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(54) **MANIFOLD INTEGRATED HANDLE ASSEMBLY FOR INTRAVASCULAR LITHOTRIPSY DEVICE**

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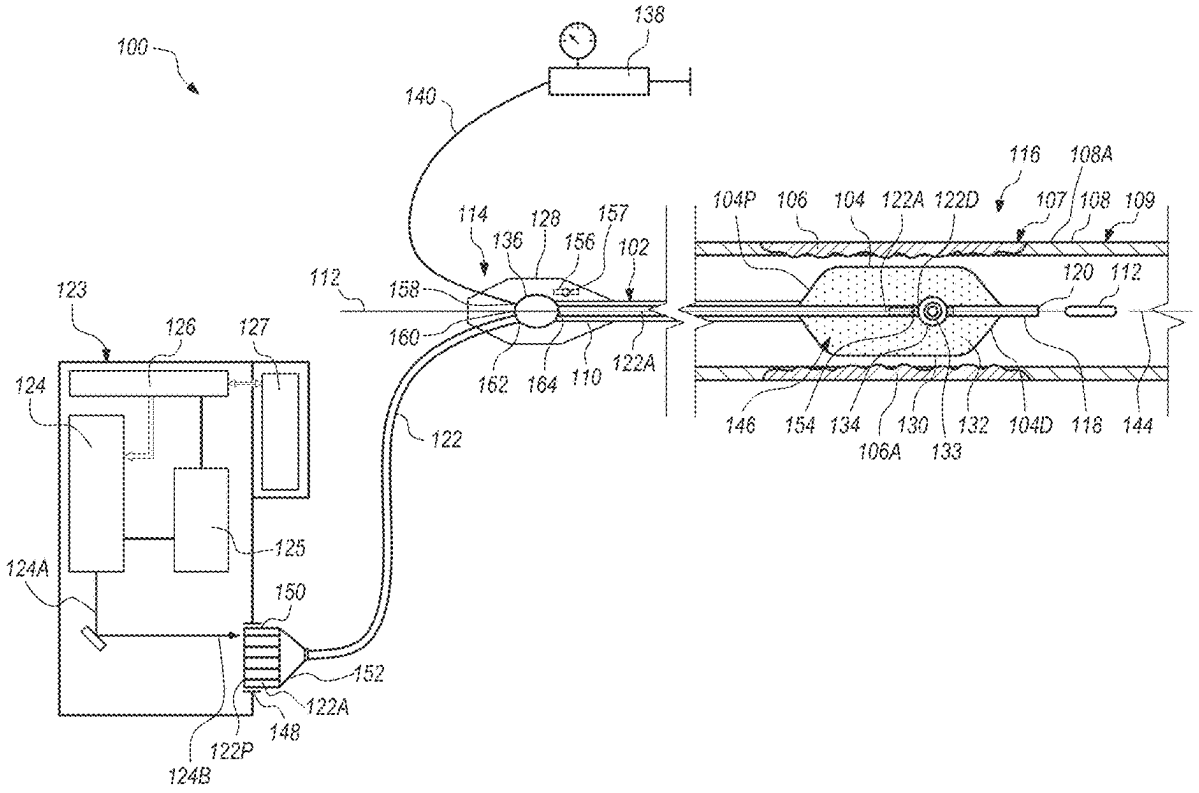
(57) **ABSTRACT**

A catheter system (**100**) for treating a vascular lesion (**106**A) within or adjacent to a vessel wall (**108**A) of a blood vessel (**108**) within a body (**107**) of a patient (**109**) includes a catheter shaft (**210**); a handle assembly (**228**); and a source manifold (**236**). The handle assembly (**228**) is coupled to the catheter shaft (**210**). The handle assembly (**228**) includes an assembly housing (**266**). The handle assembly (**228**) is usable by a user to selectively position the catheter shaft (**210**) near the vascular lesion (**106**A). The source manifold (**236**) is coupled to the assembly housing (**266**). The source manifold (**236**) includes a manifold housing (**282**) having a catheter shaft port (**264**) that is configured to receive a portion of the catheter shaft (**210**) so that the catheter shaft (**210**) is coupled to the manifold housing (**282**).



