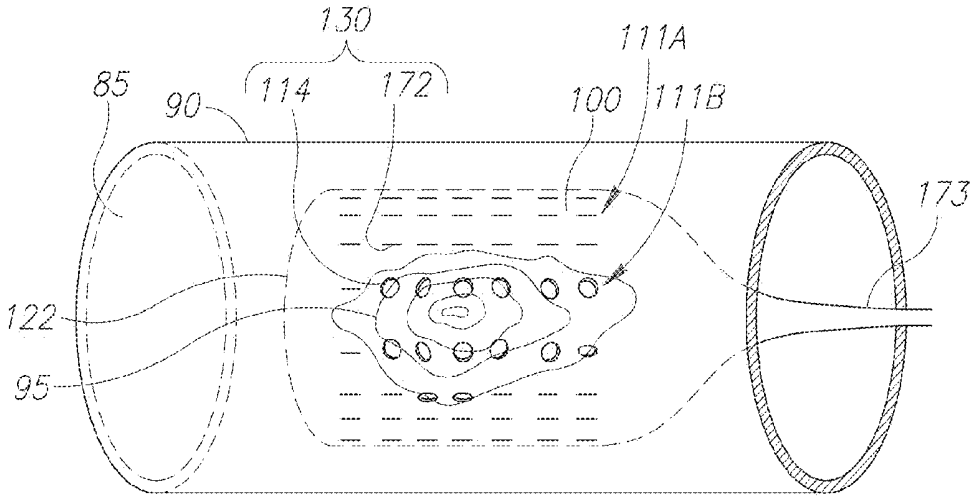

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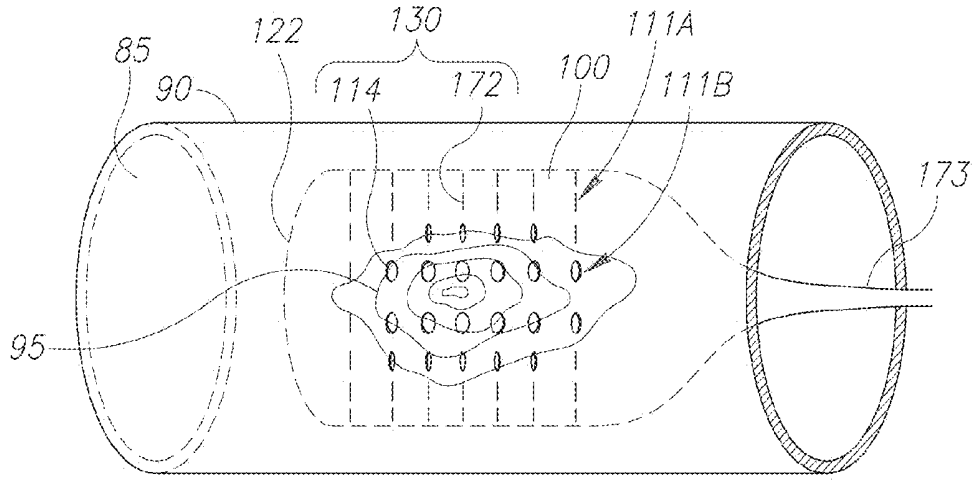

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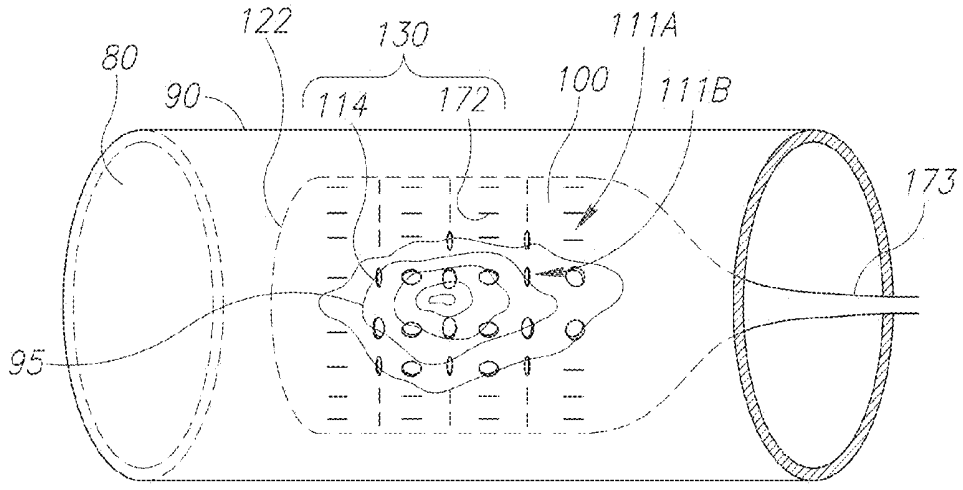

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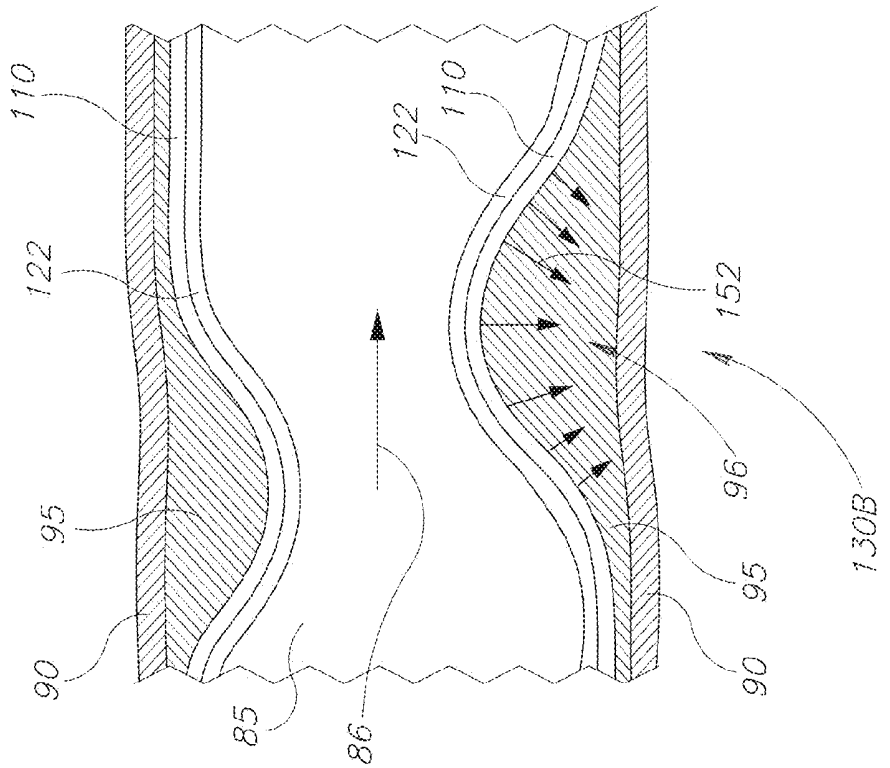

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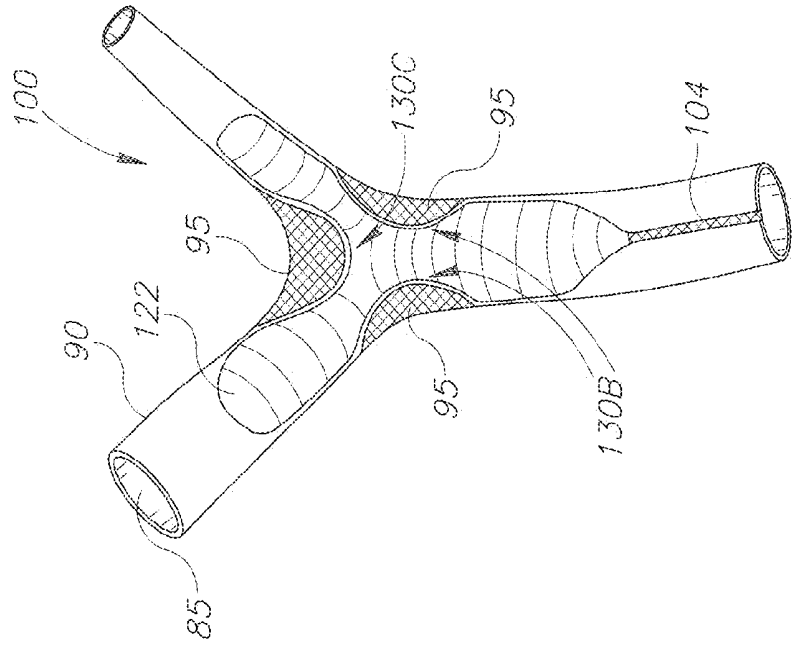

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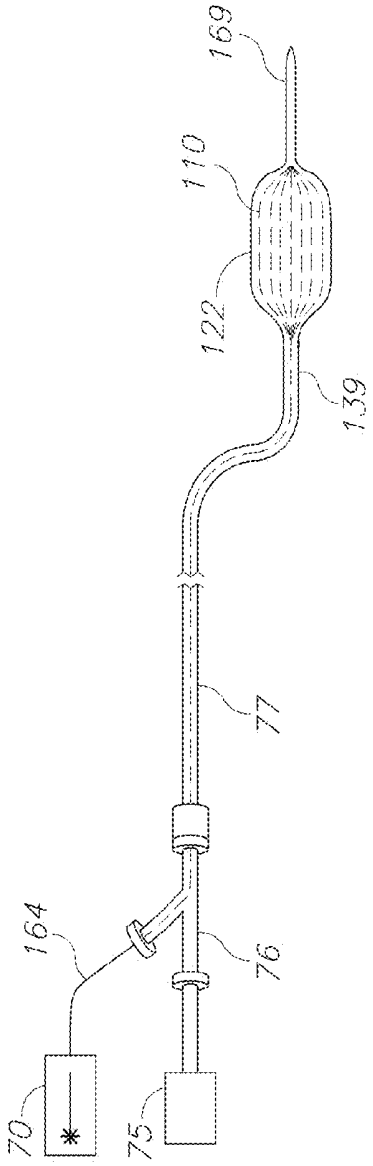

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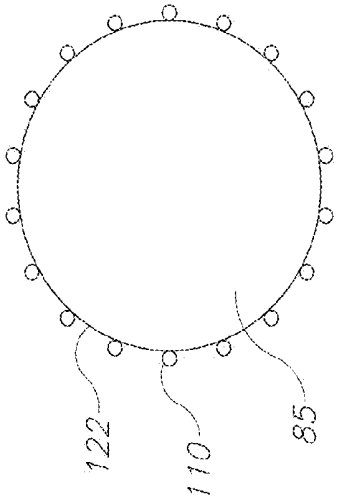

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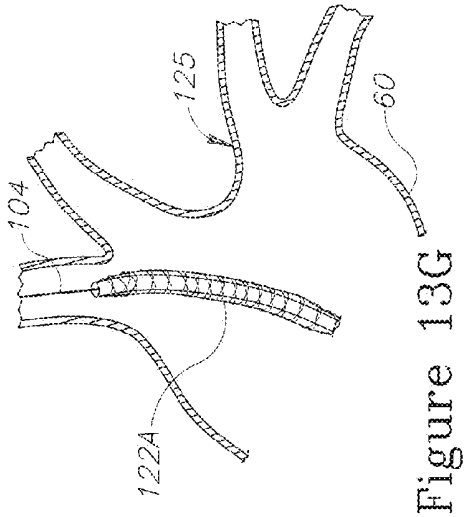

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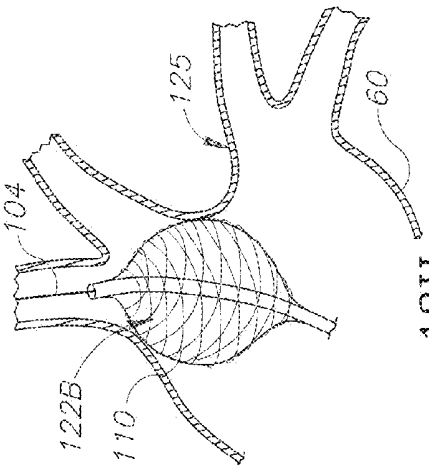
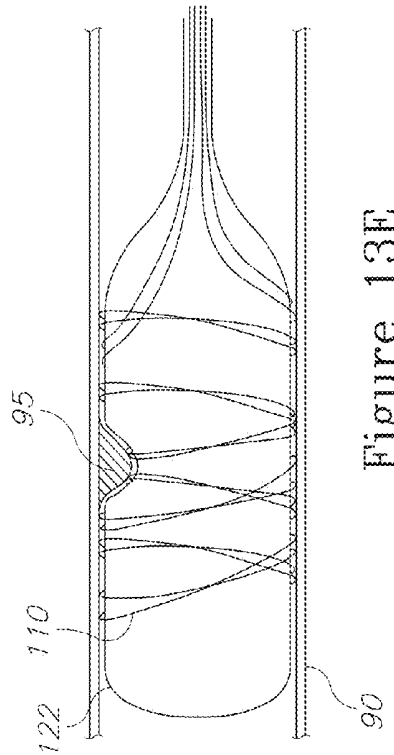


Figure 13H



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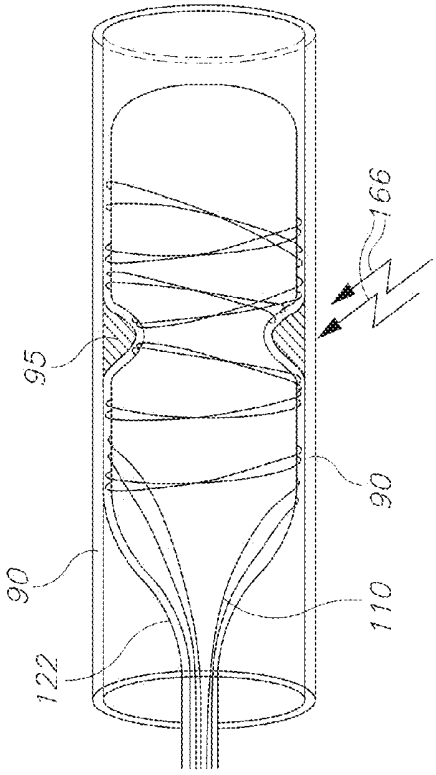

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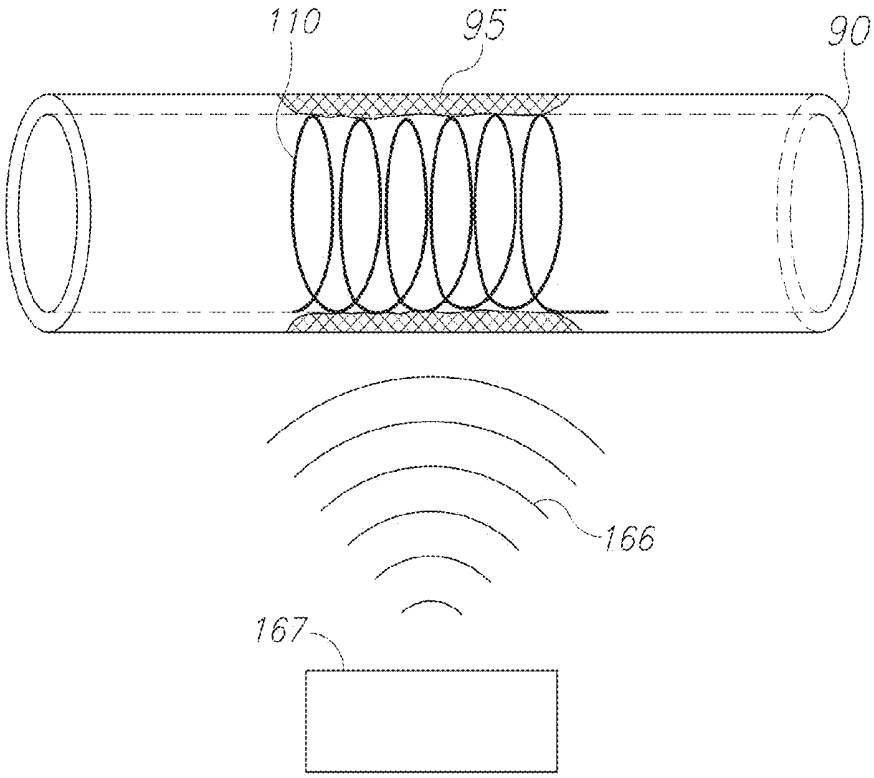

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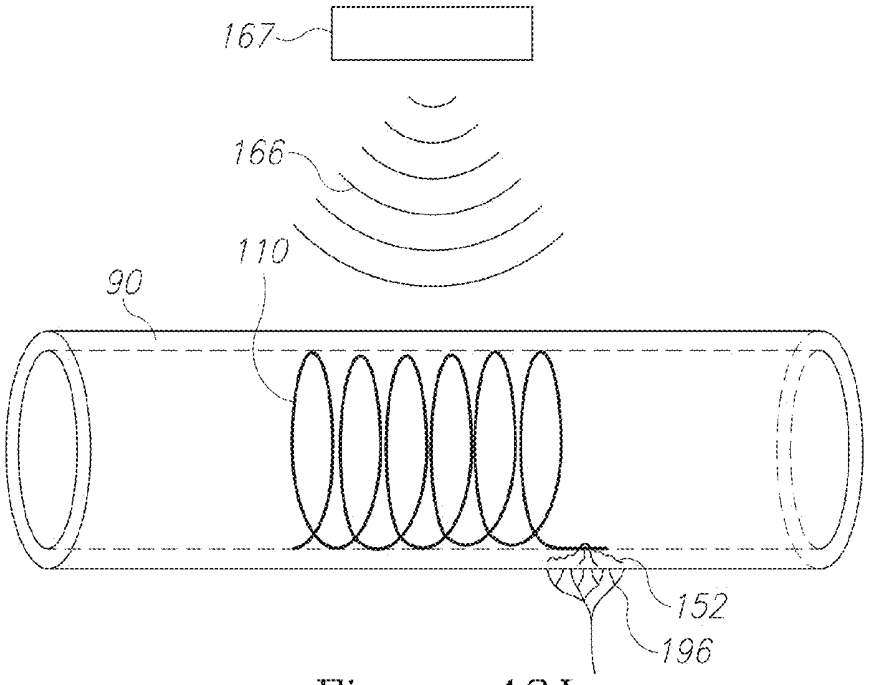

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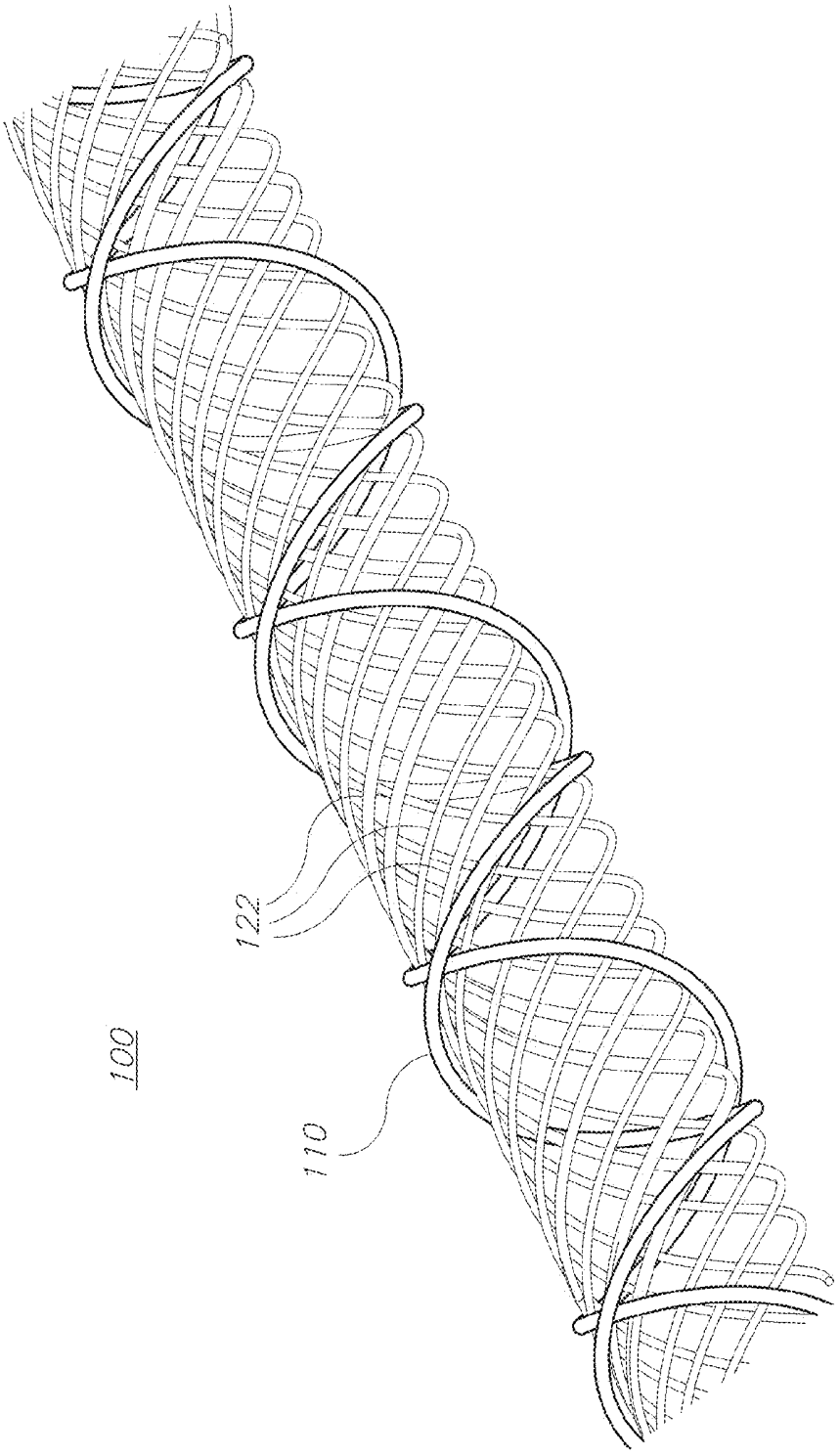

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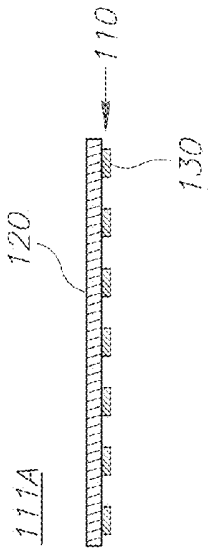
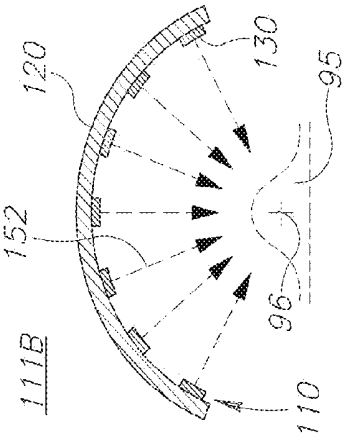


Figure 15A



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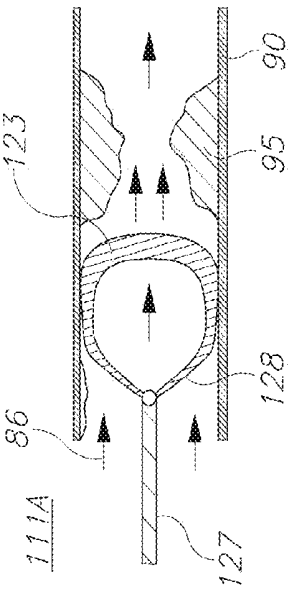

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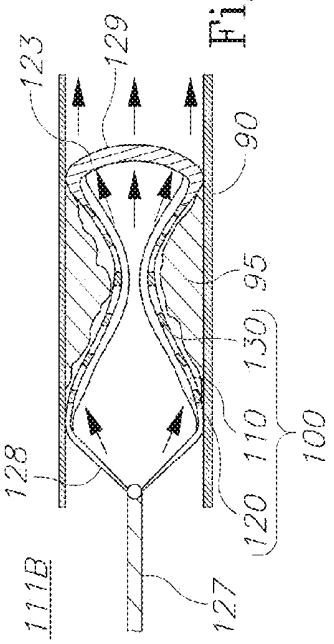

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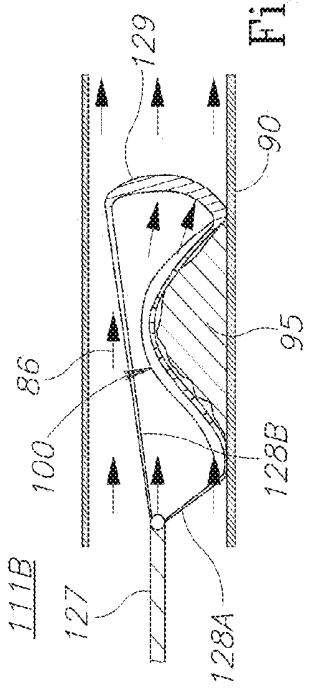

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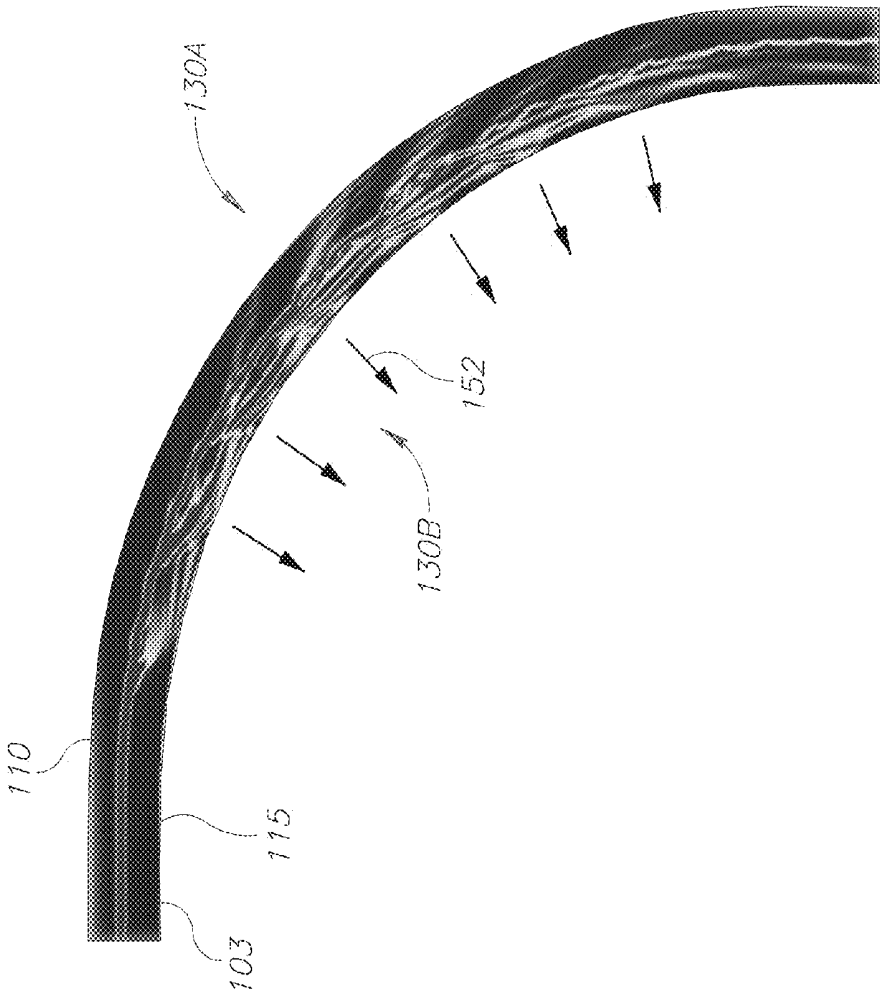

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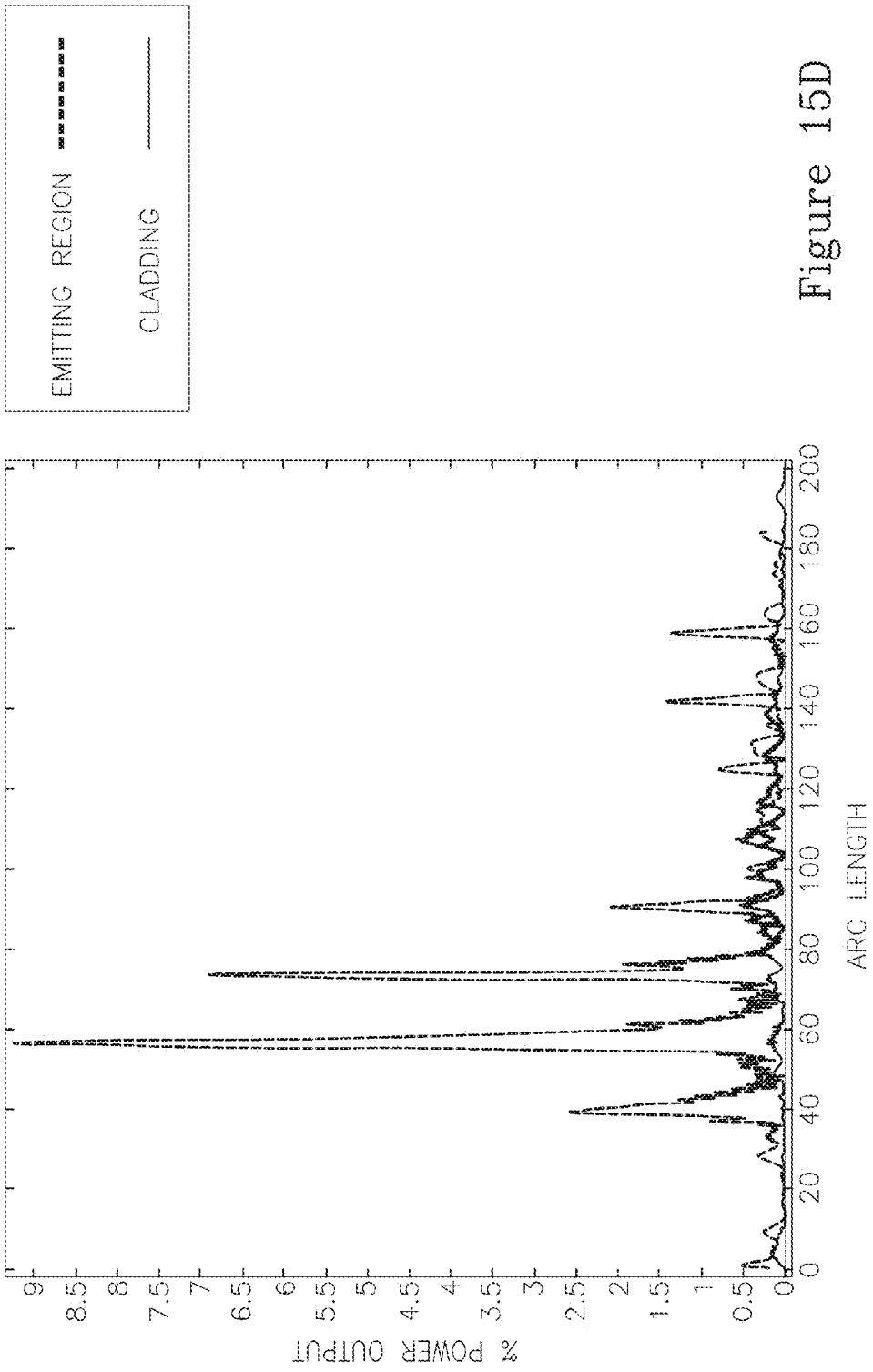
EMITTING REGION
CLADDING
% POWER OUTPUT
ARC LENGTH
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0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
5.5
6
6.5
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200

Figure 15D

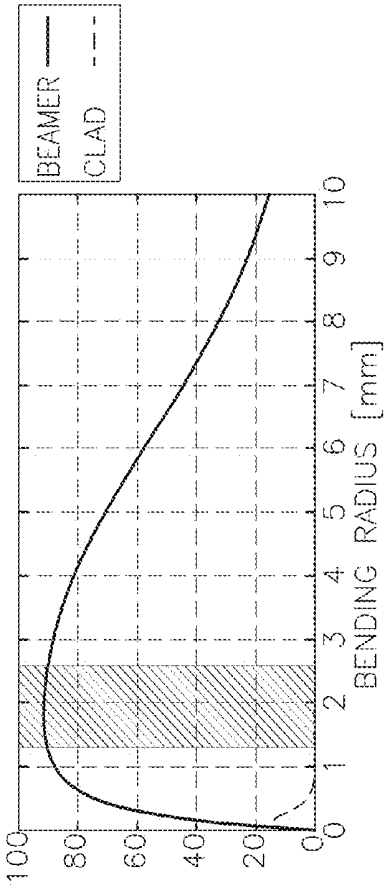
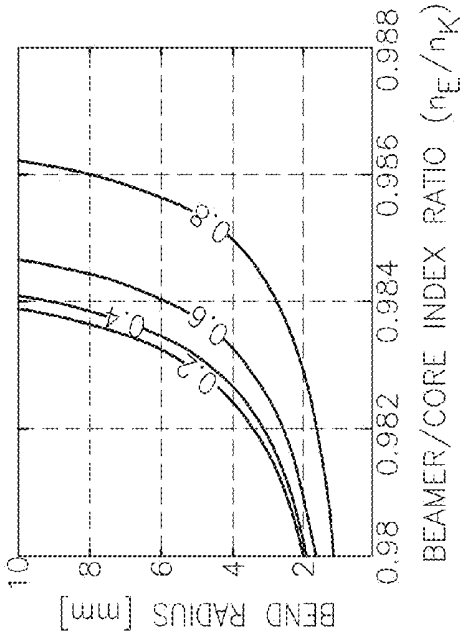


Figure 16B



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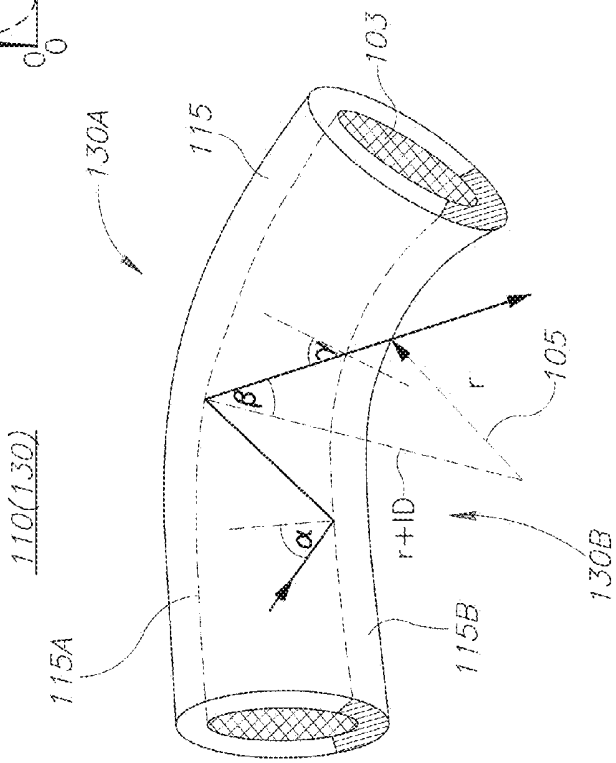
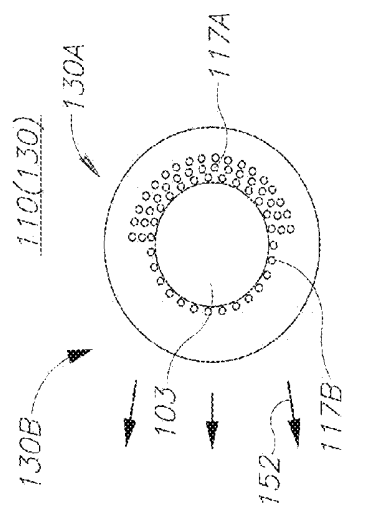


Figure 16A



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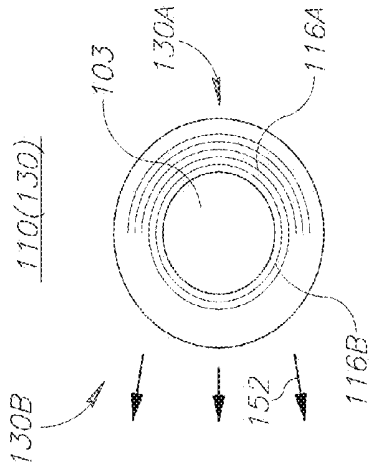

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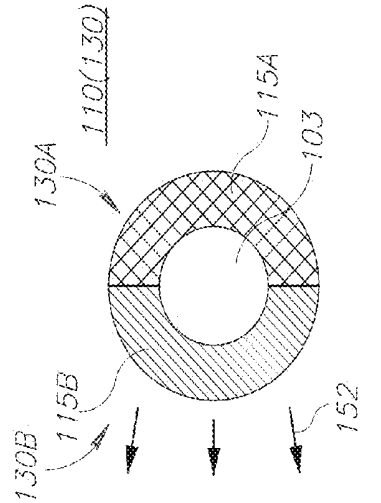


