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(74) Agents: SCHELLER, James, C., Jr. et al.; Blakely, Sokoloff, Taylor & Zafman LLP, 12400 Wilshire Boulevard, 7th Floor, Los Angeles, CA 90025 (US).

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(71) Applicant (for all designated States except US): **ABBOTT CARDIOVASCULAR SYSTEMS INC.** [US/US]; 3200 Laskeside Drive, Santa Clara, CA 95054 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WILLIS, Geoffrey, H.** [US/US]; 406 Foxborough Drive, Mountain View, CA 94041 (US). **WILLIS, Eric** [US/US]; 322 Plateau Avenue, Santa Cruz, CA 95060 (US). **UEMURA, Shuji** [JP/US]; 700 Presidio Avenue, #407, San Francisco, CA 94115 (US). **STEWART, Mike** [US/US]; 27 Jacklin Circle, Milpitas, CA 95035 (US). **CANTU, Alfredo** [US/US]; 4035 School Street, Pleasanton, CA 94566 (US).

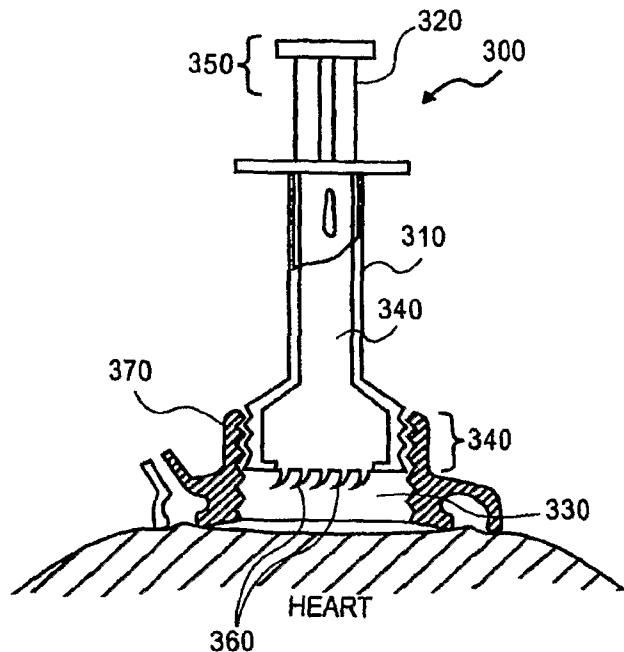
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(54) Title: NEEDLE ARRAY DEVICES AND METHODS



(57) Abstract: Delivery devices for maximizing injectate dispersion in lesioned tissue using needle-based injection devices are herein disclosed. The delivery devices (300) include injection devices with various needle arrays (360) and/or modified needle tip configurations. The needle tip configurations can include linear, hooked or corkscrew tips and/or multiple circumferential openings.

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NEEDLE ARRAY DEVICES AND METHODS

FIELD OF INVENTION

[0001] Modified needle apparatuses with needle arrays for delivery of substances into or withdrawal from a body.

BACKGROUND OF INVENTION

[0002] Percutaneous transluminal coronary angioplasty (PTCA) is a procedure for treating heart disease, particularly, stenosis. "Stenosis" refers to a narrowing or constriction of the diameter of a vessel. In a typical PTCA procedure, a catheter assembly having a balloon portion is introduced percutaneously into the cardiovascular system of a patient via the brachial or femoral artery to treat stenosis at a lesion site. The catheter assembly is advanced through the coronary vasculature until the balloon portion is positioned across the occlusive lesion. Once in position across the lesion, the balloon is inflated to a predetermined size to radially compress the atherosclerotic plaque of the lesion against the inner wall of the artery to dilate the lumen. The balloon is then deflated to a smaller profile to allow the catheter to be withdrawn from the patient's vasculature.

[0003] Restenosis of the artery commonly develops over several months after the procedure, which may require another angioplasty procedure or a surgical bypass operation. "Restenosis" is the reoccurrence of stenosis in a blood vessel or heart valve after it has been treated with apparent success. Restenosis is thought to involve the body's natural healing process. Angioplasty or other vascular procedures often injure the vessel walls, including removing the vascular endothelium, disturbing the tunica intima, and causing the death of medial smooth muscle cells. Excessive neointimal tissue formation, characterized by smooth muscle cell migration and proliferation to the intima, follows the injury. Proliferation and migration of smooth muscle cells (SMC) from the media layer

to the intima cause an excessive production of extra cellular matrices (ECM), which is believed to be one of the leading contributors to the development of restenosis. The extensive thickening of the tissues narrows the lumen of the blood vessel, constricting or blocking blood flow through the vessel.

[0004] To reduce the chance of the development of restenosis, treatment substances can be administered to the treatment site. For example, anticoagulant and antiplatelet agents are commonly used to inhibit the development of restenosis. In order to provide an efficacious concentration to the target site, systemic administration of such medication often produces adverse or toxic side effects for the patient. Local delivery is a preferred method of treatment in that smaller total levels of medication are administered in comparison to systemic dosages, but are concentrated at a specific site. Local delivery, thus, produces fewer side effects and achieves more effective results.