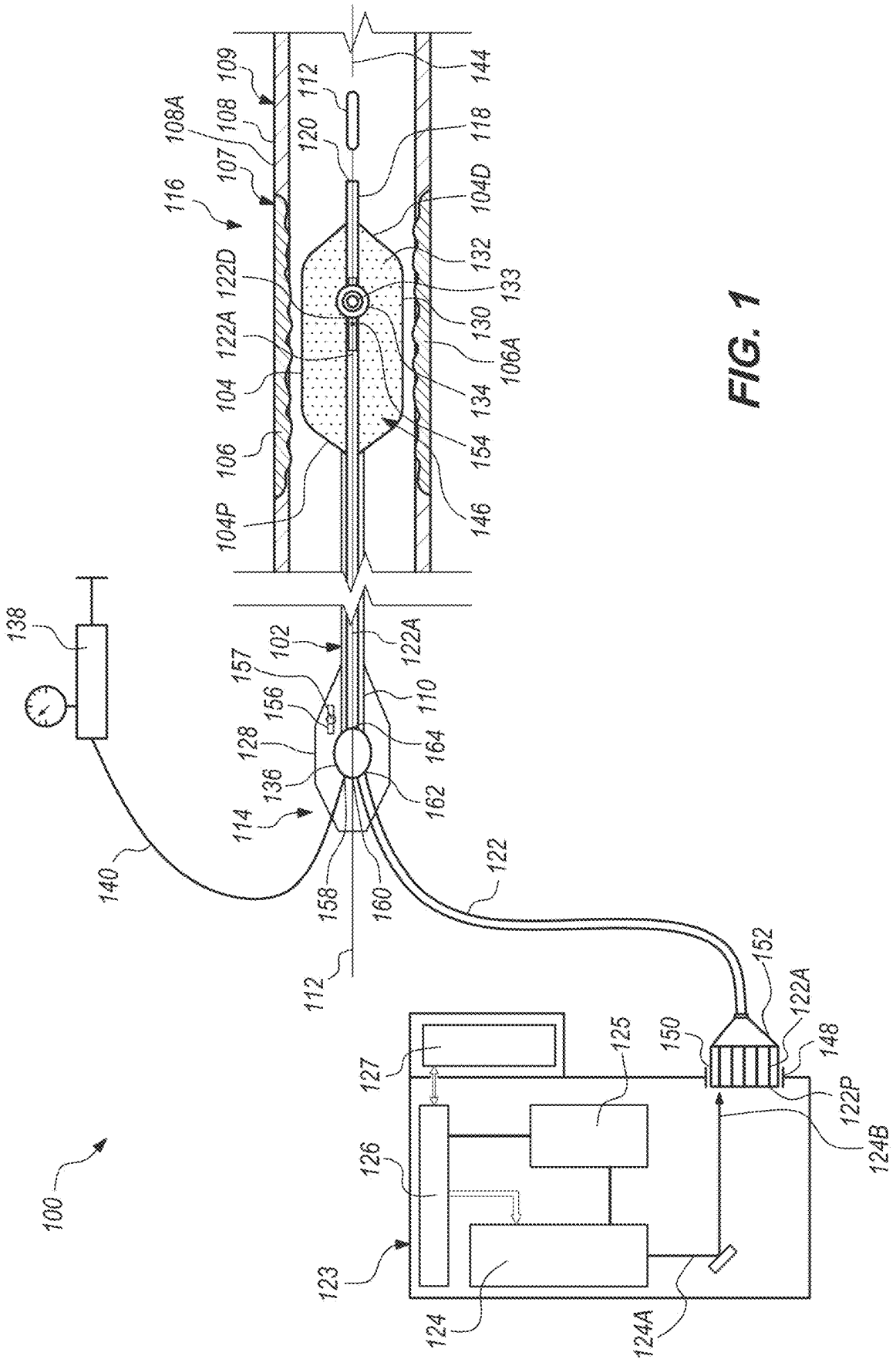

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FIG. 1

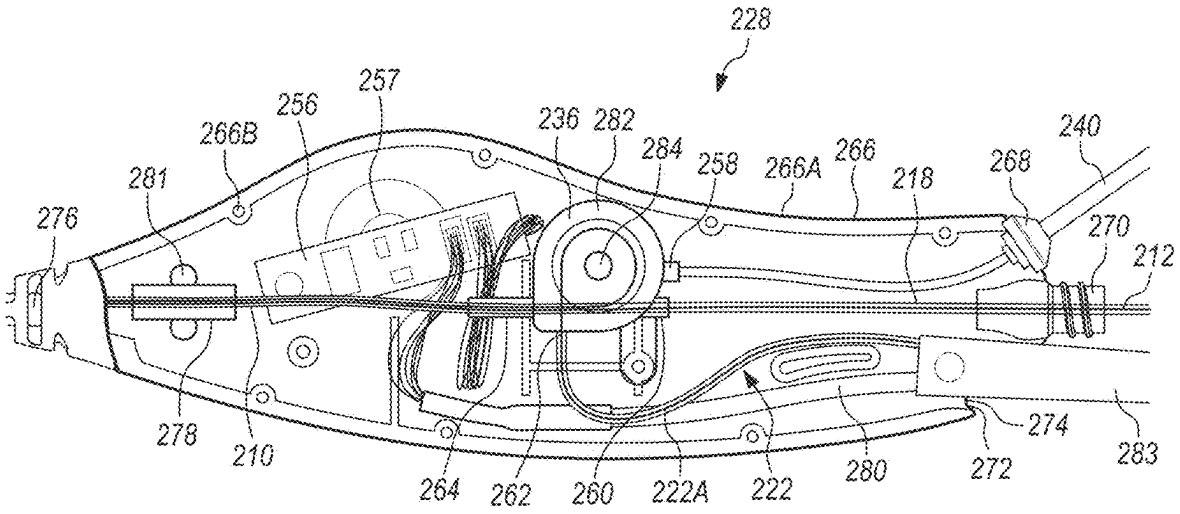
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FIG. 2

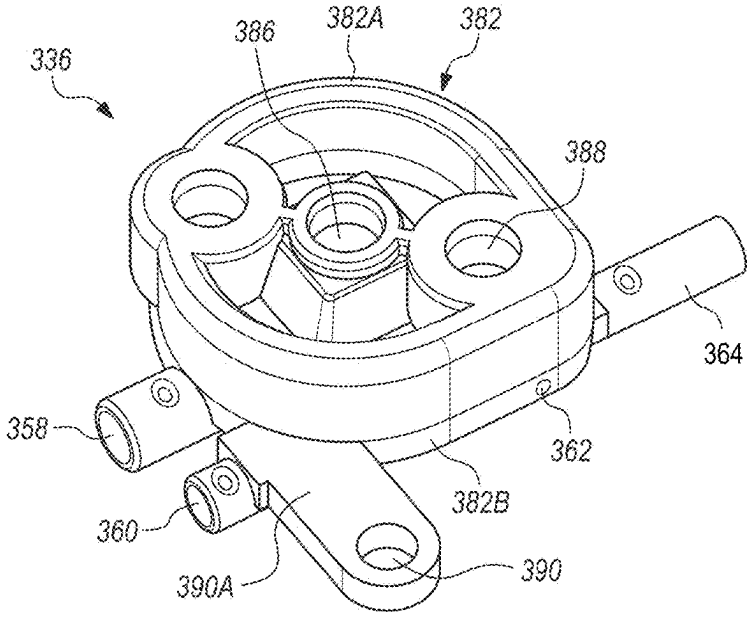
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FIG. 3

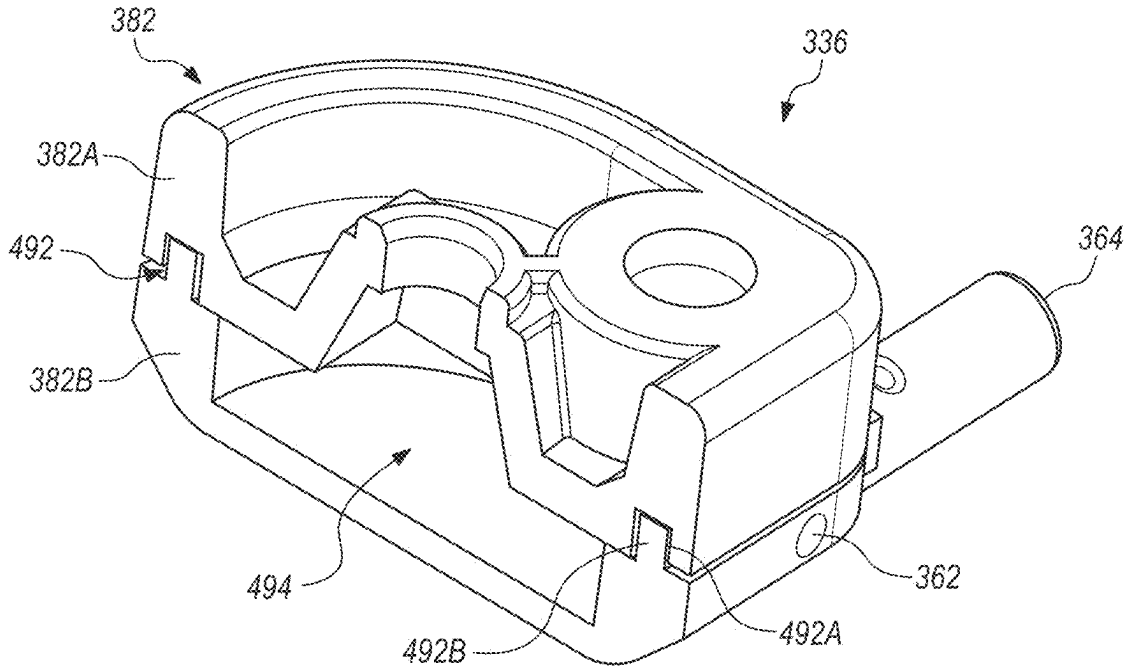

FIG. 4

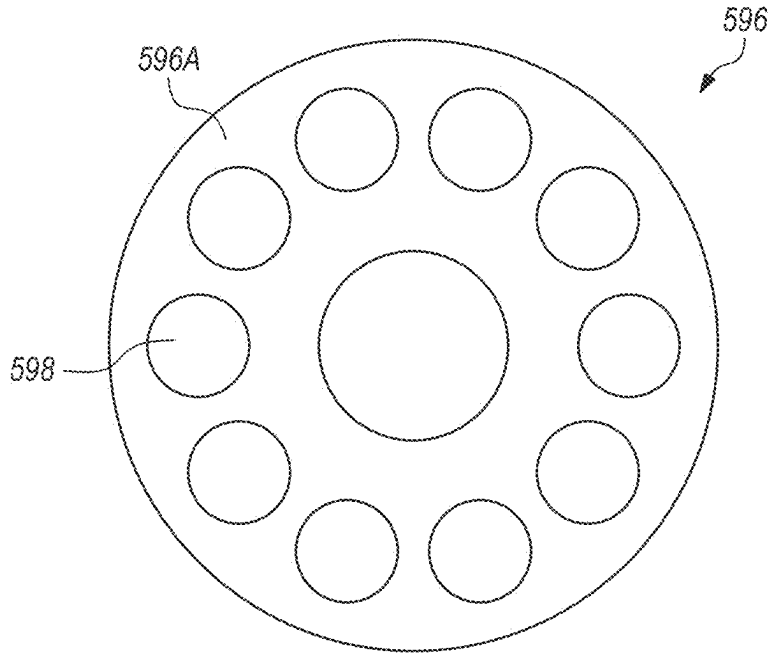

FIG. 5

MANIFOLD INTEGRATED HANDLE ASSEMBLY FOR INTRAVASCULAR LITHOTRIPSY DEVICE

RELATED APPLICATIONS

[0001] This application is a continuation application of and claims priority on U.S. patent application Ser. No. 18/106,801, filed on Feb. 7, 2023, and entitled "MANIFOLD INTEGRATED HANDLE ASSEMBLY FOR INTRAVASCULAR LITHOTRIPSY DEVICE." Additionally, U.S. patent application Ser. No. 18/106,801 claims priority on U.S. Provisional Patent Application Ser. No. 63/309,867 filed on Feb. 14, 2022, and entitled "MANIFOLD INTEGRATED HANDLE ASSEMBLY FOR INTRAVASCULAR LITHOTRIPSY DEVICE." To the extent permissible, the contents of U.S. patent application Ser. No. 18/106,801 and U.S. Provisional Application Ser. No. 63/309,867 are incorporated in their entirety herein by reference.