Figure 17A

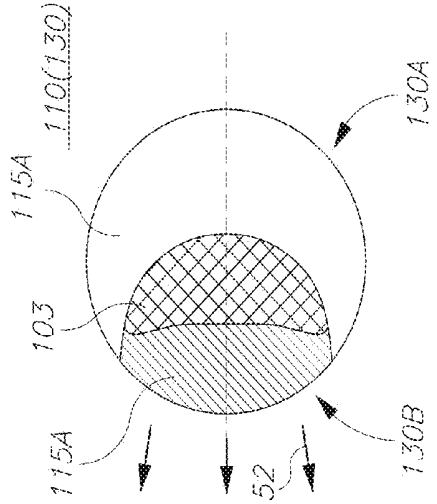


Figure 17F

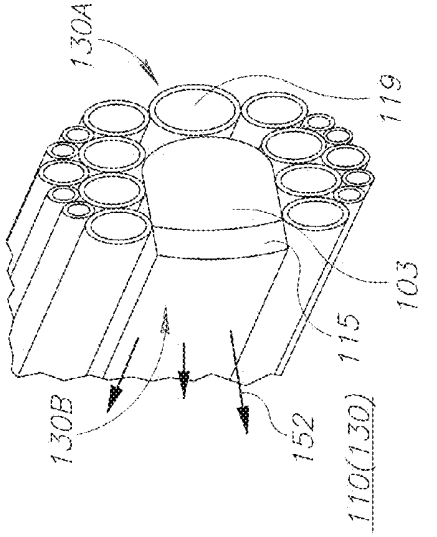


Figure 17E

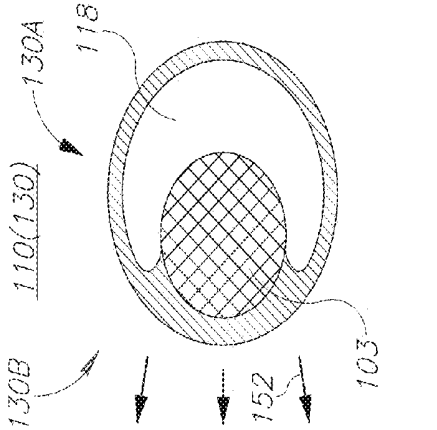


Figure 17D

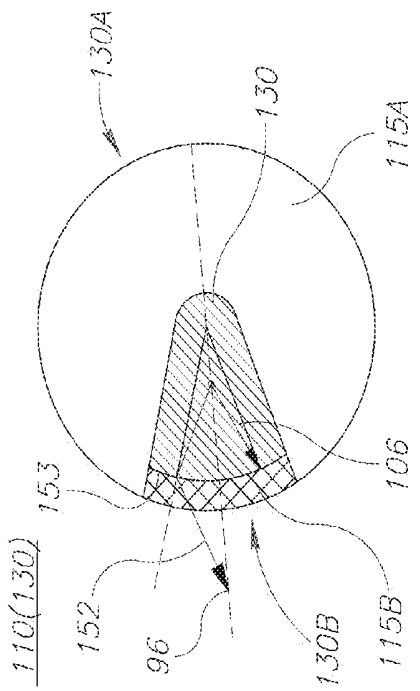


Figure 17I

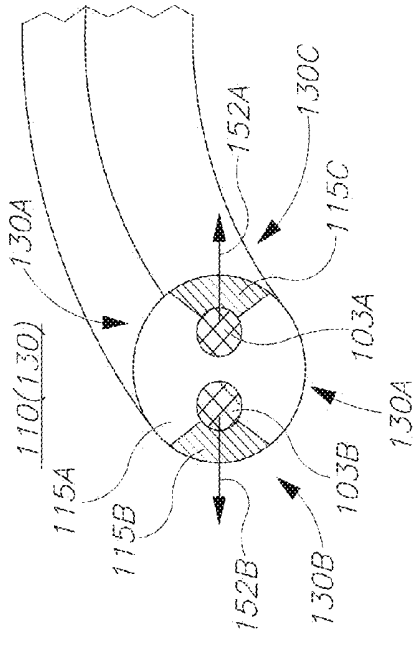


Figure 17G

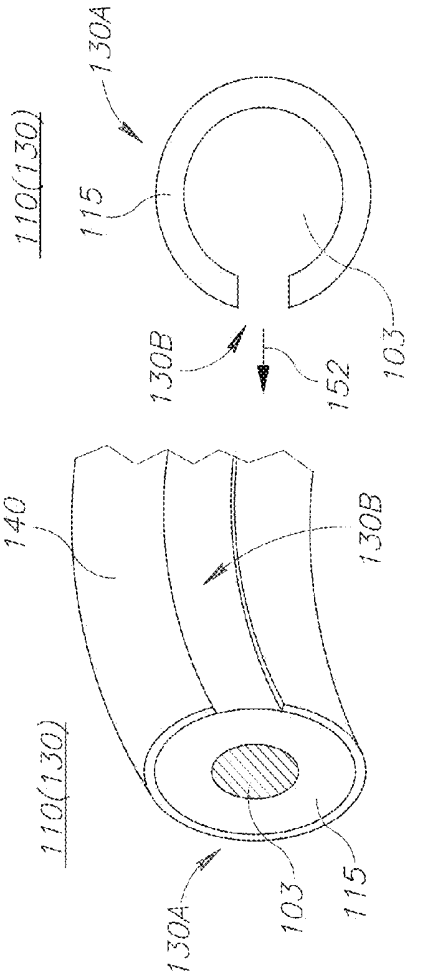


Figure 17J Figure 17K

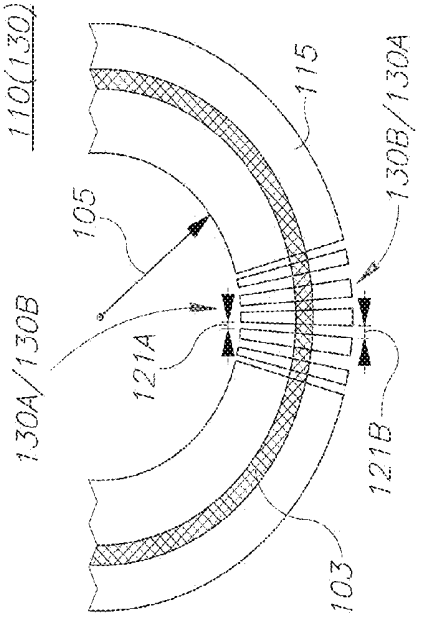


Figure 17H

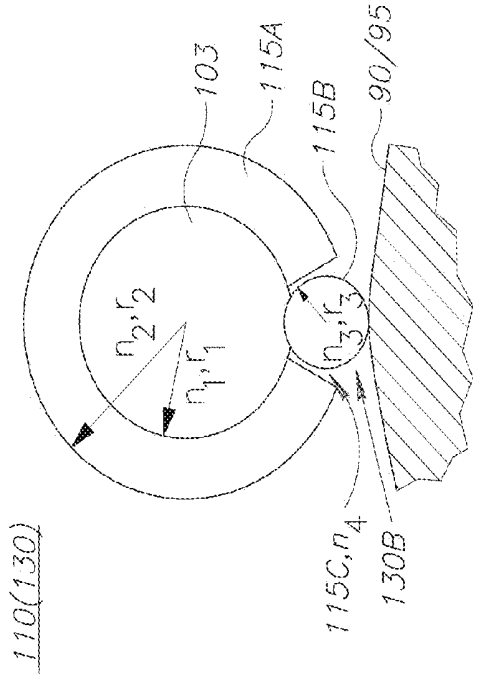


Figure 17L

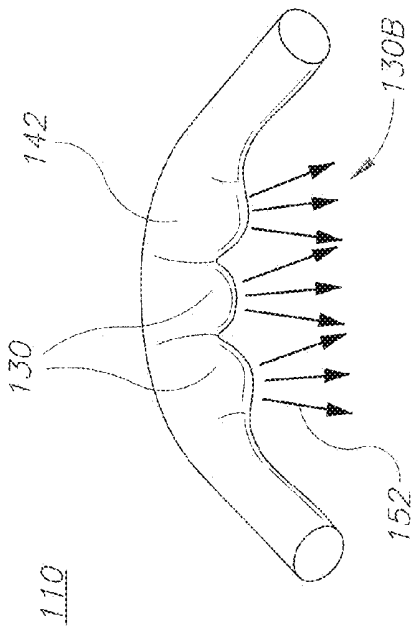


Figure 18B

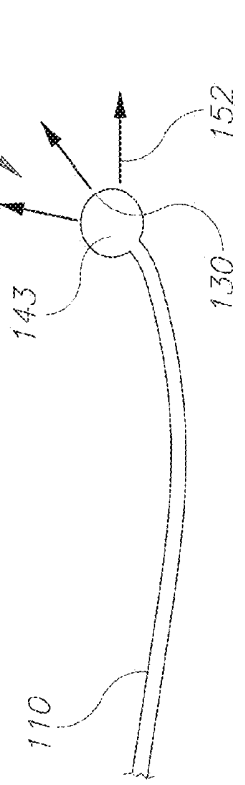


Figure 18C

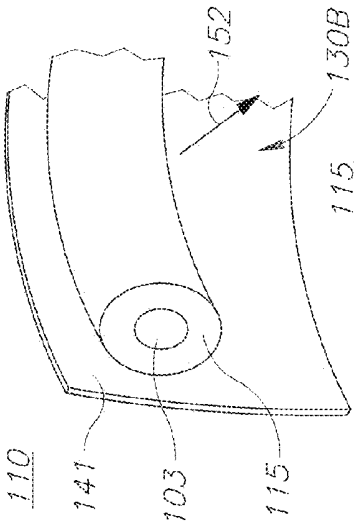
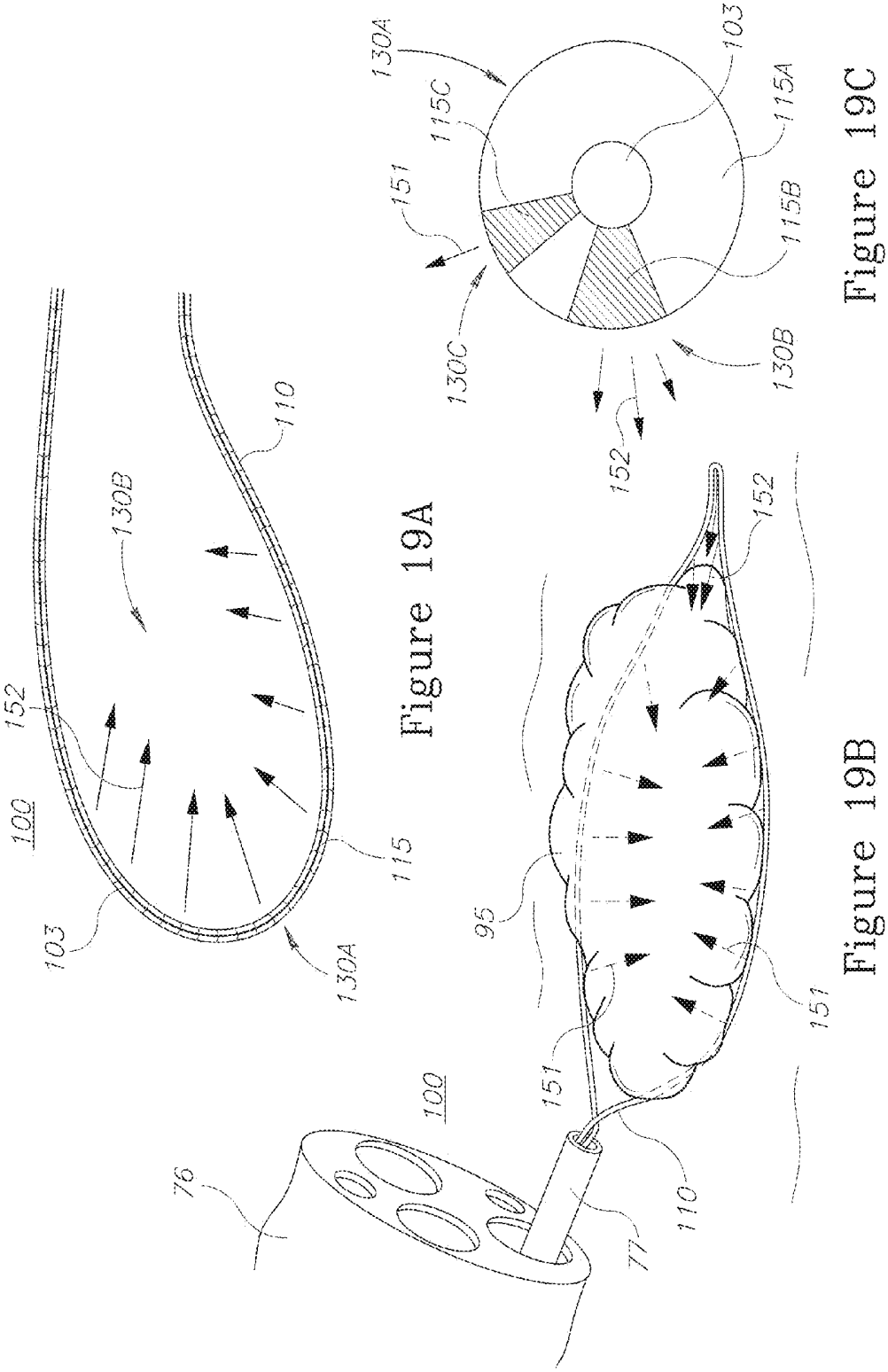


Figure 18A


130A
115C
103
115A
151
115B
130C
130B
152
110
130B
152
100
115
103
130A
Figure 19A
Figure 19C
152
95
151
100
151
110
76
77
Figure 19B

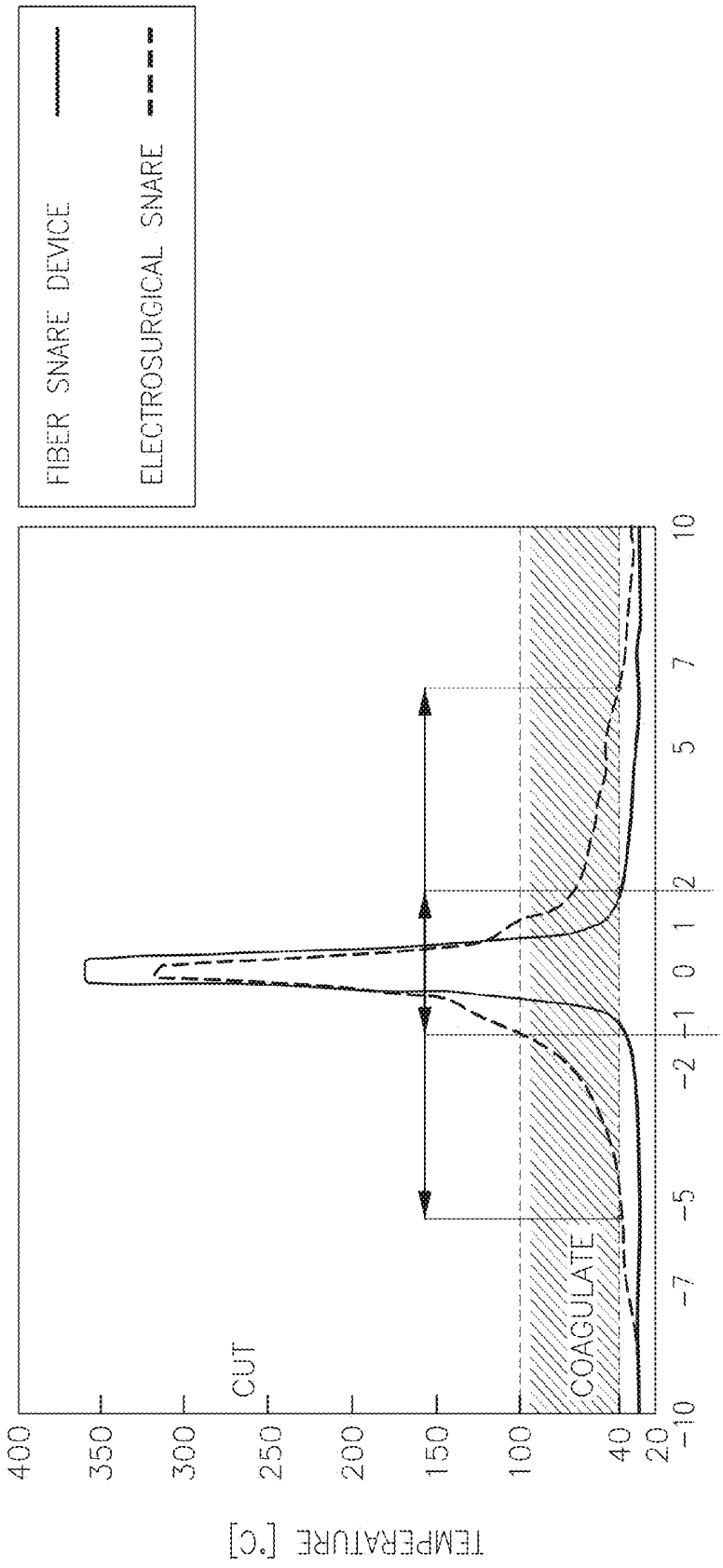

FIBER SNARE DEVICE
ELECTROSURGICAL SNARE
TEMPERATURE [°C]
400
350
300
250
200
150
100
40
20
CUT
COAGULATE
-10
-7
-5
-2
-1
0
1
2
5
7
10
DISTANCE [mm]