[0005] Techniques for the local delivery of a treatment substance into the tissue surrounding a vessel are disclosed in U.S. Pat. Nos. 6,944,490, 6,692,466 and 6,554,801 to Chow et al. In some applications, such techniques include a catheter with a needle cannula slidably disposed in a needle lumen and a balloon, which is coupled to the distal end of the catheter. When the balloon is inflated the needle lumen is brought into close engagement with the tissue and the needle cannula can be moved between a position inboard of the catheter distal surface and a position where the needle cannula is projected outboard of the catheter to deliver the treatment substance to the tissue.

[0006] Needles which are used in conjunction with percutaneous injection devices and open-chest surgical injection devices generally include beveled single-port needle tips. Some of the problems associated with these types of needle tips include backflow of the injectate to non-focal areas, damage to surrounding tissue due to high focal injection pressure and reduced treatment agent dispersion due to localized delivery from a single port. Some studies have shown that up to 90 percent of the injectate never reaches the target tissue area

due to backflow. As a result, treatment using needles often requires multiple injections which can result in increased pain and risk to the patient in addition to increased tissue damage due to multiple puncture wounds.

[0007] The treatment of organs with injection devices, in particular dynamic organs, also presents unique challenges. For example, the heart will generally be contracting during a treatment which increases backflow during each muscle contraction and decreases treatment agent dispersion. Moreover, injection devices with a single needle can be inadequate to treat a large injury region on the heart.

SUMMARY OF INVENTION

[0008] Methods and delivery devices for maximizing injectate dispersion in lesioned tissue using needle-based injection devices are herein disclosed. The delivery devices include injection devices with various needle arrays and/or modified needle tip configurations. The needle tip configurations can include, but are not intended to be limited to, linear, hooked, helical or corkscrew tips and/or one or more multiple circumferential openings. The needle tip configurations can additionally include recesses, grooves and/or indentations.

BRIEF DESCRIPTION OF DRAWINGS

[0009] FIGS. 1A-1C illustrate a substance delivery assembly which may be used in conjunction with embodiments of the present invention.

[0010] FIG. 2A illustrates an alternative delivery assembly which may be used in conjunction with embodiments of the present invention.

[0011] FIG. 2B illustrates a second alternative delivery assembly which may be used in conjunction with embodiments of the present invention.

[0012] FIGS. 3A-3B illustrate an embodiment of a modified needle apparatus with a needle array.

[0013] FIGS. 4A-4B illustrate an alternative embodiment of a modified needle apparatus with a needle array.

[0014] FIGS. 5A-5B illustrate a second alternative embodiment of a modified needle apparatus with a needle array.

[0015] FIGS. 6A-6B illustrate a third embodiment of a modified needle apparatus with a needle array.

[0016] FIG. 7 illustrates an embodiment of a positioning device which may be used pursuant to methods of the present invention.

DETAILED DESCRIPTION

Delivery Devices

[0017] FIGS. 1A, 1B, and 1C illustrate a delivery assembly or device which can be used in conjunction with embodiments of the present invention. In general, the delivery assembly provides a system for delivering a substance, such as a treatment agent or a combination of treatment agent, to or through a desired area of a vessel in order to treat a localized area of the vessel or to treat a localized area of tissue located adjacent to the vessel. The delivery assembly includes a catheter assembly 100, which is intended to broadly include any medical device designed for insertion into a vessel to permit injection and/or withdrawal of fluids, to maintain the patency of the vessel, or for any other purpose. It is contemplated that the delivery assembly has applicability for use with any vessel or organ, including blood vessels, urinary tract, intestinal tract, kidney ducts, wind pipes, and the like.

[0018] In one embodiment, catheter assembly 100 is defined by an elongated catheter body 110 having a proximal end 120 and a distal end 130. Catheter assembly 100 can include a guidewire lumen 140 for allowing catheter assembly 100 to be fed and maneuvered over a guidewire 150. A balloon 160 is incorporated at distal end 130 of catheter assembly 100 and is in fluid communication with an inflation lumen 170 of catheter assembly 100.

[0019] Balloon 160 may be inflated by the introduction of a liquid into inflation lumen 170. Liquids containing treatment and/or diagnostic agents may also be used to inflate balloon 160. In one embodiment, balloon 160 may be made of a material that is permeable to such treatment and/or diagnostic liquids. To inflate balloon 160, the fluid can be supplied into inflation lumen 170 at a predetermined pressure, for example, between about 1 and 20 atmospheres. The specific pressure depends on various factors, such as the thickness of balloon wall, the material from which balloon wall is made, the type of substance employed, and the flow-rate that is desired.

[0020] Catheter assembly 100 also includes a substance delivery assembly 180 for injecting a substance into a wall of a vessel or tissue located adjacent to the vessel. In one embodiment, delivery assembly 180 includes a needle 190 movably disposed within a hollow delivery lumen 195. Needle 190 includes a lumen with an inside diameter of, representatively, about 0.08 inches (0.20 centimeters). Delivery lumen 195 extends between distal end 130 and proximal end 120. Delivery lumen 195 can be made from any suitable material, such as polymers and copolymers of polyamides, polyolefins, polyurethanes and the like. Access to the proximal end of delivery lumen 195 for insertion of needle 190 is provided through a hub 185.

