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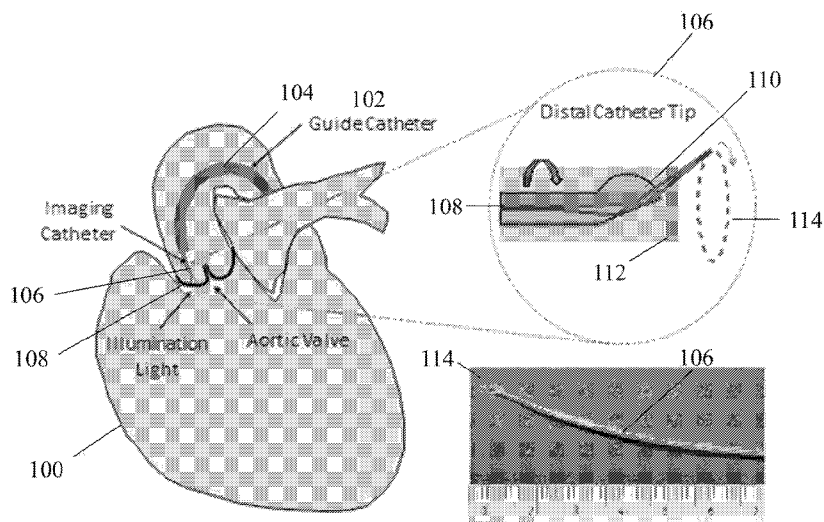
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(54) Title: APPARATUS, SYSTEMS AND METHODS FOR PROVIDING INFORMATION REGARDING THE AORTIC VALVE

**Figure 1**

(57) Abstract: An apparatus according to an exemplary embodiment of the present disclosure can include a first section(s) and a second section(s) which can have a cross-section that can be smaller than that of the first section. The first and second sections can be a particular section and can include memory-forming characteristics. An imaging arrangement can be in communication with the first section or the second section. The particular section can have a first shape when the particular section can be constrained, and the particular section can have a second shape when the particular section can be unconstrained. The second shape can be more curved than the first shape.

**APPARATUS, SYSTEMS AND METHODS FOR PROVIDING INFORMATION
REGARDING THE AORTIC VALVE**

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application relates to and claims priority from U.S. Patent Application Serial No. 61/758,161 filed January 29, 2013, and U.S. Patent Application Serial No. 61/799,344 filed March 15, 2013, the entire disclosures of which are incorporated herein by reference.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates generally to providing information regarding an anatomical structure, and more particular to exemplary embodiments of apparatus, systems and methods for providing information regarding, e.g., an aortic valve.

BACKGROUND INFORMATION

[0003] Calcific aortic valve disease (CAVD) can be present within approximately 25% of people 65-74 years of age and within 48% of people ≥ 84 years of age. CAVD is a progressive disorder characterized by focal areas of valve thickening and a build-up of calcium deposits within the aortic valve leaflet. Current noninvasive imaging techniques for detecting CAVD, such as echocardiography, CT, and MR, do not provide adequate resolution to detect microscopic calcification during the early stages of development when CAVD might be more responsive to medical therapies that could obviate the need for aortic valve surgery.

[0004] Accordingly, there may be a need to address at least some of the above-described deficiencies.

SUMMARY OF EXEMPLARY EMBODIMENTS

[0005] An apparatus can include a first section(s) and a second section(s) which can have a cross-section that can be smaller than that of the first section. The first and second sections can be a particular section, and can include memory-forming characteristics. An imaging
5 arrangement can be in communication with the first section or the second section. The particular section can have a first shape when the particular section can be constrained, and the particular section can have a second shape when the particular section can be unconstrained. The second shape can be more curved than the first shape.

[0006] In some exemplary embodiments of the present disclosure, the imaging
10 arrangement can be an optical imaging arrangement, and can include an ultrasound arrangement. A portion(s) of the first section can be at least partially transparent to light, and a portion(s) of the second section can be at least partially transparent to light. In certain exemplary embodiments of the present disclosure, there can be a third section(s) which can be coupled to the particular section, and can be configured to control a shape or a curvature of
15 the particular arrangement. The imaging arrangement can provide data that can be reflectance confocal microscopy, SECM, OFDI, SD-OCT, FFOCM, 2nd and 3rd harmonic microscopy, fluorescence microscopy or RAMAN.

[0007] In some exemplary embodiments of the present disclosure, a radius of a curvature of the second shape can vary between approximately 7 mm and 12 mm or between
20 approximately 7 mm and 10 mm. A fixed radius of a curvature of the second shape can be between approximately 7 mm and 12 mm, or between approximately 7 mm and 10 mm. In certain exemplary embodiments of the present disclosure, a fluid delivery arrangement can be configured to deliver a first fluid externally from the catheter arrangement so as to at least partially supplement bodily fluids at or near the catheter arrangement. A further arrangement

can be configured to translate or rotate the imaging arrangement, which can be performed during the fluid delivery by the fluid delivery arrangement.

[0008] According to still another exemplary embodiment of the present disclosure, a particular section that can be the first section and/or the second section can include memory-forming characteristics. Further, the imaging arrangement can include a partial ball lens that
5 can be shaped so as to direct or focus at least one electromagnetic radiation through a distal end of the imaging arrangement along approximately an extension thereof.

[0009] These and other objects, features and advantages of the exemplary embodiments of the present disclosure will become apparent upon reading the following detailed
10 description of the exemplary embodiments of the present disclosure, when taken in conjunction with the appended claims.