Figure 19D

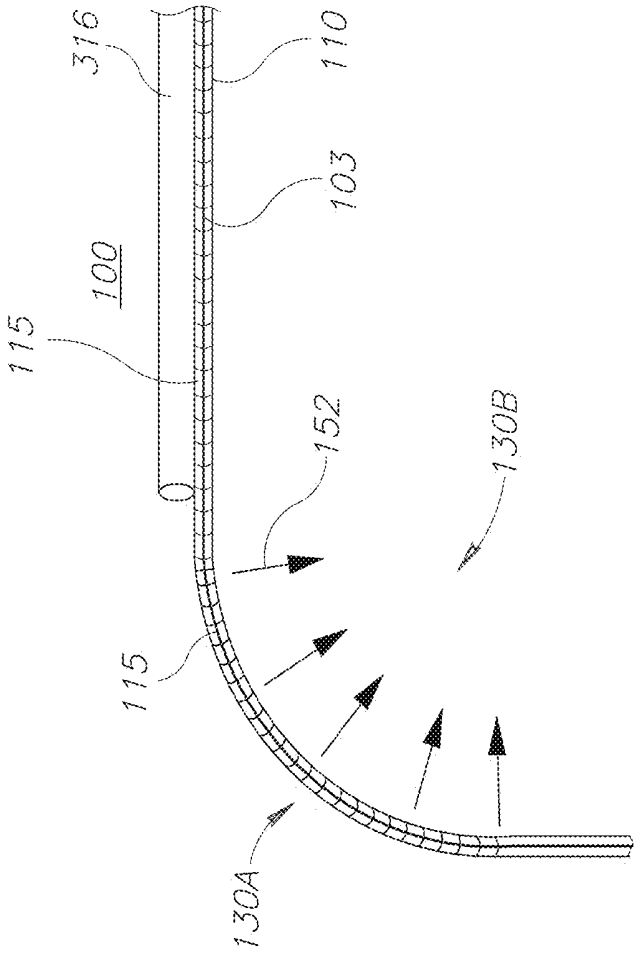


Figure 19E

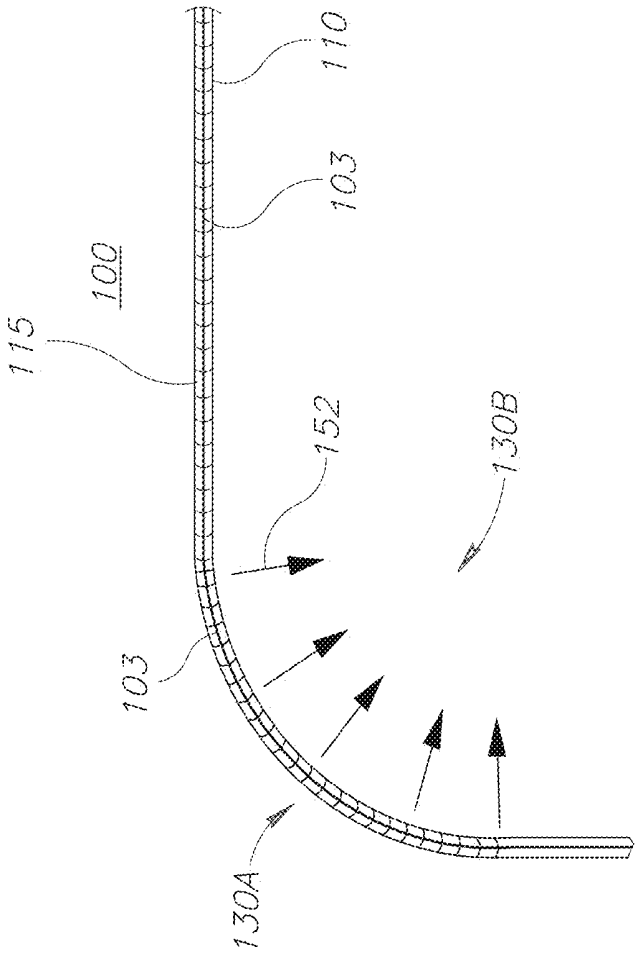


Figure 19F

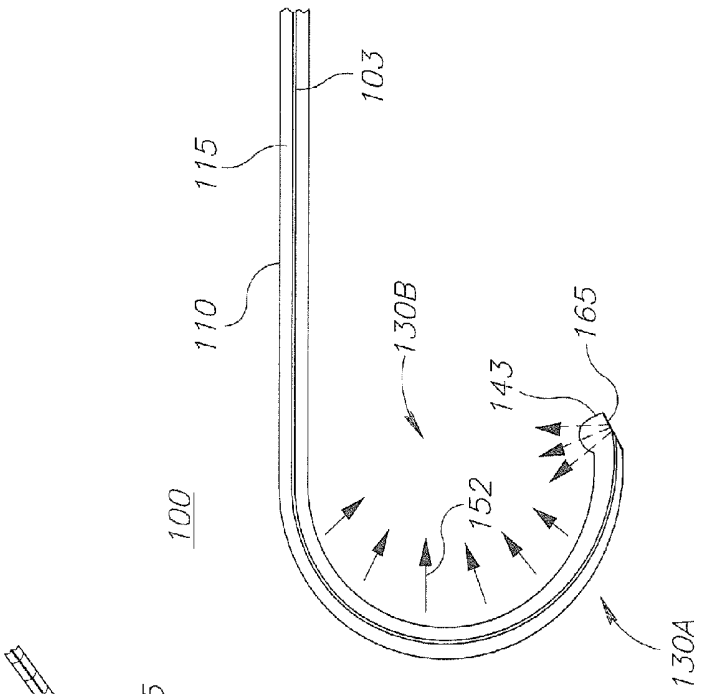


Figure 19H

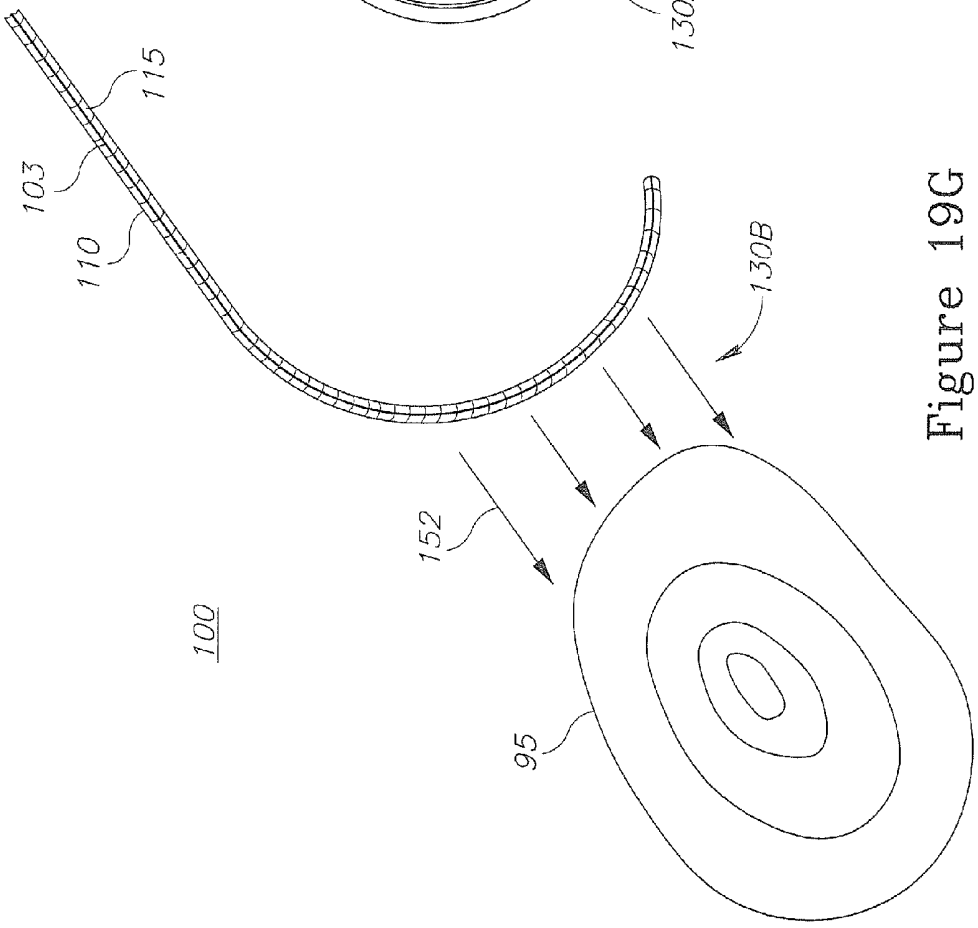


Figure 19G

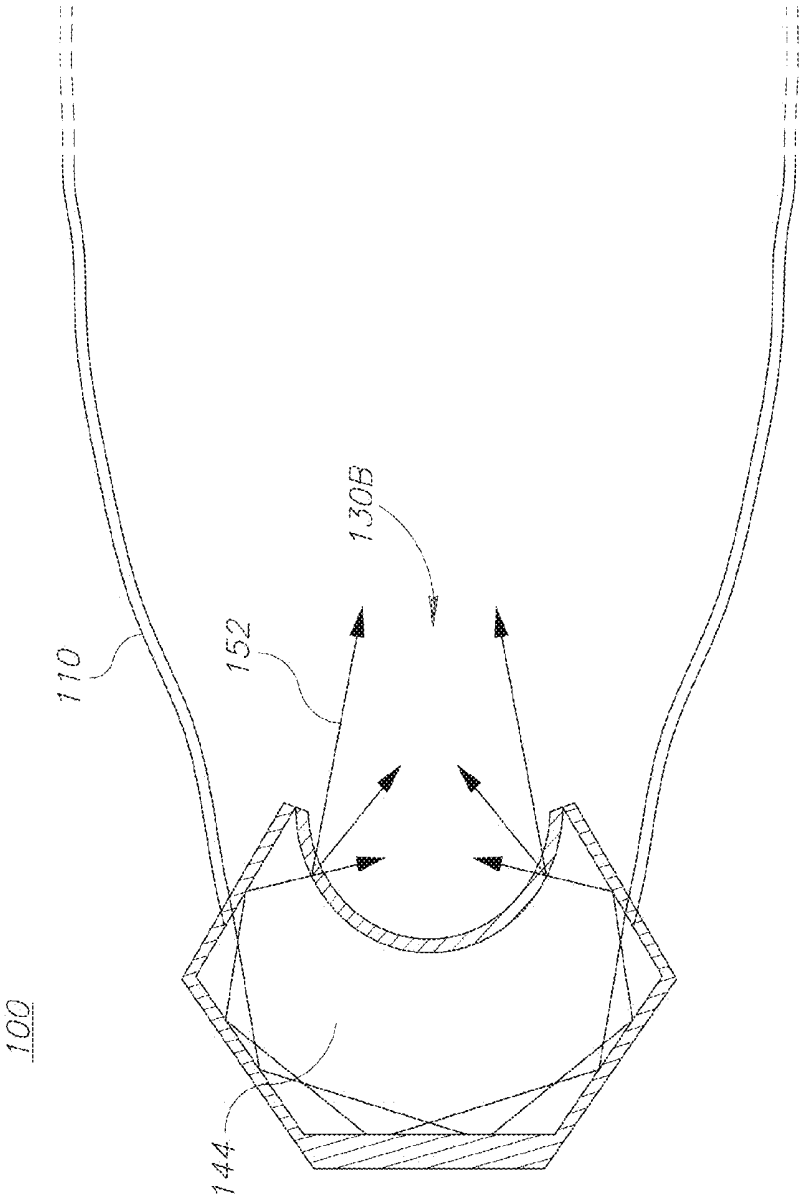


Figure 19I

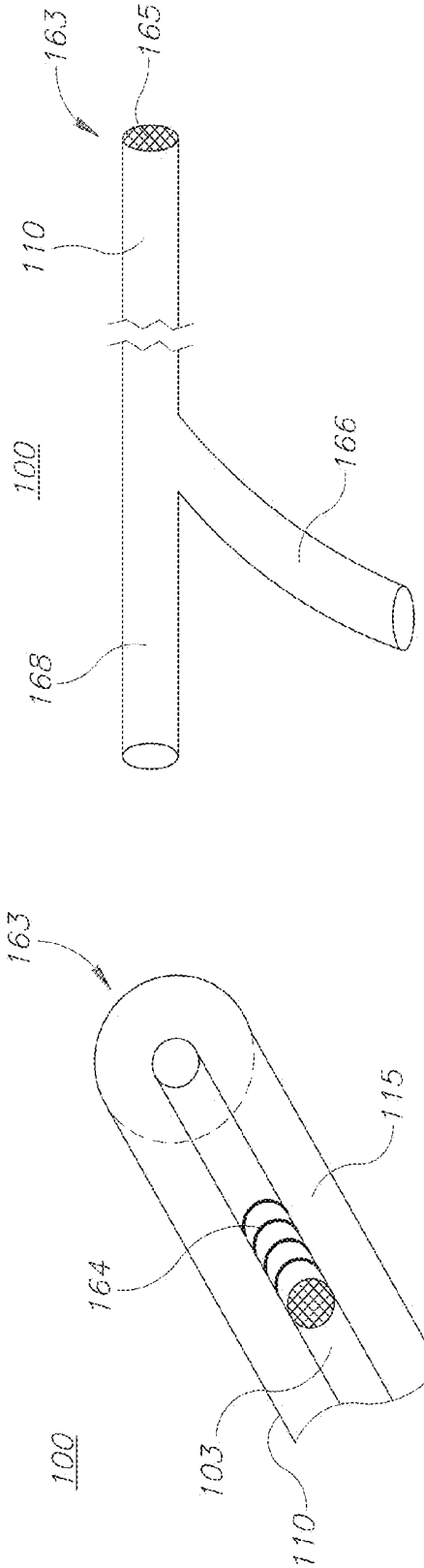


Figure 20A

Figure 20B

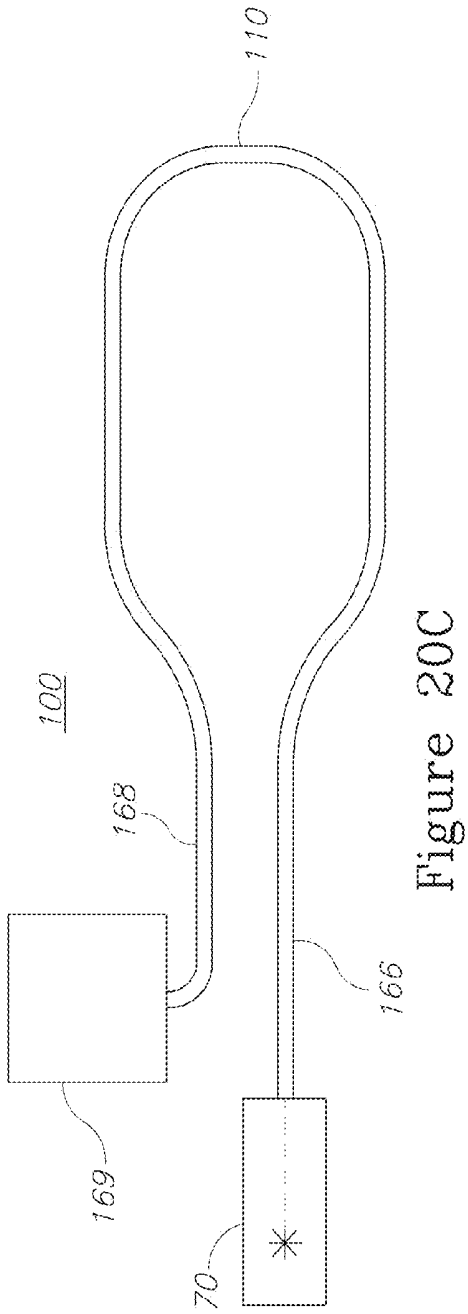


Figure 20C

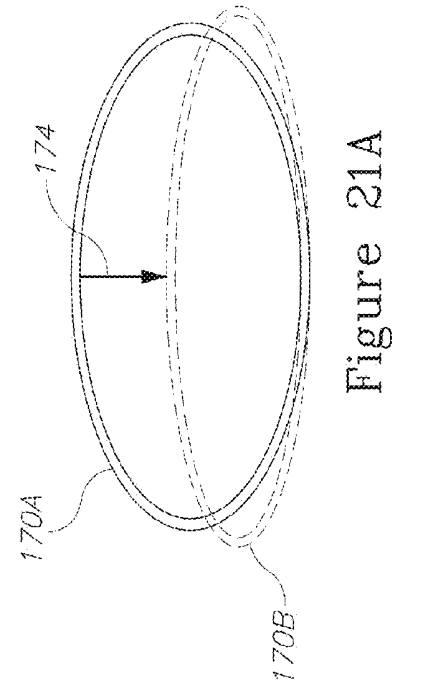


Figure 21A

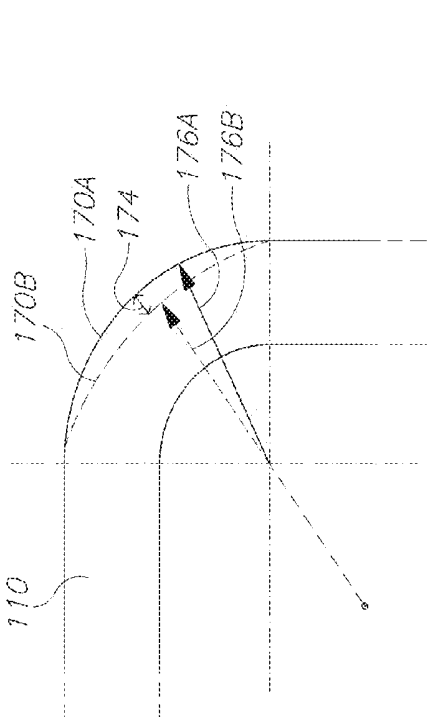


Figure 21C

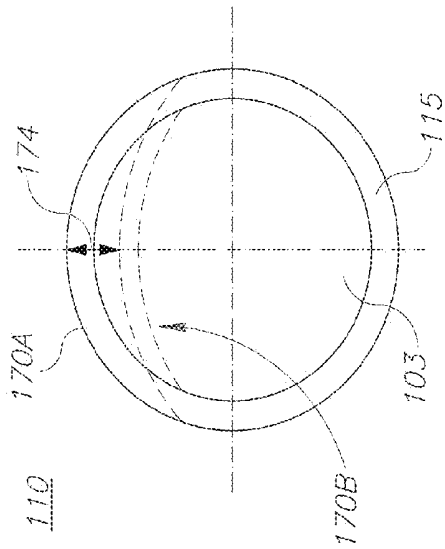


Figure 21B

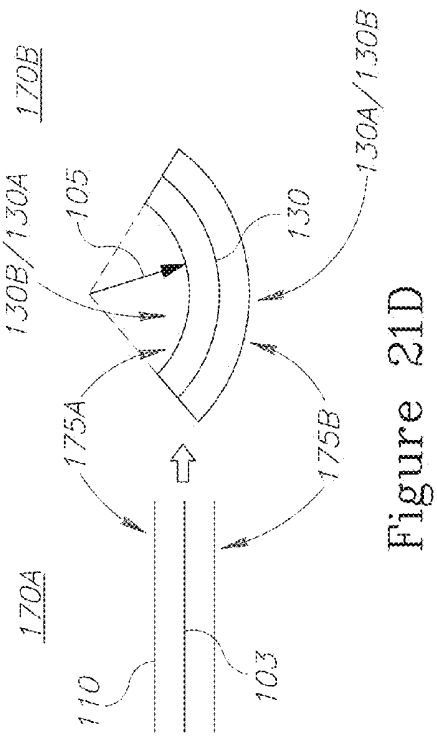


Figure 21D

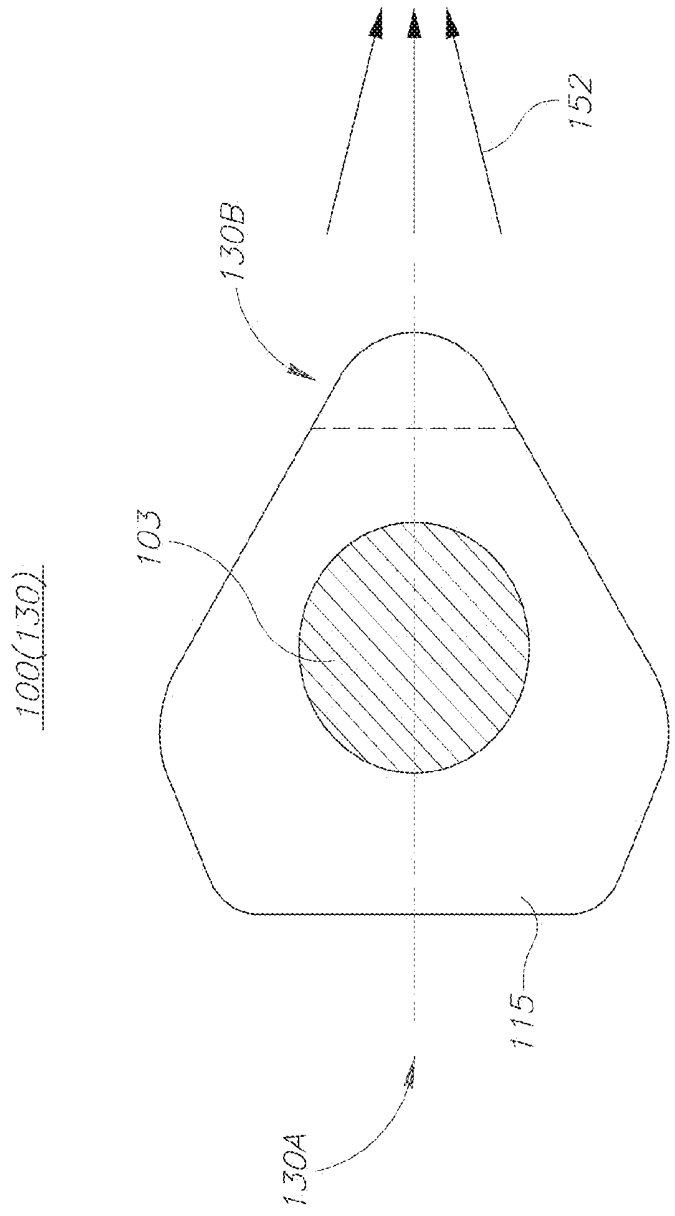


Figure 21E

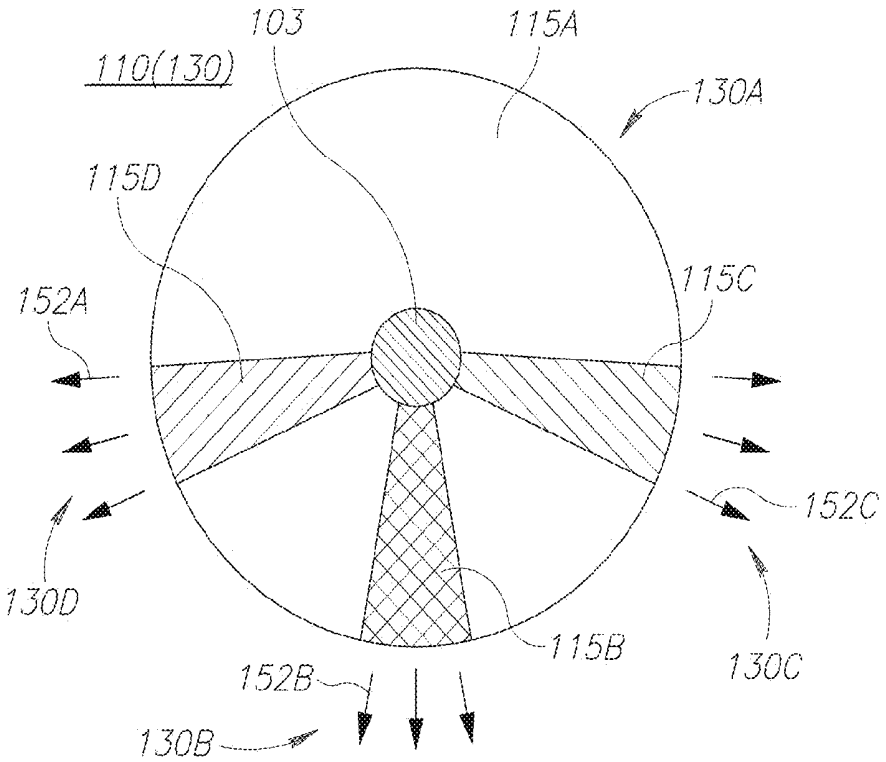


Figure 22A

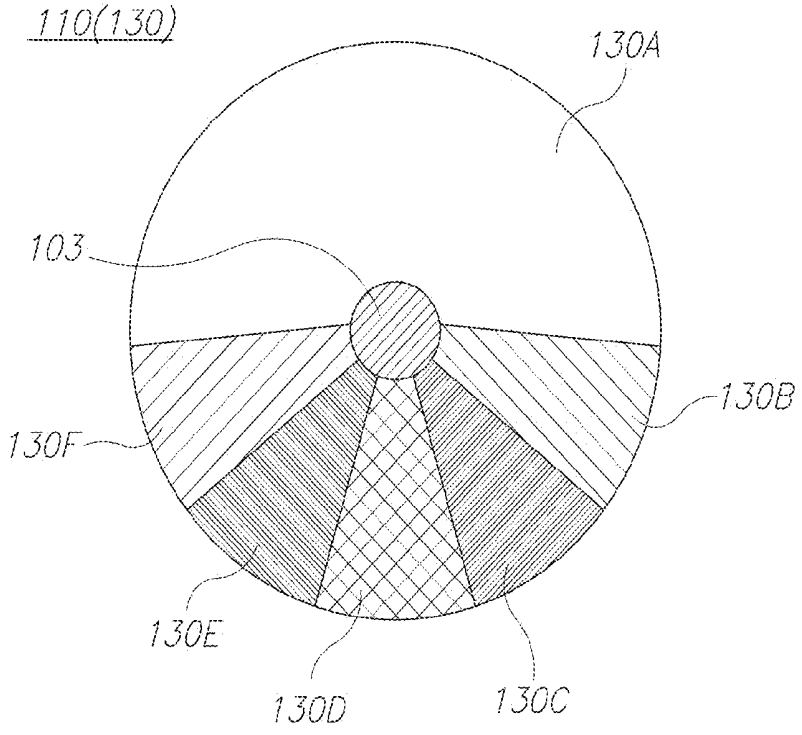


Figure 22B

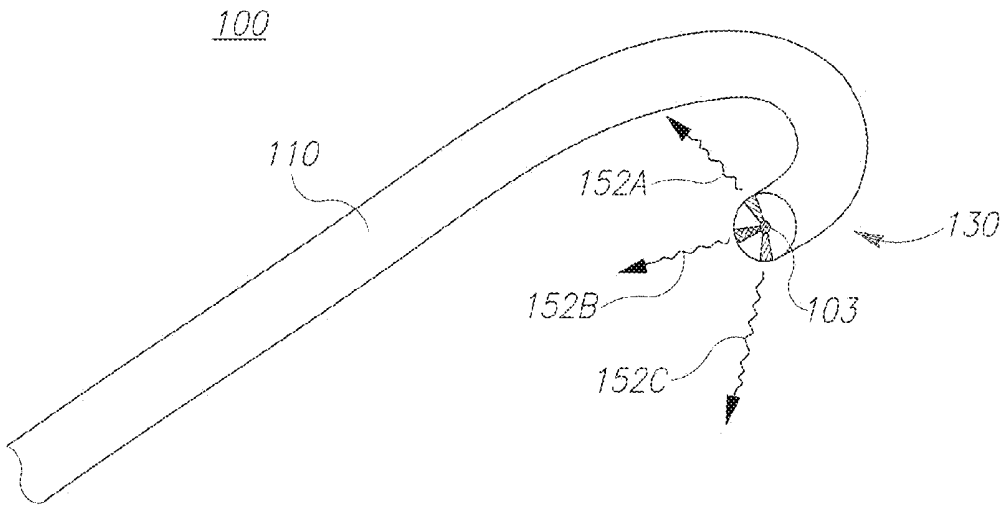


Figure 22C

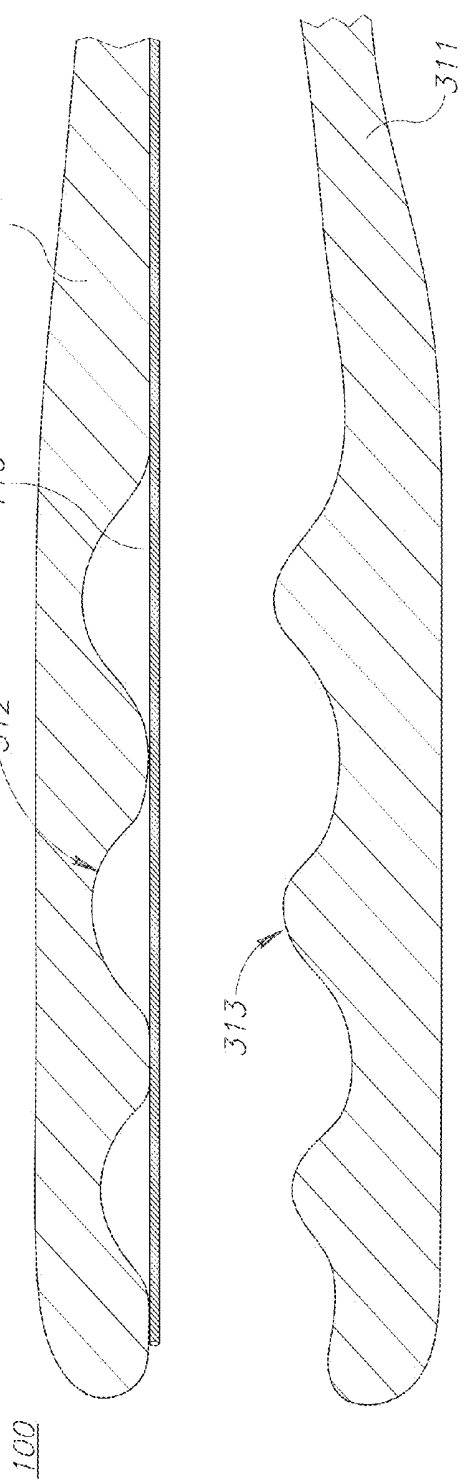


Figure 23A

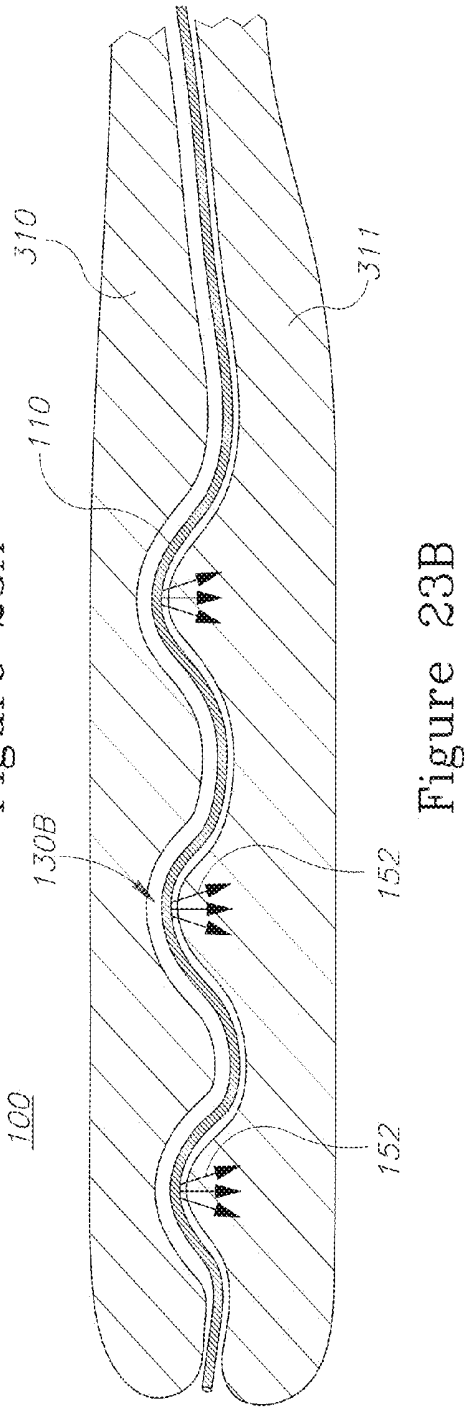


Figure 23B

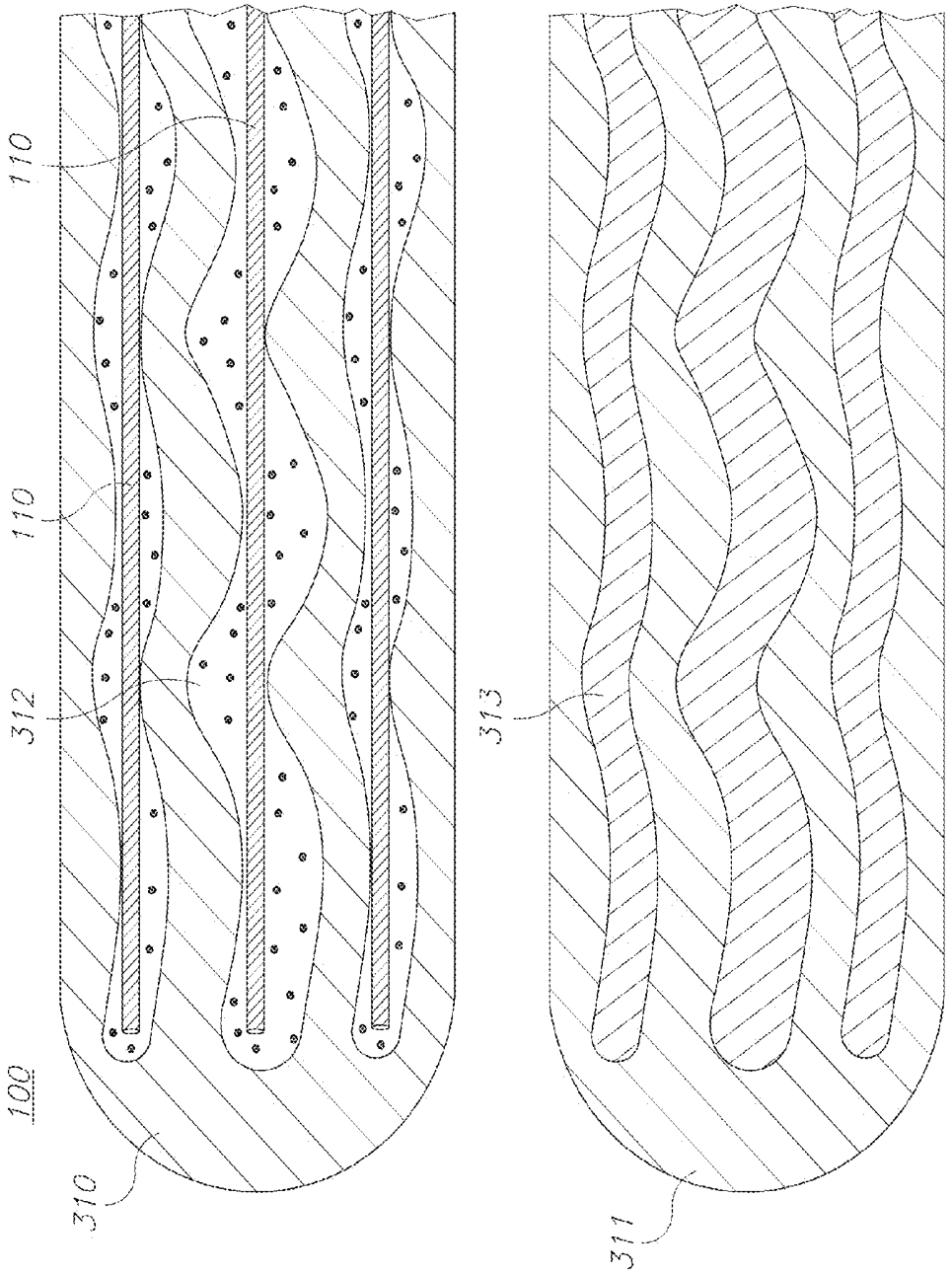


Figure 23C

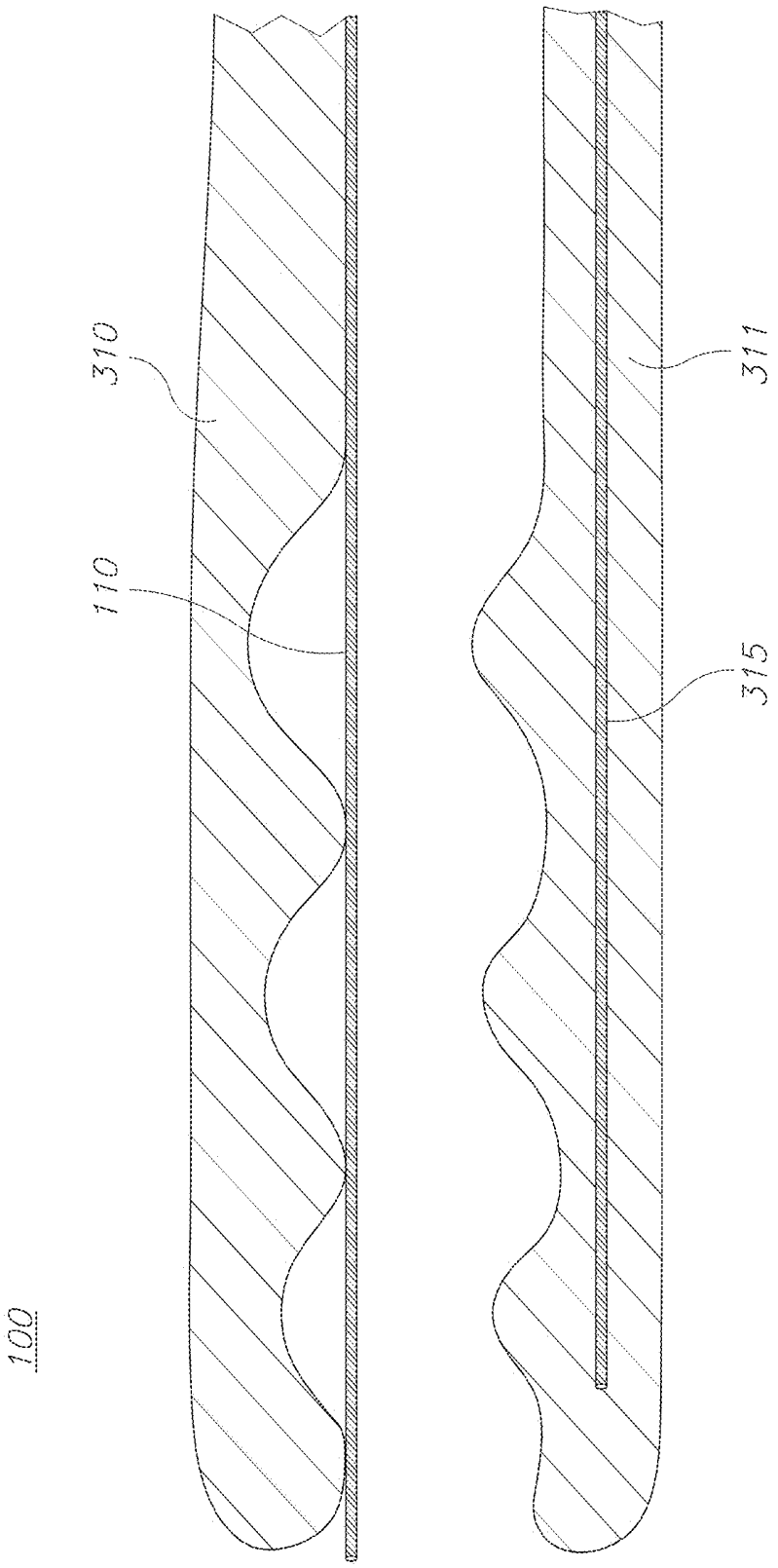


Figure 23D

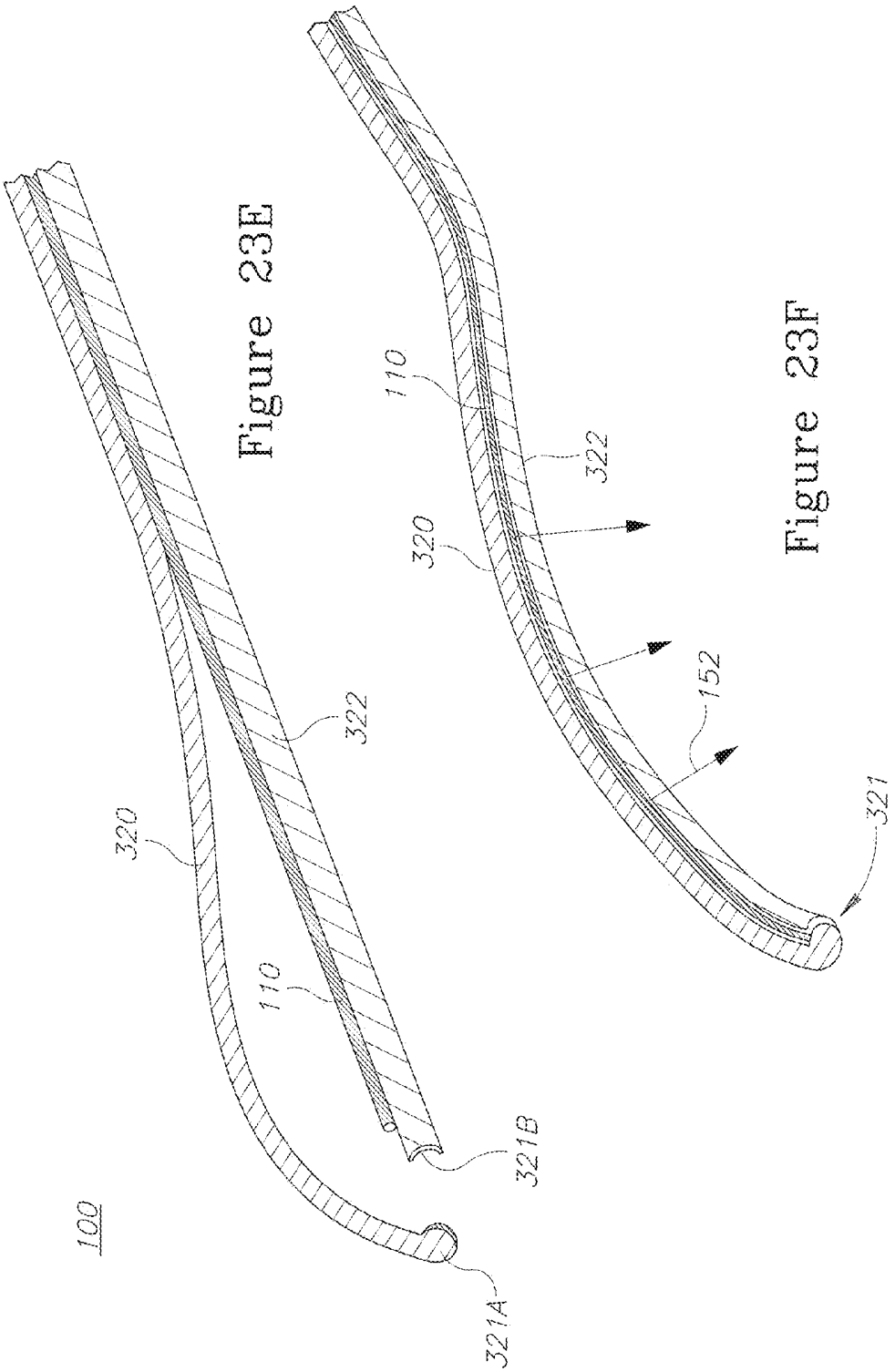


Figure 23E

Figure 23F

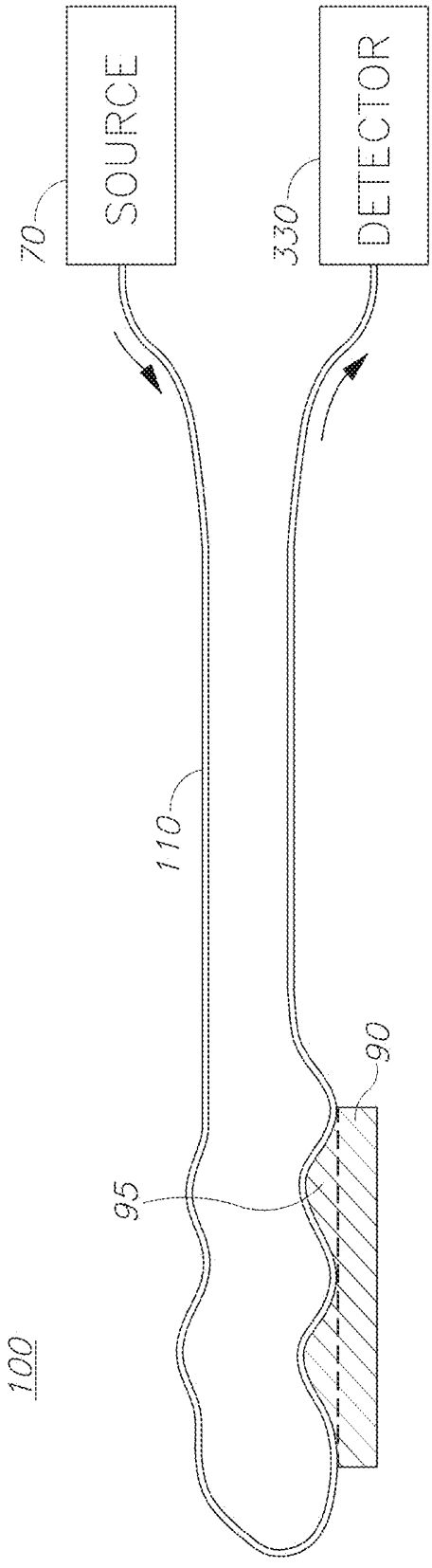


Figure 24A

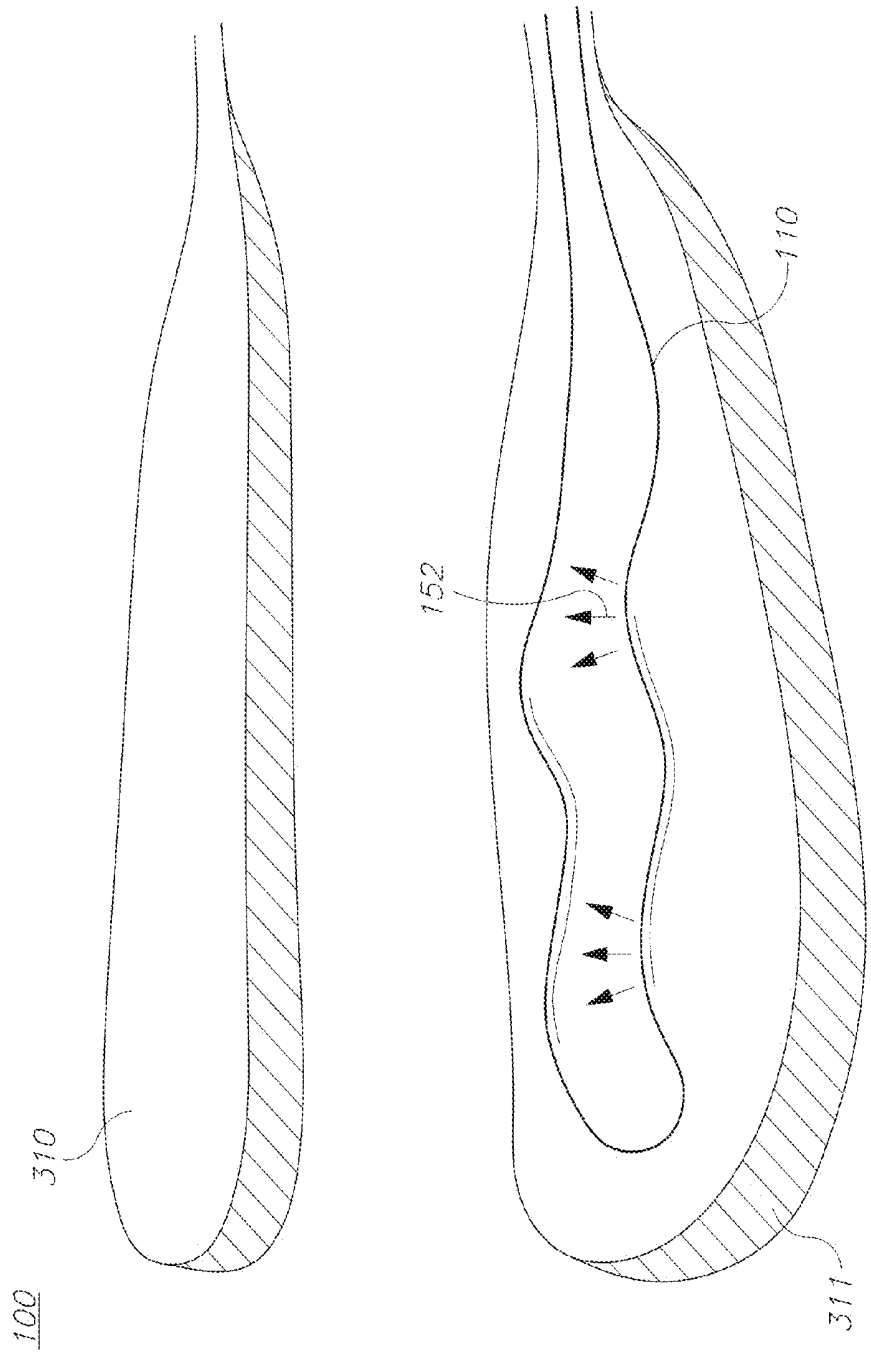


Figure 24B

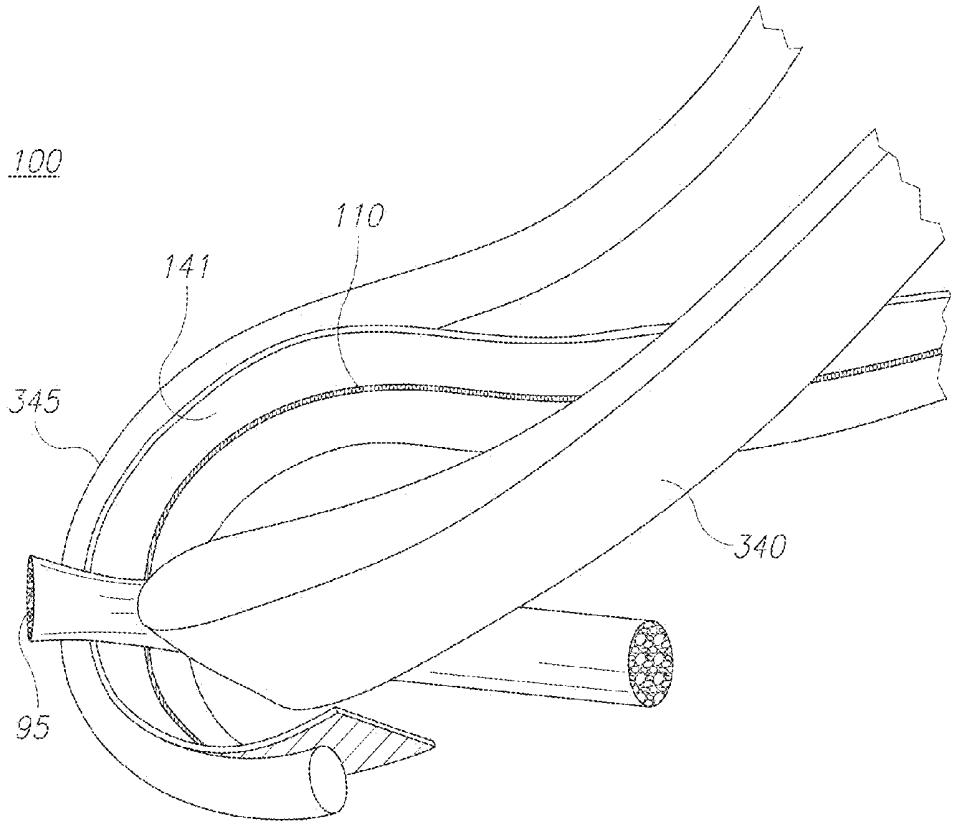


Figure 25

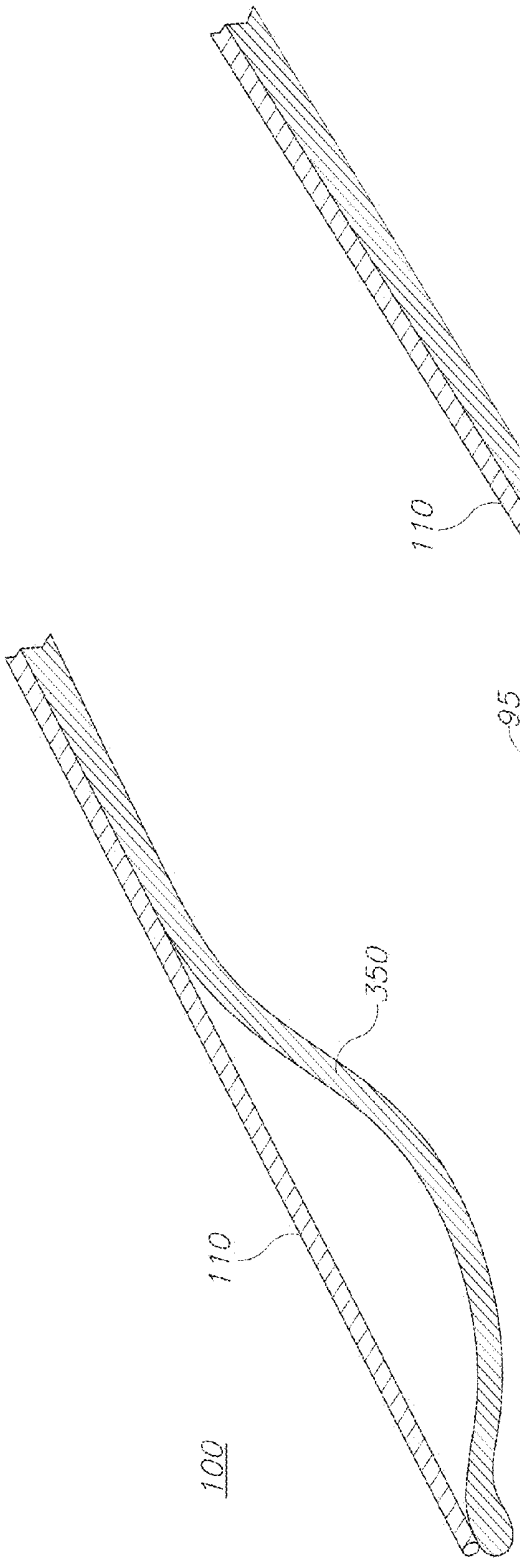


Figure 26A

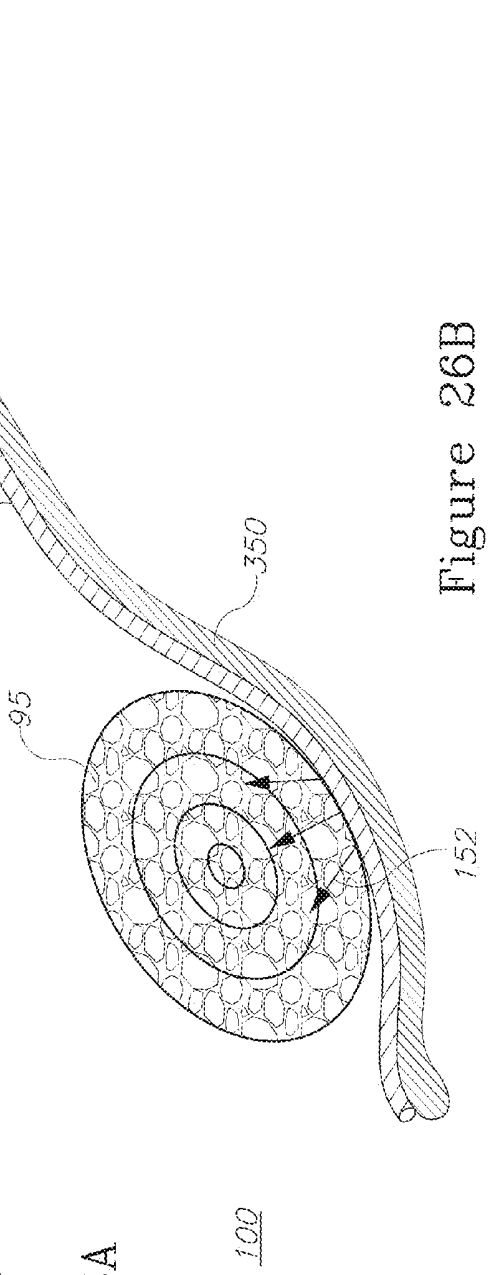


Figure 26B

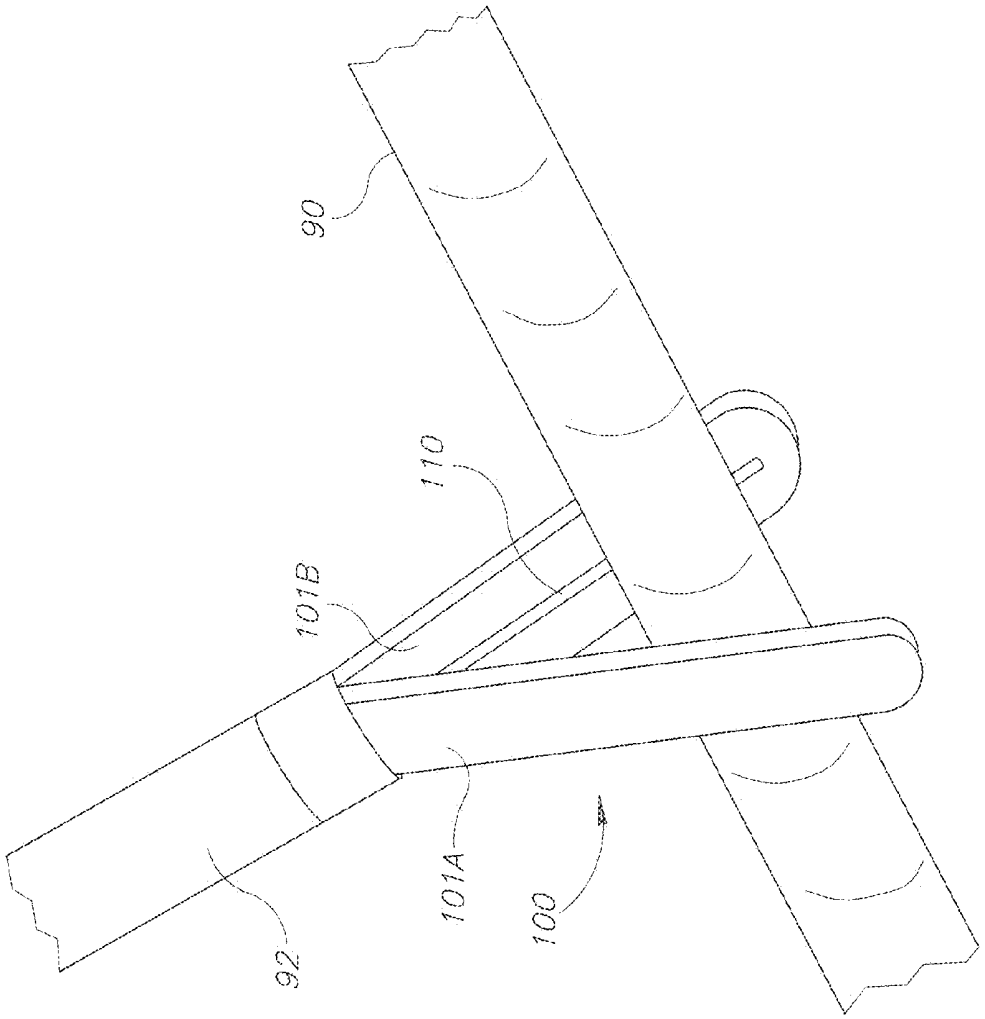