[0021] Needle 190 is slidably or movably disposed in delivery lumen 195. Needle 190 includes a tissue-piercing tip having a dispensing port (not shown). The dispensing port is in fluid communication with a central lumen (not shown) of needle 190. In one embodiment, the central lumen of needle 190 can be pre-filled with a measured amount of a substance. The central lumen of needle 190 connects the dispensing port with substance injection port 155, which is configured to be coupled to various substance dispensing means of the sort well known in the art, for example, a syringe or fluid pump. Injection port 155 allows a measured substance to be dispensed from a dispensing port as desired or on command. In some applications, catheter assembly 100 enters percutaneously through an arterial vessel of the heart.

[0022] FIG. 2A illustrates a cross-sectional side view of an alternative delivery device or apparatus which can be used in conjunction with embodiments of the present invention. In general, delivery assembly 200 provides an apparatus for delivering a substance, such as a treatment agent, to or through a desired area of a blood vessel (a physiological lumen) or tissue in order to treat a localized area of the blood vessel or to treat a localized area of tissue located adjacent to the blood vessel.

[0023] Referring to FIG. 2A, delivery assembly 200, in one embodiment, may be in the form of a catheter device that includes delivery lumen 210 that may be formed in a larger catheter body (not shown). The larger catheter body may include one or more lumens to accommodate, for example, a guidewire, an inflation balloon, and/or an imaging device. Further, such a catheter body may accommodate one or more delivery lumens, such as delivery lumen 210. Delivery lumen 210, in this example, extends between distal portion 205 and proximal portion 215 of delivery assembly 200. Delivery lumen 210 can be made from any suitable material, such as polymers and co-polymers of polyamides, polyolefins, polyurethanes, and the like.

[0024] In one embodiment, delivery assembly 200 includes needle 220 movably disposed within delivery lumen 210. Needle 220 is, for example, a stainless steel hypotube that extends a length of the delivery assembly. Needle 220 includes a lumen with an inside diameter of, representatively, about 0.16 inches (0.40 centimeters). In one example for a retractable needle catheter, needle 220 has a length of about 40 inches (1.6 meters) from distal portion 205 to proximal portion 215. The needle 220 may include at least one opening 230. At an end of proximal portion 215 is adapter 250 of, for example, a female luer housing.

[0025] When loaded, a substance may be introduced according to known substance delivery techniques such as by advancing tip 240 of needle 220 into tissue (e.g., a wall of a blood vessel) and delivering the substance through back

pressure (e.g., pressure applied at proximal portion 215, such as by a needle luer). In some applications, delivery assembly 200 enters percutaneously through the left ventricle of the heart.

[0026] FIG. 2B illustrates an alternative delivery assembly which can be used in conjunction with embodiments of the present invention. In some embodiments, delivery device 260 is a syringe. Delivery device 260 may include a body 270, a needle 280 and a plunger 290. A shaft of plunger 290 has an exterior diameter slightly less than an interior diameter of body 270 so that plunger 290 can, in one position, retain a substance in body 270 and, in another position, push a substance through needle 280. Syringes are known by those skilled in the art. In some applications, delivery device 260 may be applied directly to a treatment site during an open-chest surgery procedure.

Needle Arrays

[0027] In some embodiments, modified needle apparatuses can be used to maximize injectate dispersion into tissue or organs. In some embodiments, the modified needle apparatuses can have an array of needles configured in various conformations to maximize injectate dispersion. In some embodiments, methods, apparatuses or compositions can be used to control dynamic organs to isolate a target tissue region thereby maximizing injectate dispersion.

[0028] FIGS. 3A-3B illustrate an embodiment of a modified needle apparatus. A needle apparatus 300 includes a body 310, a plunger 320 (located at proximal end 350 of body 310) and an injectate region 330 (located at distal end 340). Injectate region 330 can include a series of needles 360 with openings (not shown) arranged in a suitable pattern to maximize injectate dispersion. Needles 360 can be in fluid communication with a fluid reservoir 340 to deliver injectate. Needles 360 can each have a diameter in the range of about 0.005 to 0.05 inches and a penetrating length in the range of about 0.5 to about 5.0 millimeters. In one embodiment, needles 360 can be arranged in a circular pattern, as shown in FIG.

3B (front view of injectate region 330). In some embodiments, needles 360 can be shaped in specific configurations, such as corkscrews or hooks. Such configurations can maximize injectate dispersion by providing multiple entries for injectate at a treatment site and by creating a non-linear pathway for the injectate to disperse throughout a wider area thereby decreasing backflow. As would be understood by one skilled in the art, other configurations can be provided in accordance with the teachings herein.

[0029] To assist in targeted delivery of the injectate, needle apparatus 300 can include an anchor 370 disposed adjacent to distal end 340. The anchor 370 includes a vacuum opening in fluid communication with a vacuum source (not shown) and helps to stabilize a treatment site when needle apparatus 300 is positioned thereon. For example, when the area to be treated is on the heart, the anchor 370 may be necessary to specifically target the treatment site because the heart will be continually contracting throughout an application of injectate. Apparatuses which stabilize the heart during such procedures include the XPOSE™ 3 Access Device and the XPOSE™ 4 Access Device developed by Advanced Cardiovascular Systems, Inc., Santa Clara, California. The embodiments shown in FIGS. 3A-3B illustrate a needle apparatus to be used in an open-chest procedure, however, it is also contemplated that a modified version can be used with a catheter assembly.