BRIEF DESCRIPTION OF DRAWINGS

[0010] Further objects, features and advantages of the present disclosure will become
15 apparent from the following detailed description taken in conjunction with the accompanying figures showing illustrative embodiment of the present disclosure, in which:

[0011] Figure 1 is an illustration of an operation of a relatively straight catheter with a forward imaging configuration according to an exemplary embodiment of the present disclosure;

20 [0012] Figure 2 is an illustration of an operation of a predefined curved catheter that can conform to an original shape after passing through the guide catheter and can be placed directly within a valve according to another exemplary embodiment of the present disclosure;

[0013] Figure 3 is an illustration of an operation of a catheter with an adjustable curvature that can fit to various regions of the valve according to still another exemplary embodiment

of the present disclosure;

[0014] Figure 4 is an illustration of an operation of a catheter with a predefined shape that anchors into a vessel to retain the placement according to yet another exemplary embodiment of the present disclosure;

5 [0015] Figure 5 is an illustration of an operation of a catheter positioned against the valve and the aorta wall according to an exemplary embodiment of the present disclosure;

[0016] Figure 6 is an illustration of an operation with a flushing port added to the catheter to remove blood in the proximity of the sampled region according to an exemplary embodiment of the present disclosure;

10 [0017] Figure 7 is an illustration of an operation a separate flushing device synched to the catheter to remove blood from the entire valve according to an exemplary embodiment of the present disclosure;

[0018] Figure 8 is an illustration of a use of a radiographic marker on the catheter according to an exemplary embodiment of the present disclosure; and

15 [0019] Figure 9 is an illustration of an imaging apparatus combined with the catheter according to an exemplary embodiment of the present disclosure.

[0020] Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present disclosure will now be described in
20 detail with reference to the figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the figures or the appended claims.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

25 [0021] According to exemplary embodiments of the present disclosure, optical catheter

techniques can be provided for obtaining information about the microstructure of the aortic valve in vivo. The exemplary optical technique may include optical coherence tomography (OCT), optical frequency domain imaging (OFDI), speckle imaging, refractive index measurement, absorption, autofluorescence, diffuse spectroscopy, photoacoustic methods, etc. Figure 1 shows a cross sectional view of a heart 100 with a guide catheter 102, which is used to deliver the imaging catheter 104 in position near the aortic valves 106. In one exemplary embodiment, the exemplary device/apparatus can include a light source, such as, e.g., a laser diode or LED, which can be transmitted through an optical fiber 108 to a lens 110 at the distal end. Imaging procedure(s) can be performed through the distal end of the catheter, which may be sealed with a window 112. The exemplary device/apparatus can include and/or utilize a full-field (non-scanning) imaging technique, a rotation and pullback helical scanner 114, micro electromechanical system (MEMS), resonating fiber, tuning fork cantilever, spatial frequency encoding, angle-polished rotating fiber, single or double rotating prisms, angle-polished gradient index (GRIN) lenses, rotating angle-polished ball lens, acousto-optic modulator, or similar. The light (or other electro-magnetic radiation) may be received through the same fiber or through additional optical fibers within the device and transmitted to a detector. The exemplary device/apparatus may be configured to also direct light to the specimen at different wavelengths or by use of a broad-bandwidth light source. In yet another exemplary embodiment, the light returned from the specimen can be detected by one or more point detectors, one- or two-dimensional array of detectors, CCD or CMOS camera, or the like.

[0022] According to another exemplary embodiment of the present disclosure, the exemplary device/apparatus can fit within a guide catheter that can be positioned within the aorta, e.g., near the valve, such that the apparatus can be directed toward the valve. For example, as shown in Figure 1, the exemplary device/apparatus with the imaging catheter 104

can be straight to collect information from a specific spot. As shown in Figure 2, the exemplary device/apparatus which includes an imaging catheter 200 and a guide catheter 202 can be provided which may have a predefined curved shape to fit along the junction of the valve and the aorta wall. The exemplary catheter 200 can be delivered by use of the guide catheter 202. When delivered, the predefined curved imaging catheter 200 can be straight, and when it reaches the distal of the guide catheter 202, the imaging catheter 200 can assume the predefined curvature, which is selected to fit along a commissure 204 in the aortic sinus. Imaging procedure(s) can be performed through a sheath 206 as the optical fiber is rotated in a direction 208, and retracted in a helical scan pattern.

[0023] Figure 3 shows an exemplary device/apparatus according to an exemplary embodiment of the present disclosure which can change shape dynamically to collect information from the valve. The exemplary device/apparatus of Figure 3 can include an adjustable curvature imaging catheter 300 that can be inserted into a guide catheter 302 in a straight shape, and, when delivered to the proximal end of the aorta, a curvature 304 of the distal imaging section of the catheter can be adjusted to fit within the aortic cusp against a commissure 306. To adjust the curvature, the exemplary device/apparatus can include and/or utilize a medical-grade wire attached to the distal end of the catheter 308, independent wires placed within the lumen of the catheter sheath, or similar. Similar to the exemplary imaging catheter of Figure 2, exemplary imaging procedure(s) can be performed via a sheath 310 as the optical fiber is rotated in a direction 312, and retracted in a helical scan pattern.

[0024] According to still another exemplary embodiment, the exemplary device/apparatus can float freely within the aorta and/or valve. Figure 4 shows an exemplary device/apparatus 400 according to an exemplary embodiment of the present disclosure which can be anchored within the vessel. For example, anchor points can be the coronary artery ostium 402, the aortic sinus 404, or similar. According to another exemplary embodiment of

the present disclosure, the exemplary device/apparatus can use the aortic wall to guide the imaging catheter into the aortic sinus, as shown in Figure 5.

[0025] According to a further exemplary embodiment of the present disclosure, as shown in Figures 6 and 7, the exemplary device/apparatus can contain a flushing port to remove blood between the apparatus and the valve. The exemplary device/apparatus of Figures 6 and 7 can include an imaging catheter 600 that can be delivered by a guide catheter 602, which is connected to a flushing system. In this exemplary embodiment, the distal end of a guide catheter 606 can be positioned close proximity to the distal end of the imaging catheter 602. Flushing medium can be introduced into the guide catheter 602 by either a manual or an automatic flushing system. A flushing medium 604 can be delivered into the field of view of the distal imaging optics and replaces the blood within the field of view. In yet another exemplary embodiment, the exemplary device/apparatus can be synchronized with a separate flushing system to remove blood from the aortic valve.