BACKGROUND

[0002] Vascular lesions within vessels in the body can be associated with an increased risk for major adverse events, such as myocardial infarction, embolism, deep vein thrombosis, stroke, and the like. Severe vascular lesions, such as severely calcified vascular lesions, can be difficult to treat and achieve patency for a physician in a clinical setting.

[0003] Vascular lesions may be treated using interventions such as drug therapy, balloon angioplasty, atherectomy, stent placement, vascular graft bypass, to name a few. Such interventions may not always be ideal or may require subsequent treatment to address the lesion.

[0004] Intravascular lithotripsy is one method that has been recently used with some success for breaking up vascular lesions within vessels in the body. Intravascular lithotripsy utilizes a combination of pressure waves and bubble dynamics that are generated intravascularly in a fluid-filled balloon catheter. In particular, during an intravascular lithotripsy treatment, a high energy source is used to generate plasma and ultimately pressure waves as well as a rapid bubble expansion within a fluid-filled balloon to crack calcification at a treatment site within the vasculature that includes one or more vascular lesions. The associated rapid bubble formation from the plasma initiation and resulting localized fluid velocity within the balloon transfers mechanical energy through the incompressible fluid to impart a fracture force on the intravascular calcium, which is opposed to the balloon wall. The rapid change in fluid momentum upon hitting the balloon wall is known as hydraulic shock, or water hammer.

[0005] There is an ongoing desire to enhance vessel patency and optimization of therapy delivery parameters within an intravascular lithotripsy catheter system in a manner that is relatively easy to control and is consistently manufacturable.

SUMMARY

[0006] The present invention is directed toward a catheter system for placement within a blood vessel having a vessel wall. The catheter system can be used by a user for treating a vascular lesion within or adjacent to the vessel wall within a body of a patient. In various embodiments, the catheter system includes a catheter shaft; a handle assembly; and a source manifold. The handle assembly is coupled to the catheter shaft. The handle assembly includes an assembly housing. The handle assembly is usable by the user to selectively position the catheter shaft near the vascular lesion. The source manifold is coupled to the assembly housing. The source manifold includes a manifold housing having a catheter shaft port that is configured to receive a portion of the catheter shaft so that the catheter shaft is coupled to the manifold housing.

[0007] In some embodiments, the source manifold is positioned substantially within the assembly housing.

[0008] In certain embodiments, the catheter system further includes a pressure sensor that is coupled to the manifold housing, the pressure sensor being configured to sense a fluid pressure of a catheter fluid within the catheter system.

[0009] In some embodiments, the handle assembly further includes circuitry that is electrically coupled to the pressure sensor.

[0010] In one embodiment, the circuitry includes a printed circuit board.

[0011] In certain embodiments, the handle assembly further includes an energy activator that is coupled to the circuitry; and the energy activator is configured to enable the user to selectively activate the catheter system.

[0012] In some embodiments, the manifold housing includes a sensor bore; and the pressure sensor is positioned within the sensor bore.

[0013] In many embodiments, the manifold housing includes a first housing member and a second housing member that are selectively attached to one another via an attachment assembly.

[0014] In some embodiments, the attachment assembly includes a first attachment member that is coupled to the first housing member and a second attachment member that is coupled to the second housing member; and the first attachment member is configured to engage the second attachment member when the first housing member is attached to the second housing member.

[0015] In one embodiment, the first attachment member includes an attachment channel; and wherein the second attachment member includes an attachment projection.

[0016] In certain embodiments, the first attachment member and the second attachment member are attached to one another with an adhesive material.

[0017] In other embodiments, the first attachment member and the second attachment member are ultrasonically sealed to one another.

[0018] In some embodiments, the catheter system further includes a balloon that is coupled to the catheter shaft, the balloon including a balloon wall that defines a balloon interior, the balloon being configured to retain a catheter fluid within the balloon interior.

[0019] In certain embodiments, the balloon is selectively inflatable with the catheter fluid to expand to an inflated state, wherein when the balloon is in the inflated state the balloon wall is configured to be positioned substantially adjacent to the vascular lesion.

[0020] In some embodiments, the catheter system further includes a pressure sensor that is coupled to the manifold housing, the pressure sensor being configured to sense a fluid pressure of the catheter fluid within the balloon interior.

[0021] In many embodiments, the catheter system further includes an energy guide that is coupled to the source

manifold, the energy guide including a guide distal end that is configured to be positioned within the balloon interior.

[0022] In some embodiments, the energy guide is configured to guide energy from an energy source through the energy guide and into the balloon interior.

[0023] In certain embodiments, the energy guide guiding the energy from the energy source into the balloon interior generates a plasma bubble in the catheter fluid within the balloon interior.

[0024] In some embodiments, energy from the plasma bubble is directed toward a portion of the balloon wall that is positioned substantially adjacent to the vascular lesion.

[0025] In various embodiments, the energy guide generates one or more pressure waves in the catheter fluid that impart a force upon the vascular lesion.

[0026] In certain embodiments, the energy guide includes an optical fiber.

[0027] In some embodiments, the energy source includes a laser.

[0028] In other embodiments, the energy source is a high voltage energy source that provides pulses of high voltage.

[0029] In one embodiment, the energy guide includes an electrode pair including spaced apart electrodes that extend into the balloon interior; and pulses of high voltage from the energy source are applied to the electrodes and form an electrical arc across the electrodes.

[0030] In certain embodiments, the manifold housing includes an energy guide port; and the energy guide is coupled to the manifold housing via the energy guide port.

[0031] In some embodiments, the catheter system further includes a plurality of energy guides that are coupled to the source manifold, each of the plurality of energy guides including a guide distal end that is configured to be positioned within the balloon interior.

[0032] In many embodiments, the plurality of energy guides are coupled into the energy guide port with an optical sealing component, the optical sealing component including a seal body and a plurality of guide channels that are formed through the seal body; and each of the plurality of energy guides is configured to extend through one of the plurality of guide channels.

[0033] In certain embodiments, the manifold housing further includes a guidewire lumen port; and a guidewire lumen is coupled to the manifold housing via the guidewire lumen port.

[0034] In some embodiments, the manifold housing further includes a media inflation port; and an inflation conduit is coupled to the manifold housing via the media inflation port.

[0035] In certain embodiments, the inflation conduit is configured to guide the catheter fluid into the balloon interior.

[0036] In one embodiment, the manifold housing includes a first housing member and a second housing member that are selectively attached to one another; and each of the catheter shaft port, the energy guide port, the guidewire lumen port and the media inflation port are formed into the second housing member.

[0037] The present invention is further directed toward a method for treating a vascular lesion within or adjacent to a blood vessel within a body of a patient, including the steps of coupling a handle assembly to a catheter shaft, the handle assembly including an assembly housing; selectively positioning the catheter shaft near the vascular lesion through use of the handle assembly; and coupling a source manifold to the assembly housing, the source manifold including a manifold housing having a catheter shaft port that is configured to receive a portion of the catheter shaft so that the catheter shaft is coupled to the manifold housing.

[0038] This summary is an overview of some of the teachings of the present application and is not intended to be an exclusive or exhaustive treatment of the present subject matter. Further details are found in the detailed description and appended claims. Other aspects will be apparent to persons skilled in the art upon reading and understanding the following detailed description and viewing the drawings that form a part thereof, each of which is not to be taken in a limiting sense. The scope herein is defined by the appended claims and their legal equivalents.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

[0040] FIG. **1** is a simplified schematic cross-sectional view illustration of an embodiment of a catheter system in accordance with various embodiments, the catheter system including a handle assembly having features of the present invention, including a source manifold that is integrated into the handle assembly;

[0041] FIG. **2** is a simplified cutaway view illustration of an embodiment of the handle assembly of FIG. **1**;

[0042] FIG. **3** is a simplified perspective view illustration of an embodiment of the source manifold of FIG. **1**;

[0043] FIG. **4** is a simplified cutaway perspective view of a portion of the source manifold illustrated in FIG. **3**; and

[0044] FIG. **5** is a simplified schematic view illustration of a multi-lumen optical sealing component that couples a plurality of energy guides into the source manifold of FIG. **3**.

[0045] While embodiments of the present invention are susceptible to various modifications and alternative forms, specifics thereof have been shown by way of example and drawings, and are described in detail herein. It is understood, however, that the scope herein is not limited to the particular embodiments described. On the contrary, the intention is to cover modifications, equivalents, and alternatives falling within the spirit and scope herein.