[0030] FIGS. 4A-4C illustrate an alternative embodiment of a modified needle apparatus which may be used for percutaneous injection using a catheter assembly. A modified needle apparatus 400 includes a body 410 with an injectate region 430 covered by a moveable rubber skirt 470 located at a distal end 440. Injectate region 430 can include a series of needles 460 with openings (not shown) arranged in a suitable pattern. The needles 460 can be in fluid communication with a fluid reservoir to deliver injectate. Additionally, needles 460 may be linear or directional. In one embodiment, needles 460 may be arranged in a linear fashion (see FIG. 4B) and angled in a direction away from the pathway in which needle apparatus 400 is delivered to the treatment site.

[0031] In one application in which the area to be treated is on the heart, representatively shown in FIG. 4C, needle apparatus 400 may be inserted intravenously (arrow 480) through a blood vessel until it reaches the treatment site. After insertion and throughout the positioning of needle apparatus 400, rubber skirt 470 serves to protect the needles 460 from puncturing healthy tissue as it is being delivered to the treatment site. Moreover, in this embodiment, needles 460 are angled in a direction away from the pathway in which the needle apparatus 400 is delivered to the treatment site thereby reducing inadvertent puncturing of healthy tissue during delivery. To release injectate, needle apparatus 400 may be positioned at a point slightly past the treatment site. Needle apparatus 400 may then be retracted (arrow 490) such that needles 460 hook into the treatment site. The moveable rubber skirt 470 may splay adjacent to the injectate region 430 to stabilize and localize the injectate as it is dispensed through needles 460 from a fluid reservoir (not shown). In this manner, injectate dispersion can be maximized through multiple entries and by creating a non-linear pathway for the injectate to disperse throughout a wider area thereby decreasing backflow.

[0032] FIGS. 5A-5B illustrate another embodiment of a modified needle apparatus. A modified needle apparatus 500 includes a body 510 with a distal end 540 and a proximal end 550. An extension and retraction knob 520 can be located at proximal end 550. In some embodiments, the body can be approximately tubular and can house at least one retractable tube 570. Retractable tubes 570 may be deployable by a spring-loaded mechanism or any other suitable mechanism. A needle 560 can be located at the distal end of each retractable tube 570. Needle 560 can be in fluid communication with a fluid reservoir to deliver injectate via a lumen (not shown).

[0033] In one application, needle apparatus 500 may be directed to a treatment site. The needle apparatus 500 remains in a retracted state with distal end 640 either positioned in body 600 or outside of body 610 (FIG. 6A) with the series of retractable tubes 570 resting in body 510 until the injectate is ready to

be delivered to the treatment site. Once positioned on the treatment site, knob 520 may be depressed (arrow 580) so that the retractable tubes 570 can extend from body 510 into the treatment site (FIG. 5B). In some embodiments, retractable tubes 570 flare outwardly to contact multiple areas on the treatment site thereby maximizing injectate dispersion. In some embodiments, retractable tubes 570 may be connected by flexible webbing to stabilize the deployment of retractable tubes 570. Thus, the injection pattern may be controllable and repeatable.

[0034] FIGS. 6A-6B illustrate still another embodiment of a modified needle apparatus. A modified needle apparatus 600 includes a body 610 with a distal end 640 and a proximal end 650. An extension and retraction knob 620 can be located at proximal end 650, while a hollow flexible member 670 may be located at distal end 640. A needle array 630 may be located within flexible member 670. Needle array 630 can include at least one needle 660. Each needle 660 can be in fluid communication with a fluid reservoir to deliver injectate.

[0035] In one application, needle apparatus 600 may be directed to a treatment site. Needle apparatus 600 remains in a retracted state (FIG. 6A) with the needle array 630 in a retracted position until the injectate is ready to be delivered to the treatment site. Once positioned on the treatment site, the knob 620 may be engaged (arrow 680) so that the needle array 630 extends from the flexible member 670 and into the treatment site (FIG. 6B). Simultaneously, the flexible member may splay outwardly into at least two arms 690. The arms 690 may be connected by a hinge 695. In this manner, the injection pattern may be controllable and repeatable.

[0036] FIG. 7 illustrates a device which can be used to isolate a target tissue region to maximize injectate dispersion. The device may be, for example, a plastic plate 700 with an array of openings 760 attached to a distal end of a vacuum source (not shown). Plate 700 may be any suitable configuration. In some applications, plate 700 may be positioned over a treatment site during an

open-chest procedure. The vacuum source may be used to immobilize the treatment site in preparation for delivering an injectate. Plate 700 can be made of an elastomer, such as silicon or any other biocompatible material, and can serve as an isolating mechanism for delivery of injectate to, for example, a treatment site on the heart. In one application, plate 700 is positioned over the treatment site by a positioning device (not shown). Plate 700 thereby serves to isolate the target tissue region. A needle assembly or a syringe, such as those described in relation to FIGS. 1A-1B, may then be used to deliver injectate.