[0026] According to yet a further exemplary embodiment of the present disclosure, the exemplary device/apparatus can include a radiographic marker that is visible under fluoroscopy, as shown in Figure 8. In another exemplary embodiment, the exemplary device/apparatus can include a full-field imaging technique within the guide catheter to visualize the placement of the apparatus and the location where information about the valve is obtained. In yet a further exemplary embodiment, the exemplary device/apparatus can fit within the working channel of an angiograph or similar imaging catheter that will allow visual positioning of the apparatus within or near the valve. For example, Figure 9 shows an exemplary embodiment of the device/apparatus according to the present disclosure, which can include an imaging catheter 900 that can be delivered by a guide catheter 902. A separate imaging device 904 which can use a wavelength of light that is weakly absorbed by blood can

be used to illuminate the aortic valve and can be used to guide the placement of the imaging catheter 900.

[0027] Further features and advantages of the exemplary embodiment of the present disclosure will become apparent taken in conjunction with the accompanying figures and drawings and upon reading the following detailed description of the exemplary embodiments of the present disclosure.

[0028] The exemplary Figures 1-5 provided herewith represent exemplary representative configurations of the exemplary device apparatus according to exemplary embodiments of the present disclosure. The exemplary Figures 6-7 provided herewith represent exemplary representative configurations of the exemplary device apparatus according to exemplary embodiments of the present disclosure to image through the blood. Further, the exemplary Figures 9 provided herewith represents exemplary representative configurations of the exemplary device apparatus according to exemplary embodiments of the present disclosure to determine the location of the catheter and the region sampled.

[0029] The foregoing merely illustrates the principles of the disclosure. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. Indeed, the arrangements, systems and methods according to the exemplary embodiments of the present disclosure can be used with and/or implement any OCT system, OFDI system, SD-OCT system or other imaging systems, and for example with those described in International Patent Application PCT/US2004/029148, filed September 8, 2004 which published as International Patent Publication No. WO 2005/047813 on May 26, 2005, U.S. Patent Application No. 11/266,779, filed November 2, 2005 which published as U.S. Patent Publication No. 2006/0093276 on May 4, 2006, and U.S. Patent Application No. 10/501,276, filed July 9, 2004 which published as U.S. Patent

Publication No. 2005/0018201 on January 27, 2005, and U.S. Patent Publication No. 2002/0122246, published on May 9, 2002, the disclosures of which are incorporated by reference herein in their entireties. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements, and procedures which, although not

5 explicitly shown or described herein, embody the principles of the disclosure and can be thus within the spirit and scope of the disclosure. In addition, all publications and references referred to above can be incorporated herein by reference in their entireties. It should be understood that the exemplary procedures described herein can be stored on any computer accessible medium, including a hard drive, RAM, ROM, removable disks, CD-ROM,

10 memory sticks, etc., and executed by a processing arrangement and/or computing arrangement which can be and/or include a hardware processors, microprocessor, mini, macro, mainframe, etc., including a plurality and/or combination thereof. In addition, certain terms used in the present disclosure, including the specification, drawings and claims thereof, can be used synonymously in certain instances, including, but not limited to, e.g., data and

15 information. It should be understood that, while these words, and/or other words that can be synonymous to one another, can be used synonymously herein, that there can be instances when such words can be intended to not be used synonymously. Further, to the extent that the prior art knowledge has not been explicitly incorporated by reference herein above, it can be explicitly being incorporated herein in its entirety. All publications referenced above can

20 be incorporated herein by reference in their entireties.

WHAT IS CLAIMED IS:

1. An apparatus, comprising:

at least one first section;

at least one second section which has a cross-section that is smaller than that of the

5 first section; and

an imaging arrangement in communication with at least one of the first section or the second section,

wherein, when the particular section is constrained, the particular section has a first shape, and when the particular section is unconstrained, the particular section has a second

10 shape, and

wherein the second shape is more curved than the first shape.

2. The apparatus according to claim 1, wherein the imaging arrangement is an optical imaging arrangement.

15

3. The apparatus according to claim 1, wherein the imaging arrangement includes an ultrasound arrangement.

4. The apparatus according to claim 1, wherein at least one portion of the first section is at least partially transparent to light.

20

5. The apparatus according to claim 1, wherein at least one portion of the second section is at least partially transparent to light.

6. The apparatus according to claim 1, further comprising at least one third section which is coupled to the particular section, and configured to control at least one of a shape or a curvature of the particular arrangement.

5 7. The apparatus according to claim 1, wherein the imaging arrangement provides data that is at least one of reflectance confocal microscopy, SECM, OFDI, SD-OCT, FFOCM, second and third harmonic microscopy, fluorescence microscopy or RAMAN.

8. The apparatus according to claim 1, wherein a radius of a curvature of the second
10 shape varies between approximately 7 mm and 12 mm.

9. The apparatus according to claim 1, wherein a radius of a curvature of the second shape varies between approximately 7 mm and 10 mm.

15 10. The apparatus according to claim 1, wherein a fixed radius of a curvature of the second shape is between approximately 7 mm and 12 mm.

11. The apparatus according to claim 1, wherein a fixed radius of a curvature of the second shape is between approximately 7 mm and 10 mm.

20

12. The apparatus according to claim 1, further comprising a fluid delivery arrangement which is configured to deliver a first fluid externally from the catheter arrangement so as to at least partially supplement bodily fluids at or near the catheter arrangement.

13. The apparatus according to claim 12, further comprising a further arrangement which is configured to at least one of translate or rotate the imaging arrangement.

14. The apparatus according to claim 13, wherein the further arrangement translates or
5 rotates the imaging arrangement during the fluid delivery by the fluid delivery arrangement.

15. The apparatus according to claim 1, further comprising a further arrangement which is configured to at least one of translate or rotate the imaging arrangement.

10 16. The apparatus according to claim 1, wherein a particular section that is at least one of the first section or the second section includes memory-forming characteristics.

17. The apparatus according to claim 1, wherein the imaging arrangement includes a partial ball lens that that is shaped so as to direct or focus at least one electromagnetic
15 radiation through a distal end of the imaging arrangement along approximately an extension thereof.