DESCRIPTION

[0046] Treatment of vascular lesions can reduce major adverse events or death in affected subjects. As referred to herein, a major adverse event is one that can occur anywhere within the body due to the presence of a vascular lesion. Major adverse events can include, but are not limited to, major adverse cardiac events, major adverse events in the peripheral or central vasculature, major adverse events in the brain, major adverse events in the musculature, or major adverse events in any of the internal organs.

[0047] In various embodiments, the catheter systems and related methods disclosed herein can include a catheter configured to advance to a vascular lesion, such as a calcified vascular lesion or a fibrous vascular lesion, at a treatment site located within or adjacent a blood vessel

within a body of a patient. The catheter includes a catheter shaft, and an inflatable balloon that is coupled and/or secured to the catheter shaft. The balloon can include a balloon wall that defines a balloon interior. The balloon can be configured to receive a catheter fluid within the balloon interior to expand from a deflated state suitable for advancing the catheter through a patient's vasculature, to an inflated state suitable for anchoring the catheter in position relative to the treatment site.

[0048] As used herein, the terms "treatment site", "intravascular lesion" and "vascular lesion" are used interchangeably unless otherwise noted. As such, the intravascular lesions and/or the vascular lesions are sometimes referred to herein simply as "lesions."

[0049] Those of ordinary skill in the art will realize that the following detailed description of the present invention is illustrative only and is not intended to be in any way limiting. Other embodiments of the present invention will readily suggest themselves to such skilled persons having the benefit of this disclosure. Reference will now be made in detail to implementations of the present invention as illustrated in the accompanying drawings. The same or similar nomenclature and/or reference indicators will be used throughout the drawings and the following detailed description to refer to the same or like parts.

[0050] In the interest of clarity, not all of the routine features of the implementations described herein are shown and described. It is appreciated that in the development of any such actual implementation, numerous implementation-specific decisions must be made in order to achieve the developer's specific goals, such as compliance with application-related and business-related constraints, and that these specific goals will vary from one implementation to another and from one developer to another. Moreover, it is recognized that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking of engineering for those of ordinary skill in the art having the benefit of this disclosure.

[0051] The catheter systems disclosed herein can include many different forms. Referring now to FIG. **1**, a simplified schematic cross-sectional view illustration is shown of a catheter system **100** in accordance with various embodiments. The catheter system **100** is suitable for imparting pressure waves to induce fractures in one or more vascular lesions within or adjacent a vessel wall of a blood vessel or on or adjacent to a heart valve within a body of a patient. In the embodiment illustrated in FIG. **1**, the catheter system **100** can include one or more of a catheter **102**, an energy guide bundle **122** including one or more energy guides **122**A, a fluid pump **138**, a system console **123** including one or more of an energy source **124**, a power source **125**, a system controller **126**, a graphic user interface **127** (a "GUI"), and a handle assembly **128** that includes a source manifold **136** integrated therein. Alternatively, the catheter system **100** can include more components or fewer components than those specifically illustrated and described in relation to FIG. **1**.

[0052] The catheter **102** is configured to move to the treatment site **106** within or adjacent to a vessel wall **108**A of a blood vessel **108** within a body **107** of a patient **109**. The treatment site **106** can include one or more vascular lesions **106**A such as calcified vascular lesions, for example. Additionally, or in the alternative, the treatment site **106** can include vascular lesions **106**A such as fibrous vascular lesions. Still alternatively, in some implementations, the catheter **102** can be used at a treatment site **106** within or adjacent to a heart valve within the body **107** of the patient **109**.

[0053] The catheter **102** can include an inflatable balloon **104** (sometimes referred to herein simply as a "balloon"), a catheter shaft **110**, and a guidewire **112**. The balloon **104** can be coupled to the catheter shaft **110**. The balloon **104** can include a balloon proximal end **104**P and a balloon distal end **104**D. The catheter shaft **110** can extend from a proximal portion **114** of the catheter system **100** to a distal portion **116** of the catheter system **100**. The catheter shaft **110** can include a longitudinal axis **144**. The catheter **102** and/or the catheter shaft **110** can also include a guidewire lumen **118** which is configured to move over the guidewire **112**. As utilized herein, the guidewire lumen **118** defines a conduit through which the guidewire **112** extends. The catheter shaft **110** can further include an inflation lumen (not shown) and/or various other lumens for various other purposes. In some embodiments, the catheter **102** can have a distal end opening **120** and can accommodate and be tracked over the guidewire **112** as the catheter **102** is moved and positioned at or near the treatment site **106**. In some embodiments, the balloon proximal end **104**P can be coupled to the catheter shaft **110**, and the balloon distal end **104**D can be coupled to the guidewire lumen **118**.

[0054] The balloon **104** includes a balloon wall **130** that defines a balloon interior **146**. The balloon **104** can be selectively inflated with a catheter fluid **132** to expand from a deflated state suitable for advancing the catheter **102** through a patient's vasculature, to an inflated state (as shown in FIG. **1**) suitable for anchoring the catheter **102** in position relative to the treatment site **106**. Stated in another manner, when the balloon **104** is in the inflated state, the balloon wall **130** of the balloon **104** is configured to be positioned substantially adjacent to the treatment site **106**. It is appreciated that although FIG. **1** illustrates the balloon wall **130** of the balloon **104** being shown spaced apart from the treatment site **106** of the blood vessel **108** when in the inflated state, this is done for ease of illustration. It is recognized that the balloon wall **130** of the balloon **104** will typically be substantially directly adjacent to and/or abutting the treatment site **106** when the balloon **104** is in the inflated state.

[0055] The balloon **104** suitable for use in the catheter system **100** includes those that can be passed through the vasculature of a patient **109** when in the deflated state. In some embodiments, the balloons **104** are made from silicone. In other embodiments, the balloon **104** can be made from materials such as polydimethylsiloxane (PDMS), polyurethane, polymers such as PEBAX™ material, nylon, or any other suitable material.

[0056] The balloon **104** can have any suitable diameter (in the inflated state). In various embodiments, the balloon **104** can have a diameter (in the inflated state) ranging from less than one millimeter (mm) up to 25 mm. In some embodiments, the balloon **104** can have a diameter (in the inflated state) ranging from at least 1.5 mm up to 14 mm. In some embodiments, the balloon **104** can have a diameter (in the inflated state) ranging from at least two mm up to five mm.

[0057] In some embodiments, the balloon **104** can have a length ranging from at least three mm to 300 mm. More particularly, in some embodiments, the balloon **104** can have a length ranging from at least eight mm to 200 mm. It is

appreciated that a balloon **104** having a relatively longer length can be positioned adjacent to larger treatment sites **106**, and, thus, may be usable for imparting pressure waves onto and inducing fractures in larger vascular lesions **106**A or multiple vascular lesions **106**A at precise locations within the treatment site **106**. It is further appreciated that a longer balloon **104** can also be positioned adjacent to multiple treatment sites **106** at any one given time.

[0058] The balloon **104** can be inflated to inflation pressures of between approximately one atmosphere (atm) and 70 atm. In some embodiments, the balloon **104** can be inflated to inflation pressures of from at least 20 atm to 60 atm. In other embodiments, the balloon **104** can be inflated to inflation pressures of from at least six atm to 20 atm. In still other embodiments, the balloon **104** can be inflated to inflation pressures of from at least three atm to 20 atm. In yet other embodiments, the balloon **104** can be inflated to inflation pressures of from at least two atm to ten atm.

[0059] The balloon **104** can have various shapes, including, but not to be limited to, a conical shape, a square shape, a rectangular shape, a spherical shape, a conical/square shape, a conical/spherical shape, an extended spherical shape, an oval shape, a tapered shape, a bone shape, a stepped diameter shape, an offset shape, or a conical offset shape. In some embodiments, the balloon **104** can include a drug eluting coating or a drug eluting stent structure. The drug eluting coating or drug eluting stent can include one or more therapeutic agents including anti-inflammatory agents, anti-neoplastic agents, anti-angiogenic agents, and the like.