[0037] In any of the above-described embodiments, the needles may include one or more circumferential openings to maximize injectate dispersion. In some embodiments, a substance may be added to the injectate to temporarily reduce contractility of the heart in order to maximize injectate dispersion throughout the treatment site. Such substances include, but are not limited to, heparin, diltiazem and verapamil.

[0038] From the foregoing detailed description, it will be evident that there are a number of changes, adaptations and modifications of the present invention which come within the province of those skilled in the art. The scope of the invention includes any combination of the elements from the different species and embodiments disclosed herein, as well as subassemblies, assemblies and methods thereof. However, it is intended that all such variations not departing from the spirit of the invention be considered as within the scope thereof.

WHAT IS CLAIMED IS:

1. A substance delivery device comprising:
a body comprising a proximal end, a distal end and a lumen;
a retractable needle array at the distal end comprising a plurality of needles in fluid communication with the lumen wherein the needles are non-linear; and
a knob at the proximal end connected to a mechanism within the body, wherein the mechanism moves fluid when the knob is engaged.
2. The device of claim 1, wherein the plurality of needles comprise multiple circumferential openings.
3. The device of claim 1, wherein the fluid is a substance.
4. The device of claim 3, wherein the substance is a treatment agent, a contractility reducing agent or a combination thereof.
5. The device of claim 1, where the contractility agent is one of heparin, diltiazem or verapamil.
6. The device of claim 1, further comprising webbing between the needles.
7. A method comprising:
positioning an isolation device on a target treatment site wherein the isolation device comprises one or more openings; and
delivering a substance to the treatment site through the openings using a delivery device.
8. The method of claim 7, wherein the delivery device is a percutaneous delivery device or a syringe.

9. The method of claim 7, wherein the isolation device is removably coupled to a vacuum device.
10. The method of the claim 7, wherein the substance comprises at least one of a treatment agent or a contractility reducing agent.
11. The method of claim 7, wherein the contractility reducing agent is one of heparin, diltiazem or verapamil.
12. The method of claim 7, wherein the target treatment site is a dynamic organ.
13. The method of claim 12, wherein the dynamic organ is a heart.