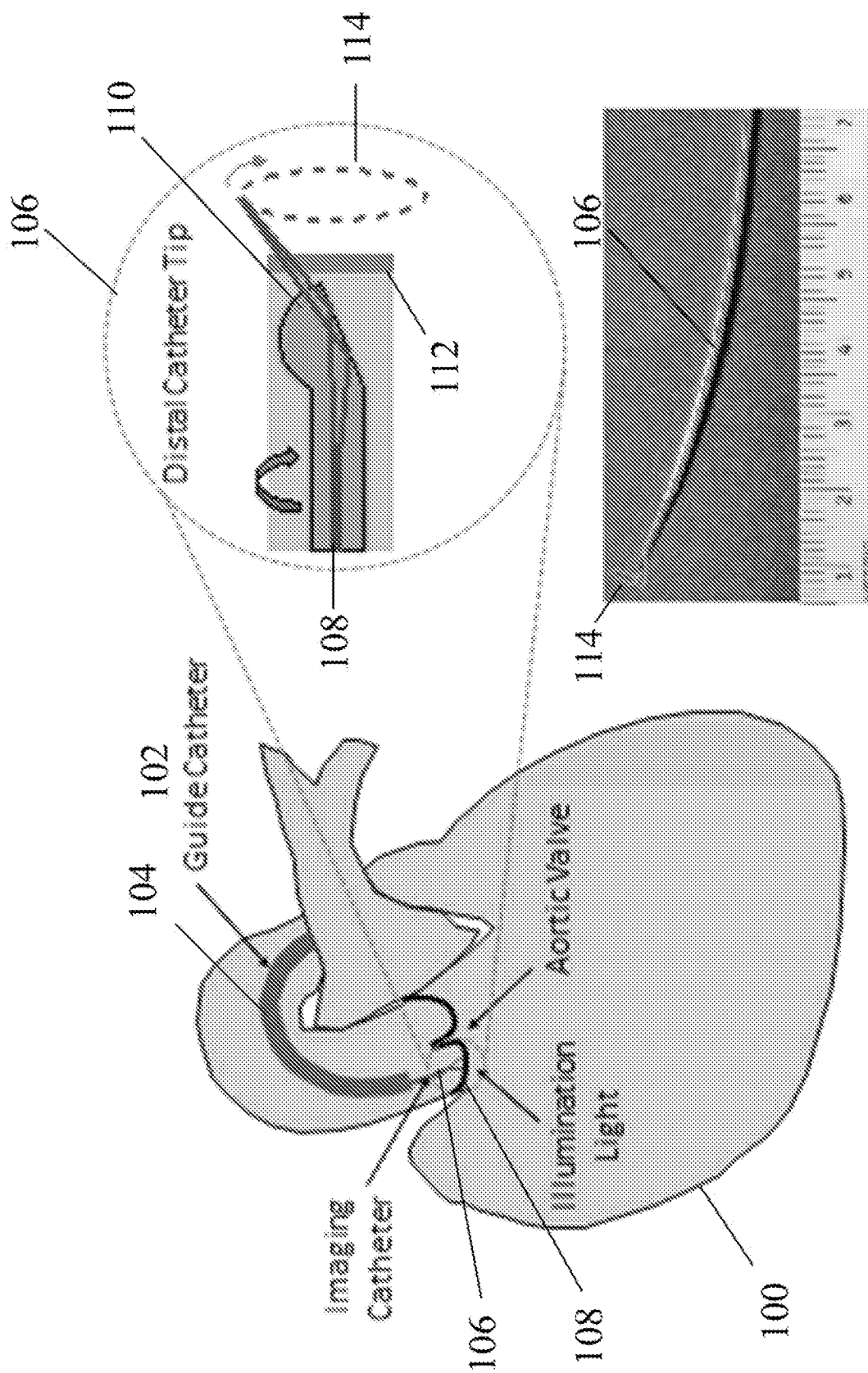


Figure 1

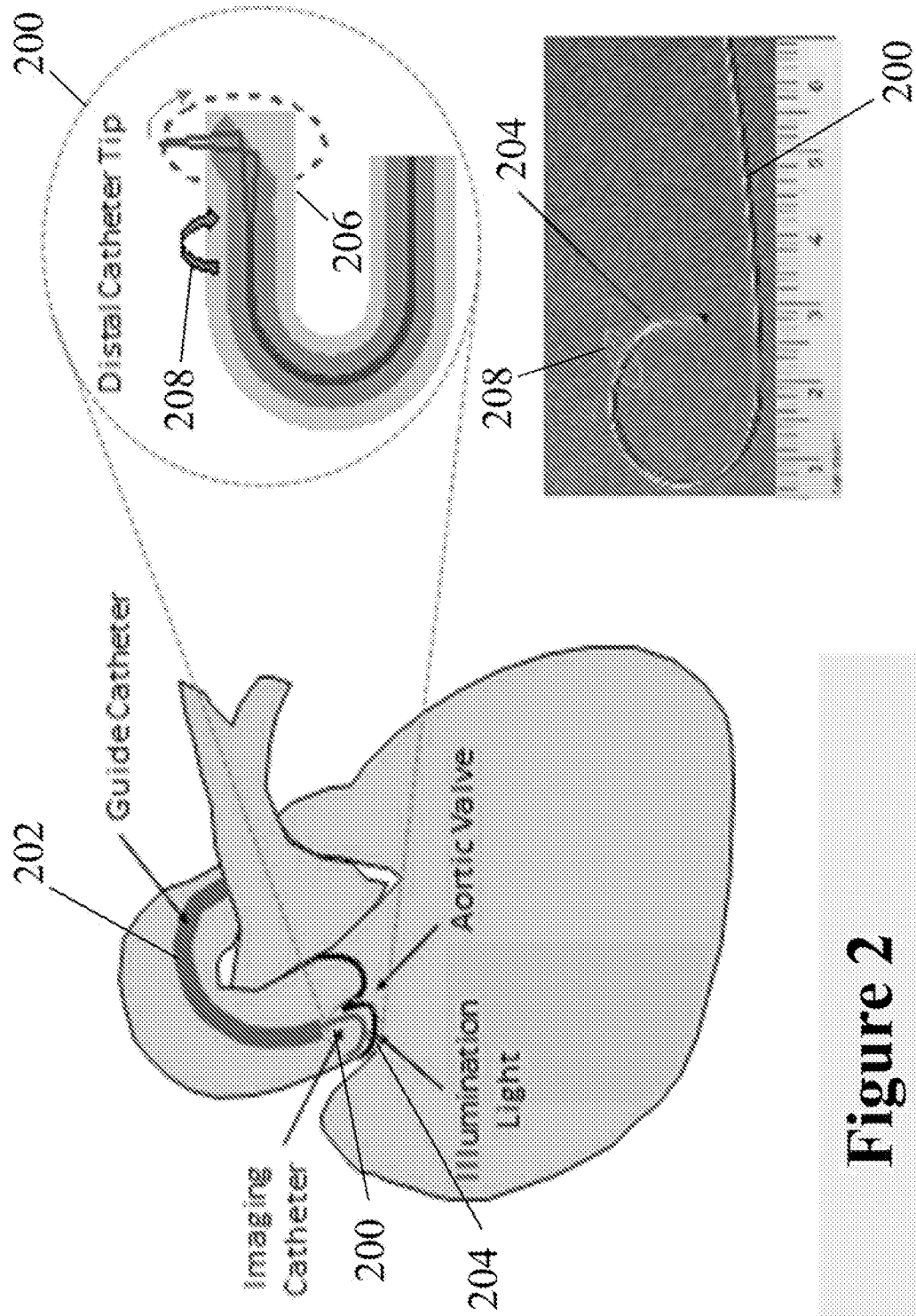


Figure 2

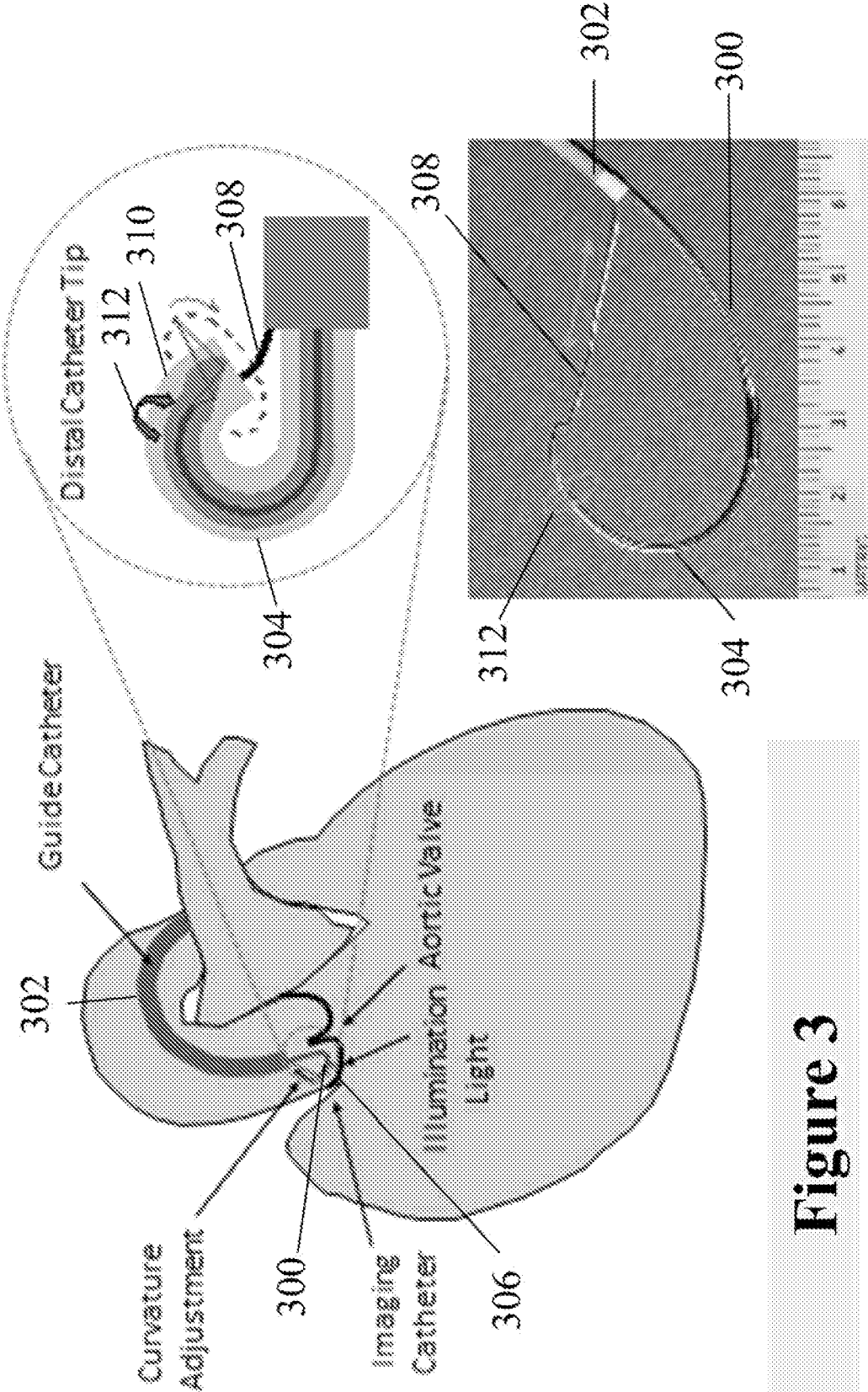


Figure 3

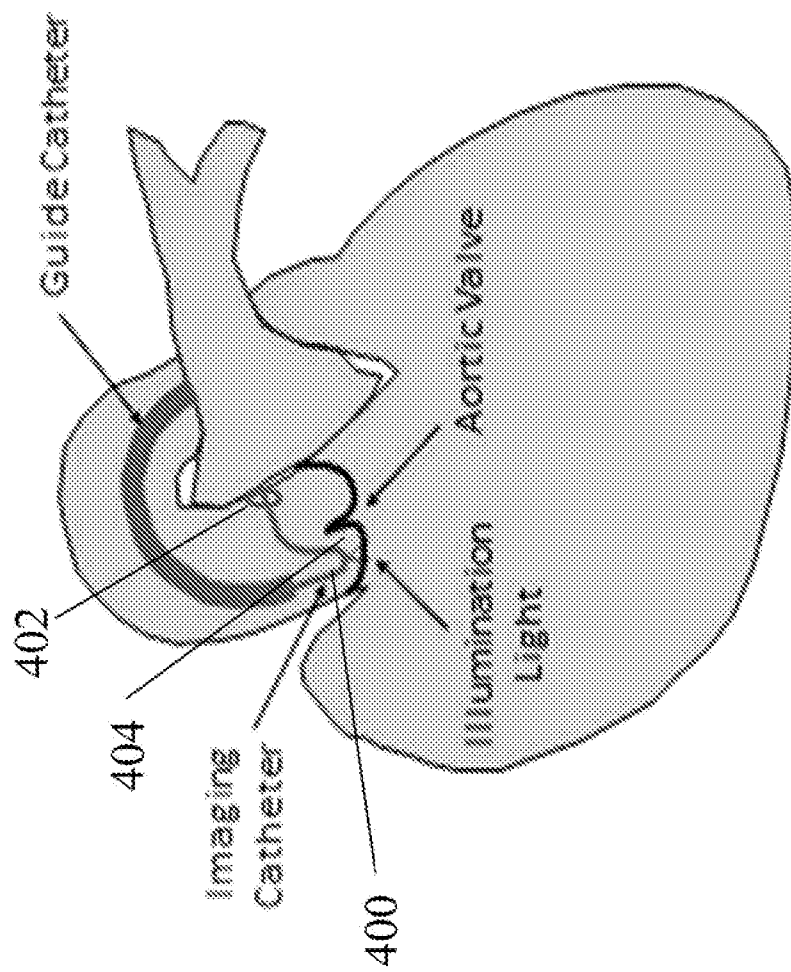


Figure 4

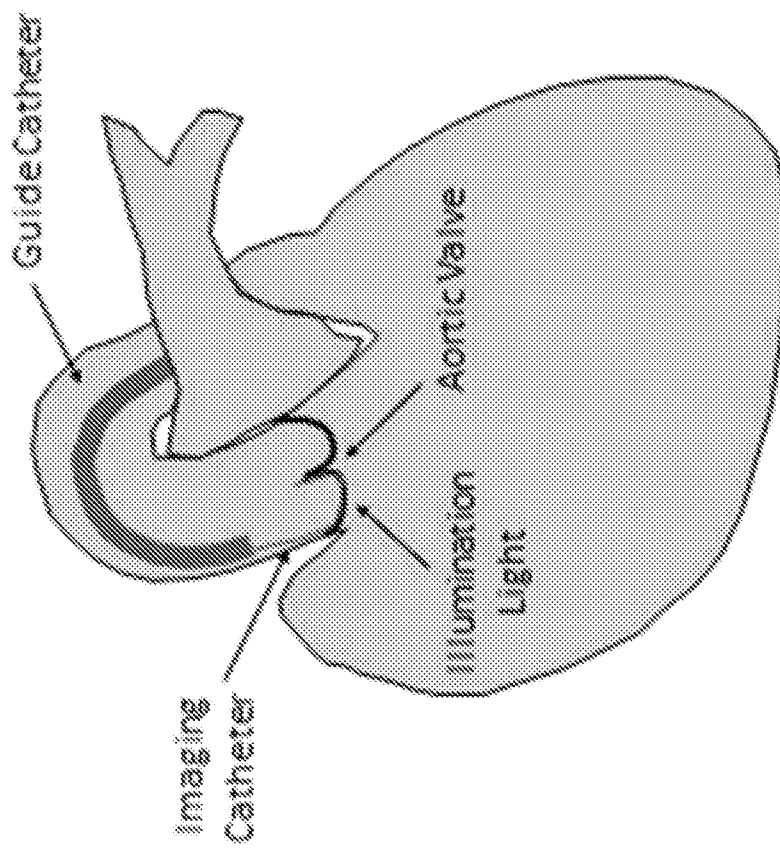


Figure 5

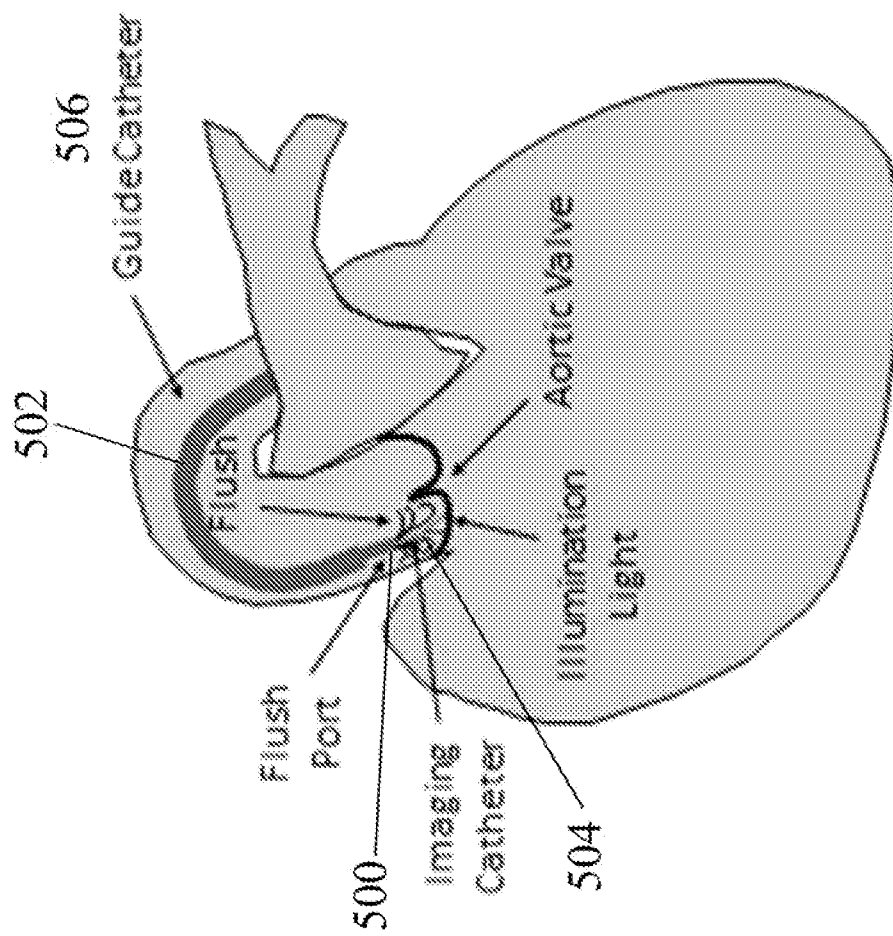


Figure 6

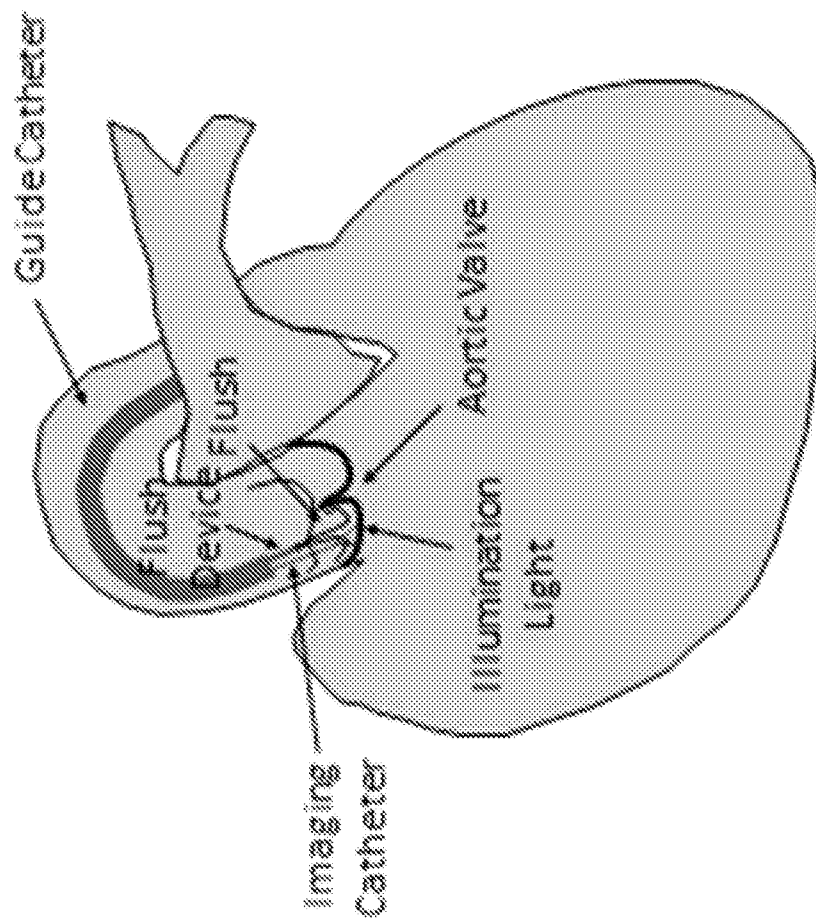


Figure 7

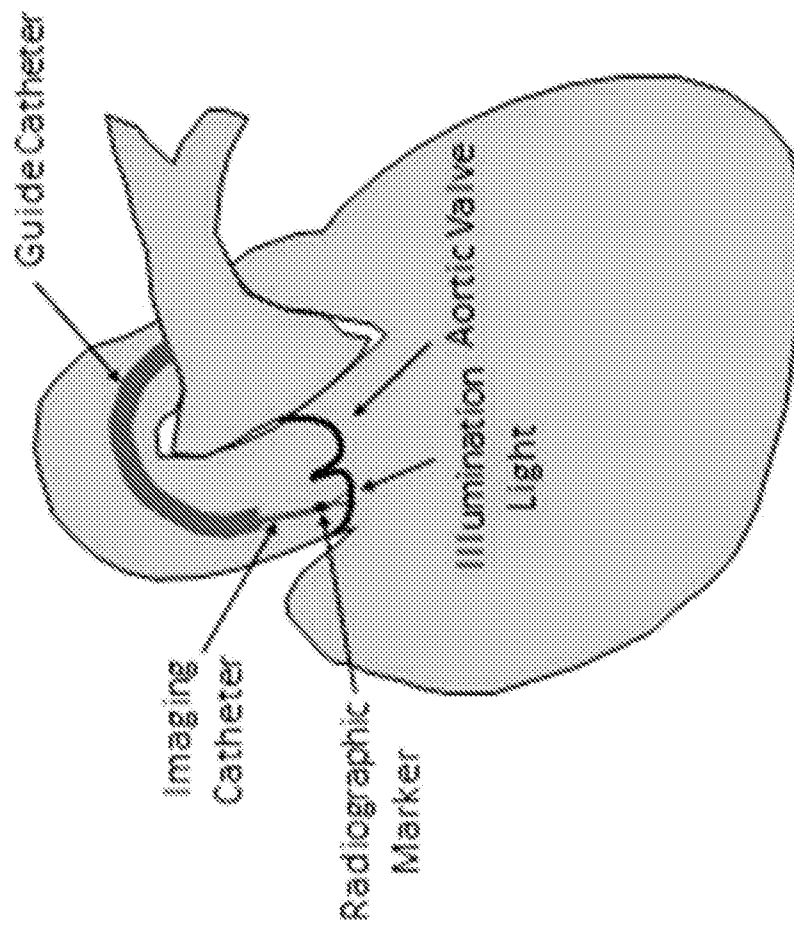


Figure 8

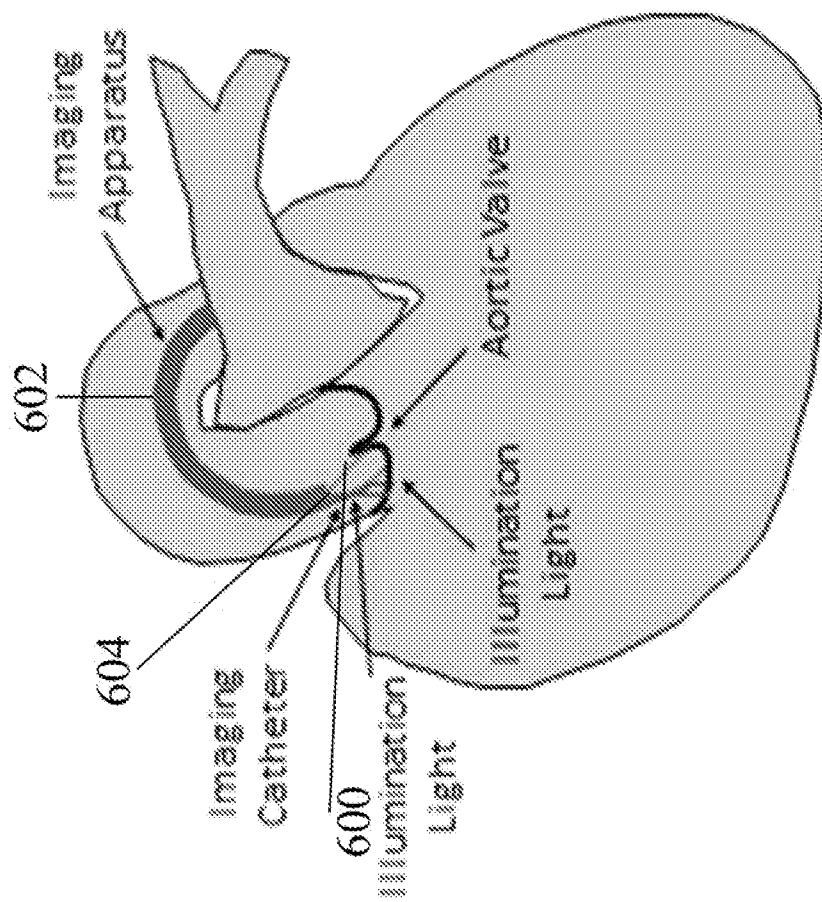


Figure 9

INTERNATIONAL SEARCH REPORT	International application No. PCT/US 2014/013628															
A. CLASSIFICATION OF SUBJECT MATTER <i>A61B 1/00 (2006.01)</i> <i>A61B 6/00 (2006.01)</i> <i>A61B 1/07 (2006.01)</i> According to International Patent Classification (IPC) or to both national classification and IPC																