[0060] The catheter fluid **132** can be a liquid or a gas. Some examples of the catheter fluid **132** suitable for use can include, but are not limited to one or more of water, saline, contrast medium, fluorocarbons, perfluorocarbons, gases, such as carbon dioxide, or any other suitable catheter fluid **132**. In some embodiments, the catheter fluid **132** can be used as a base inflation fluid. In some embodiments, the catheter fluid **132** can include a mixture of saline to contrast medium in a volume ratio of approximately 50:50. In other embodiments, the catheter fluid **132** can include a mixture of saline to contrast medium in a volume ratio of approximately 25:75. In still other embodiments, the catheter fluid **132** can include a mixture of saline to contrast medium in a volume ratio of approximately 75:25. However, it is understood that any suitable ratio of saline to contrast medium can be used. The catheter fluid **132** can be tailored on the basis of composition, viscosity, and the like so that the rate of travel of the pressure waves are appropriately manipulated. In certain embodiments, the catheter fluids **132** suitable for use are biocompatible. A volume of catheter fluid **132** can be tailored by the chosen energy source **124** and the type of catheter fluid **132** used.

[0061] In some embodiments, the contrast agents used in the contrast media can include, but are not to be limited to, iodine-based contrast agents, such as ionic or non-ionic iodine-based contrast agents. Some non-limiting examples of ionic iodine-based contrast agents include diatrizoate, metrizoate, iothalamate, and ioxaglate. Some non-limiting examples of non-ionic iodine-based contrast agents include iopamidol, iohexol, ioxilan, iopromide, iodixanol, and ioversol. In other embodiments, non-iodine-based contrast agents can be used. Suitable non-iodine containing contrast agents can include gadolinium (III)-based contrast agents. Suitable fluorocarbon and perfluorocarbon agents can include, but are not to be limited to, agents such as the perfluorocarbon dodecafluoropentane (DDFP, C5F12).

[0062] The catheter fluids **132** can include those that include absorptive agents that can selectively absorb light in the ultraviolet region (e.g., at least ten nanometers (nm) to 400 nm), the visible region (e.g., at least 400 nm to 780 nm), or the near-infrared region (e.g., at least 780 nm to 2.5 um) of the electromagnetic spectrum. Suitable absorptive agents can include those with absorption maxima along the spectrum from at least ten nm to 2.5 um. Alternatively, the catheter fluids **132** can include those that include absorptive agents that can selectively absorb light in the mid-infrared region (e.g., at least 2.5 um to 15 μm), or the far-infrared region (e.g., at least 15 μm to one mm) of the electromagnetic spectrum. In various embodiments, the absorptive agent can be those that have an absorption maximum matched with the emission maximum of the laser used in the catheter system **100**. By way of non-limiting examples, various lasers usable in the catheter system **100** can include neodymium: yttrium-aluminum-garnet (Nd:YAG-emission maximum=1064 nm) lasers, holmium: YAG (Ho:YAG-emission maximum =2.1 μm) lasers, or erbium: YAG (Er:YAG-emission maximum =2.94 μm) lasers. In some embodiments, the absorptive agents can be water-soluble. In other embodiments, the absorptive agents are not water-soluble. In some embodiments, the absorptive agents used in the catheter fluids **132** can be tailored to match the peak emission of the energy source **124**. Various energy sources **124** having emission wavelengths of at least ten nanometers to one millimeter are discussed elsewhere herein.

[0063] The catheter shaft **110** of the catheter **102** can be coupled to the one or more energy guides **122**A of the energy guide bundle **122** that are in optical communication with the energy source **124**. The energy guide(s) **122**A can be disposed along the catheter shaft **110** and within the balloon **104**. In some embodiments, each energy guide **122**A can be an optical fiber and the energy source **124** can be a laser. The energy source **124** can be in optical communication with the energy guides **122**A at the proximal portion **114** of the catheter system **100**.

[0064] In some embodiments, the catheter shaft **110** can be coupled to multiple energy guides **122**A such as a first energy guide, a second energy guide, a third energy guide, etc., which can be disposed at any suitable positions about and/or relative to the guidewire lumen **118** and/or the catheter shaft **110**. For example, in certain non-exclusive embodiments, two energy guides **122**A can be spaced apart by approximately 180 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**; three energy guides **122**A can be spaced apart by approximately 120 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**; four energy guides **122**A can be spaced apart by approximately 90 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**; six energy guides **122**A can be spaced apart by approximately 60 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**; eight energy guides **122**A can be spaced apart by approximately 45 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**; or ten energy guides **122**A can be spaced apart by approximately 36 degrees about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**. Still alternatively, multiple energy guides **122**A need not be uniformly spaced apart from one another

about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**. More particularly, it is further appreciated that the energy guides **122**A can be disposed uniformly or non-uniformly about the guidewire lumen **118** and/or the catheter shaft **110** to achieve the desired effect in the desired locations.

[0065] The catheter system **100** and/or the energy guide bundle **122** can include any number of energy guides **122**A in optical communication with the energy source **124** at the proximal portion **114**, and with the catheter fluid **132** within the balloon interior **146** of the balloon **104** at the distal portion **116**. For example, in some embodiments, the catheter system **100** and/or the energy guide bundle **122** can include from one energy guide **122**A to greater than 30 energy guides **122**A. Alternatively, in other embodiments, the catheter system **100** and/or the energy guide bundle **122** can include greater than 30 energy guides **122**A.

[0066] The energy guides **122**A can have any suitable design for purposes of generating plasma and/or pressure waves in the catheter fluid **132** within the balloon interior **146**. Thus, the general description of the energy guides **122**A as light guides is not intended to be limiting in any manner, except for as set forth in the claims appended hereto. More particularly, although the catheter systems **100** are often described with the energy source **124** as a light source and the one or more energy guides **122**A as light guides, the catheter system **100** can alternatively include any suitable energy source **124** and energy guides **122**A for purposes of generating the desired plasma in the catheter fluid **132** within the balloon interior **146**. For example, in one non-exclusive alternative embodiment, the energy source **124** can be configured to provide high voltage pulses, and each energy guide **122**A can include an electrode pair including spaced apart electrodes that extend into the balloon interior **146**. In such embodiment, each pulse of high voltage is applied to the electrodes and forms an electrical arc across the electrodes, which, in turn, generates the plasma and forms the pressure waves in the catheter fluid **132** that are utilized to provide the fracture force onto the vascular lesions **106**A at the treatment site **106**. Still alternatively, the energy source **124** and/or the energy guides **122**A can have another suitable design and/or configuration.

[0067] In certain embodiments, the energy guides **122**A can include an optical fiber or flexible light pipe. The energy guides **122**A can be thin and flexible and can allow light signals to be sent with very little loss of strength. The energy guides **122**A can include a core surrounded by a cladding about its circumference. In some embodiments, the core can be a cylindrical core or a partially cylindrical core. The core and cladding of the energy guides **122**A can be formed from one or more materials, including but not limited to one or more types of glass, silica, or one or more polymers. The energy guides **122**A may also include a protective coating, such as a polymer. It is appreciated that the index of refraction of the core will be greater than the index of refraction of the cladding.

[0068] Each energy guide **122**A can guide energy along its length from a guide proximal end **122**P to the guide distal end **122**D having at least one optical window (not shown) that is positioned within the balloon interior **146**.

[0069] The energy guides **122**A can assume many configurations about and/or relative to the catheter shaft **110** of the catheter **102**. In some embodiments, the energy guides **122**A can run parallel to the longitudinal axis **144** of the catheter shaft **110**. In some embodiments, the energy guides **122**A can be physically coupled to the catheter shaft **110**. In other embodiments, the energy guides **122**A can be disposed along a length of an outer diameter of the catheter shaft **110**. In yet other embodiments, the energy guides **122**A can be disposed within one or more energy guide lumens within the catheter shaft **110**.

[0070] The energy guides **122**A can also be disposed at any suitable positions about the circumference of the guidewire lumen **118** and/or the catheter shaft **110**, and the guide distal end **122**D of each of the energy guides **122**A can be disposed at any suitable longitudinal position relative to the length of the balloon **104** and/or relative to the length of the guidewire lumen **118** to more effectively and precisely impart pressure waves for purposes of disrupting the vascular lesions **106**A at the treatment site **106**.

[0071] In certain embodiments, the energy guides **122**A can include one or more photoacoustic transducers **154**, where each photoacoustic transducer **154** can be in optical communication with the energy guide **122**A within which it is disposed. In some embodiments, the photoacoustic transducers **154** can be in optical communication with the guide distal end **122**D of the energy guide **122**A. In such embodiments, the photoacoustic transducers **154** can have a shape that corresponds with and/or conforms to the guide distal end **122**D of the energy guide **122**A.

[0072] The photoacoustic transducer **154** is configured to convert light energy into an acoustic wave at or near the guide distal end **122**D of the energy guide **122**A. The direction of the acoustic wave can be tailored by changing an angle of the guide distal end **122**D of the energy guide **122**A.