Figure 27A

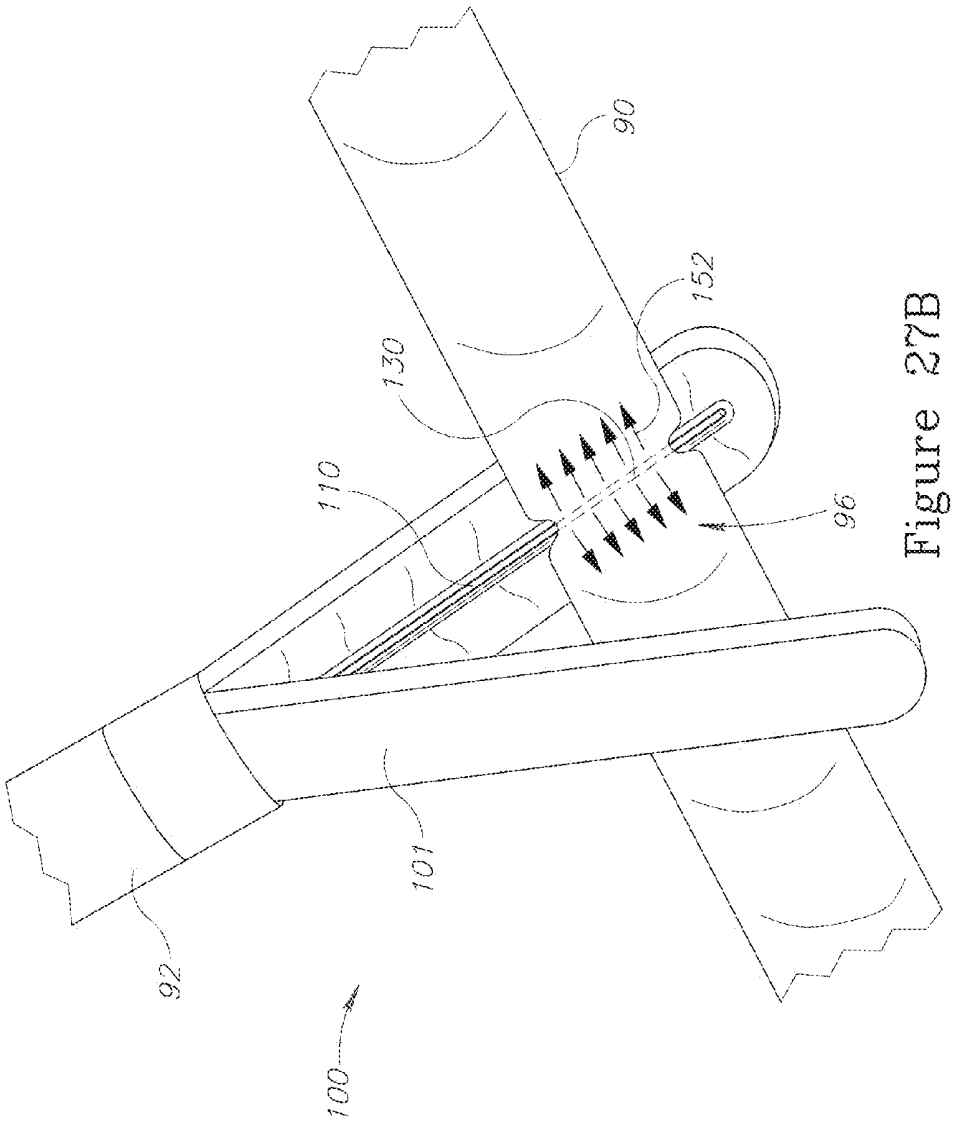


Figure 27B

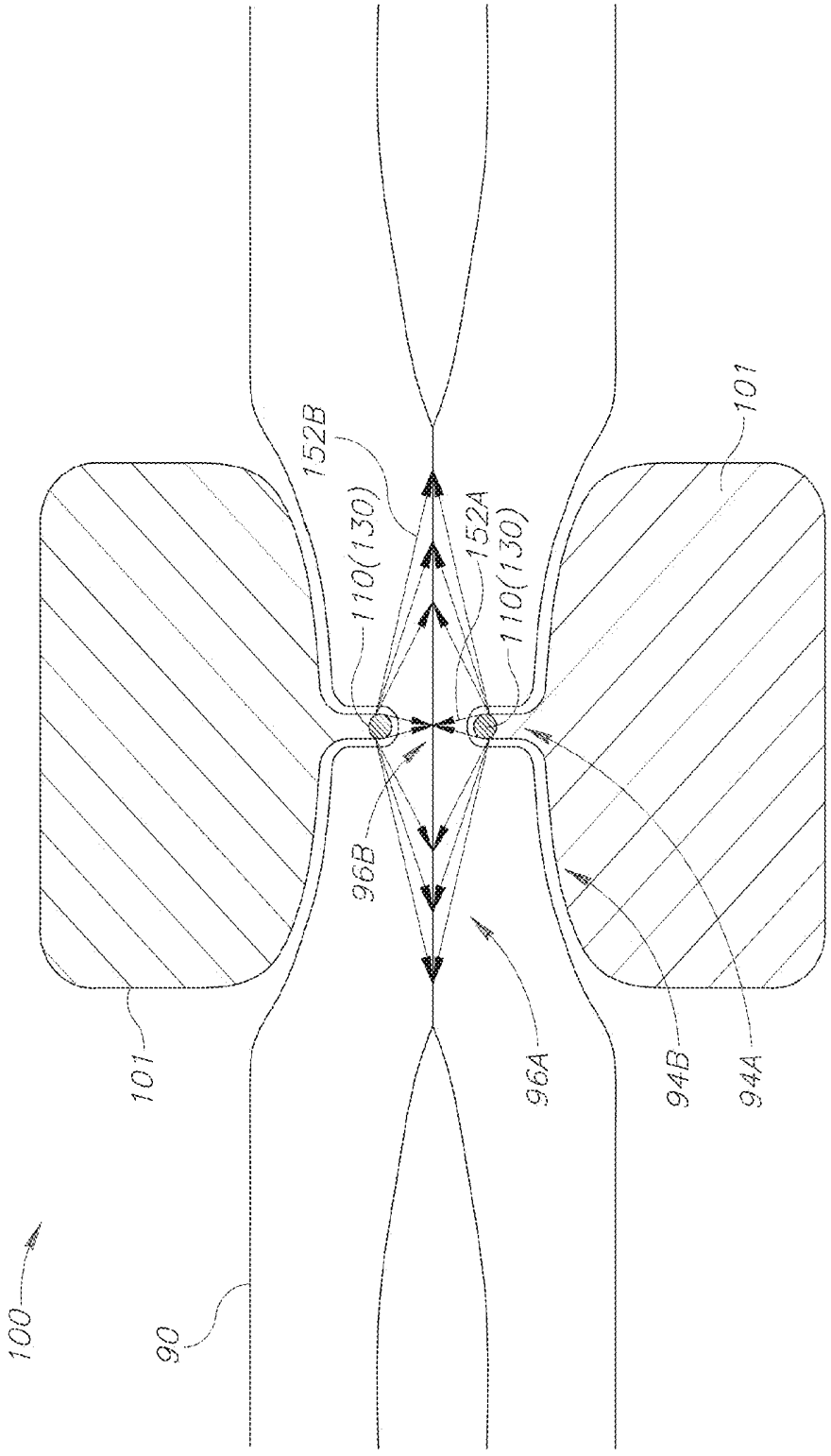


Figure 27C

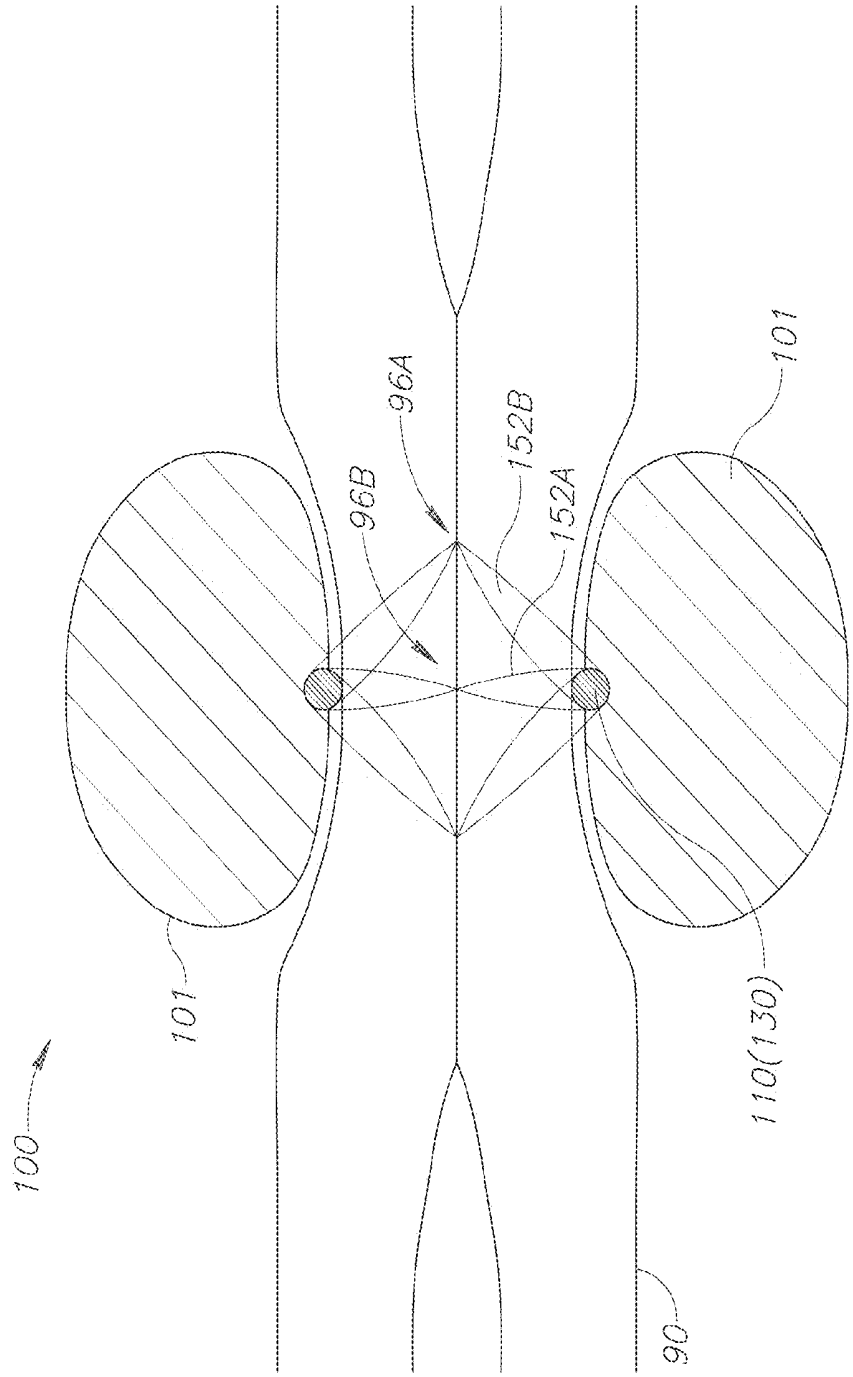


Figure 28A

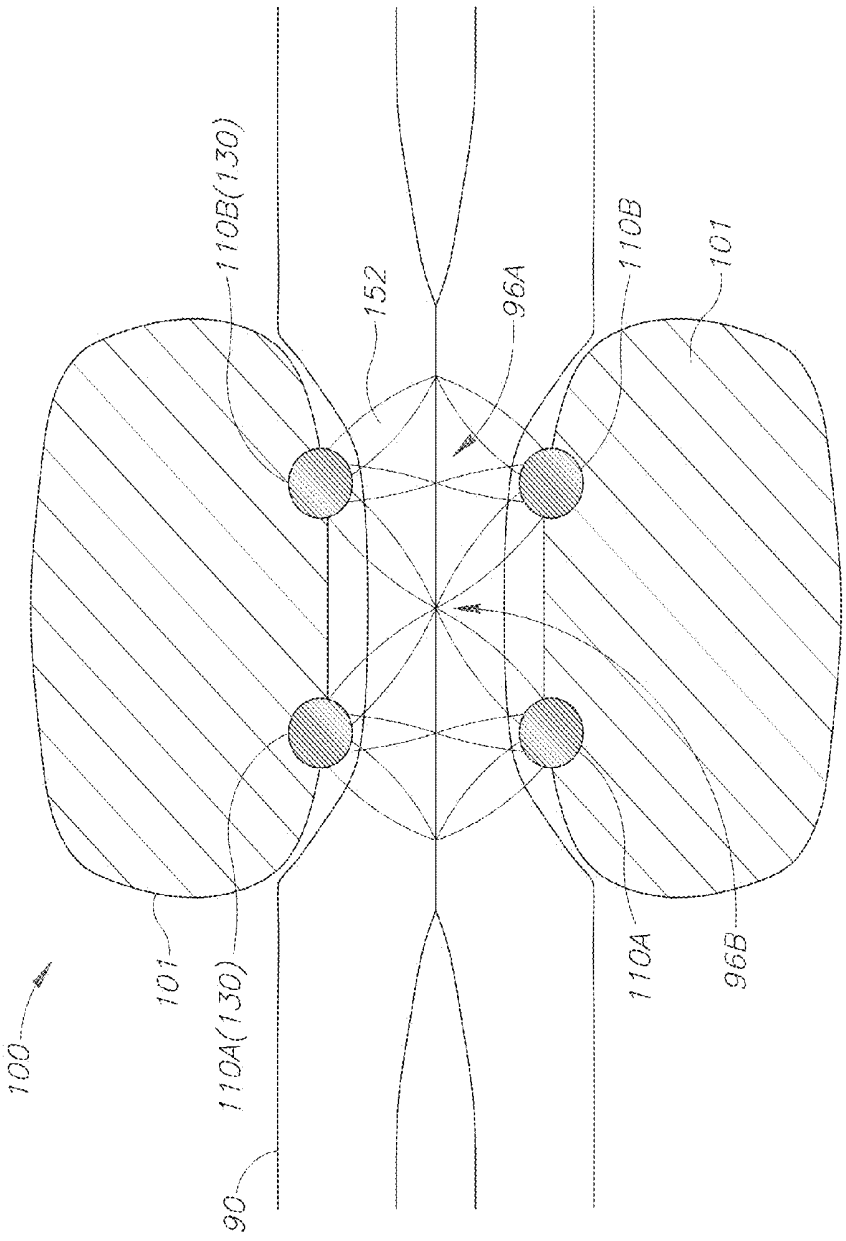


Figure 28B

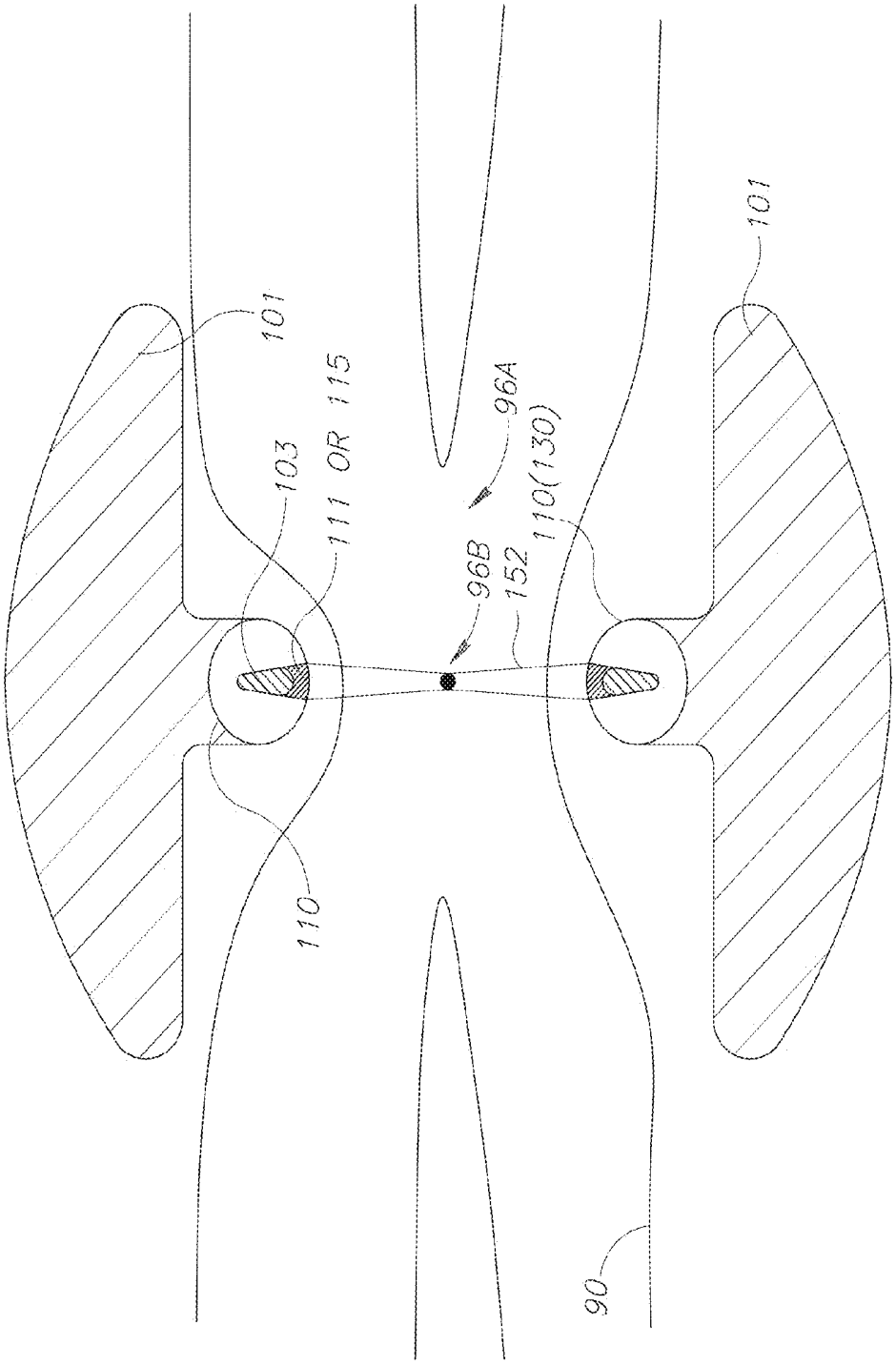


Figure 28C

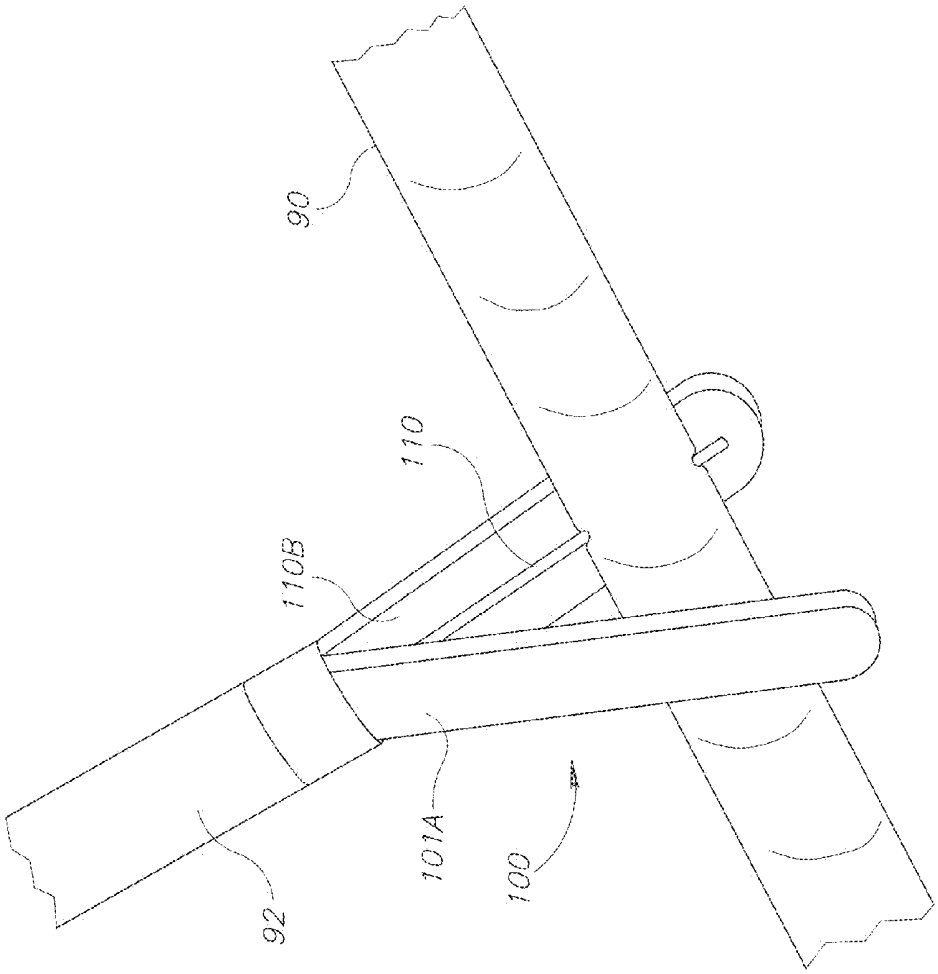


Figure 29A

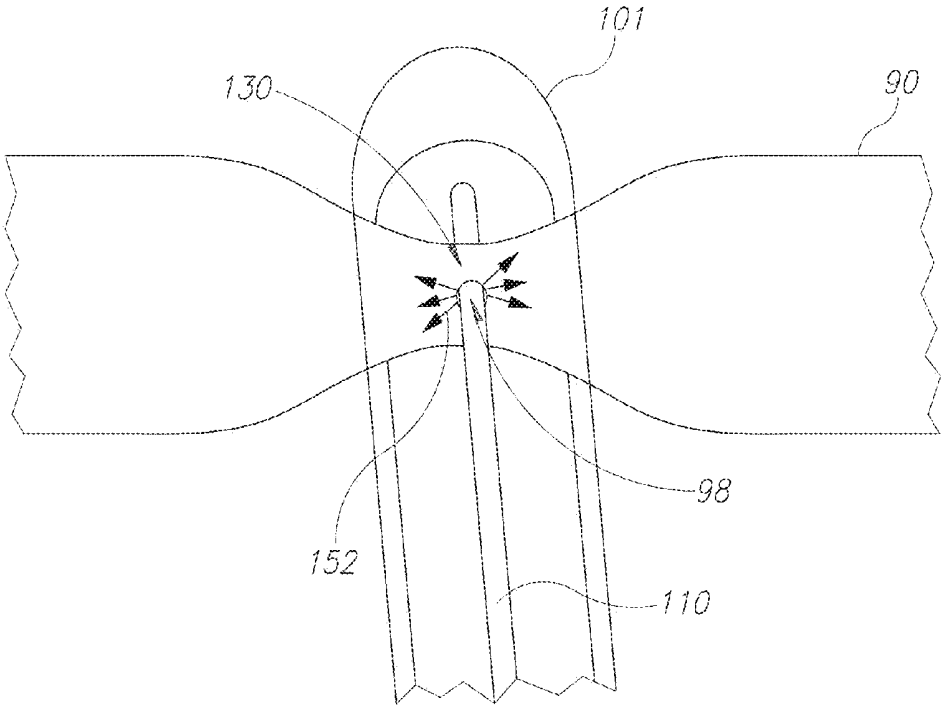


Figure 29B

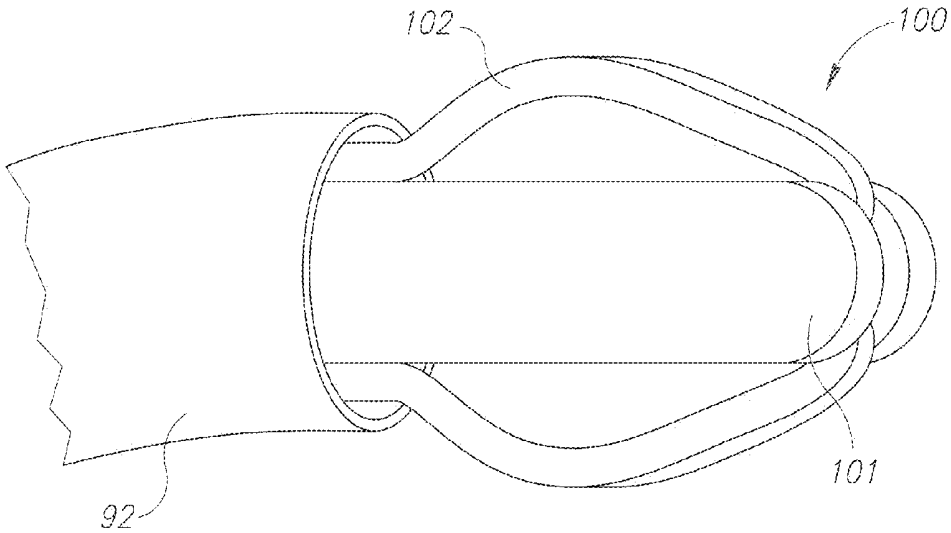


Figure 30A

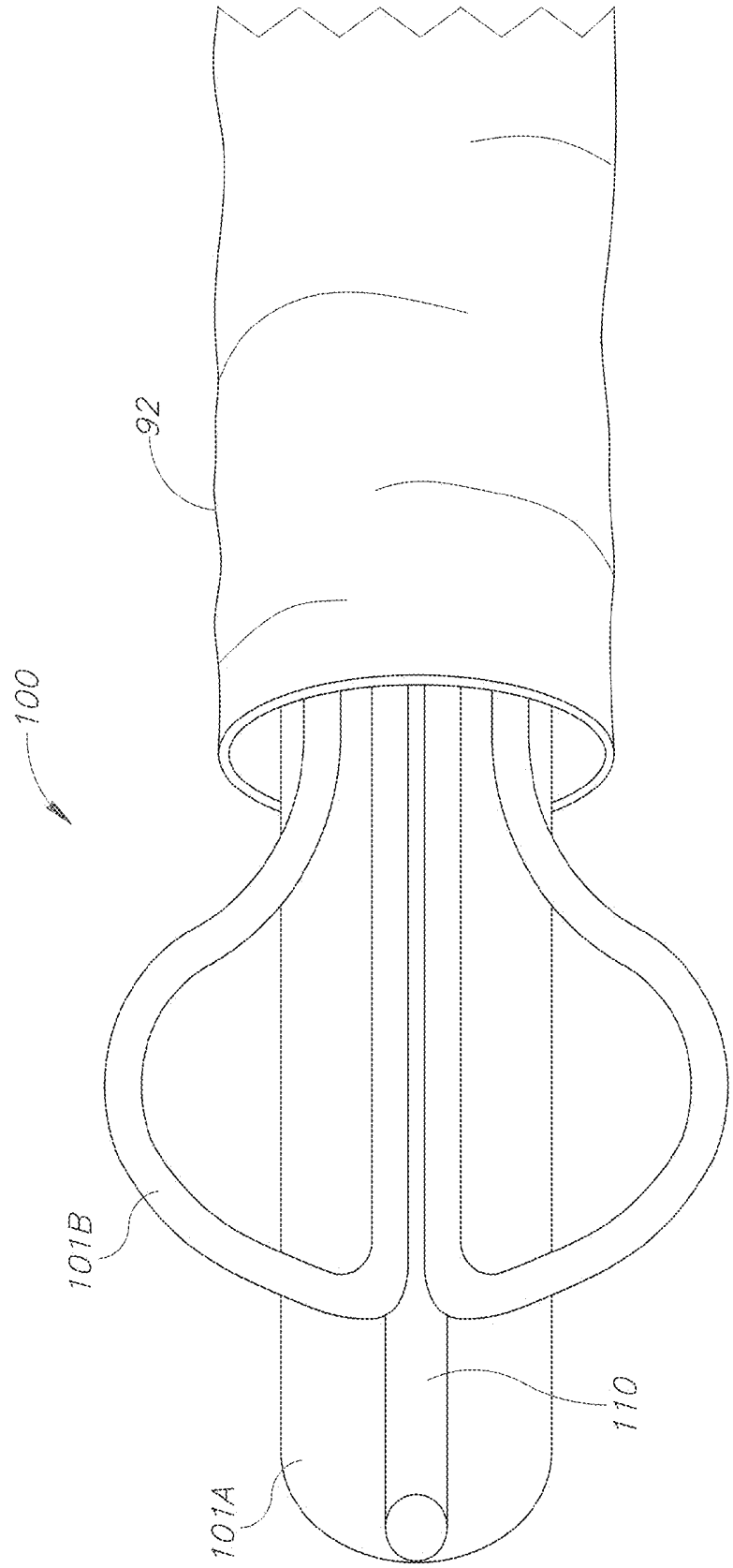


Figure 30B

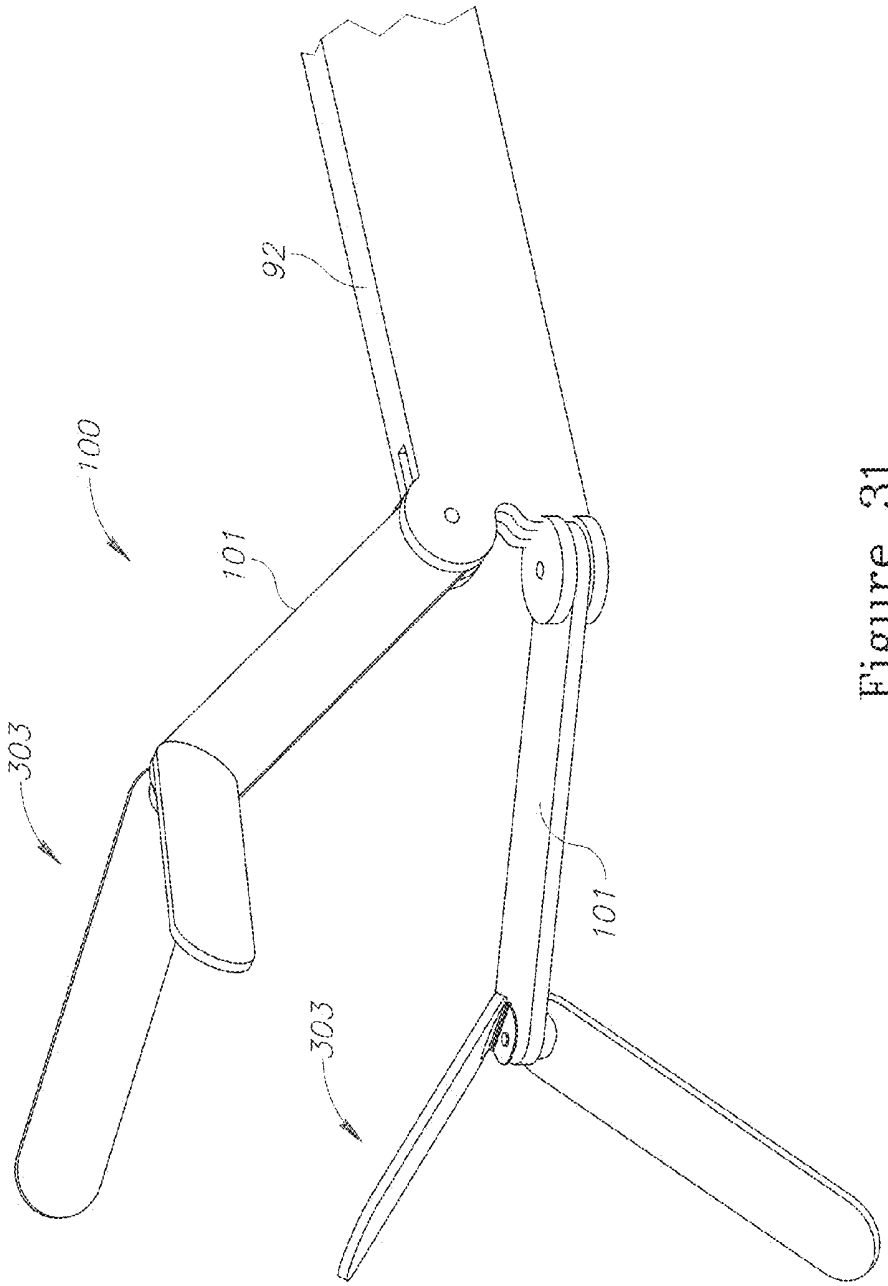


Figure 31

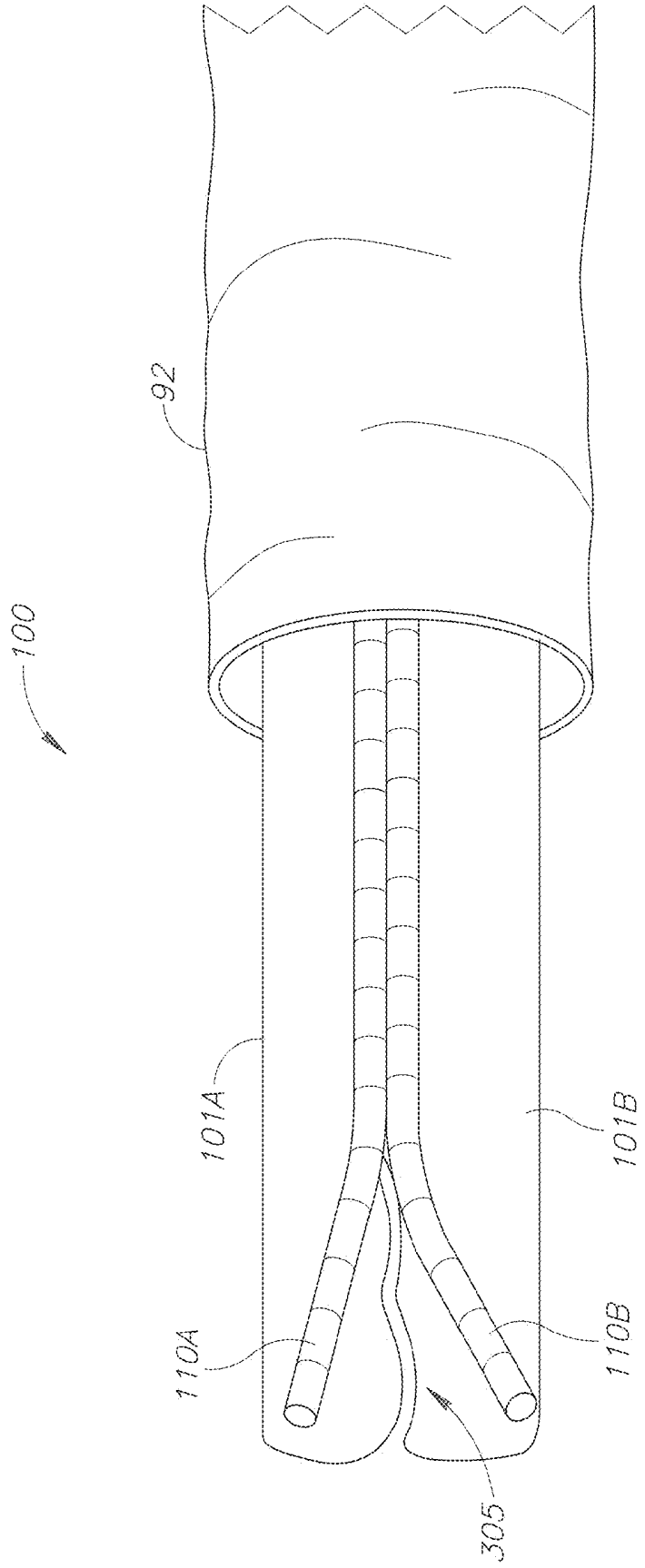


Figure 32

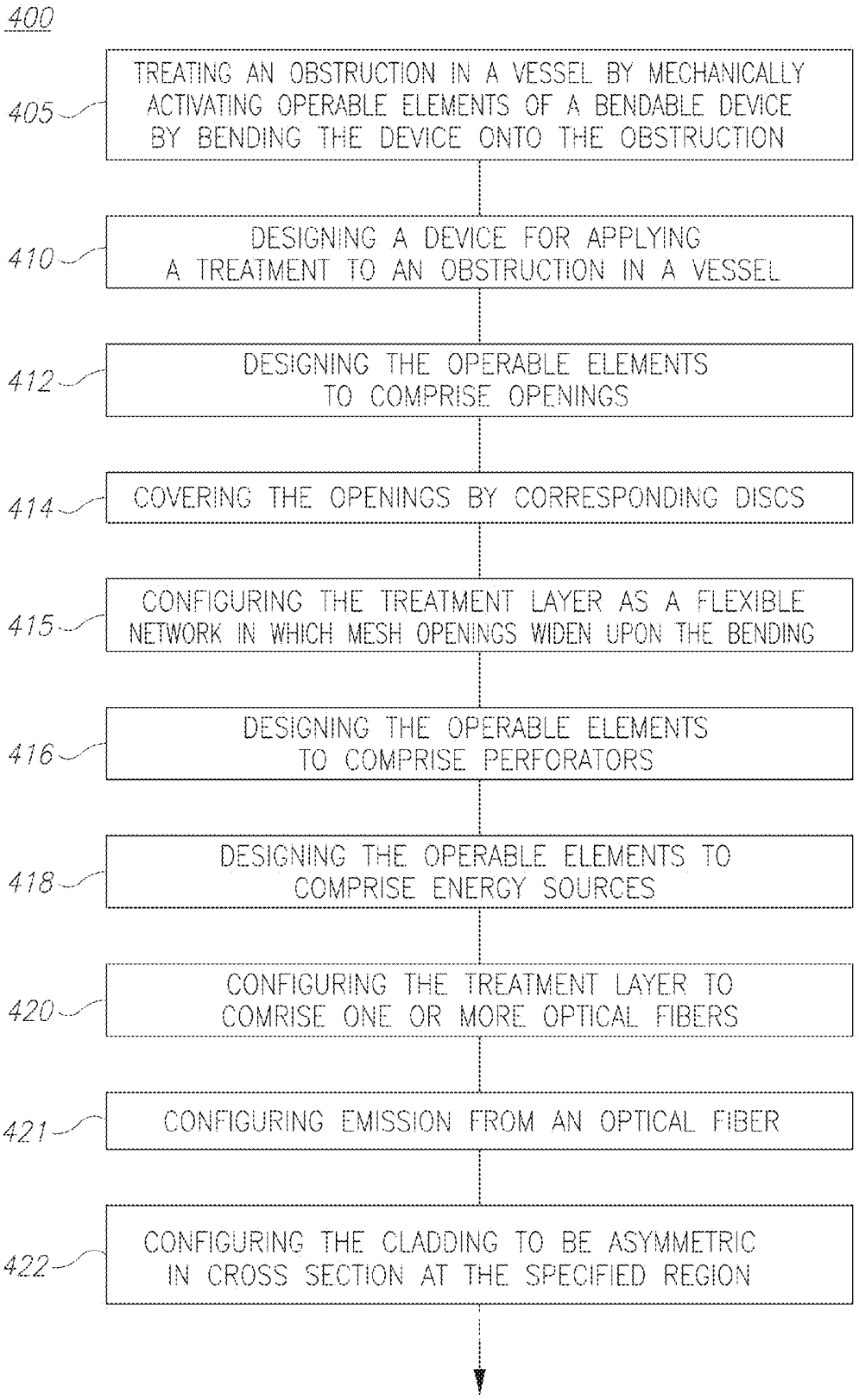

400
405
TREATING AN OBSTRUCTION IN A VESSEL BY MECHANICALLY ACTIVATING OPERABLE ELEMENTS OF A BENDABLE DEVICE BY BENDING THE DEVICE ONTO THE OBSTRUCTION
410
DESIGNING A DEVICE FOR APPLYING A TREATMENT TO AN OBSTRUCTION IN A VESSEL
412
DESIGNING THE OPERABLE ELEMENTS TO COMPRISE OPENINGS
414
COVERING THE OPENINGS BY CORRESPONDING DISCS
415
CONFIGURING THE TREATMENT LAYER AS A FLEXIBLE NETWORK IN WHICH MESH OPENINGS WIDEN UPON THE BENDING
416
DESIGNING THE OPERABLE ELEMENTS TO COMPRISE PERFORATORS
418
DESIGNING THE OPERABLE ELEMENTS TO COMPRISE ENERGY SOURCES
420
CONFIGURING THE TREATMENT LAYER TO COMRISE ONE OR MORE OPTICAL FIBERS
421
CONFIGURING EMISSION FROM AN OPTICAL FIBER
422
CONFIGURING THE CLADDING TO BE ASYMMETRIC IN CROSS SECTION AT THE SPECIFIED REGION