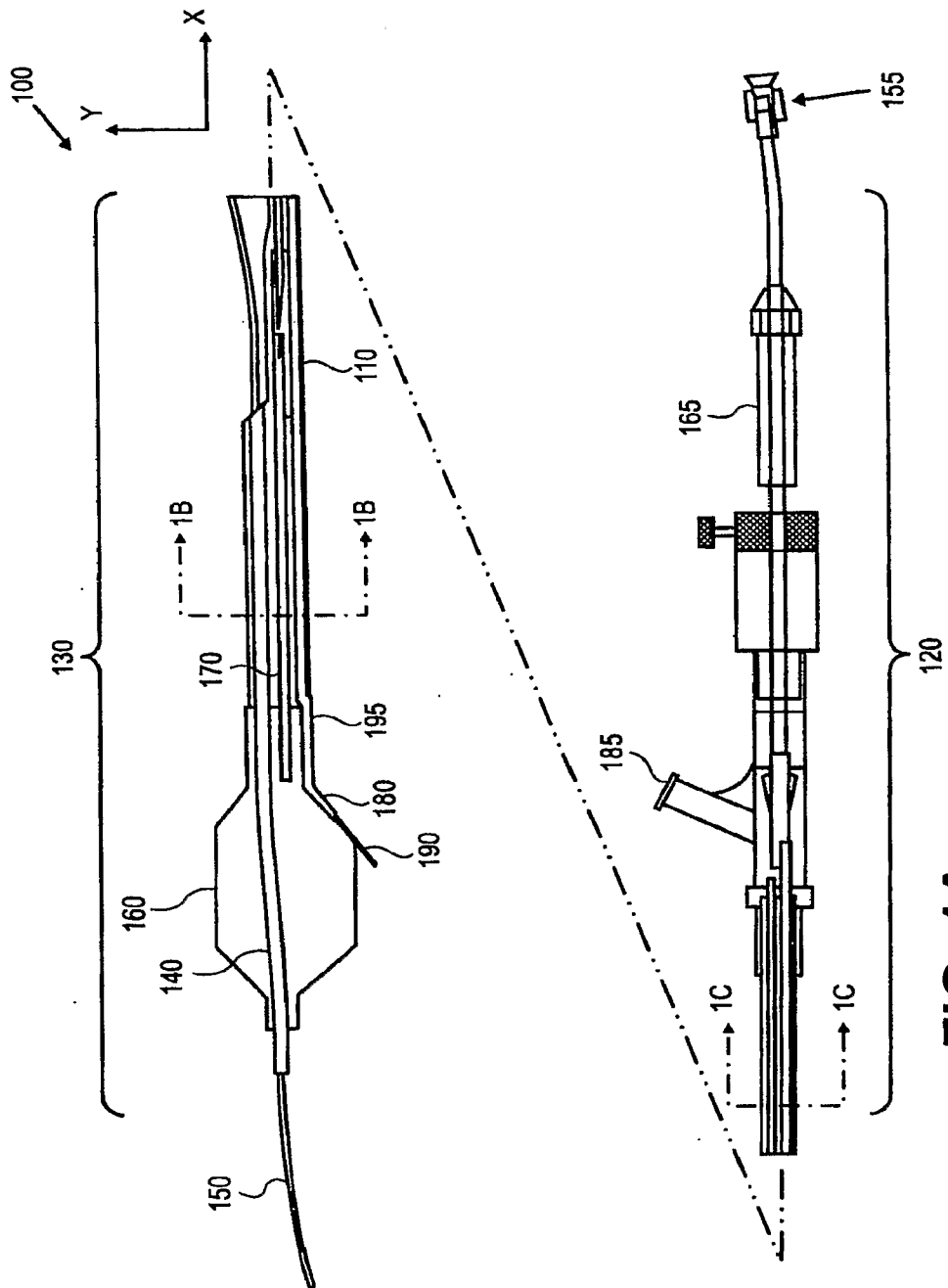


FIG. 1A

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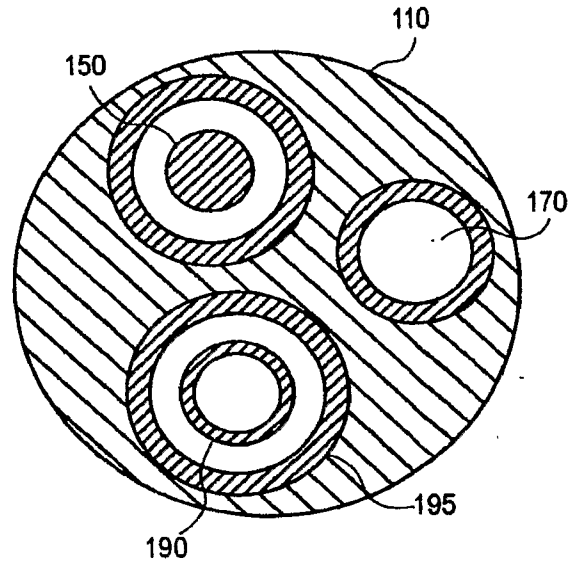


FIG. 1B

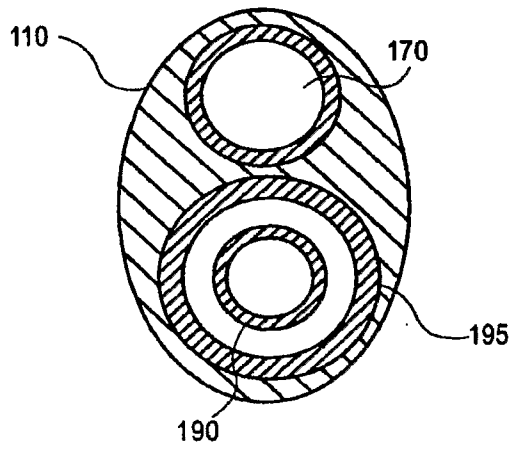


FIG. 1C

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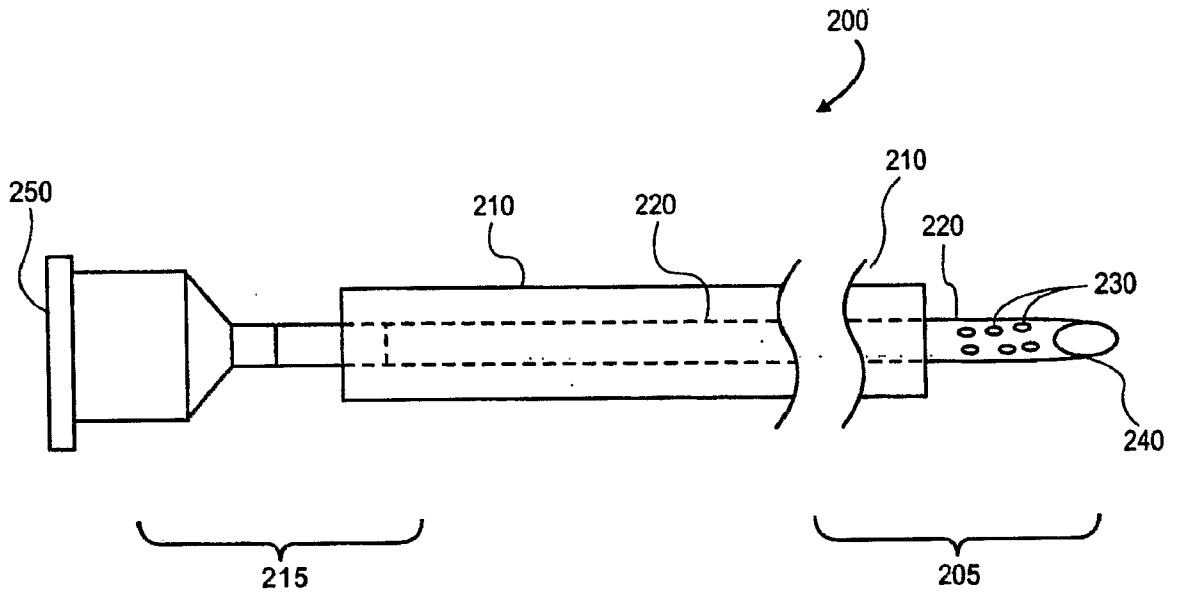