[0073] In certain embodiments, the photoacoustic transducers **154** disposed at the guide distal end **122**D of the energy guide **122**A can assume the same shape as the guide distal end **122**D of the energy guide **122**A. For example, in certain non-exclusive embodiments, the photoacoustic transducer **154** and/or the guide distal end **122**D can have a conical shape, a convex shape, a concave shape, a bulbous shape, a square shape, a stepped shape, a half-circle shape, an ovoid shape, and the like. The energy guide **122**A can further include additional photoacoustic transducers **154** disposed along one or more side surfaces of the length of the energy guide **122**A.

[0074] In some embodiments, the energy guides **122**A can further include one or more diverting features or "diverters" (not shown in FIG. **1**), such as within the energy guide **122**A and/or near the guide distal end **122**D of the energy guide **122**A, that are configured to direct energy from the energy guide **122**A toward a side surface which can be located at or near the guide distal end **122**D of the energy guide **122**A, before the energy is directed toward the balloon wall **130**. A diverting feature can include any feature of the system that diverts energy from the energy guide **122**A away from its axial path toward a side surface of the energy guide **122**A. The energy guides **122**A can each include one or more optical windows disposed along the longitudinal or circumferential surfaces of each energy guide **122**A and in optical communication with a diverting feature. Stated in another manner, the diverting features can be configured to direct energy in the energy guide **122**A toward a side surface that is at or near the guide distal end **122**D, where the side surface is in optical communication with an optical window. The optical windows can include a portion of the energy

guide **122**A that allows energy to exit the energy guide **122**A from within the energy guide **122**A, such as a portion of the energy guide **122**A lacking a cladding material on or about the energy guide **122**A.

[0075] Examples of the diverting features suitable for use include a reflecting element, a refracting element, and a fiber diffuser. The diverting features suitable for focusing energy away from the tip of the energy guides **122**A can include, but are not to be limited to, those having a convex surface, a gradient-index (GRIN) lens, and a mirror focus lens. Upon contact with the diverting feature, the energy is diverted within the energy guide **122**A to one or more of a plasma generator **133** and the photoacoustic transducer **154** that is in optical communication with a side surface of the energy guide **122**A. When utilized, the photoacoustic transducer **154** then converts light energy into an acoustic wave that extends away from the side surface of the energy guide **122**A.

[0076] As noted above, in the embodiment illustrated in FIG. **1**, the system console **123** includes one or more of the energy source **124**, the power source **125**, the system controller **126**, and the GUI **127**. Alternatively, the system console **123** can include more components or fewer components than those specifically illustrated in FIG. **1**. For example, in certain non-exclusive alternative embodiments, the system console **123** can be designed without the GUI **127**. Still alternatively, one or more of the energy source **124**, the power source **125**, the system controller **126**, and the GUI **127** can be provided at any suitable location within the catheter system **100** without the specific need for the system console **123**.

[0077] As shown, the system console **123**, and the components included therewith, is operatively coupled to the catheter **102**, the energy guide bundle **122**, and the remainder of the catheter system **100**. For example, in some embodiments, as illustrated in FIG. **1**, the system console **123** can include a console connection aperture **148** (also sometimes referred to generally as a "socket") by which the energy guide bundle **122** is mechanically coupled to the system console **123**. In such embodiments, the energy guide bundle **122** can include a guide coupling housing **150** (also sometimes referred to generally as a "ferrule") that houses a portion, such as the guide proximal end **122**P, of each of the energy guides **122**A. The guide coupling housing **150** is configured to fit and be selectively retained within the console connection aperture **148** to provide the mechanical coupling between the energy guide bundle **122** and the system console **123**.

[0078] The energy guide bundle **122** can also include a guide bundler **152** (or "shell") that brings each of the individual energy guides **122**A closer together so that the energy guides **122**A and/or the energy guide bundle **122** can be in a more compact form as it extends with the catheter **102** into the blood vessel **108** during use of the catheter system **100**.

[0079] The energy source **124** can be selectively and/or alternatively coupled in optical communication with each of the energy guides **122**A, such as to the guide proximal end **122**P of each of the energy guides **122**A, in the energy guide bundle **122**. In particular, the energy source **124** is configured to generate energy in the form of a source beam **124**A, such as a pulsed source beam, that can be selectively and/or alternatively directed to and received by each of the energy guides **122**A in the energy guide bundle **122** as an individual guide beam **124**B. Alternatively, the catheter system **100** can include more than one energy source **124**. For example, in one non-exclusive alternative embodiment, the catheter system **100** can include a separate energy source **124** for each of the energy guides **122**A in the energy guide bundle **122**.

[0080] The energy source **124** can have any suitable design. In certain embodiments, the energy source **124** can be configured to provide sub-millisecond pulses of energy from the energy source **124** that are focused onto a small spot in order to couple it into the guide proximal end **122**P of the energy guide **122**A. Such pulses of energy are then directed and/or guided along the energy guides **122**A to a location within the balloon interior **146** of the balloon **104**, thereby inducing plasma formation in the catheter fluid **132** within the balloon interior **146** of the balloon **104**, such as via the plasma generator **133** that can be located at or near the guide distal end **122**D of the energy guide **122**A. In particular, in such embodiments, the energy emitted at the guide distal end **122**D of the energy guide **122**A is directed toward and energizes the plasma generator **133** to form the plasma in the catheter fluid **132** within the balloon interior **146**. The plasma formation causes rapid bubble formation, and imparts pressure waves upon the treatment site **106**. An exemplary plasma-induced bubble **134** is illustrated in FIG. **1**.

[0081] In various non-exclusive alternative embodiments, the sub-millisecond pulses of energy from the energy source **124** can be delivered to the treatment site **106** at a frequency of between approximately one hertz (Hz) and 5000 Hz, between approximately 30 Hz and 1000 Hz, between approximately ten Hz and 100 Hz, or between approximately one Hz and 30 Hz. Alternatively, the sub-millisecond pulses of energy can be delivered to the treatment site 106 at a frequency that can be greater than 5000 Hz or less than one Hz, or any other suitable range of frequencies.

[0082] It is appreciated that although the energy source **124** is typically utilized to provide pulses of energy, the energy source **124** can still be described as providing a single source beam **124**A, i.e. a single pulsed source beam.

[0083] The energy sources **124** suitable for use can include various types of light sources including lasers and lamps. Alternatively, the energy sources **124** can include any suitable type of energy source.

[0084] Suitable lasers can include short pulse lasers on the sub-millisecond timescale. In some embodiments, the energy source **124** can include lasers on the nanosecond (ns) timescale. The lasers can also include short pulse lasers on the picosecond (ps), femtosecond (fs), and microsecond (us) timescales. It is appreciated that there are many combinations of laser wavelengths, pulse widths and energy levels that can be employed to achieve plasma in the catheter fluid **132** of the catheter **102**. In various non-exclusive alternative embodiments, the pulse widths can include those falling within a range including from at least ten ns to 3000 ns, at least 20 ns to 100 ns, or at least one ns to 500 ns. Alternatively, any other suitable pulse width range can be used.

[0085] Exemplary nanosecond lasers can include those within the UV to IR spectrum, spanning wavelengths of about ten nanometers (nm) to one millimeter (mm). In some embodiments, the energy sources **124** suitable for use in the catheter systems **100** can include those capable of producing light at wavelengths of from at least 750 nm to 2000 nm. In other embodiments, the energy sources **124** can include

those capable of producing light at wavelengths of from at least 700 nm to 3000 nm. In still other embodiments, the energy sources **124** can include those capable of producing light at wavelengths of from at least 100 nm to ten micrometers (μm). Nanosecond lasers can include those having repetition rates of up to 200 KHz.

[0086] In some embodiments, the laser can include a Q-switched thulium: yttrium-aluminum-garnet (Tm:YAG) laser. In other embodiments, the laser can include a neodymium: yttrium-aluminum-garnet (Nd:YAG) laser, holmium: yttrium-aluminum-garnet (Ho:YAG) laser, erbium: yttrium-aluminum-garnet (Er:YAG) laser, excimer laser, helium-neon laser, carbon dioxide laser, as well as doped, pulsed, fiber lasers.