Figure 33

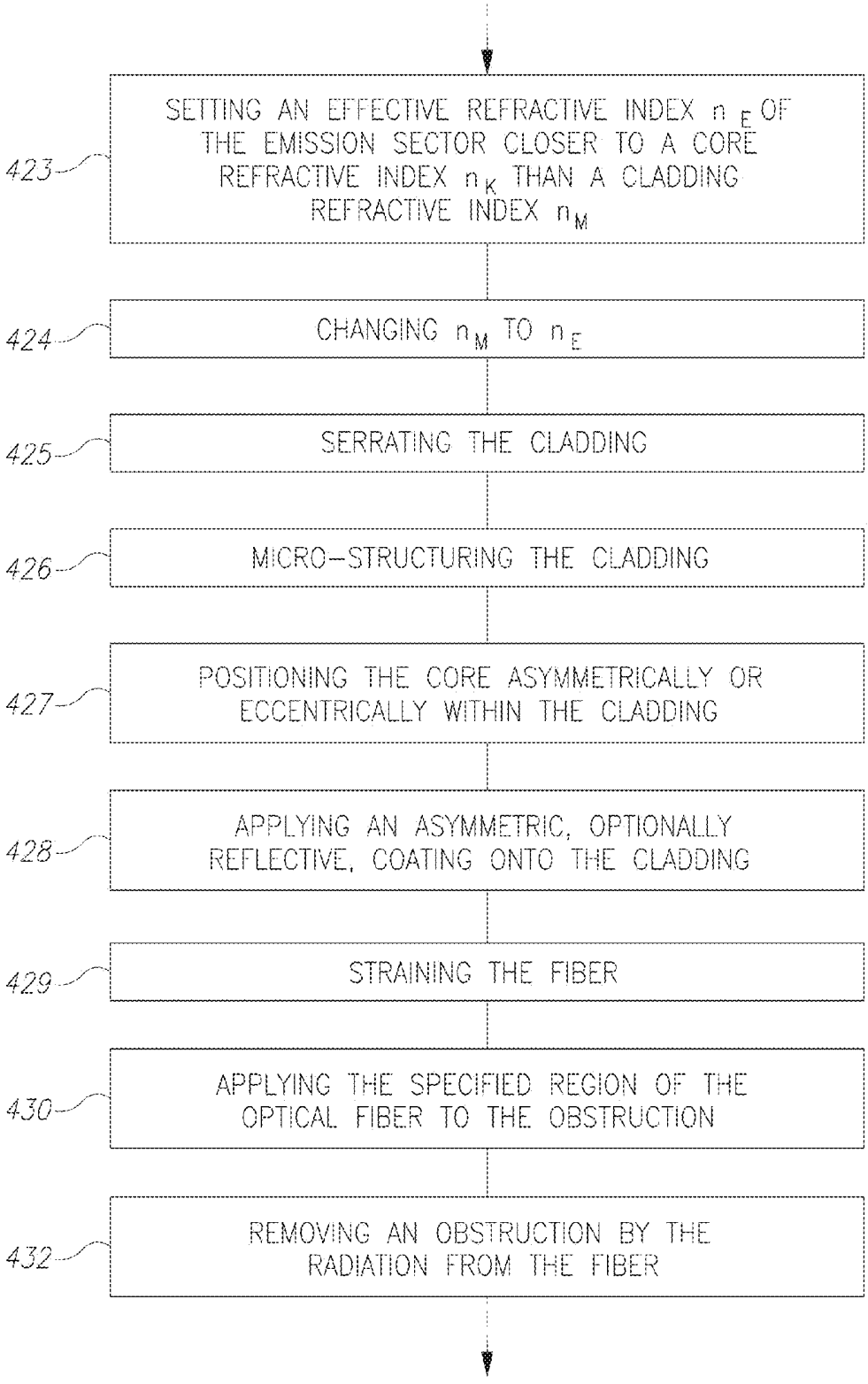


Figure 33 (cont. 1)

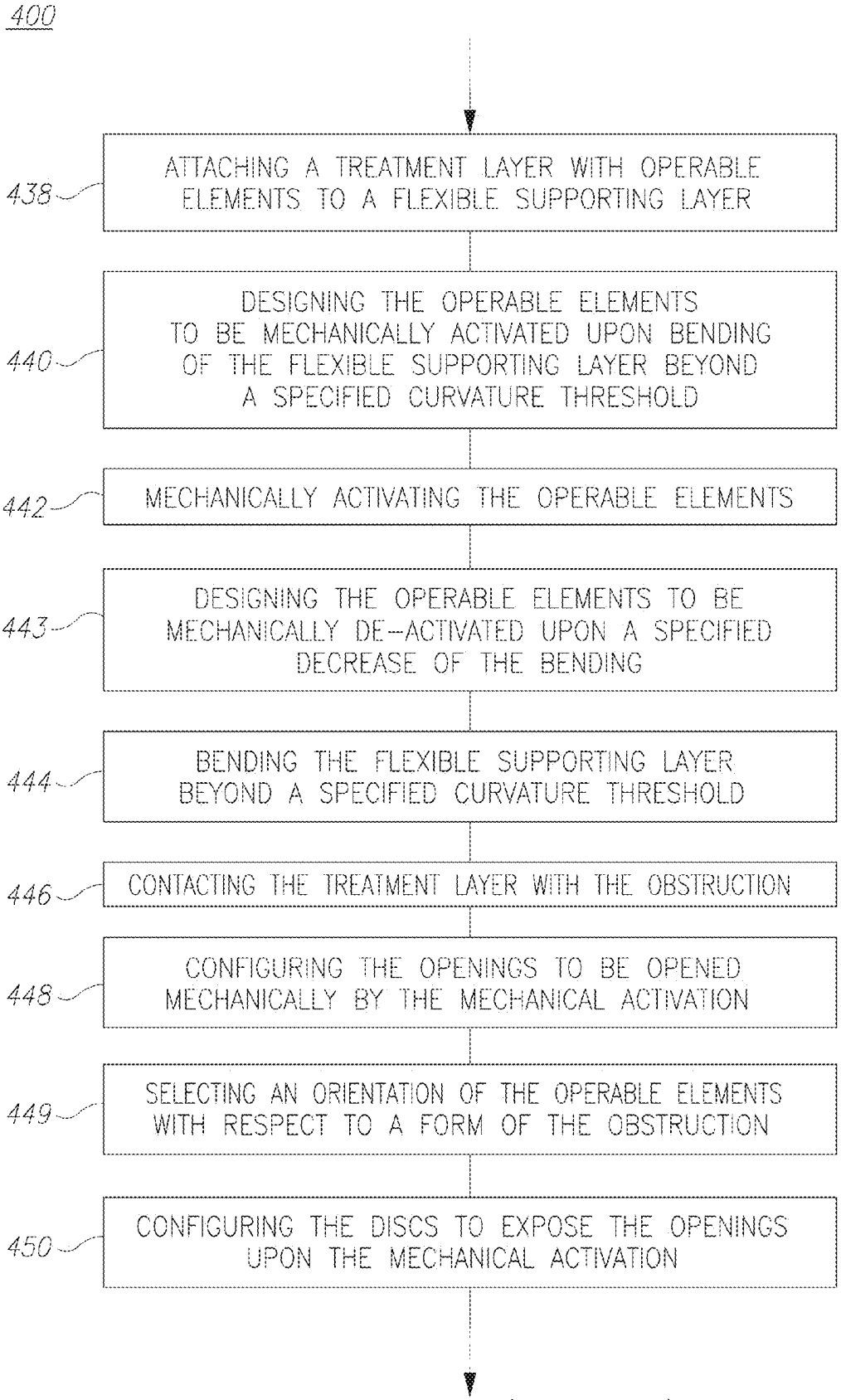


Figure 33 (cont. 2)

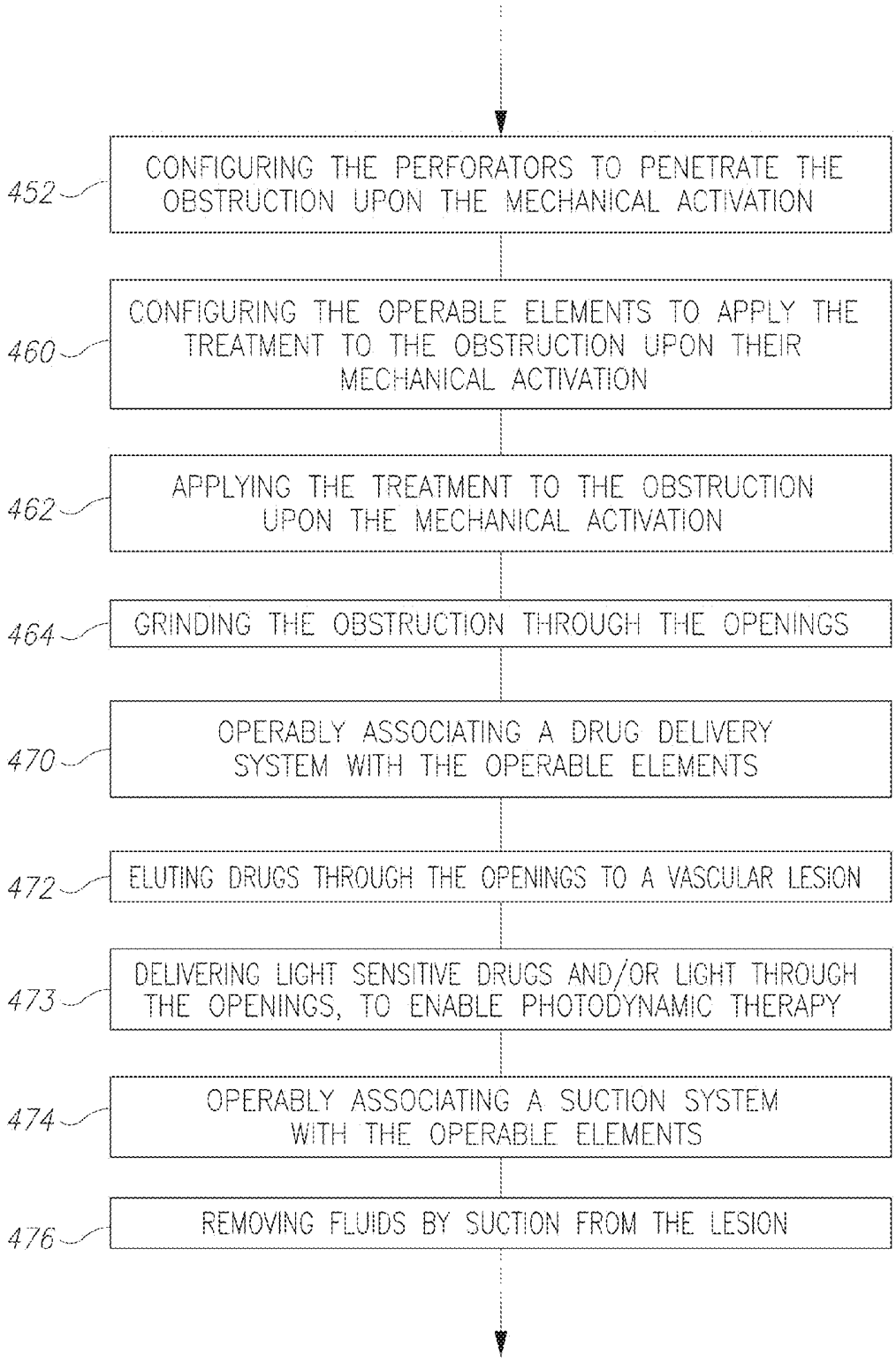


Figure 33 (cont. 3)

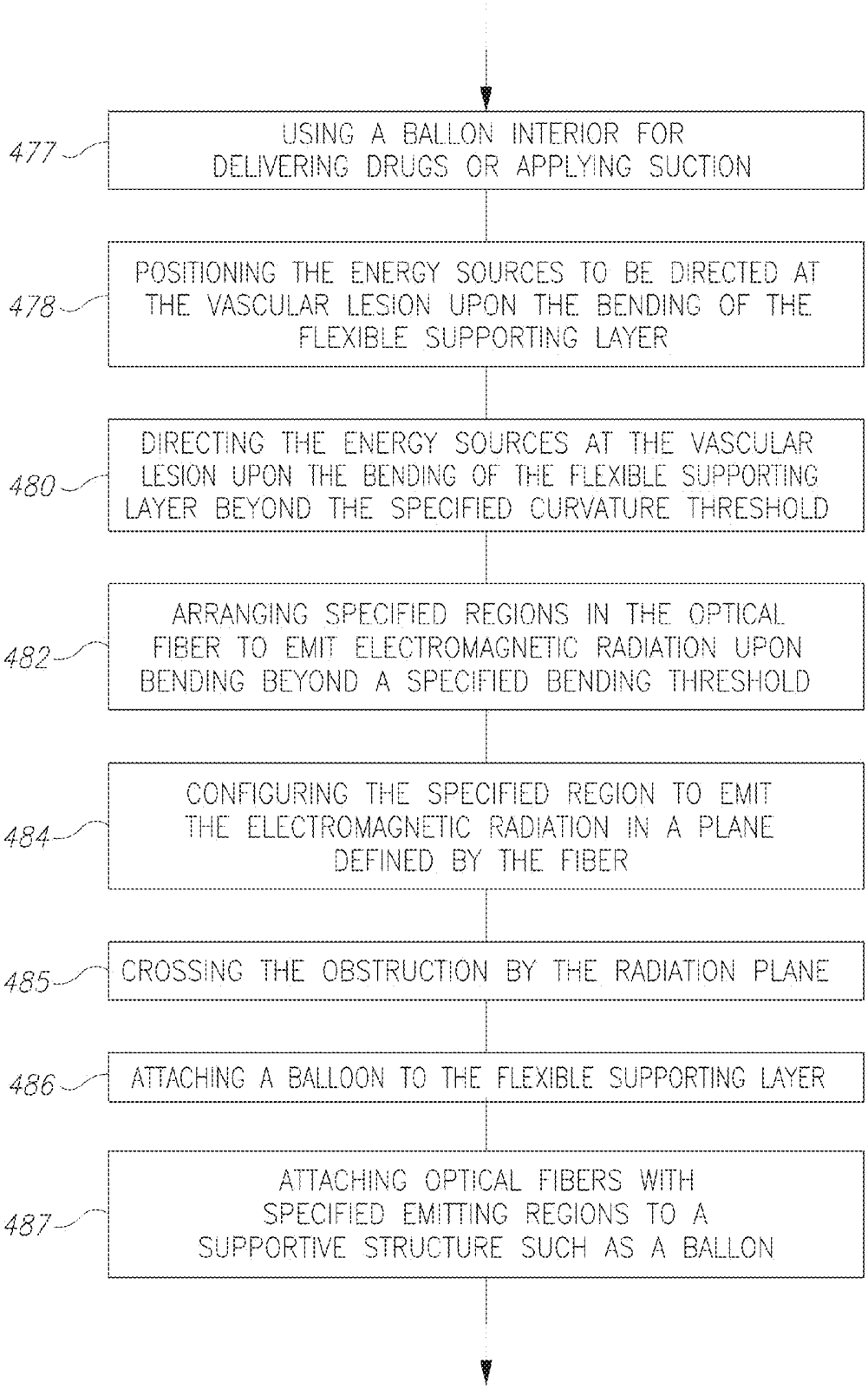


Figure 33 (cont. 4)

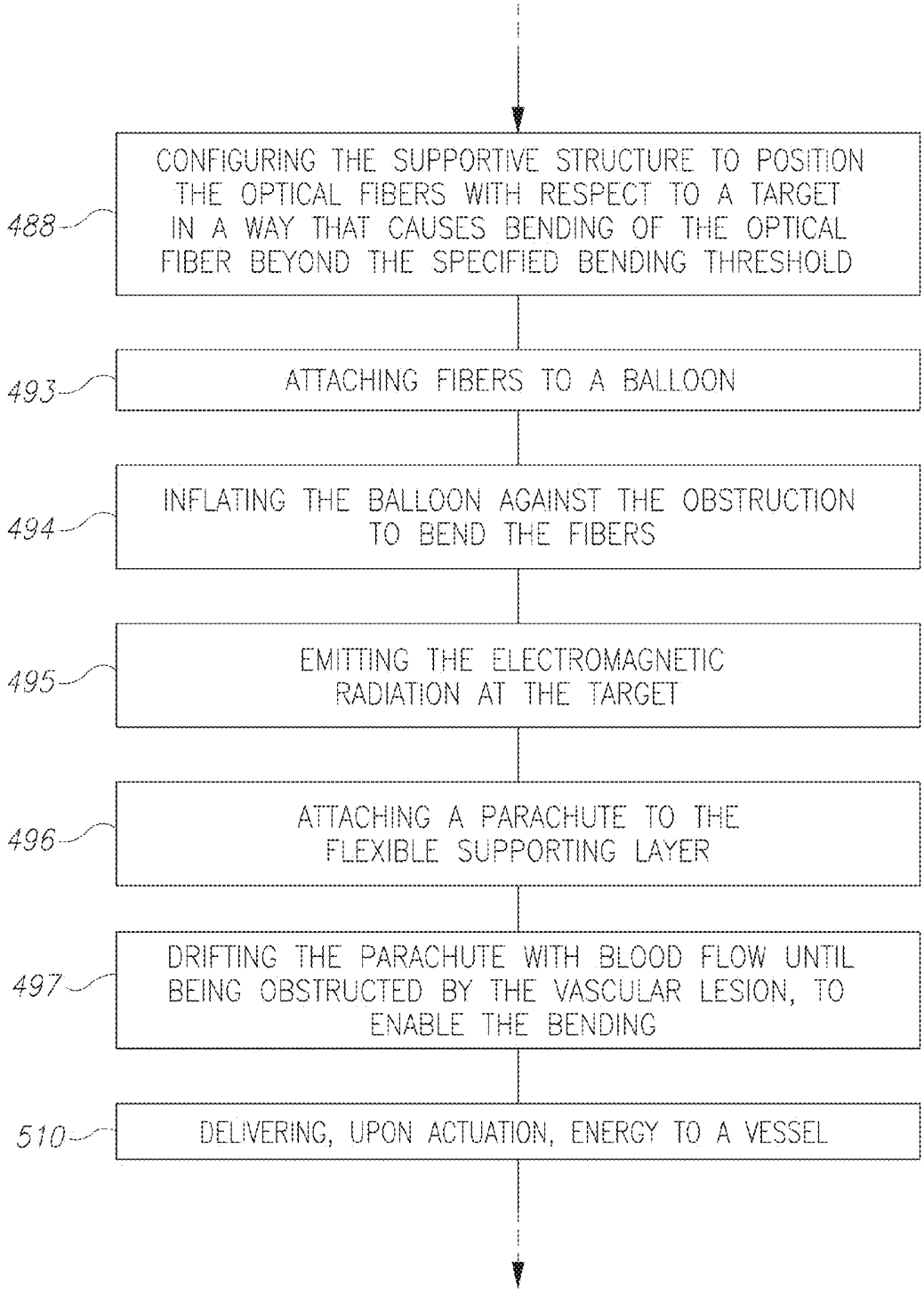


Figure 33 (cont. 5)

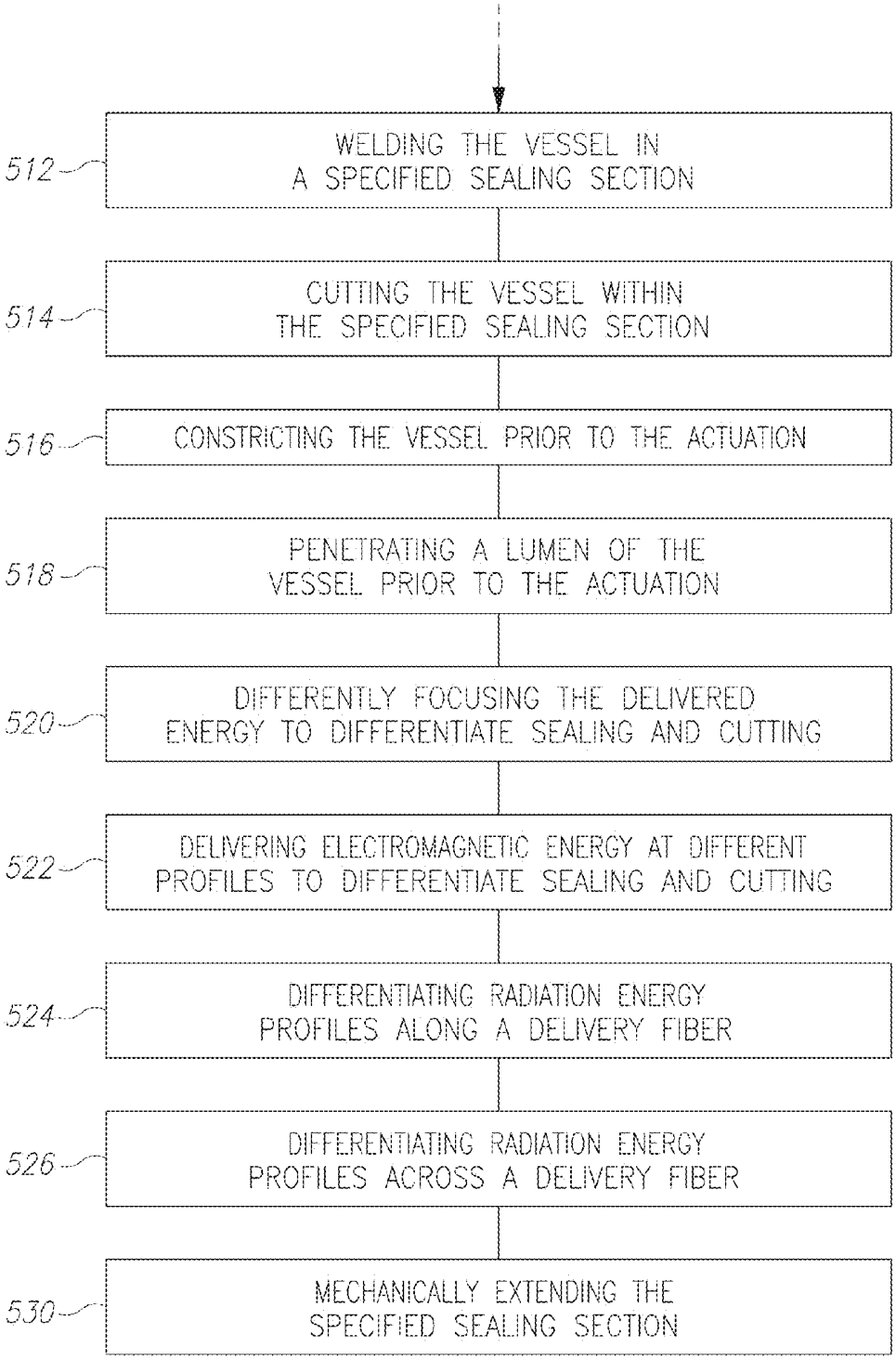


Figure 33 (cont. 6)

LESION TREATMENT DEVICE AND METHODS FOR TREATING LESIONS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of International Patent Application No. PCT/IL2012/050496, filed on Dec. 4, 2012, which claims the benefit of U.S. Provisional Patent Application No. 61/566,667, filed Dec. 4, 2011. This application also claims priority as a continuation-in-part to International Patent Application No. PCT/IL2013/050099, filed on Jan. 31, 2013, which claims priority from U.S. Provisional Patent Application No. 61/592,602, filed Jan. 31, 2012. This application also claims the benefit of U.S. Provisional Patent Application No. 61/847,090, filed Jul. 17, 2013. Each such noted application is herein incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] 1. Technical Field

[0003] The present invention relates to the field of treating flow obstructions or protrusions in vessels and/or passages in biological systems, and more particularly, to cardiovascular lesion treatment.

[0004] 2. Discussion of Related Art

[0005] Atherosclerosis, which is a major cause of cardiovascular disease resulting in myocardial infarction, stroke and other major medical complications, is characterized by the progressive accumulation of atherosclerotic deposits (known as plaque) on the inner walls of arteries. Consequently, blood flow is obstructed and there is increased likelihood of clot formation that can partially or completely block or occlude an artery. Even in cases where occlusion doesn't occur, plaque is a risk factor as certain non-stable deposits, known as vulnerable plaque, may dislodge and cause a stroke or myocardial infarction. Arteries narrowed as a result of atherosclerosis that cannot be treated effectively by drug therapy are treated by medical procedures designed to restore blood flow, including highly invasive procedures such as coronary artery bypass surgery and less invasive procedures such as balloon angioplasty, atherectomy and stenting.

[0006] Bypass surgery involves opening the patient's chest and transferring a vein cut from the patient's leg to the heart to construct a detour around the occluded artery. Bypass surgery requires prolonged hospitalization and an extensive recuperation period. Furthermore, bypass surgery also exposes the patient to a risk of major surgical complications.

[0007] Balloon angioplasty is a less invasive and costly alternative to bypass surgery and is performed in a hospital cardiac catheterization laboratory by an interventional cardiologist. In this procedure, a balloon-tipped catheter is inserted into a blood vessel through a small incision in the patient's arm or leg. The physician uses a guide catheter to feed the balloon through the patient's blood vessels to the occluded artery. At that point, a guidewire is inserted across the deposits of atherosclerotic plaque, known as lesions, to provide a pathway for the balloon catheter. The deflated balloon is advanced over the guidewire, positioned within the occluded area and inflated and deflated several times. This inflation and deflation usually tears the plaque and expands the artery beyond its point of elastic recoil. Thus, although no plaque is removed the opening through which the blood flows is enlarged.

[0008] Atherectomy employs a rotating mechanical device mounted on a catheter to cut and remove plaque from a diseased artery.

[0009] Another approach to treating atherosclerosis or thrombosis is to degrade thrombi and remove plaque using various pharmacologic agents. Many techniques currently exist to deliver medicaments and other active agents to body tissues. These include oral administration, direct injection to the tissue and intravenous administration. These mechanisms are systemic in that they deliver the active agent via the bloodstream throughout the entire body. Effective pharmacologic or drug therapy requires achieving adequate concentrations of the active drug at the desired treatment site without producing drug concentrations elsewhere in the body that may cause undesirable and even dangerous side effects.

[0010] Laser angioplasty removes plaques using light in varying wavelengths ranging from ultraviolet to infrared that is delivered to the lesion by a fiber-optic catheter. Early attempts to develop a laser angioplasty system used continuous wave thermal lasers that generated heat to vaporize plaque. These laser systems caused charring and significant thermal damage to healthy tissue surrounding the lesion. As a result, thermal laser systems have generally been regarded as inappropriate for use in coronary arteries. Conversely, excimer lasers use ultraviolet light to break the molecular bonds of the atherosclerotic plaque, a process known as photoablation. Excimer lasers use electrically excited xenon and chloride gases to generate an ultraviolet laser pulse with a wavelength of 308 nm. This UV light wavelength is absorbed by the proteins and lipids that comprise plaque, resulting in precise plaque disintegration and thus, blood flow restoration without significant thermal damage to surrounding tissue. The ablated plaque is converted into carbon dioxide and other gases, as well and minute particulate matter that can be easily eliminated. Similarly, Ultrasound and RF are sometimes used for the ablation of plaque.

[0011] The challenge remains to detect and treat vascular lesions in an effective and safe manner.

[0012] Vessel manipulation is a commonly encountered challenge, especially in minimally invasive procedures. The variety of encountered vessels and the need to manipulate vessels without causing additional damage and bleeding require time and skill which may challenge procedure success and place a significant obstacle to the further development of such procedures.

[0013] Optical fibers are a common way of delivering electromagnetic radiation, e.g. laser light, to a target. Optical fibers deliver the radiation in a tight beam originating from the end face directly or projected sideways by a mirror. An optical fiber assembly generally consists of four parts: core, cladding, coating and jacket. The core is the region in which light is guided; it is usually covered by a lower index cladding, in the case of a Total Internal Reflection (TIR) fiber. In case of a Photonic Crystal Fiber (PCF), e.g. having a beehive-like structure, an OmniGuide having photonic bandgap mirrors, a Bragg fiber etc., the cladding actually consists of a complex structure of higher index of refraction materials (disclosed e.g., in U.S. Pat. No. 7,142,756 which is incorporated herein by reference in its entirety). In a metallic waveguide, the core is lower index and the cladding is a coated metal, usually Ag coated by silver-iodide AgI. In all these fiber types light is confined to the core region under normal conditions, while in extreme bends light escapes the core and can even escape the entire fiber.

[0014] It is well known that waveguides and fibers suffer losses in bends. These losses are caused by the rays' higher angle of incidence on the core/clad (mirror) interface. This is often a major limitation most manufacturers try to avoid; see for example the Corning ClearCurve Fiber (disclosed e.g., in U.S. Pat. No. 5,278,931 which is incorporated herein by reference in its entirety). Another approach is to use outside cabling, as in U.S. Pat. No. 4,078,853, which is incorporated herein by reference in its entirety, to limit fiber bending and thus loss. Other devices take advantage of the optical power loss in the construction of sensors based on the loss in bends (disclosed e.g., in U.S. Pat. No. 4,770,047 which is incorporated herein by reference in its entirety).

[0015] In another example, U.S. Pat. No. 5,138,676 which is incorporated herein by reference in its entirety, discloses tight bending with low loss that is achieved by reducing fiber outer diameter (OD) and confining light with respect to the lower-index surrounding. OD reduction is performed by either removing part of the cladding or drawing down the fiber in the bent section. Other aspects are disclosed by U.S. Pat. No. 5,278,931, U.S. Pat. No. 4,078,853, U.S. Pat. No. 4,770,047 and U.S. Pat. No. 5,138,676, which are incorporated herein by reference in their entirety.

[0016] Tissue cutting and treatment are performed in three major methods: scalpels (cold steel techniques), electro- and laser-surgery. The main use of laser surgery is in ablation or coagulation of soft tissue. In laser surgery, an optical fiber is often used to deliver the laser energy to the desired site with minimal losses on the way.

[0017] In the case of soft tissue cutting and most other medical uses of fibers, laser light is emitted from the tip of the fiber at the treatment site. The fiber is used to safely deliver the energy to the exact location in spot form as in VersaPulse by Lumenis. In some cases local redirection of the fiber tip is used for improved targeting as disclosed e.g., in U.S. Pat. No. 7,238,180, which is incorporated herein by reference in its entirety.

[0018] In other cases, the fiber is manipulated to allow laser emission at a 90° angle to the fiber tip, term "side firing", which makes it easier to use in cases where it is geometrically harder to bend the fiber tip in the required direction. The straight angle is achieved using a mirror or a side fire mechanism. Sometimes when the side fire approach is used, specific treatment of the fiber edge is required in order to prevent local damage and facilitate effective tip side firing as disclosed e.g., in U.S. Patent Publication No. 20070106286, which is incorporated herein by reference in its entirety. In some cases tip side fire is enabled by tapering the fiber core as disclosed e.g., in U.S. Patent Publication No. 20110002584, which is incorporated herein by reference in its entirety. Alternatively, side firing is achieved by increasing the index of refraction of the cladding on one side by preferential heating, using an external laser source (disclosed e.g., in U.S. Pat. No. 6,606,431, which is incorporated herein by reference in its entirety).

[0019] The following US patents teach devices that utilize laser radiation for cutting. These patents are incorporates herein by reference in their entirety. U.S. Pat. No. 4,266,547 teaches a laser knife acting linearly between an emitter and an acceptor; U.S. Pat. No. 5,151,097 teaches a laser emitter that emits radiation through an uncovered area in an element that is otherwise covered by a light impervious material; U.S. Pat. No. 5,470,331 teaches a laser light transmissive probe system that is provided with an opposed pair of laser light transmissive probes for pinching tissue; U.S. Pat. No. 6,283,962 teaches a medical ablation device and U.S. Pat. No. 6,221,069 teaches an apparatus having an outer probe having a form of hook and an inner probe for contacting the outer probe and heating a target tissue disposed therebetween. U.S. Pat. Nos. 5,531,741 and 6,409,719, which are incorporates herein by reference in their entirety, teach devices that utilize an optical fiber to illuminate a scene in which stents are implants.

SUMMARY OF THE INVENTION

[0020] One aspect of the present invention provides a device for applying a treatment to an obstruction, comprising a flexible treatment layer that comprises a plurality of operable elements configured to be activated to apply the treatment to the obstruction upon bending of the flexible treatment layer beyond a specified curvature threshold and to be deactivated upon a specified decrease of the bending, resulting from the treatment of the obstruction.

[0021] One aspect of the present invention provides a flexible treatment layer having one or more optical fibers. The fibers comprise a core and a cladding, and have at least one specified region of the cladding that is arranged to emit electromagnetic radiation from the core upon bending the optical fiber at the at least one specified region beyond a specified bending threshold. The emission regions are operable elements of the treatment layer configured to treat the obstruction.

[0022] One aspect of the present invention provides a device such as a vessel sealing tip for surgical forceps, the vessel sealing tip comprising at least one energy delivering element arranged to deliver, upon actuation, energy to a vessel to yield a vessel welding effect in a specified sealing section of the vessel and to cut the vessel within the specified sealing section, the energy delivery being carried out via the operable elements.

[0023] These, additional, and/or other aspects and/or advantages of the present invention are set forth in the detailed description which follows; possibly inferable from the detailed description; and/or learnable by practice of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] For a better understanding of embodiments of the invention and to show how the same may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings in which like numerals designate corresponding elements or sections throughout.

[0025] In the accompanying drawings:

[0026] FIGS. **1**A-**1**C are high level schematic illustrations of a cross section of a vessel with an obstruction, contacted by a device for applying a treatment to the obstruction, according to some embodiments of the invention;

[0027] FIGS. **2**A-**2**D are high level schematic illustrations of a partial longitudinal section of a vessel with a lesion, contacted by a device for applying a treatment to an obstruction such as a vascular lesion, according to some embodiments of the invention;

[0028] FIGS. **3**A and **3**B are high level schematic illustrations of a device configuration having a non-active state and a bending-activated state, respectively, according to some embodiments of the invention;

[0029] FIGS. **4**A and **4**B are high level schematic illustrations of a device for perforating the lesion, having a non-

active state and a bending-activated state, respectively, according to some embodiments of the invention;

[0030] FIGS. **5**A and **5**B are high level schematic illustrations of a device for perforating the lesion, having a non-active state and a bending-activated state, respectively, and including an actuator, according to some embodiments of the invention;

[0031] FIGS. **6**A and **6**B are high level schematic illustrations of a device for delivering a drug to the lesion, having a non-active state and a bending-activated state, respectively, according to some embodiments of the invention;

[0032] FIGS. **7**A and **7**B are high level schematic illustrations of a device for delivering a drug to the lesion, having a non-active state and a bending-activated state, respectively, according to some embodiments of the invention;

[0033] FIGS. **8**A and **8**B are high level schematic illustrations of a device having a flexible network with varying mesh openings, according to some embodiments of the invention;

[0034] FIGS. **9**A and **9**B are high level schematic illustrations of a device for delivering a drug to the lesion, according to some embodiments of the invention;

[0035] FIGS. **10**A and **10**B are high level schematic illustrations of an obstruction grinding device, according to some embodiments of the invention;

[0036] FIGS. **11**A-**11**E are high level schematic illustrations of a one layered treatment device, according to some embodiments of the invention;

[0037] FIGS. **12**A-**12**C are high level schematic illustrations of openings as operable elements, according to some embodiments of the invention;

[0038] FIG. **13**A is a high level schematic illustration of a balloon implemented device for treating lesions at vessel bifurcations, according to some embodiments of the invention;

[0039] FIG. **13**B is a high level schematic illustration of a device for treating flow obstructions by a supportive structure, according to some embodiments of the invention.

[0040] FIGS. **13**C-**13**K are high level schematic illustrations of a device having optical fibers exhibiting bend emission wound on a supportive structure such as a balloon, according to some embodiments of the invention;

[0041] FIGS. **14**A-**14**C are high level schematic illustrations of a parachute implemented device in stages of operation, according to some embodiments of the invention;

[0042] FIGS. **15**A and **15**B are high level schematic illustrations of a device for focusing energy at the lesion, having a non-active state and a bending-activated state, respectively, according to some embodiments of the invention; FIGS. **15**C and **15**D demonstrate bend emission for the fiber configuration illustrated in FIG. **1711** (see below, serrated fiber), according to some embodiments of the invention;

[0043] FIG. **16**A is a high level schematic block diagram of an emitting region of an optical fiber, according to some embodiments of the invention;

[0044] FIG. **16**B is a schematic illustration of the dependency of the emitted radiation through the specified region on the bending radius, according to some embodiments of the invention;

[0045] FIG. **16**C is a schematic illustration of the dependency of the emitted radiation through the specified region on the bending radius (y axis) and on the ratio n_E/n_K (x axis), according to some embodiments of the invention;

[0046] FIGS. **17**A-**17**I and **17**L are high level schematic illustrations of various embodiments of the operable elements of the optical fiber having an asymmetric cladding in cross section, according to some embodiments of the invention;

[0047] FIG. **17**J illustrates an embodiment of the fiber with a coating that has a gap or is missing at the specified emission region, according to some embodiments of the invention;

[0048] FIG. **17**K illustrates an embodiment of a metallic waveguide having a gap at the specified emission region, according to some embodiments of the invention;

[0049] FIG. **18**A is a high level schematic illustration of the fiber with a flat supportive structure attached on an opposite side of the fiber with respect to the emitting region and the target, according to some embodiments of the invention

[0050] FIG. **18**B is a high level schematic illustration of the fiber with lateral circle segments, according to some embodiments of the invention;

[0051] FIG. **18**C is a high level schematic illustration of the fiber with a circular segment at the fiber tip, according to some embodiments of the invention;

[0052] FIGS. **19**A-**19**C, **19**E, **19**F, **19**H and **19**I are high level schematic illustrations of devices using bend emission, according to some embodiments of the invention;

[0053] FIG. **19**D illustrates an experimental comparison between a fiber snare device according to some embodiments of the invention and an electrosurgical snare regarding the emission profile;

[0054] FIGS. **20**A-**20**C illustrate configurations of controlling the electromagnetic radiation transmitted through the fiber, according to some embodiments of the invention;

[0055] FIG. **21**A-**21**E illustrate the cladding of the fiber, becoming asymmetric in cross section upon application of a strain at the specified region, according to some embodiments of the invention;

[0056] FIGS. **22**A-**22**C schematically illustrate operable elements on a fiber having three or more emission sectors in the emission region and a hook device using this fiber, according to some embodiments of the invention;

[0057] FIGS. **23**A-**23**F schematically illustrate a device configured as tweezers, according to some embodiments of the invention; Note **23**F

[0058] FIGS. **24**A and **24**B schematically illustrate a device with a feedback loop for controlling emitted radiation, according to some embodiments of the invention;

[0059] FIG. **25** schematically illustrates a device for cutting vessels, according to some embodiments of the invention; and

[0060] FIGS. **26**A and **26**B illustrate a device for treating target by pressing device upon it, according to some embodiments of the invention.

[0061] FIGS. **27**A-**27**C are high level schematic illustrations of a vessel sealing tip for surgical forceps according to some embodiments of the invention;

[0062] FIGS. **28**A-**28**C are high level schematic illustrations of a vessel sealing tip for surgical forceps having focusing elements, according to some embodiments of the invention;

[0063] FIGS. **29**A and **29**B are high level schematic illustrations of a vessel sealing tip for surgical forceps having vessel piercing elements, according to some embodiments of the invention;

[0064] FIGS. **30**A and **30**B are high level schematic illustrations of a vessel sealing tip for surgical forceps having transversely expanding elements, according to some embodiments of the invention;

[0065] FIG. **31** is a high level schematic illustration of a vessel sealing tip for surgical forceps enabling extension of the vessel sealing region, according to some embodiments of the invention;

[0066] FIG. **32** is a high level schematic illustration of a vessel sealing tip for surgical forceps with variable intensity treatment, according to some embodiments of the invention; and

[0067] FIG. **33** is a high level flowchart illustrating a method, according to some embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0068] Prior to setting forth the detailed description, it may be helpful to set forth definitions of certain terms that will be used hereinafter.