FIG. 2A

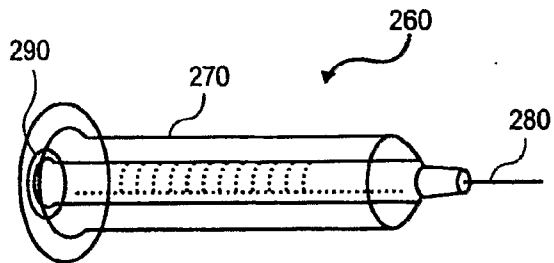


FIG. 2B

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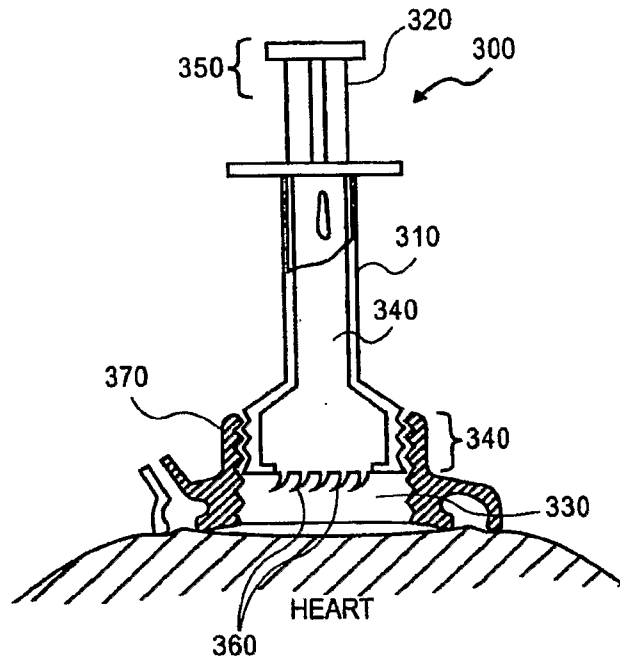