[0087] In still other embodiments, the energy source **124** can include a plurality of lasers that are grouped together in series. In yet other embodiments, the energy source **124** can include one or more low energy lasers that are fed into a high energy amplifier, such as a master oscillator power amplifier (MOPA). In still yet other embodiments, the energy source **124** can include a plurality of lasers that can be combined in parallel or in series to provide the energy needed to create the plasma bubble **134** in the catheter fluid **132**.

[0088] The catheter system **100** can generate pressure waves having maximum pressures in the range of at least one megapascal (MPa) to 100 MPa. The maximum pressure generated by a particular catheter system **100** will depend on the energy source **124**, the absorbing material, the bubble expansion, the propagation medium, the balloon material, and other factors. In various non-exclusive alternative embodiments, the catheter systems **100** can generate pressure waves having maximum pressures in the range of at least approximately two MPa to 50 MPa, at least approximately two MPa to 30 MPa, or approximately at least 15 MPa to 25 MPa.

[0089] The pressure waves can be imparted upon the treatment site **106** from a distance within a range from at least approximately 0.1 millimeters (mm) to greater than approximately 25 mm extending radially from the energy guides **122**A when the catheter **102** is placed at the treatment site **106**. In various non-exclusive alternative embodiments, the pressure waves can be imparted upon the treatment site **106** from a distance within a range from at least approximately ten mm to 20 mm, at least approximately one mm to ten mm, at least approximately 1.5 mm to four mm, or at least approximately 0.1 mm to ten mm extending radially from the energy guides **122**A when the catheter **102** is placed at the treatment site **106**. In other embodiments, the pressure waves can be imparted upon the treatment site **106** from another suitable distance that is different than the foregoing ranges. In some embodiments, the pressure waves can be imparted upon the treatment site **106** within a range of at least approximately two MPa to 30 MPa at a distance from at least approximately 0.1 mm to ten mm. In some embodiments, the pressure waves can be imparted upon the treatment site **106** from a range of at least approximately two MPa to 25 MPa at a distance from at least approximately 0.1 mm to ten mm. Still alternatively, other suitable pressure ranges and distances can be used.

[0090] The power source **125** is electrically coupled to and is configured to provide necessary power to each of the energy source **124**, the system controller **126**, the GUI **127**, and the handle assembly **128**. The power source **125** can have any suitable design for such purposes.

[0091] The system controller **126** is electrically coupled to and receives power from the power source **125**. The system controller **126** is coupled to and is configured to control operation of each of the energy source **124** and the GUI **127**. The system controller **126** can include one or more processors or circuits for purposes of controlling the operation of at least the energy source **124** and the GUI **127**. For example, the system controller **126** can control the energy source **124** for generating pulses of energy as desired and/or at any desired firing rate.

[0092] The system controller **126** can also be configured to control operation of other components of the catheter system **100** such as the positioning of the catheter **102** adjacent to the treatment site **106**, the inflation of the balloon **104** with the catheter fluid **132**, etc. Further, or in the alternative, the catheter system **100** can include one or more additional controllers that can be positioned in any suitable manner for purposes of controlling the various operations of the catheter system **100**. For example, in certain embodiments, an additional controller and/or a portion of the system controller **126** can be positioned and/or incorporated within the handle assembly **128**.

[0093] The GUI **127** is accessible by the user or operator of the catheter system **100**. The GUI **127** is electrically connected to the system controller **126**. With such design, the GUI **127** can be used by the user or operator to ensure that the catheter system **100** is effectively utilized to impart pressure onto and induce fractures into the vascular lesions **106**A at the treatment site **106**. The GUI **127** can provide the user or operator with information that can be used before, during and after use of the catheter system **100**. In one embodiment, the GUI **127** can provide static visual data and/or information to the user or operator. In addition, or in the alternative, the GUI **127** can provide dynamic visual data and/or information to the user or operator, such as video data or any other data that changes over time during use of the catheter system **100**. In various embodiments, the GUI **127** can include one or more colors, different sizes, varying brightness, etc., that may act as alerts to the user or operator. Additionally, or in the alternative, the GUI **127** can provide audio data or information to the user or operator. The specifics of the GUI **127** can vary depending upon the design requirements of the catheter system **100**, or the specific needs, specifications and/or desires of the user or operator.

[0094] As shown in FIG. **1**, the handle assembly **128** can be positioned at or near the proximal portion **114** of the catheter system **100**. In this embodiment, the handle assembly **128** is coupled to the balloon **104** and is positioned spaced apart from the balloon **104**. Alternatively, the handle assembly **128** can be positioned at another suitable location.

[0095] The handle assembly **128** is attached to the catheter shaft **110** and is handled and used by the user or operator to operate, position and control the catheter **102**. The design and specific features of the handle assembly **128** can vary to suit the design requirements of the catheter system **100**. In the embodiment illustrated in FIG. **1**, the handle assembly **128** is separate from, but in electrical and/or fluid communication with one or more of the system controller **126**, the energy source **124**, the fluid pump **138**, and the GUI **127**.

[0096] In some embodiments, the handle assembly **128** can integrate and/or include at least a portion of the system controller **126** within an interior of the handle assembly **128**. For example, as shown, in certain such embodiments, the handle assembly **128** can include circuitry **156**, which is

electrically coupled between catheter electronics and the system console **123**, and which can form at least a portion of the system controller **126**. In one embodiment, the circuitry **156** can include a printed circuit board having one or more integrated circuits, or any other suitable circuitry. In an alternative embodiment, the circuitry **156** can be omitted, or can be included within the system controller **126**, which in various embodiments can be positioned outside of the handle assembly **128**, such as within the system console **123**. It is understood that the handle assembly **128** can include fewer or additional components than those specifically illustrated and described herein.

[0097] Further included with the handle assembly **128** is an energy activation member **157** (also sometimes referred to herein simply as an "energy activator"), such as an energy activation button, that can be coupled to the circuitry **156** within the handle assembly **128** which forms a part of the system controller **126**. The energy activator **157** is configured to enable the user or operator to selectively activate the catheter system **100** as desired.

[0098] In various embodiments, as noted above, the source manifold **136** can be integrated and/or incorporated within the handle assembly **128**, and can positioned at or near the proximal portion **114** of the catheter system **100**. As shown, the source manifold **136** can include one or more openings that can receive an inflation conduit **140** that is coupled in fluid communication with the fluid pump **138**, the guidewire **112** and/or the guidewire lumen **118**, one or more energy guides **122**A of the energy guide bundle **122**, and/or the catheter shaft **110**. More particularly, the source manifold **136** can include one or more of a media inflation port **158**, a guidewire lumen port **160**, an energy guide port **162**, and a catheter shaft port **164**.

[0099] The catheter system **100** can also include the fluid pump **138** that is configured to inflate the balloon **104** with the catheter fluid **132** as needed.

[0100] Various embodiments of the source manifold **136**, and the specific components included therewith, are illustrated and described in detail herein below within subsequent Figures.

[0101] As with all embodiments illustrated and described herein, various structures may be omitted from the figures for clarity and ease of understanding. Further, the figures may include certain structures that can be omitted without deviating from the intent and scope of the invention.

[0102] FIG. **2** is a simplified cutaway view illustration of an embodiment of the handle assembly **228**. The design of the handle assembly **228** and the various components retained therein can be varied to suit the requirements of the catheter system **100** (illustrated in FIG. **1**). As illustrated in this embodiment, the handle assembly **228** can include an assembly housing **266** that includes and/or defines one or more of an inflation conduit inlet **268**, a guidewire inlet **270**, an energy guide inlet **272**, an electrical inlet **274**, a handle distal outlet **276**, and a catheter shaft hub **278**; circuitry **256** with an integrated energy activator **257**; and a source manifold **236**. Alternatively, the handle assembly **228** can include more components or fewer components than those specifically illustrated and described herein.

[0103] In some embodiments, the assembly housing **266** can be formed from two housing members **266**A (only one of which is shown in FIG. **2**) formed as a first housing side and a second housing side that are selectively coupled together to form the complete assembly housing **266**. FIG. **2** further illustrates that the housing member **266**A can include a plurality of coupling members **266**B that are configured to engage corresponding coupling members on the other housing member **266**A. In one embodiment, the coupling members **266**B can include a series of pins and corresponding apertures that are configured to engage one another when the housing members **266**A are being coupled together to form the complete assembly housing **266**. Alternatively, the coupling members **266**B can have another suitable design.

[0104] The inflation conduit inlet **268** is configured to couple the inflation conduit **240** into the assembly housing **266**.