[0069] The term "obstruction" as used herein in this application refers to any piece of matter that retards flow through a vessel. In particular, the term "obstruction" as used herein in this application includes lesions, or vascular lesions, which are deposits on arteries (e.g., plaque) as well as other distractions to normal blood flow. The terms "obstruction" and "lesion" are used interchangeably throughout the specifications, in a non-limiting manner.

[0070] The term "vessel" as used herein in this application refers to any hollow container or pipe for moving fluids. For example, the term "vessel" refers to a blood vessel, especially an artery, parts of the gastrointestinal tract, fallopian tubes, urinary or bile tracts, airways and bronchi and other bodily vessels, as well as to pipes and tubes for industrial uses. The term "vessel" is used in this application in two contexts, first in referring to vessels that enclose treated tissue such as an obstruction (e.g., a lesion in a blood vessel) and second in referring to the vessel as the treated tissue itself (e.g., welding or cutting vessels). The term "vessel" is denoted by numerals **90** or **95**, depending on the context.

[0071] The terms "energy" or "treatment energy" as used herein in this application refer to any type of energy which is usable for treating or affecting vessels, for example mechanical energy, electromagnetic energy in any form (e.g., optical energy, laser energy in any effective bandwidth, radiofrequency radiation—RF etc.), electrical or magnetic energy (e.g., electric currents or magnetic fields), heat, ultrasonic radiation etc.

[0072] The terms "treatment layer" and "supporting layer" as used herein in this application refer to device elements which are involved, respectively, in energy emission and in structural support. The term "operable elements" as used herein in this application refers to any element that is associated with the treatment layer and delivers energy of any type. The term "operable elements" is further used herein in this application in a broader sense to refer to sensing and material delivery functions of the operable elements, in addition to energy delivery. The association between the operable elements and the treatment layer may be of different kinds. Non-limiting examples are mechanical structures (e.g., a surface with pores, a flexible sheet with orienting structures), radiation emitting structures (e.g., optical fibers which emit by bending), and combinations thereof (e.g., structures which direct bending and bend-emitted energy). The supporting layer may be present (e.g., a balloon, forceps jaws, a stent etc.) or be embodied into the treatment layer (e.g., balloon skin or stent surface as the treatment layer, optical fiber with emitting regions). Specifically, the terms "bend-emitting region", "emitting region" etc. of a fiber, as used herein in this application refer to is a region of the fiber which is implemented as an operable element, according to the principles specified below.

[0073] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

[0074] Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is applicable to other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0075] Tissue and vessel treatment devices and respective methods are provided. Devices comprise a flexible treatment layer that comprises a plurality of operable elements configured to be activated to apply the treatment to the obstruction upon bending of the flexible treatment layer beyond a specified curvature threshold and to be de-activated upon a specified decrease of the bending. The treatment layer may comprise optical fiber(s) with the operable elements as emission regions that emit electromagnetic radiation from the core upon bending the optical fiber beyond a specified bending threshold. Devices may be configured as vessel sealing tips for surgical forceps, in which the treatment layer is configured to yield vessel welding and vessel cutting effects.

[0076] The present invention enables removing and/or treating obstructions in vessels and in some cases simultaneously delivering pharmacologic therapy to a selected site in the body lumen in a simple way. The invention may treat any type of obstruction in any type of vessel, combines an automatic mechanical obstruction identification mechanism with a treatment procedure to remove and/or treat the obstruction. In an example of the obstruction being a vascular lesion, the invention may be used to remove plaque without generating embolic material which can create a risk of ischemic stroke. Furthermore, the devices described by this invention automatically identify and restrict treatment to the sclerotic area, leaving adjacent tissue unharmed.

[0077] Among other, this invention relates to methods and apparatuses for excising and/or treating mobile and non-mobile atheromas. The device includes an automated lesion identification mechanism and a treatment mechanism. In general both automated lesion detection unit and the treatment head may be inserted into the body via a catheter which may operate in different regions of the human body. For example, the aorta, common carotid artery, external and internal carotid arteries, brachiocephalic trunk, middle cerebral artery, anterior cerebral artery, posterior cerebral artery, vertebral artery, basilar artery, subclavian artery, brachial artery, axillary artery, Iliac artery, renal artery, femoral artery, popliteal artery, celiac artery, superior mesenteric artery, inferior mesenteric artery, anterior tibial artery, posterior tibial artery,

the coronary arteries and all other arteries. The catheter may optionally include a blood filter means which enable to capture plaque inadvertently dislodged during an atherectomy procedure.

[0078] FIGS. **1**A-**1**C are high level schematic illustrations of a cross section of a vessel **90** with an obstruction **95**, contacted by a device **100** for applying a treatment to obstruction **95**, according to some embodiments of the invention. FIGS. **2**A-**2**D are high level schematic illustrations of a partial longitudinal section of vessel **90** contacted by device **100** for applying a treatment to obstruction **95** such as a vascular lesion, according to some embodiments of the invention.

[0079] Device **100** comprises a flexible supporting layer **120** and a treatment layer **110** comprising a plurality of operable elements **130** attached to flexible supporting layer **120** and configured to be mechanically activated to apply the treatment to obstruction **95** upon bending of flexible supporting layer **120** due to its contact with obstruction **95**. For example, operable elements **130** may be mechanically activated upon bending of flexible supporting layer **120** beyond a specified curvature threshold, as illustrated in examples below. Generally, a smaller curvature radius causes a stronger bending which activated device **100**. Upon reduction if the curvature radius, de-activation may commence when the curvature radius is larger than the threshold. Hence the expression "beyond a specified curvature threshold" in the application should be interpreted as relating to a larger curvature and a smaller curvature radius.

[0080] The bending of device **100** may result from its contact with obstruction **95** or by active pressing of device **100** upon obstruction **95** to activate operable elements **130**.

[0081] In embodiments, device **100** comprises a single layer having operable elements **130** such as openings going through the whole thickness of device **100**. Such embodiment is illustrated in FIGS. **1**C, **14**A-E and **15**A-C. In embodiments, the material of device **100** itself may be used to treat obstruction **95**.

[0082] In embodiments, operable elements **130** are further configured to be mechanically de-activated upon a specified decrease of the bending, due to the treatment of obstruction **95**. For example, after the size of obstruction **95** decreases due to the treatment, the treatment may be mechanically interrupted as the curvature of device **100** decreases to a certain degree, e.g. below the specified curvature threshold or below a different threshold, determined according to the structure of the surrounding tissue.

[0083] As illustrated in FIGS. **1**A and **1**B, device **100** is configured to bend upon contact with obstruction **95**. The bending causes a mechanical activation of operable elements **130**, as illustrated below. In some embodiments, operable elements **130** may comprise or be sensors. Device **100** may be hollow, and enable blood flow through cavity **85** in device **100**.

[0084] The following are some non-limiting examples for curvature thresholds with respect to various obstructions. It should be noted, as illustrated below, that generally there are two dimensions related to the curvature radius. One is in the radius of vessel **90** (in a plane perpendicular to the vessel) and the other is related to the longitudinal way along vessel **90** (in a longitudinal cross section of vessel **90**). As a result, operable elements **130** (such as openings **114**) may be asymmetric and have different dimensions in different directions, or be oriented in different ways along device **100** (and with respect to vessel **90**). Curvature thresholds may differ in different directions, as in the longitudinal axis the reference radius (that of vessel **90** without any obstruction **95**) is very large, while in the cross sectional axis the reference radius (without obstruction **95**) is much smaller. Hence, different activation and de-activation thresholds may be defined for these directions and may be used to apply coarser of finer treatments, possibly simultaneously in different regions or sequentially and complementary in one region of obstruction **95**.

[0085] In non-limiting examples, the following may be typical parameters for the curvature threshold in cases of different obstructions. In case of coronary lesions having a radius between 0.1 mm and 2 mm, the specified curvature threshold may be about two times the lesion radius, or up to five times the lesion radius to achieve a more thorough removal of the lesion. Device **100** may be adapted or selected according to the specific lesion that is to be treated therewith.

[0086] In case of vascular lesions having a radius between 1 mm and 10 mm, the specified curvature threshold may be about two times the lesion radius, or up to five times the lesion radius to achieve a more thorough removal of the lesion. Device **100** may be adapted or selected according to the specific lesion that is to be treated therewith.

[0087] In case of airway obstruction having a radius between 0.5 mm and 5 mm for small obstructions and having a radius between 5 mm and 20 mm for large obstructions, the specified curvature threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0088] In case of gastrointestinal obstructions having a radius between 10 mm and 100 mm, the specified curvature threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0089] In case of obstructions in water or sewage pipes, having a radius between 50 mm and 500 mm, the specified curvature threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0090] Device **100** may be part of an arterial catheter system which includes a flexible elongate member or catheter with an outer surface, a distal region adapted to enter an artery and a proximal region extending from a patient's vessel, permitting control outside the patient's body by a physician. At the distal region of the catheter is the atherosclerosis treating assembly which may include suction and/or drug administration surface and a balloon expansion unit. Alternatively, in some embodiments it may include an atherectomy assembly which includes a cutting blade, abrasive member, snare etc. and a trapping mechanism which in certain embodiments comprises of openings in the trapping surface which extend to the proximal region of the catheter and are attached to a vacuum source. Alternatively, in some embodiments it may include an energy source like ultrasound, laser or RF.

[0091] The physician typically determines the presence and location of the plaque using one or several visualization techniques. The distal end of the arterial catheter is inserted and deployed through an incision in the femoral or brachial artery in a manner widely used in coronary and other arteries angio-

plasty, atherectomy and ultrasonography catheters. The catheter's distal region is advanced within the femoral or brachial artery until the distal end reaches the region of interest. Advancement of the catheter may be facilitated by X-ray fluoroscopy and the distal region of the catheter may include one or more fluoroscopic markers to enable such visualization. Advancement may also be facilitated by IVUS, TEE or by conventional guidewire and/or guiding catheter. In some cases, a distal protection unit or other filtration means will be used, either as part of the device or as a separate tool.

[0092] Once filtration/distal-protection and general lesion identification are established, the precise lesion identification mechanism is deployed. The precise lesion identification mechanism then enables the simple delivery of treatment via drug-administration, suction and/or one of several available energy sources.

[0093] FIGS. **2**A-**2**D schematically illustrate variations of treatment application by operable elements **130**. For example, operable elements **130** may comprise openings that are configured to be opened mechanically by the bending of flexible supporting layer **120** beyond the specified curvature threshold. Through the openings, drugs **135** may be eluted (FIG. **2**B) or suction **136** may be applied to lesion **95**. Drug elution or suction may be applied through a cavity **125** that is additional to flexible supporting layer **120** or within flexible supporting layer **120**. As illustrated in FIGS. **2**B and **2**C respectively, device **100** may comprise a drug delivery layer **125** or a suction layer **126** in fluid communication with the openings. In embodiments (FIG. **2**D), flexible supporting layer **120** itself may comprise a drug delivery volume or a suction volume in fluid communication with the openings.

[0094] The precise obstruction identification by the bending of flexible supporting layer **120** upon contact of treatment layer **110** with obstruction **95** may be facilitated by a compliant balloon **122**. Balloon **122** may be inflated such that its surface takes the shape of obstruction **95**. Balloon **122** may be inflated in a manner that permits blood flow while inflated. The balloon's surface may enable the administration of treatment by mechanical, electrical, chemical or other means only at the areas made concave due to the occlusion, as illustrated in the following examples.

[0095] During the operation of device **100**, lesions **95** such as plaque is reduced by suction, mechanical wear, laser, RF radiation, ultrasound or drug administration. The removal of lesion material results in a reduction of surface concavity to a level in which the bending of flexible supporting layer **120** is reduced, e.g. below the specified curvature threshold. As a result, treatment of lesion **95** may be stopped and concluded. Alternatively or additionally, the occlusion status may be monitored by sensing a status of operative elements **130** (e.g. the size of openings, the position of perforators etc. as explained below) or by detecting radio-opaque marking on device **100** the outline of a radio-opaque balloon supporting device **100**. When the treatment of lesion **95** (e.g. of an occlusion) is completed, device **100** is removed, e.g. by deflation of balloon **122**.

[0096] FIGS. **3**A and **3**B are high level schematic illustrations of device **100** configuration having a non-active state **111**A and a bending-activated state **111**B, respectively, according to some embodiments of the invention. In state **111**B, treatment layer **110** is connected to flexible supporting layer **120** only at specified connection areas **132**, leaving the rest of treatment layer **110**, including operable elements **130**, to be separated from flexible supporting layer **120** upon inwards bending thereof. As a result, spaces **134** are formed between treatment layer **110** and flexible supporting layer **120**, which allow application of a treatment (e.g. drug elution) through operable elements **130**.

[0097] FIGS. **4**A and **4**B are high level schematic illustrations of device **100** for perforating lesion **95**, having non-active state **111**A and bending-activated state **111**B, respectively, according to some embodiments of the invention. Operable elements **130** may comprise perforators **133** configured to penetrate vascular lesion **95** upon bending of flexible supporting layer **120** beyond the specified curvature threshold. The perforation may be the sole treatment of lesion **95** or it may instrumental for delivering drugs to lesion **95**, e.g. through openings in treatment layer **110** as described above and below, or for applying suction to fluids in lesion **95** via suction **136** as described above.

[0098] In the illustrated example, perforators **133** may be connected by supports **131** to connecting areas **132** on flexible supporting layer **120**. Upon bending flexible supporting layer **120**, perforators **133** may extend into lesion **95**, guided by supports **131**. Perforators may be hollow and extend distally to openings in flexible supporting layer **120**, in drug delivery layer **125** or in suction layer **126** and function as miniature needles for drug delivery or suction. Alternatively, perforators **133** may be mounted on guides **112** for stabilization and protection in non-operative state **111**A. Perforators **133** may then slide along guides **112** and extend beyond them in operative state **111**B. In embodiments, guides **112** may be hollow and deliver drugs or apply suction by connection to openings in flexible supporting layer **120**, in drug delivery layer **125** or in suction layer **126**.

[0099] In embodiments, perforators **133** may be extended into lesion **95** by mechanical or electrical means which cause perforators **133** to penetrate the artery's inner surface to enable easy access to lesion **95**. As the bending of flexible supporting layer **120** occurs only upon contact with lesion **95**, all other potential administration areas remain closed and do not affected the artery's surface during the procedure. This basically serves as an "automated" procedure in the sense that it only affects the occluded areas. The holes made by perforators **133** on the surface of lesion **95** may serve as openings for drug administration, suction or mechanical mining devices designated for the treated area mainly. Referring to FIG. **4**B, in the case of the mechanical apparatus, the surface's concave structure covering balloon **122** may be twisted due to side leverage by supports **131**. Referring to FIG. **3**B, a sliding or a radial movement between flexible supporting layer **120** and treatment layer **110** may be generated due to the varying radii of curvature of the layers. Either movement may be used, by appropriate configuration of device **100**, to facilitate an opening through treatment layer **110** for application of the various treatment methods. An electrical apparatus may also be used to perforate lesion **95**, by using curvature sensitive wiring to sense the concave surface of device **100** and electrically or mechanically open an opening in treatment layer **110** to access the plaque or perforate lesion **95**. In embodiments, drugs **135** may be eluted or suction **136** may be applied through perforators **133**.

[0100] FIGS. **5**A and **5**B are high level schematic illustrations of device **100** for perforating obstruction **95**, having non-active state **111**A and bending-activated state **111**B, respectively, and including an actuator **145**, according to some embodiments of the invention. Actuator **145** is arranged to control mechanically the bending of device **100** and

thereby to control mechanically the operation of operable elements **130**. In this example, actuator **145** controls the extent to which perforators **133** are exposed (by withdrawal of tubes **112** due to the bending) and hence the depth of perforation applied to obstruction **95**.

[0101] Similar actuators **145** may be incorporated in other embodiments of the invention to add a control to the extent of bending experienced by device **100** and the operation of operable elements **130**. For example, actuator **145** may control the extent to which openings (see below) are opened, drugs are eluted etc. Actuator **145** may be drugs **135** themselves, that may be pressurized to control the activation of operable elements **130**. Actuator **145** may incorporate sensors for the bending of device **100** that may be used to monitor the treatment. In case drugs **135** are eluted in activated state **111**B, drugs **135** may be stored in non-activated state **111**A, e.g. within treatment layer, instead or in addition to actuator **145** as illustrated in FIG. **5**A. Alternatively, drugs **135** may be stored in non-activated state **111**A in supporting layer **120** as illustrated below.

[0102] Actuator **145** may be part of treatment layer **110**, of flexible supporting layer **120**, or be implemented as an additional layer of device **100** at any location with respect to layers **120** and **110**. Actuator **145** may be implemented as an elastic or a rigid wire, may be made of the same material as tubes **112** to control the extent of perforation resiliently or be associated with supports **131**.

[0103] FIGS. **6**A and **6**B are high level schematic illustrations of device **100** for delivering a drug to lesion **95**, having non-active state **111**A and bending-activated state **111**B, respectively, according to some embodiments of the invention. In the illustrated embodiment, operable elements **130** comprise openings that are mechanically controlled by the extent of bending of device **100**.

[0104] Treatment layer **110** comprises tubes **112** that are covered by caps **242** in non-active state **111**A. Caps **242** may be supported by supports **241** or may be connected to the edges of tubes **112** or to supporting later **120**. Upon bending flexible supporting layer **120**, caps **242** move to create a gap **243** with respect to tubes **112**. Gap **243** may operate as an opening for eluting drugs **135**. Drugs **135** may be delivered by flexible supporting layer **120**, drug delivery layer **125** or treatment layer **110**, the latter e.g. via spaces **134** (FIG. **6**B).

[0105] FIGS. **7**A and **7**B are high level schematic illustrations of device **100** for delivering a drug to lesion **95**, having non-active state **111**A and bending-activated state **111**B, respectively, according to some embodiments of the invention. In the illustrated embodiment, operable elements **130** comprise openings **114** connected to flexible supporting layer **120**, drug delivery layer **125** or suction layer **126**, as explained above, and configured to elute drugs **135** or enable suction **136** there through.

[0106] In embodiments, operable elements **130** may comprise openings **114** that are covered by corresponding discs **138**, configured to expose at least one of openings **114** upon the bending of flexible supporting layer **120** beyond the specified curvature threshold. Each disc **138** may be connected to treatment layer **110** or to flexible supporting layer **120** by a holder **137**, that keeps disc **138** in place while opening **114** moves behind it due to the bending of flexible supporting layer **120**. Upon straightening of flexible supporting layer **120**, or in areas where flexible supporting layer **120** is not bend (e.g. as device **100** is not in contact with lesion **95**), discs **138** cover openings **114** and prevent drug elution or suction.

[0107] The density of openings **114** on the surface of obstruction **95** may vary according to the type of obstruction, type of treatment, type and size of openings, type of mechanical activation etc. A minimum of 5-10 openings **114** per obstruction is required. In non-limiting examples, the following may be typical parameters for the density of openings **114** of different types, in cases of different obstructions.

[0108] In case of coronary lesions having a radius between 0.1 mm and 2 mm, the distance between adjacent openings **114** may be between 0.02 mm and 0.2 mm. In case of vascular lesions having a radius between 1 mm and 10 mm, the distance between adjacent openings **114** may be between 0.2 mm and 1 mm. In case of airway obstruction having a radius between 0.5 mm and 5 mm for small obstructions and having a radius between 5 mm and 20 mm for large obstructions, the distance between adjacent openings **114** may be between 0.1 mm and 0.5 mm for small obstructions and between 1 mm and 5 mm for large obstructions. In case of gastrointestinal obstructions having a radius between 10 mm and 100 mm, the distance between adjacent openings **114** may be between 2 mm and 10 mm. In case of obstructions in water or sewage pipes, having a radius between 50 mm and 500 mm, the distance between adjacent openings **114** may be between 0.1 mm and 0.5 mm. In all these application cases, the density of openings **114** in device **100** and device **100** itself may be adapted or selected according to the specific obstruction or lesion that is to be treated therewith. Some of the applications involve continuous activation of operable elements **130** over a range of curvature radii (e.g. drug elution or suction), while other applications may involve activating the operable elements discretely (e.g. energy sources activation).

[0109] FIGS. **8**A and **8**B are high level schematic illustrations of device **100** having a flexible network **150** with varying mesh openings **155**, according to some embodiments of the invention.

[0110] Treatment layer **110** may comprise flexible network **150** and have mesh openings **155** in network **150** as operable elements **130**. Network **150** is arranged to flex upon the bending to increase an opening size in a bended area of flexible network **150**. For example, network **150** may be compliant to the bending by lesion **95** and designed to widen its mesh openings **155** upon the network's compliance to the lesion's form.

[0111] In the illustrated example, mesh openings **155** in the bended regions are of a width **156** that is larger than a width **157** of mesh openings **155** in non-bended regions of network **150**. For example, width **156** may be three times width **157**. As illustrated in FIG. **8**A, network's wires **158** may be configured to be wide enough to prevent fluid communication through mesh openings **155** having width **157** but allow fluid communication through mesh openings **155** having width **156**. In another example, network wires **158** may have flaps of width **157** (not shown, the wires are shown schematically to illustrate mesh openings only), that are separated from each other only when the distance between wires **158** exceeds width **157** significantly, e.g. reach width **156**.

[0112] As illustrated in FIG. **8**B, wires **158** may be wide enough to leave no gap **155** between them at a low radius of curvature (left side of FIG. **8**B, on vessel **90**), but spread apart to expose gap **155** upon bending beyond the curvature threshold due to obstruction **95** (middle of FIG. **8**B, on lesion **95**).

[0113] In embodiments, the space within network **150** and/or treatment layer **110** may be used to elute drugs **135** or apply suction **136** to lesion **95**.

[0114] In embodiments, eluted drugs **135** may be photo activated to apply photodynamic therapy (PDT). Either or both drugs **135** and activating light may be delivered to lesion **95** via openings **114** or gap **155**.

[0115] FIGS. **9**A and **9**B are high level schematic illustrations of device **100** for delivering drug **135** to lesion **95**, according to some embodiments of the invention. In the illustrated embodiment, openings **114** in treatment layer **110** are operable elements **130**. treatment layer **110** may comprise multiple segments **148** which are held together by an expandable scaffold **147** that interconnects them and allow their separation upon bending of device **100** (FIG. **9**A). In a view from above, FIG. **9**B illustrates the interface between operable elements **130** and obstruction **95**—below the bending threshold segment **148** are close together and conceal closed openings **149**, while beyond bending threshold segment **148** are spread apart to expose openings **114**.

[0116] FIGS. **10**A and **10**B are high level schematic illustrations of an obstruction grinding device **100**, according to some embodiments of the invention. Device **100** is designed to erode obstruction **95** through openings **114** in treatment layer **110**.

[0117] For example, a grinder **160** may be inserted into balloon **122** and rotated via handle **161**. Grinder **160** may have grinding protrusions **162** that may pass through openings **114** in activated state **111**B and erode obstruction **95**. Protrusions **162** may either be foldable in a deactivated state or spatially removed from layer **110** in inactive state **111**A.

[0118] FIGS. **11**A-**11**E are high level schematic illustrations of a one layered treatment device **100**, according to some embodiments of the invention. FIGS. **11**A-**11**E illustrate in more detail an embodiment of device **100** depicted in FIG. **1**C, having openings **114** as operable elements. One layered treatment device **100** may be configured to be a part of a balloon skin, and activating openings **114** may create fluid communication between the balloon's interior **171** and obstruction **95**, that may be used for drug elution or application of suction, e.g. via channel **173**.

[0119] FIGS. **11**A, **11**C and **11**B, **11**D, respectively, illustrate inactive state **111**A and activated state **111**B, the former with slits **172** that prevent fluid communication therethrough, and the latter with openings **114** resulting from the expansion of device **100** that turns slits **172** into openings **114** and provides fluid communication therethrough, for application of the treatment.

[0120] FIG. **11**E illustrates both states, the activated state over obstruction **95** and the inactive state over level areas of vessel **90**. The bending of device **100** over obstruction **95** yields the stretching and expansion of device **100** that turns slits **172** into openings **114** and provides fluid communication therethrough, for application of the treatment.

[0121] FIGS. **12**A-**12**C are high level schematic illustrations of openings **114** as operable elements, according to some embodiments of the invention. FIG. **12**A illustrates a design of device **100** (one or two layered) with slits **172** and corresponding openings **114** along the direction of vessel **90** (and of flow **85** along vessel **90**). FIG. **12**B illustrates a design of device **100** (one or two layered) with slits **172** and corresponding openings **114** that are perpendicular to the direction of vessel **90** (and of flow **85** along vessel **90**). FIG. **12**C illustrates a design of device **100** (one or two layered) with a mixed configuration of slits **172** and corresponding openings **114**, some of slits **172** along the direction of vessel **90** and some perpendicular thereto.

[0122] The direction of slits **172** influences and allows spatial control of the mechanical activation of operable elements **130** (in the illustrated case openings **114**, but not limited thereto). In particular, the specified curvature threshold is defined with respect to slit direction—the radius of curvature of obstruction **95** must decrease below the given threshold curvature radius along a direction that is perpendicular to slit **172** to induce the maximal opening thereof. A direction of radius of curvature decrease that is tangential to the direction of slit **172** generates much less spreading of opening **114**, if at all (depending on the threshold values). Hence, the direction of slits **172** and openings **114** may be selected according to the local topography of obstruction **95** to apply the selected treatment. Any mixture of slits **172** having different orientations induces a different level of activation of operable elements with respect to a given obstruction topography, and hence allow a spatially differentiated treatment of obstruction **95**, i.e. certain regions in obstruction **95** may be treated at different intensities, or a given region may be treated at different intensities sequentially by different areas of device **100**.

[0123] In embodiments, the material of device **100** itself may be used to treat obstruction **95**. For example, device **100** may be implemented as balloon **122** or as the parachute itself and activate the treatment upon bending of device **100** as balloon or parachute skin upon obstruction **95**.

[0124] FIG. **13**A is a high level schematic illustration of balloon implemented device **100** for treating lesions **95** at vessel bifurcations, according to some embodiments of the invention. FIG. **13**A illustrates an embodiment with fibers **110** wound transversely to the direction of application of balloon **122**

[0125] Device **100** may be configured as balloon **122** (see also FIG. **2**A for a hollow balloon, allowing flow such as blood flow through cavity **85** in the balloon) with flexible supporting layer **130** being part of or externally attached to a skin of balloon **122**. In such embodiment, the bending of flexible supporting layer **120** is carried out by inflating balloon **122** against vascular lesion **95** and device **100** thus utilizes the lesion's natural curvature to activate operable elements **130**.

[0126] Balloon **122** may be connected to a delivery system **104** that is in fluid communication with drug delivery layer **125**, suction layer **126** or flexible supporting layer **120** to elute drugs **135** or apply suction **136**.

[0127] FIG. **13**A illustrates flow obstructions **95** such as vascular lesions in an arterial bifurcation. While prior art treatment of lesions in bifurcations is particularly difficult due to the geometry of the treated area, device **100** utilizes the difficult geometry to enhance the treatment, as the bending of balloon **122** and fibers **110** attached to it is enhanced by the difficult geometry and thus facilitates treatment. In embodiments, removal of obstructions **95** may complete the treatment simply by the resulting increase in the bending radius beyond the specified threshold. Device **110** clearly allows treatment of several obstructions, as illustrates in FIGS. **19**F and **13**A. Lesion **95** is located at sides of vessel **85** and at the apex of the bifurcation. Emission regions **130**B, **130**C may be multiple, and fibers **110** may be configured to emit radiation based on different thresholds in regions **130**B, **130**C and thus enable specialized treatment of the bifurcation. For example, parameters of different emission regions may be determined by geometrical considerations of target **95** and operation surrounding and its relation to the structure of device **100** as well

as by treatment considerations (types of applied treatments at different regions, radiation intensity, safety considerations etc.).

[0128] Furthermore, while vessel bifurcations are especially hard to treat with customary devices (because the prior art device must be shaped according to the bifurcation in advance), device **100** is particularly efficient is such cases as the curvature is enhanced by the bifurcation. In addition, device **100** is particularly efficient in treating the apex of the bifurcation, as the prior art disadvantage of the apex lesion having a small curvature radius become an advantage for the present invention, which utilizes the small curvature radius to enhance activation and treatment efficiency.

[0129] FIG. **13**B illustrates a device for treating flow obstructions and treatment of flow obstructions **95** by a supportive structure **122** that allows continued flow **86** through lumen **85**, such as of a vessel **90** (e.g., an artery), according to some embodiments of the invention. Bending of fibers **110** attached to supportive structure **122** applies radiation **152** from operable elements **130** (represented by arrows) as treatment of obstructions **95**, possibly focused **96**, and upon their removal, the bending flattens and treatment ceases.

[0130] FIGS. **13**C-**13**K are high level schematic illustrations of device **100** having optical fibers **110** exhibiting bend emission, that are wound on a supportive structure **122** such as a compliant or non-compliant balloon, according to some embodiments of the invention.

[0131] FIG. **13**C illustrates supportive structure **122** embodied as balloon **122**, to which fibers **110** are attached. Balloon **122** may be inflated by pump **75** and inserted via delivery system **76** and channel **77**, such as an endo scope, possibly guided by a guide wire **138** (see FIG. **13**G). Balloon **122** may be fixated and controlled by a guide **104** close thereto. Balloon **122** may comprise absorptive sink **169** at its end, or wound fibers **110** may be circular and guide back excessive radiation (as illustrated schematically in FIG. **20**C).

[0132] Fibers **110** may be wound and attached to balloon **122** in different configurations. FIG. **13**D illustrates a balloon cross section with fibers **110** evenly distributed on the skin of balloon **122**. FIGS. **13**E, **13**F, **13**I and **13**J illustrate more complex winding patterns involving spiral windings in two directions. Winding of fibers **110** may be transverse or longitudinal with respect to the length axis of balloon **122** or exhibit any combination thereof or other form. In general, optical fibers **110** may be wound in a configuration that is perpendicular, parallel or oblique to a longitudinal axis of balloon **122** or in a combination thereof.

[0133] Winding of fibers **110** may be stent-like, having a collapsible stent-like or balloon-like configuration **122**A (FIG. **13**G) and an expanded stent-like or balloon-like configuration **122**B (FIG. **1311**). FIGS. **13**I and **13**J may also be implemented in a stent-like design. FIGS. **13**I and **13**J illustrate implanted stents **100** comprising active fibers **110** which upon energy transfer **166** from a source **167** within or outside the body emit energy **152** through bended emission regions **130**B (not shown in this figure). FIG. **13**I illustrates device **100** which may be implanted in a region of obstruction **95** such as plaque or other diseased region in e.g. the esophagus (Gastroesophageal reflux disease GERD) or bronchi (asthma), to enable gradual ablation of plaque/tissue **95**, or localized treatment by drug activation PDT. For example, one or more fibers **110** may be incorporated in a stent of any kind to deliver radiation that activates a drug that is associated with the stent. Furthermore, device **100** may comprise in any of the embodiments, a drug eluting means such as a needle, arranged to elute a drug in the vicinity of the radiation emission. The radiation may be then utilized to activate the drug or the drug may be used to enhance the effect of the laser treatment. FIG. **13**J illustrates device **100** in which emitted energy **152** may be used to inhibit or activate nerve firing **196**, for example in the renal arteries to block sympathetic outflow from the kidney and thus reduce systemic blood pressure, to block pain signals in certain cases, or to control the sensation of hunger in eating disorders or obesity. Such states may also be treated by fibers **110** and devices **100** illustrated in other embodiments. FIG. **13**K illustrates device **100** comprising fibers **110** wound around a stent **112** or replacing one or more of the wires of braided stent as supporting structure **122**. Bended fiber **110** may be arranged to emit radiation that supports the placing of stent **122**, ablates tissue surrounding stent **122** (e.g. before, during or after the healing process) or interacting with eluted drugs.

[0134] In embodiments, any optical fiber may be used in combination with a stent for activating a treatment such as ablation, activation of a radiation sensitive drug or activation of nerve endings for various purposes. Regular emission from fiber tips may be used in addition to or in place of bend emission to deliver the required radiation and apply specified treatments.

[0135] Supportive structure **122** of device **100** is configured to position optical fibers **110** with respect to a target **95** (such as a flow obstruction) in a way that causes bending of all, some or at least one optical fiber **110** beyond the specified bending threshold thereof over target **95**, to emit electromagnetic radiation **152** at target **95**. In the case of balloon **122**, inflating balloon **122** may cause fibers **110** to bend upon contacting target **95** beyond the emission threshold.

[0136] The topographically induced bending can be utilized to deliver energy specifically to those areas where the treatment is required, such as flow obstructing plaque (see e.g., FIGS. **13**A and **13**B). Balloon **122**, which may be delivered with a standard catheter delivery system, may be inflated in-situ, causing fibers **110** on the surface of balloon **122** to be pressed against the artery and plaque and be imprinted with the topography. The imprint causes bends in the fiber that induce the desired bend emission which is used to treat the lesions.

[0137] FIG. **13**F illustrates an embodiment of device **100** that is operated by an external source **166**. External source **166** may activate device **100** by any kind of radiation or field applied to device **100**. Such device **100** may have a balloon as supportive structure **122**, or fibers **110** may be stent-like, having a collapsible stent-like configuration (FIG. **13**G) and an expanded stent-like configuration (FIG. **1311**). Device **100** may be used acutely during procedure or be implanted for permanent use.

[0138] In embodiments, fibers **110** may be arranged as resonators that amplify induced radiation from source **166** and thus generate the required radiation for treatment without using an internal light source **70**.

[0139] FIGS. **13**G and **13**H illustrate a collapsed configuration and an expanded configuration of device **100** (configured either as a balloon or as a stent) in treating an obstruction in a heart **60**. Such embodiments may comprise a stop point for fibers energy or an energy sink, as illustrated e.g., in FIGS. **13**C and FIGS. **20**A-**20**C below.

[0140] FIGS. **14**A-**14**C are high level schematic illustrations of a parachute implemented device **100** in stages of

operation, according to some embodiments of the invention. The parachute form allows utilizing patterns of fluid flow **86** (e.g. blood flow through arteries) to deploy device **100** upon obstruction **95** by utilizing the flow distracting characteristics of obstruction **95**, in addition to utilizing the form of obstruction **95** for applying the treatment itself. Device **100** is configured to contact obstruction such as vascular lesion **95** by being carried along by blood flow **86** until being obstructed by vascular lesion **95**.

[0141] In embodiments, parachute **123** comprises a holder **127** connected via strings **128** to device **100** and configured to guide device **100** to bend upon obstruction **95** by utilizing fluid flow patterns in the vicinity of obstruction **95**. In embodiments, parachute **123** may further comprise a frontal leading area **129** configured to maintain a force resulting from fluid flow **86** and acting to position device **100** on obstruction **95**. In embodiments, leading area **129** may be part of device and may be used to apply treatment. Using parachute **123** further ensures maintaining fluid flow **86** through vessel **90** during the treatment, which may be an essential requirement, e.g. when treating lesions in the carotid arteries.

[0142] In embodiments, the parachute may be replaced by a torus shaped balloon (not shown) that allows blood flow therethrough. The operation of the torus shaped balloon may similarly utilize blood flow to place device **100** upon the lesion, or generally utilize fluid flow to place device **100** upon obstruction **95**.

[0143] FIGS. **14**B and **14**C illustrate examples for deployment of parachute implemented device **100**, in a case of opposing lesions **95** or bilateral narrowing of vessel **90**, and in a case of a single lesion **95**, respectively. In the former case (FIG. **14**B), strings **128** may stabilize device **100** on both lesions **95** while frontal leading area **129** may ensure an appropriate coverage of lesions **95** by device **100**. In the latter case (FIG. **14**C), strings **128** may act asymmetrically to stabilize device **100** on lesion **95** while frontal leading area **129** may ensure an appropriate coverage of lesions **95** by device **100**. A string **128**B farther from lesion **95** may expand or be released to allow a far end of device drift further and cover lesion **95**, while a string **128**A closer to lesion **95** may shrink or be kept short to place a close end of device onto the beginning of lesion **95**. Such asymmetric operation utilizes fluid flow **86** to place device **100** onto lesion **95** and utilize its bending to apply the treatment.

[0144] Parachute **123** may be deployed by first releasing device **100** into the blood stream far enough from lesion **95**, such that flow is not affected by lesion **95**. Second, device **100** is deployed such that regions of device **100** that are in low flow or low flow resistance regions are anchored onto lesion **95** and regions of device **100** that are in high flow regions are not restricted. In this way device **100** tends to physically cover and deploy itself over the regions of lesion **95** which obstruct flow **86** the most. Parachute **123** may then be designed to include a therapeutic agent, an electric source, an ultrasound source or have light energy conducting properties to facilitate treatment by operable elements **130** at lesion **90** and prevent treatment or protect adjacent healthy regions. Furthermore, parachute **123** may be anchored to a catheter system for deployment and consequent retraction after treatment.

[0145] In embodiments, device **100** further comprises a flow sensor (not shown) for measuring the flow patterns near lesion **95**. The flow measurements may be used to plan the application of parachute implemented device **100**.

[0146] In embodiments, holder **127** may further comprise delivery system **139** in fluid communication with drug delivery layer **125**, suction layer **126** or flexible supporting layer **120** to elute drugs **135** or apply suction **136**.

[0147] FIGS. **15**A and **15**B are high level schematic illustrations of device **100** for focusing energy at obstruction **95**, having non-active state **111**A and bending-activated state **111**B, respectively, according to some embodiments of the invention.

[0148] In embodiments, operable elements **130** may comprise energy sources configured to deliver energy to vascular lesion **95**. For example, the energy sources may deliver electromagnetic radiation to obstruction **95** such as laser energy. Operable elements **130** may comprise the energy sources themselves or optical elements that are configured to direct and deliver the electromagnetic radiation from an external energy source (not shown) to obstruction **95**. In another example, the energy sources may deliver mechanical energy, e.g. in the form of ultrasound pressure waves, or electric energy, e.g. in the form of current. Operable elements **130** may comprise the energy sources themselves or transducers that receive energy from an external source (not shown).

[0149] The energy sources may be activated by the bending or may radiate at a low level that doesn't harm the surrounding. The effective energy level may be reached only upon adding several sources by the bending. Alternatively or complementary, the energy sources may be covered by treatment layer **110** and exposed to obstruction **95** upon widening of openings **114** in the cover, as described in other embodiments.

[0150] The concavity of device **100** may be used as a focusing mechanism of the energy sources. Emitted energy **152**—from multiple operable elements **130** such as openings or bending regions of treatment layer **110** such as an energy delivering device, e.g., an optical fiber **110**—may be concentrated due to the bending of device **100** at a focal point **96** on lesion **95**. Curving treatment layer **110** over obstruction **95** points the energy sources to the same point **96** in the plaque body (in case of a vascular lesion), e.g., to the center of the plaque buildup.