FIG. 3A

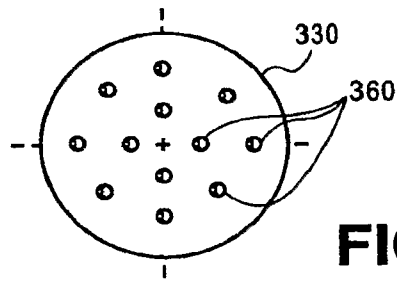


FIG. 3B

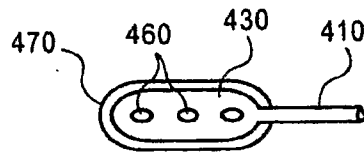


FIG. 4A

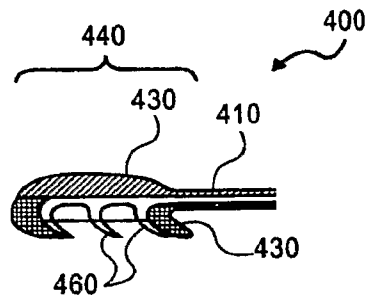


FIG. 4B

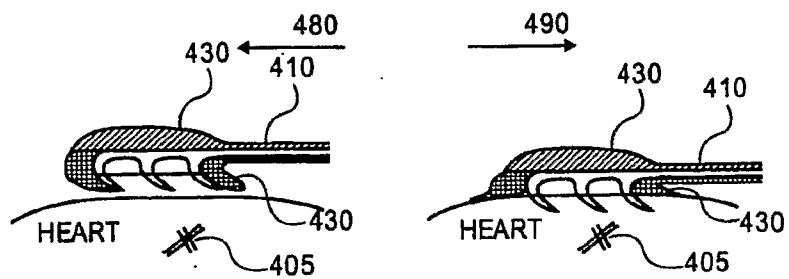


FIG. 4C

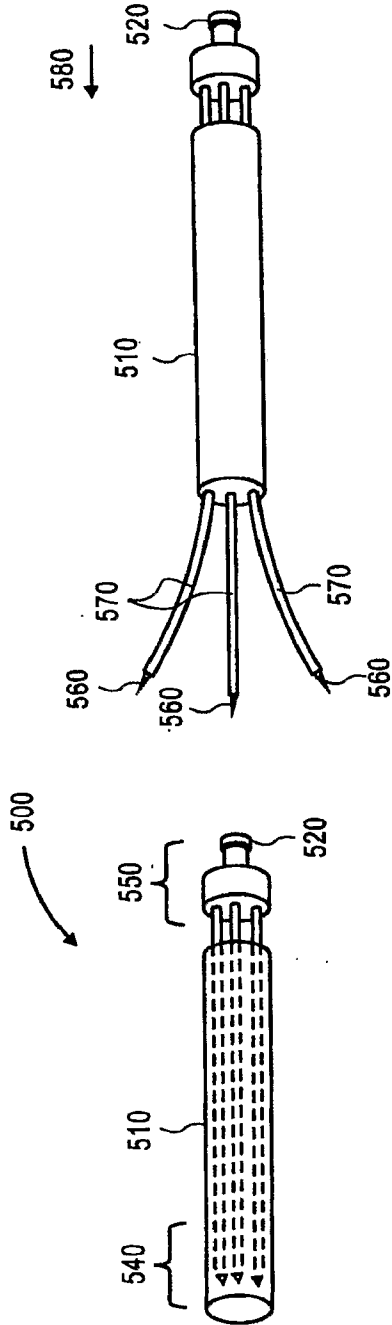


FIG. 5B

FIG. 5A

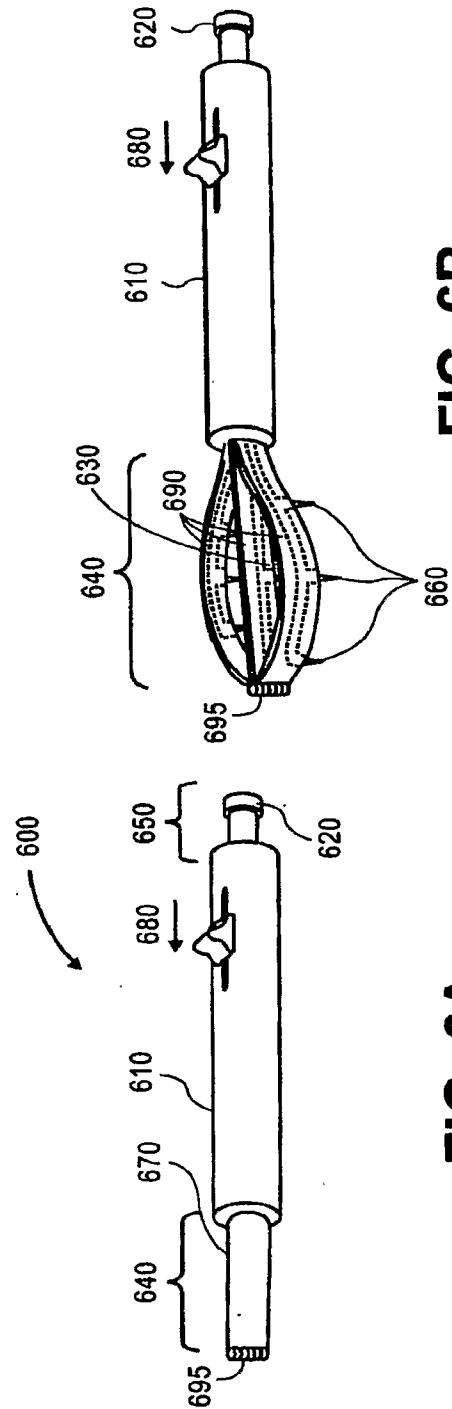


FIG. 6B

FIG. 6A

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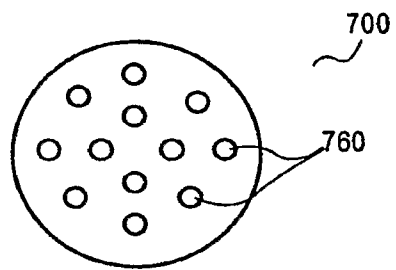


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/009790

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M25/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 10 2004 063798 A1 (RIEK SIEGFRIED [DE]; BACHMANN KARL-HEINZ [DE]; GAISELMANN THOMAS [DE]) 11 May 2006 (2006-05-11) figures 1,9-12 paragraphs [0005], [0008], [0011], [0014], [0029] - [0038], [0040] - [0043]	1,3,4,6
A	-----	2,5
Y	US 4 578 061 A (LEMELSON JEROME H [US]) 25 March 1986 (1986-03-25) figures 1,6 column 1, line 10 - line 24 column 1, line 48 - line 61 column 8, line 23 - column 9, line 35 ----- -/--	1-6
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
A document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search 27 September 2007		Date of mailing of the international search report 10/10/2007
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Przykutta, Andreas

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 99/48545 A (TRANSVASCULAR INC [US]) 30 September 1999 (1999-09-30) figures 1A-1E, 5A-5C page 1, line 13 - line 35 page 6, line 13 - page 7, line 24 page 8, line 29 - page 9, line 24 page 16, line 13 - line 35 page 19, line 31 - page 20, line 25 page 22, line 1 - line 23 page 23, line 29 - page 24, line 21 page 30, line 29 - page 31, line 9	1-6
Y	WO 00/67647 A (SCIMED LIFE SYSTEMS INC [US]) 16 November 2000 (2000-11-16) figures 1, 2, 4-8 page 1, line 15 - line 17 page 3, line 25 - page 5, line 7 page 6, line 6 - line 10 page 7, line 4 - page 8, line 2 page 9, line 31 - page 11, line 14 page 12, line 16 - page 15, line 10 page 16, line 10 - page 18, line 27	1, 3-5
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Y	US 6 629 949 B1 (DOUGLAS JOEL S [US]) 7 October 2003 (2003-10-07) figures 1, 4 column 1, line 10 - line 16 column 4, line 19 - line 63 column 5, line 5 - line 25 column 6, line 31 - line 34	1, 3-5
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A	WO 00/74763 A (GEORGIA TECH RES INST [US]) 14 December 2000 (2000-12-14) abstract page 4, line 1 - line 24 page 8, line 10 - page 9, line 3	1-6
P, X	WO 2006/118804 A (SDGI HOLDINGS INC [US]; MCKAY WILLIAM F [US]; DRAPEAU SUSAN J [US]) 9 November 2006 (2006-11-09) the whole document	1-4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/009790

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 7-13
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/009790

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