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B 1/00-1/07, A61F 2/24, G01B 5/02, G01N 21/01, 29/06, A61B 6/00 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 practicable, search terms used) USPTO, DEPATISnet, Espacenet, Information Retrieval System of FIPS, EAPATIS, K-PION, SIPO, PubMed, SCOPUS																
C. DOCUMENTS CONSIDERED TO BE RELEVANT																
Category*	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 60%;">Citation of document, with indication, where appropriate, of the relevant passages</th> <th style="width: 25%;">Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Y</td> <td>US 2007/0073271 A1 (GREGORY G. BRUCKER et al.) 29.03.2007, paragraphs [0006] - [0011], [0026], fig. 1A-1D, abstract</td> <td style="text-align: center;">1-17</td> </tr> <tr> <td style="text-align: center;">Y</td> <td>US 2005/0216078 A1 (GUIDED DELIVERY SYSTEMS, INC.) 29.09.2005, fig. 1, paragraphs [0019], [0024], [0029], [0032], [0055] - [0066], [0093]</td> <td style="text-align: center;">1-17</td> </tr> <tr> <td style="text-align: center;">Y</td> <td>US 2003/0233142 A1 (GUIDED DELIVERY SYSTEMS, INC.) 18.12.2003, paragraphs [0020], [0030], [0043]</td> <td style="text-align: center;">4-5</td> </tr> <tr> <td style="text-align: center;">Y</td> <td>US 2007/0229801 A1 (THE GENERAL HOSPITAL CORPORATION) 04.10.2007, p. 6-8, paragraphs [0038], [0058]</td> <td style="text-align: center;">7, 14</td> </tr> </tbody> </table>		Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	Y	US 2007/0073271 A1 (GREGORY G. BRUCKER et al.) 29.03.2007, paragraphs [0006] - [0011], [0026], fig. 1A-1D, abstract	1-17	Y	