[0151] Operable elements **130** may be positioned at such spaces and orientations that, upon the bending of flexible supporting layer **120** at a certain curvature, operable elements **130** deliver energy **152** to specified focal areas **96** on obstruction **95**. In this way, energy **152** from different energy sources is added and may be configured to be beyond a specified treatment threshold. In such a configuration, energy **152** delivered from any single operable elements **130** (such as an opening in an energy delivering device, or bending regions of respective fiber **110**) may be selected to be harmless to surrounding tissue (in state **111**A), while upon concentration of several energy sources, due to the bending of device **100** on obstruction **95** (in state **111**B), an effective treatment is applied. In embodiments, operable elements **130** may comprise sensors that detect the bending of obstruction **95** and activate an external energy source (not shown) to deliver energy to operable elements **130** only upon detection of obstruction **95**.

[0152] FIGS. **15**C and **15**D demonstrate bend emission for the fiber configuration illustrated in FIG. **1711** (see below, serrated fiber), according to some embodiments of the invention. FIGS. **15**C and **15**D thus illustrate an embodiment of operable elements **130** as features of fiber **110** as treatment layer **110** or as part thereof. In certain embodiments, operable

elements **130** may be embodied in fiber **110** as treatment layer **110** by various means, such as configuration of any of coating **140**, cladding **115**, emitting regions **130**A, **130**B, core **103** or supporting structures **122**. Operable elements **130** as configurations of fiber(s) **110** may be associated with different supportive layers **120**, as illustrated in any of the embodiments disclosed herein, and elements of supportive layers **120** may be configured to support the configuration and/or operation of fiber based operable elements **130**.

[0153] FIG. **15**C is a direct photograph of transmitted light in fiber **110**, showing emission through the bended side **130**B of fiber **110**. Generally speaking, the mechanical tension in the bent fiber lowers the refractive index on the external side and increases the refractive index on the inner side, to generate bend emission as a combined result of the geometry and material influence of the bending.

[0154] FIG. **15**D illustrates the power output as percent of the transmitted radiation from the specified region upon bending (broken line) in comparison to emitted radiation through cladding **115**A outside emitting sector **130**B (solid line). Clear emission peaks are evident at an arc length range of 40-160 μm of the circular fiber cross section, i.e. in the specified bended sector.

[0155] It is noted that operable elements **130** as illustrated in FIGS. **15**A and **15**B may be implemented in many of the embodiments which illustrate bending regions **130**B of optical fibers **110** in following illustrations (as non-limiting examples, FIGS. **18**B, **19**A, **19**E, **19**G, **22**A, **23**B, **27**B, **27**C, **28**A-C). As explained below (FIGS. **16**A-C and **17**A-K), implementation of energy emitting operable elements **130** as emitting fiber regions **130**B may be used in various implementations. However, other disclosed embodiments of operable elements **130** in such implementations are likewise included within the scope of the present invention.

[0156] FIG. **16**A is a high level schematic block diagram of an emitting region of an optical fiber **110**, according to some embodiments of the invention. Optical fiber **110** comprises a core **103** having a refractive index n_K and a cladding **115** having a refractive index n_M. Optical fiber **110** has at least one specified region of cladding **115** that is arranged to emit electromagnetic radiation from core **103** upon bending optical fiber **110** at the specified region beyond a specified bending threshold with respect to a bending radius r **105**. The emission of electromagnetic radiation from core **103** upon bending optical fiber **110** is related to in the following as bend-emission (BE). The bend emission depends on various fiber and radiation characteristics such as the size, structure and materials of the fiber, bending radius **105**, radiation frequency and so forth. The fiber is designed to enable bend emission in the specified region and sectors only, while continuing to prevent transmission through the cladding in other parts of the fiber.

[0157] It is noted that bend-emission may be configured to occur inwards or outwards with respect to the direction of bending. It is further noted that the disclosed principles are also applicable to other types of waveguides, e.g., RF waveguide (see e.g., FIG. **17**K illustrating a metallic waveguide), which may be tailored for specific geometrical parameters allowing highly controlled and specific emission patterns.

[0158] Bend emission may be achieved by bending fiber **110** prior to an actual application thereof, e.g. bending fiber **110** to have a snare-like form, and angled form, a stent-like form etc. (see examples below), and then controlling the bend emission by the light source upon placing the bended regions of fiber **110** in an operative position. Alternatively or complementary, bend emission may be under geometrical control, achieved by making use of the natural curvature of the targeted object to generate the desirable energy discharge profile from the waveguide. Certain regions in fiber **110** may be designed to bend-emit upon curving in contact with the target, as exemplified below, and the energy that is emitted in bends in these regions is actually used to achieve the desired goal. In such case, emission may be controlled by the actual bending, in addition or in place of controlling the light source.

[0159] Any type of fiber **110** may be arranged to emit radiation upon a specific bending, e.g. a waveguide (which may comprise metallic waveguides), a solid core optical fiber, a hollow fiber and a photonic crystal fiber (such as a holey fiber, a Bragg fiber or any other micro-structured fiber). The non-emitting sector(s) may be micro-structured (e.g. with a grating or air holes) to reduce an effective refractive index thereof below a refractive index of the emission sector and/or to direct radiation toward the emission sector.

[0160] Optical fiber **110** may be single-mode or multi-mode, in the latter case, the specified emission region and bending threshold may be selected with respect to the required modes, to control the emitted energy. In addition, the specified emission region and bending threshold may be selected with respect to, and controlled by, the beam polarization.

[0161] Bends in fiber **110** that may be used in emitting regions **130**B include both micro-bends (local deviations from the fiber's linearity, with relative small bending radii) and macro-bends (changes of angle of the fiber's direction, usually larger bending radii). For example, the emitted radiation from a macro-bend may be estimated, for single mode fibers, by the expression: $\mathrm{Exp}\,(8.5-519\cdot D\cdot(\lambda_{ce}/(2\lambda\cdot MFR))^3)$ in dB/m, where D is the bending radius in mm, λ is the wavelength in μm, λ_{ce} is the fiber cut-off wavelength in μm and MFR is the mode fiber radius in μm.

[0162] FIG. **16**A illustrates the condition for bend emission, according to some embodiments of the invention, by illustrating an example of a possible trajectory of light travelling down fiber **110**. The light reaches the beginning of the bended specified region **130**B at an angle α that is not yet sufficient for BT due to the bend radius which is not sufficiently small at this point (i.e. a is still larger than $\theta_{emitting\ region}=\sin^{-1}(n_E/n_K)$). The light is thus reflected to cladding side **115**A and is internally reflected at angle which is larger than $\theta_{cladding}=\sin^{-1}(n_M/n_K)$, and stays within core **103**. Upon reflection from cladding **115**A the light reaches sector **130**B with cladding **115**B at an angle γ which is now smaller than $\theta_{emitting\ region}=\sin^{-1}(n_E/n_K)$, as the bending radius reaches at this point the threshold radius and goes beyond a specified bending threshold of the specified region of fiber **110** (i.e. bending radius becomes smaller than the threshold radius). The transmitted light exits region **130**B at an angle θ. The exact calculation follows Wang et al. (2007) "Investigation of Macrobending Losses of Standard Single Mode Fiber with Small Bend Radii", in Microwave and optical letters 49:9, 2133-2138. Bend-emission can be approximated as starting to occur at angle θ_{bend} that is defined using bending radius r **105** as: $\theta_{bend}=\sin^{-1}(r_{bend}(r_{bend}+ID))$, ID being the internal diameter i.e. core diameter. The condition for bend-emission is that $\sin^{-1}(n_M/n_K)=\theta_{cladding}<\theta_{bend}<\theta_{emitting\ region}=\sin^{-1}(n_E/n_K)$.

[0163] Other than the prior art, the present invention utilizes conditional and controllable side emissions from an optical fiber. In contrast to side firing fibers, fibers of the present invention do not emit any radiation when straight or bended below the bending threshold. The side emission is activated only upon the bending of the fiber at a predetermined bending radius, for example by an obstruction that is to be removed by the fiber, or according to a specific device design.

[0164] During treatment by emitted radiation **152**, parts of the treated target (e.g. a flow obstruction or a polyp) are removed, causing the target to be decimated and flattened. In some embodiments, target flattening reduced the bending of fiber **110** (increases the bending radius thereof) and causes a reduction in bend emission until conclusion of the treatment. Such effect may be desired and taken into account when selecting the bending threshold. In some embodiments, a different specified region may take over the treatment, and be activated by a different bending threshold to allow multi-stage treatment.

[0165] FIG. **16**B is a schematic illustration of the dependency of the emitted radiation through the specified region on bending radius **105**, according to some embodiments of the invention. FIG. **16**B illustrates a broad peak of emitted radiation at about 1-3 mm of bending radius, in which over 90% of the electromagnetic radiation transferred through optical fiber **110** is emitted through the specified region. Furthermore, FIG. **16**B illustrates that radiation is emitted from cladding **115** upon bending, not specifically from the specified region (dashed line), is much smaller in intensity and occurs at much smaller bending radii (mostly under 0.5 mm). Hence, FIG. **16**B illustrates the good controllability of the emitted radiation by the design of the specified region.

[0166] In one example, the specified region has a cladding **115**A having a refractive index n_M in a non-emitting sector **130**A and a cladding **115**B having a refractive index n_E in an emission sector **130**B. In case of a solid core fiber, the refractive indices satisfy $n_K \geq n_E > n_M$. In case of a hollow (air) core fiber, the refractive indices satisfy $n_M, n_E > n_K$. In the latter case, embodiments may comprise either $n_M \geq n_E$ or $n_E \geq n_M$ depending on the indices of refraction and on the material's absorption, scattering and micro-structure.

[0167] FIG. **16**C is a schematic illustration of the dependency of the emitted radiation through the specified region on bending radius **105** (y axis) and on the ratio n_E/n_K (x axis), according to some embodiments of the invention. The lines in FIG. **16**C indicate ratios of electromagnetic radiation emitted through the specified region to electromagnetic radiation transferred through optical fiber **110**, namely 0.2, 0.4, 0.6 and 0.8, which are also the values indicated on the y axis of FIG. **16**B. FIG. **16**C illustrates increasing emission with n_E/n_K ratio nearing 0.99 (with constant radius **105**) and increasing emission with decreasing bending radius **105** (with constant n_E/n_K ratio), i.e. with stronger bending of optical fiber **110**.

[0168] In embodiments, one or more optical fibers **110** may be incorporated in a device **100** (see e.g. FIGS. **20**C, **13**A and **13**C) having at least one light source arranged to transmit electromagnetic radiation through one or more optical fibers **110**. The following description starts with embodiments of optical fiber **110** and continues with embodiments of device **100**. For the sake of brevity of description, it is understood that any one of the optical fiber embodiments may be implemented in any one of the device embodiments, and all possible combinations are included therefore in the present invention.

[0169] FIGS. **17**A-**17**I are high level schematic illustrations of various embodiments of operable elements **130** of optical fiber **110** having an asymmetric cladding **115** in cross section, according to some embodiments of the invention. FIGS. **17**A-**17**I illustrate cross sections through the specified region. Generally, operable element(s) **130** as emitting sector(s) is numbered **130**B (and **130**C, in case of several emitting sectors) while the non-emitting sector is numbered **130**A. The respective coating sections are numbered **115**B and **115**A respectively. FIGS. **17**A-**17**I illustrate one or two emitting sectors as examples, operable element(s) **130** of fiber **110** may be arranged to comprise more than two emitting sectors **130**B, **130**C, multiple different sectors at different specified regions along fiber **110** and any other region and sector configuration according to given requirements.

[0170] FIG. **17**A illustrates fiber **110** with two differing cladding types **115**A, **115**B having different refraction indices n_M, n_E respectively. n_E is generally closer to n_K so that bending fiber **110** at the specified region beyond the bending threshold results is emission **152** of radiation through section **130**B in the specified region, as exemplified in the calculations below.

[0171] In embodiments, the normalized refractive index difference between the cladding of the specified emission region and the cladding of non-emitting regions may be larger than ca. 0.1% (e.g. as $\Delta=(n_E-n_M)/n_E$), and may be larger than ca. 0.5%. Differences may be larger or smaller, depending on the exact materials and structures used and operational (predefined or resulting) bending radii **105** (as a non-limiting rule of thumb, the larger the difference in refractive indices, the smaller is the threshold bending radius).

[0172] Two non-limiting examples, which refer to commercial SiO_2 fibers having a refractive index of $n_K=1.457$ (at 633 nm) are (i) $n_M=1.456$ and $n_E=1.457$ and (ii) $n_M=1.000$ and $n_E=1.450$.

[0173] FIG. **17**B illustrates fiber **110** with two differing cladding types **115**A, **115**B having different types of microstructures **116**A, **116**B respectively, in the illustrated cases different Bragg type structuring of cladding **115**. In the illustrated example, Bragg structures **116**A are more extensive in cladding **115**A than Bragg structures **116**B in cladding **115**B, resulting in emission **152** through sector **120**B upon bending beyond the threshold. Other embodiments may comprise one sided Bragg micro-structuring or multiple zones with differing Bragg micro-structuring. Furthermore, structure **116**B may have no Bragg layers and may be constructed of a single material.

[0174] FIG. **17**C illustrates fiber **110** with two differing cladding types **115**A, **115**B the latter having microstructures **117**A, **117**B such as holes (e.g. air holes), that reduce n_M in non-emitting region **130**A with respect to n_E in emitting region **130**B. In general, optical fiber **110** may be an asymmetric photonic crystal fiber, which can also be used for additional purposes. Optical fiber **110** may be an asymmetric Photonic Crystal Fiber (PCF), e.g. according to one of the illustrated embodiments, which can also be used for additional purposes. Microstructures **117**A, **117**B may be present in emitting region **130**B and in non-emitting region **130**A to different extents (regarding the number of microstructures **117**A, **117**B, their parameters and their spatial expansion), or

be present on one side only, e.g. only microstructures **117**A in non-emitting region **130**A, to prevent emission therefrom.

[0175] FIG. **17**D illustrates fiber **110** having cladding **115** designed to have a large air gap **118** in non-emitting region **130**A and additionally core **103** that may be asymmetrically positioned (i.e. off-center or eccentrically) with fiber **110**. Core **103** may further be non-circular (e.g. elliptic in FIG. **17**D) to define the bending threshold according to requirements. The form and extent of air gap **118**, the specific design of cladding **115** and of core **103** may be adapted to specific bend-emission parameters and specifications.

[0176] FIG. **17**E illustrates another asymmetric fiber configuration, comprising asymmetric core **103** positioned off-center of fiber **110** and cladding **115** comprising multiple air holes **119** arranged to define non-emitting region **130**A. The exact configuration of core **103** and cladding **115** may be selected according to specific bend-emission parameters and specifications.

[0177] FIG. **17**F illustrates another example of asymmetric fiber **110**, namely an embodiment having a specified form and position of the emitting sector **115**B of cladding **115** and of core **103**.

[0178] FIG. **17**G illustrates optical fiber **110** having multiple emission sectors, that may be designed at various positions in the cross section of fiber **110**. In the illustrated case as a non-limiting example, two opposite emission sectors **130**B, **130**C, that may have similar or different emission characteristics. Emission sectors **130**B, **130**C may be at different angles to each other and may comprise more than two emission sectors. Emission sectors **130**B, **130**C may be associated with different cores **103**B, **103**A respectively, e.g. to be configured to emit electromagnetic radiation **152**B, **152**A with different parameters (e.g. wavelength, intensity). Emission sector **130**C may be associated with additional core **103**A. Emission sectors **130**B, **130**C may have different bending thresholds, also in respect to the direction of emission (may emit upon inwards or outwards bending).

[0179] Electromagnetic radiation, such as laser energy, may be delivered to either or both cores **103**B, **103**A simultaneously or sequentially. Without loss of generality, fiber **110** may have several specified regions and/or several emission sectors **130**B, **130**C etc. which may be constructed axially so as to deliver energy along fiber **110** to different specified regions and/or the emission sectors may be constructed tangentially to deliver energy to several regions along fiber **110** simultaneously or sequentially.

[0180] FIG. **17**H illustrates optical fiber **110** having radially serrated cladding **115** at the specified region, in which spaces **121**A, **121**B between the serrations are defined according to the specified bending threshold. Upon bending fiber **110**, serrations on one side of fiber **110** move closer to each other (spaces **121**A become smaller with respect to a straight fiber **110**), while serrations on the opposite side of fiber **110** spread apart (spaces **121**B become larger with respect to a straight fiber **110**). The cladding serrations may thus be configured to define distinct operable elements **130**, as illustrated in FIGS. **15**A-D. Operable elements **130** as emitting region **130**B may be on either side of fiber **110**, depending on the relation between n_K and n_M. For $n_K > n_M$ (solid core), the crowding together of the serrations increases the effective refractive index of cladding **115** to near n_K and emitting region **130**B is hence on the concave side, while the spreading apart of the serrations reduces the effective refractive index of cladding **115** and non-emitting region is hence on the convex side of fiber **110**.

[0181] The serrations on the concave side can guide the energy in a periodic manner (see FIG. **15**C), focusing energy to desired regions along the specified region. FIG. **15**D (see above) illustrates the energy delivery in a simulated 90° bend in optical fiber **110**. The energy delivery through the cladding is in solid line and the radiation through the specified region is in dashed line. The emitted radiation is focused periodically due to the serration in the concave bended region. In addition, serrations also enable mechanically the bending of fiber **110** in smaller bend radii.

[0182] FIG. **17**I illustrates another example of asymmetric fiber **110**, namely an embodiment having a specified form and position of the emitting sector **115**B of cladding **115** and of core **103**. Core **103** is elongated and eccentric relative to cladding **115**, and has an effective radius **131**. The cross sectional structure may be designed to direct emitted radiation **152** to focal point **96** (see also FIGS. **15**B, **27**C, etc.), e.g., on a radial symmetry axis of emitting sector **115**B. A core-cladding interface **153** may be shaped to influence the emission characteristics.

[0183] The fiber's cross section may be configured to emit radiation **152** not only in a specific direction but also in a specific profile. The light from core **103** may be optically manipulated to exit the waveguide in a narrow flat profile or alternatively in a dispersive profile as needed. Core-cladding interface **153** may be designed to serve as a lens to focus the naturally dispersive energy. For example, FIG. **17**I illustrates a cross-sectional view of one of the profiles that serves to focus the energy. In this case, trajectory **153** of emitted radiation **152** reaches core-cladding interface **153** and is then focused inward to focal point **96** closer thereto than would have been emitted radiation from a radially symmetric interface, due to the shorter effective radius **131** of core **103**. The unique assembled structure allows to asymmetrically emit the energy away from core **103** to one side only and also manipulates interface **153** in a very specific manner that dictates the exact emission profile. Other profiles may be generated by fiber cross sectional profiles exemplified in FIGS. **17**D-**17**F.

[0184] The index of refraction also depends on temperature. Generally, an increase of temperature causes an increase in the index of refraction. In one embodiment, in which fiber **110** is inherently asymmetric as in FIG. **17**I, energy discharge **152** may be asymmetric as well. Since energy **152** is discharged on the inner side of the bend, this side gets warmer, creating a positive feedback loop which increases discharge **152** and thus the accuracy and safety as well since this effect occurs only at the treatment site. The increase of temperature leads to an increase in the index of higher refraction in emitting section **130**B and thus to increased energy discharge and more heating, reinforcing the discharge mechanism. Straightening the bend halts and reverses the process. The precise target energy of the tissue's cutting/heating is tuned to enhance and increase the effectiveness of bend emitted radiation **152**. The cladding material may be chosen with specific absorption to control the effect of bend-emission.

[0185] FIG. **17**J illustrates an embodiment of fiber **110** with a coating **140** that has a gap or is missing at specified emission region **130**B, according to some embodiments of the invention. Coating **140** may have an inner reflective surface that yields or enhances the bend emission and its directionality. Generally, coating **140** may be asymmetric in cross section at

specified region **130**B. Other parts of fiber **110** or the device (see below) may be configured to enhance beam emission.

[0186] FIG. **17**K illustrates an embodiment of a metallic waveguide having a gap at specified emission region **130**B, according to some embodiments of the invention. The design and applicative concepts for fiber **110** and device **100** that are presented herein, may be applied to metallic waveguides, delivering e.g. electromagnetic radiation. The gap in the metallic waveguide may be used to emit radiation **152** therethrough for applying a treatment.

[0187] FIG. **17**L illustrates an embodiment of fiber **110** with an emitting region **115**B at specified emission region **130**B, according to some embodiments of the invention. Emitting region **115**B is connected at the vertical dimension with core **103** of fiber **110** and may contact tissue **90** and/or **95**; and is separated at the horizontal dimension from the rest of cladding **115**A, e.g., by an air gap **115**C. The configuration of dimensions r_1, r_2, r_3 and width of gap **115**C and of refractive indices n_1, n_2, n_3, n_4 may be selected to yield side emission at specified conditions, such as upon bending fiber **110**. In a non-limiting example, r_1=100 μm n_1=1.445, r_2=150 μm n_2=1.42, r_3=50 μm n_3=1.438 and n_4=1 may be used to yield required bend-emission under specified conditions. In certain embodiments, fiber **110** may be configured to have substantially $r_2=r_1+r_3$ and $n_4<<n_2<n_3<n_1$ to yield effective side emission upon bending. In certain embodiments, the refractive indices may be selected according to the following relations: $n_1>1.005\cdot n_2$; $0.999\cdot n_1\geq n_3>1.001\cdot n_2$ and $n_4<0.99\cdot n_2$.

[0188] FIG. **18**A is a high level schematic illustration of fiber **110** with a supportive structure **141** attached on an opposite side of fiber **110** with respect to emitting region **130**B and the target, according to some embodiments of the invention. Supportive structure **141** may be used to orient fiber **110** to position emitting region **130**B at a correct orientation with respect to the target and reflect excessive energy upon the target. Supportive structure **141** may be associated in various embodiments of device **100** (see below).

[0189] For construction purposes, fiber **110** may be attached to or embedded in reinforcing structure or stabilizer **141**, to ensure stability and prevent breakage. Reinforcing structure **141** may be a semi-tube (e.g., similar to coating **140** in FIG. **17**J) or a ribbon (e.g. as in FIG. **18**A), made of plastic or metal. In some cases fiber **110** may be inserted into stabilizer **141** after it is set in the desired location, for example, after stabilizer **141** has been inserted around obstruction **95** (e.g., a polyp or a tumor) to be excised. Furthermore, reinforcing structure **141** may serve for inward reflection of emitted energy **152**.

[0190] FIG. **18**B is a high level schematic illustration of fiber **110** with lateral circle segments **142**, according to some embodiments of the invention. Segments **142** have arcs that define the emission sectors and further emit electromagnetic radiation **152** at a plane defined by the arcs. Fiber **110** may comprise one or more such segments **142** at the specified region. Segments **142** may be part of cladding **115**, e.g. produced by cutting into cladding material, be part of coating **140** or be attached structures. Segments **142** may further focus radiation **152** onto the target.

[0191] FIG. **18**C is a high level schematic illustration of fiber **110** with a circular segment **143** such as a disc, at the fiber tip, according to some embodiments of the invention. Circular segment **143** has at least one circle segment **143** having an arc defining at least one tip emission sector emitting electromagnetic radiation **152** at a plane defined by the arc. Tip emission sector may operate upon bending of fiber **110** or independently therefrom.

[0192] Embodiments of the invention further comprise optical fibers with an asymmetric cross section, and in particular optical fibers with asymmetric cladding, in which the asymmetry defines at least one emission sector and at least one non-emitting sector in cross section. The difference in the refractive indices between the emitting and non-emitting sectors may be larger than 0.1%, larger than 0.5% or larger than the difference in the refractive indices between the emitting sector and the fiber's core.

[0193] The following illustrations depict examples for devices **100** which implement optical fibers **110** exhibiting bend-emission. Each device **100** may be implemented using any embodiment of optical fiber **110** described above according to the device's specifications, under constraints resulting from manufacturing issues but not from conceptual issues.

[0194] FIGS. **19**A-**19**C and **19**E-**19**I are high level schematic illustrations of devices **100** using bend emission, according to some embodiments of the invention. FIGS. **19**A-**19**C illustrate a fiber snare device **100**, FIG. **19**D illustrates an experimental comparison between a fiber snare device and an electro surgical snare regarding the emission profile; FIGS. **19**E-**19**H illustrate fiber hook devices and FIG. **19**I illustrates a device with an optical element **144** designed to generate plane emission from the fiber. Optical element **144** may be one or more of operable elements **130**.

[0195] Device **100** comprises at least one optical fiber **110** and at least one light source **70** (see e.g., FIG. **20**C), arranged to transmit electromagnetic radiation through the at least one optical fiber **110**. Optical fiber **110** comprises at least one core **103** and cladding **115**. Each optical fiber **110** has at least one specified region that is arranged to emit electromagnetic radiation from core **103**, upon bending optical fiber **110** at the region(s) beyond a specified bending threshold. Emitting regions **130**B may be single or multiple, and may be used to deliver radiation at different intensities and wavelength ranges, possibly for different purposes, such as cutting, ablation, different kinds of treatment and marking.

[0196] For example, optical fiber **110** may be formed as a snare (FIGS. **19**A, **19**B) with an apical bended region arranged to emit electromagnetic radiation **152** in a plane defined by the snare. Device **100** may improve on prior art electrosurgical snares by creating a much more precise and cleaner cut of an obstruction **95**, e.g. of polyps, as illustrated in FIG. **19**B. The plane of emission **152** is in the inner part of the snare and emission **152** results from the bending of optical fiber **110** at the apical region of the snare. In embodiments, no or very low radiation is emitted outwards, in region **130**A. As an applicative example, FIG. **19**B illustrates snare-like optical fiber **110** applied through a channel **77** of an endo scope **76**.

[0197] In embodiments, optical fiber **110** of the snare may have an additional emitting region **130**C, e.g. defined by a sector **115**C of the cladding at an angle to main emitting sector **115**B of the cladding. Region **130**C may emit electromagnetic radiation **151** having different characteristics than electromagnetic radiation **152** used for cutting, for example, weaker radiation or radiation in a different wavelength range, that may be useful e.g. for ablating the edges of obstruction **95** to prevent bleeding and prevent infection. It is noted that such ablation is more effective than prior art laser ablation, as

radiation **151** is applied smoothly and in the correct direction due to the structure of the snare itself (see FIG. **19**B).

[0198] A further advantage of fiber snare **110** with respect to a prior art electrosurgical snare is illustrated in experimental results depicted in FIG. **19**D, namely the cutting plane of fiber snare **110** is much narrower than the cutting plane of electro surgical snare, causing hence less damage to adjacent tissue and producing a cleaner cut.

[0199] FIGS. **19**E and **19**F illustrate fiber hook device **100** in which optical fiber **110** is bended at an angle and held by a holder **316** or self-sustained (respectively) and the bend is arranged to emit electromagnetic radiation **152** in a plane defined by the predefined bending angle (respectively). Such fiber hook device **100** may operate similarly to the fiber snare under different geometries of obstruction **95**. For example, fiber hook may replace a similar electrosurgical hook in treating upper GI lesions by Endoscopic Submucosal Dissection (ESD).

[0200] In embodiments of device **100**, light source **70** may comprise at least two light sources **70** configured to transmit at least one treatment beam and at least one guiding beam through at least one optical fiber **110**. For example, a guiding beam may be used to mark the treatment plane of fiber snare **110** or fiber hook **110** without affecting obstruction **95**. Such a guiding beam may be very useful for surgical planning and may further enhance the accuracy of operation using device **100**.

[0201] FIGS. **19**G and **19**H illustrate fiber **110** as a J shaped device in which emitted radiation **152** is emitted in a plane from the curved part of the "J", either outwardly, as illustrated in FIG. **19**G, or inwardly, as illustrated in FIG. **1911**, selected according to clinical needs and design consideration (a single device **100** may have both functions, e.g., have a different fiber for each purpose, or operate differently at different wavelength regions, or different devices may be designed for these emission patterns). FIG. **1911** further illustrates an embodiment in which the fiber tip is designed to direct energy emitted therefrom sideways, in the plane of radiation, e.g. by designing a reflective element **165** (e.g. a coating or an attached mirror) at the tip which is coupled to circular segment **143** designed to direct emitted tip energy sideways in the emission plane.

[0202] FIG. **19**I illustrates device **100** with an optical element **144** designed to generate plane emission **152** from fiber **110**, according to some embodiments of the invention. For example, optical element **144** may be designed to reflect radiation **152** emitted from the bended emission region **130**B of fiber **110** in a designated plane (e.g. as an enhancement of the snare-like device described above).

[0203] FIGS. **20**A-**20**C illustrate configurations of controlling the electromagnetic radiation transmitted through fiber **110**, according to some embodiments of the invention. With respect to the design of device **100**, the transmitted radiation that is not emitted must be controlled and regulated.

[0204] In an embodiment illustrated in FIG. **20**C, transmitted radiation may go through fiber **110** from source **70** and introductory fiber **166** to exiting fiber **168** and an absorptive sink **169** at the fiber's end (of course introductory fiber **166**, treatment fiber **110** and exiting fiber **168** may be implemented as a single fiber, with only fiber **110** exhibiting bend emission in the specified region). Such configuration may also be applied when fibers **110** are weaved around balloon **122** (see below) and then guide the transferred radiation to exiting fiber **168**. Absorptive sink **169** may also be located at the end of device **100**, as illustrated in FIG. **13**C above.

[0205] In embodiments illustrated in FIGS. **20**A and **20**B, a tip **163** of optical fiber **110** is reflective to reflect non-emitted electromagnetic radiation. In FIG. **20**A, the reflectance is achieved by a Bragg grating **164** of appropriate characteristics, in FIG. **20**B, the reflectance is achieved by a coating **165** (or an attached mirror **165**) and exiting fiber **168** is arranged to receive reflected electromagnetic radiation. Using reflective tip **163** not only helps dealing with excessive radiation, but also doubles the potential bending emission, by running the radiation twice through the specified region.

[0206] FIG. **21**A-**21**E illustrate cladding **115** of fiber **110**, becoming asymmetric in cross section upon application of a strain **174** at the specified region, according to some embodiments of the invention.

[0207] Normally, fiber materials like silica tend to have lower values of tensile stress than compressive stress. Basically this means that when bending a symmetrical fiber the breaking point is typically determined by reaching the tensile stress limit. In one embodiment, the effective tensile stress limit is geometrically increased using hollow structures such as tubes. Fiber **110** may be constructed as a hollow tube (FIGS. **21**A, **21**B), or the hollow tube may be located only on the outer convex rim of bended fiber **110** (e.g., the large air gap **118** in FIG. **17**D). The hollow tube may have a circular, oval, or other cross-section so as to increase the natural tendency to collapse inward (FIG. **21**A). When fiber **110** is bent, strain **174** increases on the outer rim of fiber **110** (FIG. **21**B). Since the center is hollow, an inward collapse is possible. This collapse means a larger bending radius **105** (**176**A to **176**B in FIG. **21**C), which in turn means effectively weaker stress, hence the possibility of smaller bend radiuses (sharper bends) for the same stress breakage values. The tube wall thickness and material are accommodated to the possibility of bending. This method allows tighter bending of fiber **110** without breaking it. Another possible embodiment is to use serrations on the outside of the fiber bend region, as in FIG. **1711**, which also effectively reduces the stress values on the outer convex rim.

[0208] In embodiments, cladding **115** may be arranged to become asymmetric in cross section upon application of strain **174** at the specified region. The asymmetry may be expressed in a form of cladding **115**, a thickness of cladding **115** and/or in the refractive index of cladding **115**. The asymmetry may be configured to focus emitted electromagnetic radiation **152**.

[0209] FIGS. **21**A-**21**C illustrate three type of strains **174**. FIG. **21**A illustrates an asymmetric cross-section of fiber **110**, e.g. an elliptic cross-section, which is deformed from state **170**A to state **170**B with an increased eccentricity. FIG. **21**B illustrates circular cross-section fiber **110** that is deformed on one side from state **170**A to state **170**B, resulting in a change in strain **174**. FIG. **21**C illustrates bended fiber **110**, in which bending strain is decreased by strain **174** while the bending radius of fiber **110**, increases from **176**A in state **170**A to **176**B in state **170**B.

[0210] FIG. **21**D illustrates that a bend of fiber **110** from state **170**A to state **170**B results in different strains in an inner side **175**A of fiber **110** and in an outer side **175**B of fiber **110**, both sides with respect to the bending. Hence different strains are experienced by sides **175**A, **175**B, which may result in

changes in the refractive indices of the two sides, causing bend emission to occur on either side, depending on fiber type and design.

[0211] In embodiments, photoelasticity may be used to change the index of refraction under stress, in order to fine-tune the ability of the waveguide (e.g., fiber **110**) to discharge energy asymmetrically. The index of refraction of most materials depends on stress. Typically in glass, when stress is increased the index of refraction increases as well. Photoelasticity is caused by the deformation of the electron shells of atoms and molecules and by the orientation of optically anisotropic molecules or components of such molecules; in polymers, it is caused by the uncoiling and orientation of polymer chains. For a small uniaxial tension or compression, Brewster's law is satisfied, such that the optical path equals the index of refraction times the geometrical, or the stress index multiplied by the stress and the geometrical path.

[0212] When a waveguide like an optical fiber is bent, a symmetry break occurs in the stress distribution in the fiber's cross-section. Inner side **175**A is compressed and outer side **175**B expands, resulting in an increase in tensile stress. Solving the Euler-Bernoulli beam equation implies that pure (convex) bending causes zero stress at the neutral axis (FIG. **21**D), tensile stress at convex rim **175**B, and compressive stress at concave rim **175**A; it also implies that the maximum tensile stress occurs at the convex surface and the maximum compressive stress at the concave surface.

[0213] The bend causes a symmetry break between cladding **115** on the inside of the bend, the radiation emitting section, and cladding **115** on the outside of the bend. Typically, the cladding's refraction index is lower than that of core **103** by about 0.5%. A bend in the fiber effectively closes the index gap in compressed side **175**A and on the other hand increases the gap on outer side **175**B. This makes the light confinement weaker on the inner side making it leakier.

[0214] The asymmetry due to the bend guides the discharge **152**. By bending the waveguide and the subsequent increase in the index of refraction specifically at inner side of the bend **175**A, the direction of the discharge **152** is controlled. The index differential at the boundary between core **103** and cladding **115** is tailored in accordance with the desired bend that causes discharge **152**.

[0215] FIG. **21**E illustrates bended fiber **110** in cross section, with different thicknesses of cladding **115** that result in sector **130**B focusing the emitted electromagnetic radiation **152**. The deformation of cladding **115**, and the subsequent index change, may further assist in focusing radiation **152** by emitting sector **130**B.

[0216] The cross-section of fiber **110** may be designed to control the stress profile. FIG. **21**E, for example, illustrates emitting sector **130**B as a concave part of cladding **115** that is structured to serve as a converging lens at emitting sector **130**B. In this case, compressive stresses are increased in the concave side, which changes the indices of refraction in this area, so that in effect a lens in the concave side of cladding **115** is obtained.

[0217] FIGS. **22**A and **22**C schematically illustrate operable elements **130** on fiber **110** having three emission sectors **130**B, **130**C and **130**D in the emission region and a hook device **100** using this fiber, according to some embodiments of the invention. Emission sectors **130**B, **130**C and **130**D have cladding materials **115**B, **115**C and **115**D respectively, which are different from cladding material **115**A in non-emitting sectors **130**A and may also be different from each other in the characteristics of emitted radiation **152**B, **152**C, **152**A respectively. For example, central emission sector **130**B may be configured to cut tissue, while lateral emission sectors **130**C and **130**D may be configured to coagulate the sides of the cut by emitting radiation **152**C and **152**D with specified parameters (e.g., different wavelength ranges, different bending thresholds and different intensities than emitted radiation **152**B).

[0218] FIG. **22**B schematically illustrates operable elements **130** on fiber **110** having multiple emission sectors **130**B, **130**C, **130**D, **130**E and **130**F in the emission region, according to some embodiments of the invention. The emission sectors may be designed to have different bending thresholds, such that emission intensity from fiber **110** has a specified profile with respect to the circumference of the emission region. For example, central sectors may have the lowest bending thresholds (i.e., the largest threshold bending radii) to emit first and most intense for e.g., a cutting treatment, while peripheral sectors may have higher bending thresholds (i.e., smaller threshold bending radii) to emit last and weaker for less intensive tissue treatment e.g., a coagulation or soldering treatment. In embodiments, the configuration of the emission sectors may be symmetric around central sector **130**D.

[0219] In addition to providing an emission profile, devices **100** and fibers **110** may be designed to correlate the forces applied thereupon to the intensity of radiation **152**, as larger forces produce stronger bending of fibers **110**, resulting in more intense radiation. Such designs may enhance the feel provided by device **100** and make the feel more similar to cutting with a regular scalpel mechanically.

[0220] FIGS. **23**A-**23**E schematically illustrate device **100** configured as tweezers, according to some embodiments of the invention. FIGS. **23**A and **23**B illustrate an open, non-emitting, position and an active position of device **100**, respectively. Fiber **110** is integrated within tweezers device **100** in a way that causes bending of fiber **110** upon handling tissue with device **100** to yield radiation emission from operable elements **130** embodied as bended regions **130**B which enhances treatment of the handled tissue. For example, fiber **110** may be associated with one arm **310** of tweezers device **100** and fiber bending may occur upon pressing the fiber against a second arm **311** of tweezers device **100**. Any of the tweezers' arms may comprise protrusions **313** and/or corresponding recesses **312** to enhance fiber bending upon handling tissue by tweezers **100**. Tweezers-like device **100** may comprises surface features designed to control the bending of optical fiber **110** upon tissue contact. FIG. **23**C illustrates tweezers device **100** having multiple fibers **110** which may have differing emission characteristics, e.g., configured to apply different effects to the treated tissue.

[0221] Tweezers device **100** hence allows mechanical handling while using laser for cutting tissue. The emission may be dependent on the extent of the force applied by the physician through the extent of resulting bending of fiber(s) **110**. The closer arms **310**, **311** are pressed together, the larger becomes the fiber bending and the emitted radiation.

[0222] FIG. **23**C schematically illustrates designing the surface area of arms **310**, **311**, i.e., protrusions **313** and recesses **312**, to cause different levels of bending of fibers **110** upon using the tweezers. The surfaces of the arms may be designed to cause different intensities of radiation from fibers **110** (as fibers **110** are bended at different levels) and thus applying different levels of treatment to the handled tissue.

Fiber parameters and arm surface parameters may be combined to induce variable treatment levels and effects along and across tweezers device **100**. For example, a middle more curvy line in FIG. **23**C may lead to more emission from the central fiber **110** and thereby cut tissue, while the lateral less curvy lines may lead only to a soldering effect on the tissue by the lesser bending of lateral fibers **110**. FIG. **23**D illustrates an embodiment that comprises an additional sensing fiber **315** that may be used to control emitted radiation by fiber **110** by sensing the radiation level emitted therefrom. Some of emitted radiation **152** may enter sensing fiber **315** when the fiber **110** is close to fiber **315** due to the closing of tweezers device **100** and when no tissue obstructs the radiation path. The intensity of the entering radiation may be used to indicate treatment efficiency and provide information on the handled tissue. Any other sensor may be used in place or in addition to additional fiber **315**, e.g., a temperature or an impedance sensor.

[0223] FIGS. **23**E and **23**F illustrate an open, non-emitting, position and an active position of device **100**, respectively. Fiber **110** is integrated within tweezers device **100** in a way that causes bending of fiber **110** upon handling tissue with device **100** and radiation emission from the bended regions which enhances treatment of the handled tissue. For example, fiber **110** may be associated with one arm **310** of tweezers device **100** and fiber bending may occur upon pressing the fiber against a second arm **311** of tweezers device **100**. In the illustrated embodiment, tweezers-like device **100** comprises one arm **320** that is curved and stiff and a second arm **322** which is flexible to which fiber **110** is attached. Arms **320**, **322** may comprise reciprocally engaging tips **321**A, **321**B respectively that engage upon full closure of device **100**. Fiber **110** may be arranged to emit at the resulting bending of flexible second arm **322**. Multiple fiber embodiments may be designed to provide varying tissue handling effects.

[0224] In embodiments, fiber **110** may reach tip **321**A of arm **322** and be used additionally as a tip-emitting fiber ("straight shot laser").

[0225] FIGS. **24**A and **24**B schematically illustrate device **100** with a feedback loop for controlling emitted radiation **152**, according to some embodiments of the invention. For example, the feedback loop may be used for sensing data from additional sensing fiber **315** or other sensor illustrated in FIG. **23**D. FIG. **24**A illustrates radiation source **70** and a radiation detector **330** which measures radiation after emitted radiation **152** was emitted along the fiber, to determine the extent of radiation emission **152** and hence of treatment. Radiation detector may be replaced or enhanced by a temperature sensor. FIG. **24**B illustrates tweezers device **100** with fiber **110**'s emitting regions, from which radiation is emitted. Data from detector **330** may be used to control radiation parameters such as activation, wavelength range and intensity as well as parameters of device **100**—e.g., provide feedback to the treating physician, change device **100**'s electronic parameters etc. Detector **330** may measure changes in bend-emitted radiation **152** via the natural changes that occur to the tissues' index of refraction as it is being coagulated or cut.

[0226] FIG. **25** schematically illustrates device **100** for cutting vessels, according to some embodiments of the invention. Device **100** comprises a fixating arm **340** (e.g., a hook) and a cutting arm that comprises fiber **110** that is optionally supported by supporting structure **141** and a second fixating arm **345** that stabilizes target **95** (such as a blood vessel) and fiber **110**'s contact thereto. The cutting arm may comprise a single fiber **110**, e.g. fiber **110** with multiple emission sectors as illustrated in FIGS. **22**A, **22**B, or multiple fibers **110** with similar or varying characteristics, optionally attached to supporting structure **141**. In embodiments, fixating arms **340** and **345** may be part of the supportive structure, as a variation of tweezers-like device **100**. Upon pressing fixating arm **340** against the cutting arm (supported by second fixating arm **345**) around target **95** such as a blood vessel, cutting of vessel **95** and immediate soldering of the cut ends of vessel **95** are carried out, e.g. by activation of different treatment effects as described above. Alternatively, the cutting arm with second fixating arm **345** may press vessel **95** against fixating arm **340** and either arm may emit radiation to apply the treatment upon vessel **95**.

[0227] FIGS. **26**A and **26**B illustrate device **100** for treating target **95** by pressing device **100** upon it, according to some embodiments of the invention. Device **100** may be mechanically configured similarly to tweezers device **100** illustrates in FIGS. **23**E and **23**F, and emit radiation externally, onto target **95** against which device **100** is pressed. Device **100** may have a single arm **350** that supports fiber **110** and allows bending of fiber **110** upon contact with target **95**, in accordance with the applied pressure and in correspondence to the form of target **95**. For example, fiber **110** may be loosely or movably attached to the tip of arm **350**, fiber **110** may be flexible or device **100** may be designed to provide for some lengthening of fiber **110** upon contact with target **95**.

[0228] The illustrated tweezers with arms **310** and **311**, **320** and **322**, **340** and **345** may be embodiments of supportive structure **141** described above.

[0229] Embodiments of the invention provide device **100** as a vessel sealing tip **100** for surgical forceps which allows, via operable elements **130** implemented e.g., in fiber **110**, both sealing a vessel section and cutting therethrough without extracting the tip out of the body or exchanging the tip. Either a single action yields the sealing and the cutting, or two or more tip actions may be carried out sequentially to perform the sealing and cutting operations. In addition, the tip may be used for cutting through tissue. Embodiments of the tip may utilize any energy source via operable elements **130**, in particular optical laser energy but also RF or ultrasound energy. The different effects (sealing, cutting) may be achieved by varying the emitted energy spatially, by manipulating the vessel prior or during energy delivery, by changing a configuration of the tip during operation and by combining tensile forces or ablation at appropriate locations of the vessel.

[0230] FIGS. **27**A-**27**C are high level schematic illustrations of a vessel sealing tip **100** for surgical forceps **92** according to some embodiments of the invention.

[0231] Vessel sealing tip **100** may comprise an energy delivery element **110** such as at least one optical element **110** arranged to deliver, upon actuation, electromagnetic radiation **152** to a vessel **90** to cut vessel **90** at a cutting region **96**B (FIG. **27**B) or to yield a vessel welding effect in a specified sealing section **96**A of vessel **90** (FIG. **27**C), and to cut vessel **90** at a cutting location **96**B within specified sealing section **96**A. For example, at least one optical element **110** may comprise at least one optical fiber **110** arranged to deliver electromagnetic radiation such as laser energy. In case of cutting region **96**B, radiated energy **152** may also seal edges of the cut vessel during the cutting.

[0232] Energy delivery element **110** may be attached to any one of two jaws **101** (**101**A, **101**B) of forceps tip **100**, or may also be a free element, at least on a part of the length thereof (see below).

[0233] In cases of energy delivery element **110** being an optical fiber, fiber **110** may emit radiation **152** (FIG. **27**B) that yields a vessel sealing effect and radiation **152** that yields a vessel cutting effect. Radiation characteristics may be temporally varied in a controlled manner or may be designed in advance with respect to one or more vessel types. Radiation **152** may further be used to ablate the vessel wall prior to sealing and/or cutting vessel **110**. Radiation **152** may further be used to cut tissue during the advancement of tip **100**; for example, fiber **110** may continue beyond the illustrated extension to the very tip of either jaw **101**, to their external sides or may extend beyond tip **100** itself (e.g., form a loop ahead of tip **100**).

Fiber cross section may be designed according to the principles outlined in FIG. **22**A, **22**B, in which fiber **110** may be arranged to emit at least two radiation types **152**A, **152**B at at least two corresponding zones (**130**A, **130**B, FIG. **27**C) of fiber **110**. The radiation types may differ in at least one of their intensity, spectral range, spatial and/or temporal patterns. Emission zones **130**A, **130**B may comprise, in cross section, different corresponding fiber sectors **115**A, **115**B made of different cladding materials or having different refractive indices. In embodiments, emission zones **130**A, **130**B may have different cross-sections and thus different spatial energy density profiles. In certain embodiments, fiber **110** may comprise a solid core optical fiber (having core **103**), a hollow fiber or a photonic crystal fiber (such as a holey fiber, a Bragg fiber or any other micro-structured fiber). In certain embodiments, fiber **110** may comprise a metallic waveguide. The different fiber sections may be differently micro-structured or have a different spatial arrangement of core **103** and cladding (e.g., core **103** may be asymmetrically positioned within the cladding). Fiber **110** may be single-mode or multi-mode. Beam polarization may also be used to differentiate radiation types **152**A, **152**B and control the emitted energy density spatial distribution.

[0234] In certain embodiments, at least one jaw **101** of the forceps may comprise at least one protrusion **94**A (FIG. **27**C) arranged to constrict vessel **90** prior to the actuation of energy delivery element **110** (such as at least one optical element **110**, a RF source, an ultrasound source etc.). Protrusion **94**A protrudes from a surface **94**B of jaw **101** and constricts vessel **90** at the region of energy deliver to reduce the local thickness of vessel **90** and to provide more spatial variability in possible energy delivery directions. Energy delivery element **110** may be positioned fully or partially within protrusion **94**A; for example, at least one optical element **110** may be set within at least one protrusion **94**A.

[0235] Certain embodiments of the invention comprise a tip **100** with at least two jaws **101** for surgical forceps **92**. At least one of jaws **101** may comprise at least one protrusion **94**A positioned to contact tissue held by tip **100** and deliver both pressure and external energy to the tissue. The pressure may be a tip holding force (the force applied to the forceps and thereby transferred to the tip's jaws), concentrated by at least one protrusion **94**A. The external energy may be any of electromagnetic (e.g., optical, RF), electrical and ultrasound energy, or a combination thereof. At least one protrusion **94**A may comprise one or more thin element that concentrates applied forces onto a small section of vessel **90**. At least one protrusion **94**A may comprise an abrasive or an ablative element that reduces vessel wall thickness or even cuts the vessel, in addition to constricting the vessel.

[0236] FIGS. **28**A-**28**C are high level schematic illustrations of vessel sealing tip **100** for surgical forceps **92** having focusing elements **111**, according to some embodiments of the invention. Energy delivery elements **110** may comprise focusing elements **111** (FIG. **28**C) arranged to focus any type of delivered energy (e.g., optical energy, RF, ultrasound, electrical energy, etc.). For example, optical elements **110** may comprise at least one focusing element **111**, such as a lens **111** or a sector **115** of the cladding arranged to focus emitted radiation **152**. In the non-limiting example illustrated in FIG. **28**C, a combination of asymmetric core **103** and focusing element **111** may be arranged to yield the welding and/or cutting of vessel **90** (depending on the delivered radiation and tip manipulation). Vessel **90** may be seen in the context of the forceps devices as obstruction **95** to which energy is delivered and/or as a vessel occluded by obstruction **95**. The focusing of the emitted radiation may be in a cross-sectional plane of optical element **110**. In certain embodiments, focusing elements **111** may focus different types of radiation **152**A, **152**B at different regions of vessel **90**, e.g., radiation **152**B may be focused to produce a sealing effect at sealing region **96**A, and radiation **152**A may be focused to cut vessel **90** at cutting region **96**B. Focusing elements **111** may be embedded in or attached to forceps jaws **101**. Focusing elements **111** may be multiply associated with at least one of jaws **101**, as illustrated in FIG. **28**B. The focusing elements may be embedded in multiple fibers **110**A, **110**B and be arranged to jointly apply the sealing and cutting to regions **96**A, **96**B of vessel **90** respectively. Particularly, at least two focusing elements **111** may be positioned on each jaw **101** and arranged to yield a specified extension of specified sealing section **96**A, which is broader than sealing section **96**A produced by a single focusing element **111** or solely by optical element **110**.

[0237] In certain embodiments, energy delivery element **110** may be arranged to reduce a vessel wall thickness prior to the welding. For example, optical element **110** may operate in an ablative mode to reduce vessel wall thickness prior of holding vessel **90** sealing it and cutting through vessel **90**. The reduction of wall thickness allows energy to be delivered to the internal walls of vessel **90** without causing thermal damage to the external wall of vessel **90**. Furthermore, reducing the wall thickness may reduce the wall resistance to mechanical pressure and thus allow a more effective application of pressure to vessel **90**, e.g., by protrusions **94**A (FIG. **27**C), to create a more effective gripping of vessel **90** by forceps **92** and a better sealing effect.

[0238] FIGS. **29**A and **29**B are high level schematic illustrations of vessel sealing tip **100** for surgical forceps **92** having vessel piercing elements **110**, according to some embodiments of the invention. Energy delivery element **130** may comprise at least one optical element **110** comprising at least one optical fiber **110** arranged to penetrate a lumen of vessel **90**, piercing thereby a hole **98** in vessel **90**, prior to the actuation thereof and emission of energy **152** from fiber **110**. In certain embodiments, penetrating the vessel lumen enables more efficient sealing and/or cutting of vessel **90**. Delivering energy from the interior of vessel **90** allows treating its inner layers directly, without having to apply high pressure on the vessel wall in order to flatten vessel **90**. In certain embodi-

ments, penetrating and flattening may be applied simultaneously or sequentially to reciprocally enhance the sealing effect.

[0239] FIGS. **30**A and **30**B are high level schematic illustrations of vessel sealing tip **100** for surgical forceps **92** having transversely expanding elements **102**, according to some embodiments of the invention. At least one jaw **101** of tip **100** may comprise transversely expandable element **102** arranged to yield a specified extension of specified sealing section **96**A. Mechanically pressing a wider section of vessel **90** increases the potential sealing section of vessel **90** and hence may improve sealing and vessel manipulation conditions. Transversely expanding elements **102** may be retracted in a tool delivery channel and expand only in situ, upon using tip **100**. In certain embodiments, transversely expanding elements **102** are controllably expandable, e.g., by a user of forceps **92** or responsive to applied pressure on respective jaw **101** or sensed resistance of vessel **90**. In certain embodiments, transversely expanding elements **102** may mechanically extend specified sealing section **96** during the welding. The welding (e.g., by radiation **152**B aimed at sealing section **96**) may be combined with transverse forces applied to vessel **90** at the sealing section and aimed to expand the treated section. A reduced resistance of vessel **90** due to the energy radiation and/or the mechanical extending may thus be exploited to expand the sealing section. In certain embodiments (FIG. **30**B), at least one of jaws **101** may be designed as a transversely expanding element. For example, one jaw **101**A may be a regular jaw and the other jaw **101**B may be expandable to broaden the sealing region of vessel **90**. Expandable jaw **101**B may be made of two or more parts and tip **100** may comprise means to separate the parts to further enhance the stretching effect on vessel **90**.

[0240] FIG. **31** is a high level schematic illustration of vessel sealing tip **100** for surgical forceps **92** enabling extension of the vessel sealing region, according to some embodiments of the invention. In certain embodiments, one or both jaws **101** may be hingedly attached to forceps **92** and may be controllably pivotally movable to stretch vessel **90**, e.g., during sealing or cutting thereof. One or both jaws **101** may comprise a forceps element **303** arranged to hold and/or pull a respective vessel section to generate the stretching effect of the vessel, which expands the sealing region. Jaws **101** may be moveable along different spatial directions, to yield an additional twist of vessel **90**, selected to further enhance the stretching of the sealing region. Any of the above mentioned movements and actions may be combined with energy delivery to enhance the sealing and/or cutting effect. Accordingly, control of any of these movements may be carried out by a user or responsive to sensed forces in tip **100**. Jaws **101** may by controlled by mechanical compliance to exerted forces.

[0241] In certain embodiments, vessel sealing tip **100** for surgical forceps **92** may comprise at least one transversely expandable element **102** or **303** arranged to yield a specified extension of a specified section of vessel **90** and energy delivery element **110** arranged to deliver external energy, upon actuation, to vessel **90** to yield a vessel welding effect in a specified sealing section of vessel **90** and to cut vessel **90** within the specified sealing section. The external energy may be at least one of optical, electrical and ultrasound energy. Tip **100** may thus open up and create a seal larger than half width of tool (e.g., tip **100**) or just separate regions of cut and seal. The specified sealing section may be mechanically extended during the welding with or without additional energy delivery. In embodiments, tip **100** may comprise two transversely expandable elements **103**, each arranged to yield a specified extension of the specified section of vessel **90** in a different plane.

[0242] FIG. **32** is a high level schematic illustration of vessel sealing tip **100** for surgical forceps **92** with variable intensity treatment, according to some embodiments of the invention. In certain embodiments, each jaw **101**A, **101**B of the forceps may comprise at least one optical fiber **110**A, **110**B respectively, positioned at a distance from an edge **305** of the respective jaw, wherein the distance may vary along the jaws. For example, the varying distance with respect to treating edge **305** of the jaws may diminish from a tip to a base of jaws **101**A, **101**B to yield the welding effect at the jaw tip and perform the cutting between the tip and the base of the jaw. In certain embodiments, the sealing and cutting effects are thus spatially differentiated along the jaws instead or in addition to the spatial differentiation across the jaws illustrated previously (cf., e.g., FIG. **28**A). In certain embodiments, one or more fibers **110**A, **110**B may have longitudinally varying characteristics that generate radiation **152** of different characteristics along the fiber. For example, radiation **152** designed for sealing may be applied at the jaw tips where the distance to vessel **90** is also the largest, and radiation **152** designed for cutting may be applied at the jaw bases where the distance to vessel **90** is also the smallest. Hence jaws **101** and energy delivery elements **110** may be designed to jointly differentiate welding and cutting effects.

[0243] In certain embodiments, vessel sealing tip **100** may be constructed from non-metallic materials to allow use of tip **100** simultaneously with MRI imaging. For example, tip **100** may be made of plastic and energy may be delivered via optical fibers.

[0244] In certain embodiments, vessel sealing tip **100** may comprise at least one wave guide (not shown) arranged to deliver, upon actuation, electromagnetic radiation to the vessel to yield a vessel welding effect in a specified sealing section of the vessel and to cut the vessel within the specified sealing section. In certain embodiments, at least one jaw of the forceps may comprise at least one protrusion arranged to constrict the vessel prior to the actuation of the at least one wave guide.

[0245] In certain embodiments, vessel sealing tip **100** for surgical forceps **92** may be configured to be applied for any of the following treatments: Sealing blood vessels, arteries, veins; Sealing biliary ducts; Sealing urinary tract; Sealing reproductive tract; Sealing airways; Sealing in the GI tract; Sealing the dura; Treating septums (nasal, atrial, etc.); Sealing organs such as lung, liver, spleen, heart, stomach, pancreas, uterus, bladder, kidney etc. While the above description mainly referred to treating vessels **90**, tip **100** for surgical forceps **92** may be configured for treating any other type of tissue, as well as to carry out further surgical tasks, such as cutting or ablating tissue.

[0246] In a non-limiting example, vessel sealing tip **100** may be configured to apply pressures in the at least a part of the range 20-400 PSI. The outer diameter of fiber(s) **110** may be between 0.05-2 mm and fiber(s) **110** may be arranged to deliver power levels between e.g. 1 W-100 W. Tip **100** may be configured to have a jaw **101** length between 2-50 mm, a jaw **101** width between 0.5-10 mm, and a ridge width of at least one protrusion **95**A between 0.1-5 mm. The dimensions of jaws **101** may be configured with respect to the specific use of

tip **100**, as illustrated in the examples above. For example, larger tips **100** may be designed to seal larger or stiffer vessels **90**.

[0247] Table 1 is a non-limiting exemplary overview of possible tip characteristics for various applications of tip **100**.

TABLE 1

Tip parameters for various applications

Vessel type (Sealing operation, unless otherwise indicated)	Anatomical size (mm)	Jaw length (mm)	Jaw width (mm)	Working area length (mm)
Blood vessels, arteries, veins	<1 to 10	20 and up	2 to 10	17 and up
Extremely large blood vessel, aorta, aneurisms, etc.	up to 25	40 to 60	2 to 10	35 and up
Biliary ducts	5-10	20 and up	2 to 10	8 and up
Urinary tract	up to 10	20 and up	2 to 10	17 and up
Reproductive tract	Fallopian tubes up to 2, general tissue much more	20 and up	2 to 10	17 and up
Airways		20 and up	2 to 10	17 and up
GI tract		30 and up	2 to 10	25 and up
Dura		20 and up	2 to 10	15 and up
Septum (nasal, atrial, etc.)		3 and up	1 to 10	2 and up
Operating on organs such as lung, liver, spleen, heart, stomach, pancreas, uterus, bladder, kidney, etc.		20 and up	2 to 10	17-70
Neurological operations		3 and up	2 to 10	3 and up
Kidney operations		20 and up	2 to 10	17 and up

[0248] FIG. **33** is a high level flowchart illustrating a method **400**, according to some embodiments of the invention. Method **400** comprises stages for treating an obstruction in a vessel, for configuring emission from an optical fiber and removing an obstruction therewith and for vessel sealing, according to some embodiments of the

[0249] Method **400** may comprise designing a device for applying a treatment to an obstruction (stage **410**) comprises the following stages: attaching a treatment layer comprising a plurality of operable elements to a flexible supporting layer (stage **438**); designing (stage **440**) the operable elements to be mechanically activated (stage **442**) upon bending of the flexible supporting layer beyond a specified curvature threshold (stage **444**) due to contact of the treatment layer with the obstruction (such as a vascular lesion) (stage **446**); and configuring the operable elements (stage **460**) to apply the treatment (stage **462**) to the obstruction upon their mechanical activation.

[0250] Method **400** may further comprise designing the operable elements to be mechanically de-activated upon a specified decrease of the bending (stage **443**), due to the treatment of the obstruction.

[0251] Method **400** may further comprise designing the operable elements to comprise openings (stage **412**) and configuring the openings to be opened mechanically by the mechanical activation (stage **448**).

[0252] Method **400** may further comprise selecting an orientation of the operable elements with respect to a form of the obstruction (stage **449**) for example to apply a spatially differentiated treatment. Curvature thresholds may be selected according to the orientation of the operable elements or vice versa. Curvature thresholds may vary for different orientations on obstruction **95**.

[0253] Method **400** may further comprise covering the openings by corresponding discs (stage **414**), and configuring the discs to expose the openings upon the mechanical activation (stage **450**).

[0254] Method **400** may further comprise configuring the treatment layer as a flexible network in which mesh openings widen upon the bending (stage **415**). The treatment may be applied utilizing the wider mesh openings to treat the lesion specifically.

[0255] Method **400** may further comprise designing the operable elements to comprise perforators (stage **416**), and configuring the perforators to penetrate the obstruction (e.g. a vascular lesion) upon the mechanical activation (stage **452**).

[0256] Method **400** may further comprise operably associating a drug delivery system with the operable elements (stage **470**) and eluting drugs to the lesion thereby (stage **472**). Method **400** may further comprise delivering light sensitive drugs and/or light through the openings, to enable photodynamic therapy (stage **473**).

[0257] Method **400** may further comprise operably associating a suction system with the operable elements (stage **474**) and removing fluids by suction from the lesion thereby (stage **476**).

[0258] Method **400** may further comprise designing the operable elements to comprise energy sources (**418**), and positioning the energy sources (stage **478**) to be directed (**480**) at the obstruction upon the bending of the flexible supporting layer beyond the specified curvature threshold (**444**).

[0259] Method **400** may further comprise attaching a balloon to the flexible supporting layer (stage **486**) to enable the bending (stage **444**) by inflating the balloon (stage **292**).

[0260] Method **400** may further comprise attaching a parachute to the flexible supporting layer (stage **496**) to enable the bending (stage **444**) by drifting the parachute with flow (e.g. blood flow) until being obstructed by the vascular lesion (stage **497**).

[0261] In embodiments, method **400** comprises treating an obstruction (stage **405**) by mechanically activating operable elements of a bendable device (stage **442**) by bending the device onto the obstruction (stage **444**).

[0262] For example, treating a vascular lesion (stage **405**) comprises eluting drugs into the lesion (stage **472**) through openings, exposed (stage **448**) or perforated (stage **452**) by the operable elements. In another example, treating the vascular lesion (stage **205**) comprises removing fluids by suction from the lesion (stage **476**) through openings, exposed (stage **448**) or perforated (stage **452**) by the operable elements.

[0263] In embodiments, treating the vascular lesion (stage **405**) comprises directing the energy sources at the vascular lesion upon the bending of the flexible supporting layer beyond the specified curvature threshold (stage **480**).

[0264] Contacting the vascular lesion may be carried out by inflating a balloon attached (stage **486**) to the flexible supporting layer or by drifting a parachute attached to the flexible supporting layer (stage **296**) with blood flow until being obstructed by the vascular lesion, to enable the bending (stage **297**).

[0265] Method **400** may further comprise configuring emission from an optical fiber (stage **421**) and removing an obstruction therewith (stage **432**), according to some embodiments of the invention.

[0266] Method **400** comprises arranging at least one specified region in the optical fiber to emit transferred electromagnetic radiation from a core through a cladding of the optical fiber upon bending of the optical fiber at the at least one specified region beyond a specified bending threshold (stage **482**).

[0267] Method **400** may further comprise configuring the cladding to be asymmetric in cross section at the at least one specified region (stage **422**) and to comprise at least one emission sector and at least one non-emitting sector. Method **400** may further comprise setting an effective refractive index n_E of the at least one emission sector closer to a core refractive index n_K than a cladding refractive index n_M (stage **423**), to yield transmission through the at least one emission sector upon bending of the optical fiber at the at least one specified region beyond a specified bending threshold.

[0268] Setting the effective refractive index n_E (stage **423**) may be carried out by at least one of: changing n_M to n_E (stage **424**); serrating the cladding (stage **425**); micro-structuring the cladding (stage **426**); optionally positioning the core asymmetrically or eccentrically within the cladding (stage **427**); applying an asymmetric coating onto the cladding (stage **428**); and straining the fiber (stage **429**), e.g., mechanically, thermally, or using radiation (e.g. ultraviolet light).

[0269] Method **400** may comprise configuring the at least one specified region to emit the electromagnetic radiation in a plane defined by the fiber (stage **484**) and removing the obstruction (stage **432**) by crossing the obstruction by the plane (stage **485**).

[0270] Method **400** may further comprise attaching at least one optical fiber with the at least one specified region to a supportive structure (stage **487**) and configuring the supportive structure to position the at least one optical fiber with respect to a target in a way that causes bending of the at least one optical fiber beyond the specified bending threshold thereof over the target (stage **488**), to emit the electromagnetic radiation at the target (stage **495**).

[0271] Removing the obstruction (stage **432**) may be carried out by applying to the obstruction at least one specified region of at least one optical fiber arranged to emit transferred electromagnetic radiation from a core through a cladding of the optical fiber upon bending of the optical fiber at the at least one specified region beyond a specified bending threshold (stage **430**).

[0272] The at least one optical fiber may be applied to the obstruction (stage **430**) by inflating a balloon (stage **494**) to which the at least one optical fiber is attached (stage **493**) against the obstruction to yield bending of the at least one optical fiber at the at least one specified region beyond a specified bending threshold.

[0273] In embodiments, device **100** and method **400** are used to assist in medical procedures, specifically by soft tissue cutting utilizing fiber-optic bends for laser energy discharge. The natural curvature in clinical settings is used to induce safe, controlled and predetermined laser discharge from the fiber's side for various purposes like soft tissue, cartilage and bone cutting, ablation and coagulation. Furthermore the controlled discharge may be used for other purposes without limitation such as sensing, material processing and other applications.

[0274] Device **100** and method **400** may be used for cutting and/or removing polyps, lesions, soft tissue sarcomas, benign and malignant tumors and other soft tissue applications. In another embodiment it is used for moderate tissue damage treatments like atrial fibrillation, denervation or nerve inhibition and/or excitation and drug activation through photodynamic therapy. Device **100** and method **400** may be used to provide means of transporting of light energy to the desired location, adjusted to the specific geometry and emission of energy to the tissue to allow safe ablation/coagulation/cutting of the tissue in a precise and controlled manner. Device **100** and method **400** may be used in different parts of the animal or human body, such as: the colon, ileum, cecum, esophagus, stomach and all other parts of the digestive system; the urethra, urinary bladder, ureter, kidney or any other part of the urinary system also the vagina, cervix, uterus, ovaries, prostate gland, penis and all other parts of the reproductive system; the nasal and oral cavities, the epiglottis, trachea, bronchus, lungs and all other parts of the respiratory system; the brain, spinal cord and all other parts of the nervous system; as well as all parts of the circulatory system, veins, arteries the heart etc. It may also operate on parts of the skin or dermatology related procedures, plastic and general surgery procedures.

[0275] In embodiments, device **100** and method **400** may be used to treat atherosclerosis by laser atherectomy by delivering the laser energy specifically to the calcified lesion by using its topography to induce the tight bends in the fiber, which in turn causes the beam to "leak" out of the fiber and be transmitted to the lesion. Thus, device **100** and method **400** take advantage of the geometry of the lesion to target the discharge exclusively at the treatment site.

[0276] The following are some non-limiting examples for bending thresholds with respect to various obstructions. It should be noted, as illustrated below, that generally there are two dimensions related to the bending, or curvature radius. One is in the radius of vessel **90** (in a plane perpendicular to the vessel) and the other is related to the longitudinal way along vessel **90** (in a longitudinal cross section of vessel **90**). As a result, fiber **110** may be asymmetric and have different dimensions in different directions, or be oriented in different ways along device **100** (and with respect to vessel **90**). Bending or curvature thresholds may differ in different directions, as in the longitudinal axis the reference radius (that of vessel **90** without any obstruction **95**) is very large, while in the cross sectional axis the reference radius (without obstruction **95**) is much smaller. Hence, different emission parameters may be defined for these directions and may be used to apply coarser of finer treatments, possibly simultaneously in different regions or sequentially and complementary in one region of obstruction **95**.

[0277] In non-limiting examples, the following may be typical parameters for the bending threshold in cases of different obstructions. In case of coronary lesions having a radius between 0.1 mm and 2 mm, the specified bending threshold may be about two times the lesion radius, or up to five times the lesion radius to achieve a more thorough removal of the lesion. Fiber **110** and device **100** may be adapted or selected according to the specific lesion that is to be treated therewith.

[0278] In case of vascular lesions having a radius between 1 mm and 10 mm, the specified bending threshold may be about two times the lesion radius, or up to five times the lesion radius to achieve a more thorough removal of the lesion. Fiber

110 and device **100** may be adapted or selected according to the specific lesion that is to be treated therewith.

[0279] In case of airway obstruction having a radius between 0.5 mm and 5 mm for small obstructions and having a radius between 5 mm and 20 mm for large obstructions, the specified bending threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Fiber **110** and device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0280] In case of gastrointestinal obstructions having a radius between 10 mm and 100 mm, the specified bending threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Fiber **110** and device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0281] In case of obstructions in water or sewage pipes, having a radius between 50 mm and 500 mm, the specified bending threshold may be about two times the obstruction radius, or up to five times the obstruction radius to achieve a more thorough removal of the obstruction. Fiber **110** and device **100** may be adapted or selected according to the specific obstruction that is to be treated therewith.

[0282] Device **100** may be part of an arterial catheter system which includes a flexible elongate member or catheter with an outer surface, a distal region adapted to enter an artery and a proximal region extending from a patient's vessel, permitting control outside the patient's body by a physician. At the distal region of the catheter is the atherosclerosis treating assembly which may include suction and/or drug administration surface and a balloon expansion unit.

[0283] Method **400** may further comprise vessel sealing by delivering, upon actuation, energy to a vessel (stage **510**) to yield a vessel welding effect in a specified sealing section of the vessel and to cut the vessel within the specified sealing section. Method **400** may comprise welding the vessel in a specified sealing section (stage **512**) and cutting the vessel within the specified sealing section (stage **514**). In certain embodiments, the welding and the cutting may be carried out by a single actuation. The delivered energy may comprise at least one of optical, electrical and ultrasound energy

[0284] For example, the delivered energy may be electromagnetic radiation and method **400** may further comprise creating the welding and cutting by differently focusing the delivered electromagnetic radiation on the specified sealing section and on the cutting location, respectively, to differentiate sealing and cutting (stage **520**).

[0285] In another example, the delivered energy may be electromagnetic radiation method **400** may further comprise using at least one optical fiber arranged to emit the electromagnetic radiation at at least two radiation profiles, one corresponding to welding **512** and another corresponding to cutting **514** the vessel. Generally, certain embodiments may comprise delivering electromagnetic energy at different profiles to differentiate sealing and cutting (stage **522**). For example, radiation energy profiles may be differentiated along a delivery fiber (stage **524**), across a delivery fiber (stage **526**) or by a combination thereof and in respect to the positioning of the delivery fibers in jaws of a forceps tip arranged to perform method **400**.

[0286] In certain embodiments, method **400** may further comprise constricting the vessel prior to the actuation (stage **516**). The constriction may be arranged to yield more effective sealing and/or cutting by reducing the vessel diameter and increasing the usable spatial variability of energy delivery.

[0287] In certain embodiments, method **400** may further comprise penetrating a lumen of the vessel prior to the actuation (stage **518**). Penetrating the vessel enables sealing the vessel from within and thereby applying the delivered energy efficiently and in a controllable manner to seal and cut the vessel.

[0288] In certain embodiments, method **400** may further comprise mechanically extending the specified sealing section (stage **530**). The extending may be carried out prior, during or after sealing the vessel to broaden the sealing section to allow more effective cutting and healing of the cutting location.

[0289] In the above description, an embodiment is an example or implementation of the invention. The various appearances of "one embodiment", "an embodiment", "certain embodiments" or "some embodiments" do not necessarily all refer to the same embodiments.

[0290] Although various features of the invention may be described in the context of a single embodiment, the features may also be provided separately or in any suitable combination. Conversely, although the invention may be described herein in the context of separate embodiments for clarity, the invention may also be implemented in a single embodiment.

[0291] Certain embodiments of the invention may include features from different embodiments disclosed above, and certain embodiments may incorporate elements from other embodiments disclosed above. The disclosure of elements of the invention in the context of a specific embodiment is not to be taken as limiting their used in the specific embodiment alone.

[0292] Furthermore, it is to be understood that the invention can be carried out or practiced in various ways and that the invention can be implemented in certain embodiments other than the ones outlined in the description above.

[0293] The invention is not limited to those diagrams or to the corresponding descriptions. For example, flow need not move through each illustrated box or state, or in exactly the same order as illustrated and described.

[0294] Meanings of technical and scientific terms used herein are to be commonly understood as by one of ordinary skill in the art to which the invention belongs, unless otherwise defined.

[0295] While the invention has been described with respect to a limited number of embodiments, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of some of the preferred embodiments. Other possible variations, modifications, and applications are also within the scope of the invention. Accordingly, the scope of the invention should not be limited by what has thus far been described, but by the appended claims and their legal equivalents.

1. A device for applying a treatment to an obstruction, the device comprising a flexible treatment layer that comprises a plurality of operable elements configured to be activated to apply the treatment to the obstruction upon bending of the flexible treatment layer beyond a specified curvature threshold and to be de-activated upon a specified decrease of the bending.

2. The device of claim **1**, wherein the operable elements are energy sources configured to deliver energy to the obstruction

and positioned to be directed upon the bending of the flexible supporting layer beyond the specified curvature threshold at the obstruction.

3. The device of claim **1**, configured as a balloon with the flexible supporting layer being part of or externally attached to a skin of the balloon, wherein the bending of the flexible supporting layer is carried out by inflating the balloon against the obstruction.

4. The device of claim **1**, wherein the obstruction is a vascular lesion and the treatment layer is configured to treat the vascular lesion.

5. The device of claim **1**, wherein the operable elements configured to be activated due to contact thereof with the obstruction and de-activated upon reduction of the bending resulting from the treatment of the obstruction.

6. The device of claim **1**, wherein the treatment layer comprises at least one optical fiber comprising a core having a refractive index and a cladding having a refractive index, wherein the operable elements comprise at least one specified region of the fiber's cladding that is arranged to emit electromagnetic radiation from the core upon bending the optical fiber at the at least one specified region beyond a specified bending threshold.

7. The device of claim **6**, wherein the cladding is asymmetric in cross section at the at least one specified region and comprises at least one emission sector and at least one non-emitting sector.

8. The device of claim **6**, wherein the at least one emission sector comprises at least two emission sectors that differ in their specified bending threshold for emission.

9. The device of claim **6**, wherein the cladding comprises, at the at least one specified region, at least one circle segment having an arc defining the at least one emission sector and further emitting the electromagnetic radiation at a plane.

10. The device of claim **9**, wherein the at least one optical fiber is formed as a snare arranged to emit the electromagnetic radiation in a plane defined by the snare.

11. The device of claim **1**, configured as a vessel sealing tip for surgical forceps, wherein the treatment layer comprises at least one optical fiber having the operable elements which are arranged to deliver, upon actuation, electromagnetic radiation to a vessel to yield a vessel welding effect in a specified sealing section of the vessel and to cut the vessel within the specified sealing section.

12. The device of claim **11**, wherein at least one jaw of the forceps comprises at least one protrusion arranged to constrict the vessel prior to the actuation of the operable elements.

13. The device of claim **12**, wherein the at least one protrusion is configured to contact tissue held by the tip and deliver both pressure and external energy to the tissue, wherein the pressure is a tip holding force concentrated by the at least one protrusion and the external energy delivered by the operable elements is at least one of optical, electrical and ultrasound energy

14. The device of claim **1**, wherein the treatment layer comprises at least one optical fiber arranged to emit at least two radiation types at at least two corresponding zones of the fiber, the radiation types differing in at least one of: intensity, spectral range and temporal pattern.

15. A method of designing a device for applying a treatment to an obstruction, the method comprising:

attaching a treatment layer comprising a plurality of operable elements to a flexible supporting layer;

designing the operable elements to be activated upon bending of the flexible supporting layer beyond a specified curvature threshold; and

configuring the operable elements to apply the treatment to the obstruction upon their activation.

16. The method of claim **15**, further comprising designing the operable elements to be activated due to contact thereof with the obstruction and de-activated upon reduction the bending resulting from the treatment of the obstruction.

17. The method of claim **15**, further comprising integrating at least one optical fiber into the treatment layer and configuring the operable elements to comprise at least one specified region of a fiber's cladding that is arranged to emit electromagnetic radiation from a fiber's core upon bending the optical fiber at the at least one specified region beyond a specified bending threshold.

18. The method of claim **17**, further comprising configuring the cladding to be asymmetric in cross section at the at least one specified region and to comprise at least one emission sector and at least one non-emitting sector, and setting an effective refractive index n_E of the at least one emission sector closer to a core refractive index n_K than a cladding refractive index n_M, to yield transmission through the at least one emission sector upon bending of the optical fiber at the at least one specified region beyond the specified bending threshold.

19. The method of claim **17**, further comprising configuring the treatment layer as a vessel sealing tip for surgical forceps, and configuring the operable elements to deliver, upon actuation, electromagnetic radiation to a vessel to yield a vessel welding effect in a specified sealing section of the vessel and to cut the vessel within the specified sealing section.

20. A method of treating a vessel or a vessel obstruction by applying thereto energy from a plurality of operable elements within a treatment layer attached to a flexible supporting layer, wherein the operable elements are configured to be activated upon bending of the flexible supporting layer beyond a specified curvature threshold to apply the energy.

* * * * *

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摘要(译)

提供了组织和血管治疗装置以及相应的方法。装置包括柔性处理层，该柔性处理层包括多个可操作元件，所述多个可操作元件被配置成在柔性处理层弯曲超过指定的曲率阈值时被激活以将治疗施加到障碍物并且在指定的弯曲减小时被去激活。处理层可以包括光纤，其中可操作元件作为发射区域，当弯曲光纤超过指定的弯曲阈值时，发射区域从芯发射电磁辐射。装置可以配置为用于外科手术钳的血管密封尖端，其中治疗层配置成产生血管焊接和血管切割效果。