US 2005/0216078 A1 (GUIDED DELIVERY SYSTEMS, INC.) 29.09.2005, fig. 1, paragraphs [0019], [0024], [0029], [0032], [0055] - [0066], [0093]	1-17	Y	US 2003/0233142 A1 (GUIDED DELIVERY SYSTEMS, INC.) 18.12.2003, paragraphs [0020], [0030], [0043]	4-5	Y	US 2007/0229801 A1 (THE GENERAL HOSPITAL CORPORATION) 04.10.2007, p. 6-8, paragraphs [0038], [0058]	7, 14
	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.														
Y	US 2007/0073271 A1 (GREGORY G. BRUCKER et al.) 29.03.2007, paragraphs [0006] - [0011], [0026], fig. 1A-1D, abstract	1-17														
Y	US 2005/0216078 A1 (GUIDED DELIVERY SYSTEMS, INC.) 29.09.2005, fig. 1, paragraphs [0019], [0024], [0029], [0032], [0055] - [0066], [0093]	1-17														
Y	US 2003/0233142 A1 (GUIDED DELIVERY SYSTEMS, INC.) 18.12.2003, paragraphs [0020], [0030], [0043]	4-5														
Y	US 2007/0229801 A1 (THE GENERAL HOSPITAL CORPORATION) 04.10.2007, p. 6-8, paragraphs [0038], [0058]	7, 14														
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.																
<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> * 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 </td> <td style="width: 50%; vertical-align: top;"> "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 </td> </tr> </table>		* 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													
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Date of the actual completion of the international search 15 April 2014 (15.04.2014)	Date of mailing of the international search report 07 May 2014 (07.05.2014)															
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