[0105] The guidewire inlet **270** is configured to couple the guidewire **212** into the assembly housing **266**.

[0106] The energy guide inlet **272** is configured to couple the energy guide bundle **222** including the one or more energy guides **222**A into the assembly housing **266**.

[0107] The electrical inlet **274** is configured to couple an electrical cable **280** into the assembly housing **266**.

[0108] As shown, it is appreciated that in certain embodiments, the energy guide inlet **272** and the electrical inlet **274** can be formed together into a single inlet. For example, in one embodiment, the energy guides **222**A and the electrical cable **280** can be shrouded within an optical/electrical cable **283** as the energy guides **222**A and the electrical cable **280** enter into the assembly housing **266** through the energy guide inlet **272** and the electrical inlet **274**, respectively. Alternatively, the energy guide inlet **272** and the electrical inlet **274** can be formed independently of one another.

[0109] The handle distal outlet **276** provides an outlet from the assembly housing **266** for each of the inflation conduit **240**, the guidewire **212**, the guidewire lumen **218**, the energy guide bundle **222**, and the catheter shaft **210**, as such components extend toward the balloon **104** (illustrated in FIG. **1**).

[0110] The catheter shaft hub **278** is configured to support the catheter shaft **210** so that the catheter shaft **210** can be coupled into the handle distal outlet **276**. In one embodiment, the catheter shaft hub **278** is adhered to the catheter shaft **210**. In certain embodiments, the handle assembly **228** can further include locking features **281** that are configured to fix the catheter shaft hub **276** in place when the housing members **266**A are coupled together to form the complete assembly housing **266**.

[0111] The source manifold **236** is configured to help guide various components of the catheter **102** (illustrated in FIG. **1**), such as the catheter shaft **210**, the guidewire lumen **218**, the guidewire **212**, the energy guides **222**A, and the inflation conduit **240**, within the handle assembly **228** so that they can extend together to the balloon **104** (illustrated in FIG. **1**).

[0112] The design of the source manifold **236** can be varied. As illustrated in FIG. **2**, the source manifold **236** can include a manifold housing **282**, and a pressure sensor **284** that is coupled to the manifold housing **282**. In certain embodiments, the pressure sensor **284** is configured to sense a fluid pressure of the catheter fluid **132** (illustrated in FIG. **1**) at one or more locations within the catheter system **100** (illustrated in FIG. **1**). For example, in certain embodiments, the pressure sensor **284** can be configured to sense a fluid pressure of the catheter fluid **132** within the balloon interior **146** (illustrated in FIG. **1**) or at any desired location along the inflation conduit **240**. Alternatively, the pressure sensor

284 can be configured to sense a fluid pressure of the catheter fluid **132** at one or more other locations within the catheter system **100**. In some non-exclusive embodiments, the pressure sensor **284** can be configured to sense the fluid pressure within the catheter fluid at any suitable locations up to approximately 10 atm, 15 atm, 20 atm, 25 atm, 30 atm, 35 atm, 40 atm, 45 atm, 50 atm, 55 atm, 60 atm, 65 atm, 70 atm, 75 atm, 80 atm, 85 atm, 90 atm, 95 atm, or 100 atm.

[0113] As above, the source manifold **236** can also include one or more of the media inflation port **258**, the guidewire lumen port **260**, the energy guide port **262**, and the catheter shaft port **264** that can be coupled to and/or integrated into the manifold housing **282**. In some embodiments, the energy guide bundle **222** and/or the one or more energy guides **222**A can be coupled into the energy guide port **262** through use of a guide sealing component **585** (illustrated in FIG. **5**). It is appreciated that the energy guide bundle **222** and/or the one or more energy guides **222**A can be routed through the handle assembly **228** and/or the source manifold **236** in any suitable manner.

[0114] The circuitry **256** and the integrated energy activator **257** are substantially similar to what was illustrated and described herein above. More particularly, in some embodiments, the circuitry **256** can be provided in the form of a printed circuit board (PCB) that is attached to the pressure sensor **284** in the source manifold **236**, and the energy activator **257** is integrated onto the circuitry **256** and is in electrical communication with the system console **123** (illustrated in FIG. **1**) through the electrical cable **280**.

[0115] FIG. **3** is a simplified perspective view illustration of an embodiment of the source manifold **336**. The design of the source manifold **336** can be varied to suit the requirements of the catheter system **100** (illustrated in FIG. **1**). In various embodiments, as shown, the source manifold **336** can include a manifold housing **382** having a first housing member **382**A and a second housing member **382**B. In certain embodiments, the manifold housing **382** can include a sensor bore **386**, one or more sensor controller attachment apertures **388** (two are shown in FIG. **3**), at least one housing attachment aperture **390**, the media inflation port **358**, the guidewire lumen port **360**, the energy guide port **362**, and the catheter shaft port **364**. Alternatively, the source manifold **336** and/or the manifold housing **382** can include more components or fewer components than what has been illustrated and described herein.

[0116] As shown, the first housing member **382**A of the manifold housing **382** is selectively coupled to the second housing member **382**B. The first housing member **382**A and the second housing member **382**B can be selectively coupled to one another in any suitable manner.

[0117] The sensor bore **386** is formed into the manifold housing **382**, into the first housing member **382**A in certain embodiments, and is configured to receive and retain the pressure sensor **284** (illustrated in FIG. **2**). In some embodiments, the sensor bore **386** is substantially circular-shaped. Alternatively, the sensor bore **386** can be another suitable shape and/or can be positioned in another suitable manner.

[0118] The sensor controller attachment apertures **388** are usable to couple the circuitry **256** (illustrated in FIG. **2**) to the source manifold **336** and/or the manifold housing **382**. More particularly, in certain embodiments, a controller attacher (not shown), such as a screw or other suitable attacher, can extend through a portion of the circuitry **256** (or through another suitable device that is coupled to the circuitry **256**) and can be received and retained in each of the sensor controller attachment apertures **388** to couple the circuitry **256** to the source manifold **336** and/or the manifold housing **382**. In some embodiments, the source manifold **336** and/or the manifold housing **382** can include two sensor controller attachment apertures **388** that are positioned substantially adjacent to the sensor bore **386**. In certain embodiments, the sensor controller attachment apertures **388** can be formed into the first housing member **382**A of the manifold housing **382**. Alternatively, the sensor controller attachment apertures **388** can have a different design and/or can be positioned in another suitable manner.

[0119] In one non-exclusive embodiment, an O-ring can be situated with grease against a wall within the sensor bore **386**, and washers can be positioned between the circuitry **256**, such as the PCB, and the manifold housing **382** of the source manifold **336** adjacent to the sensor controller attachment apertures **388**.

[0120] The at least one housing attachment aperture **390** is usable for attaching the source manifold **336** to the assembly housing **266** (illustrated in FIG. **2**) of the handle assembly **228** (illustrated in FIG. **2**). More particularly, in certain embodiments, a manifold attacher (not shown), such as a screw or other suitable attacher, can extend through the at least one housing attachment aperture **390** and into an assembly aperture (not shown) formed into the assembly housing **266** of the handle assembly **228** to attach the source manifold **336** and/or the manifold housing **382** to the assembly housing **266**. With such design, the source manifold **336** can be maintained in a desired position within the assembly housing **266** of the handle assembly **228**.

[0121] In some embodiments, the housing attachment aperture **390** can be formed into an attachment arm **390**A that cantilevers away from the second housing member **382**B of the manifold housing **382**. Alternatively, the at least one housing attachment aperture **390** can have a different design and/or be positioned in another suitable manner.

[0122] The design and general function of the media inflation port **358**, the guidewire lumen port **360**, the energy guide port **362**, and the catheter shaft port **364** has been described in detail herein above. Accordingly, the media inflation port **358**, the guidewire lumen port **360**, the energy guide port **362**, and the catheter shaft port **364** will not again be described in detail.

[0123] It is noted, however, that in one embodiment, each of the media inflation port **358**, the guidewire lumen port **360**, the energy guide port **362**, and the catheter shaft port **364** are coupled to and/or formed into the second housing member **382**B of the manifold housing **382**. With this design, all lumens are kept on the same axis plane. Alternatively, one or more of the media inflation port **358**, the guidewire lumen port **360**, the energy guide port **362**, and the catheter shaft port **364** can be coupled to and/or formed into the first housing member **382**A of the manifold housing **382**.

[0124] FIG. **4** is a simplified cutaway perspective view of a portion of the source manifold **336** illustrated in FIG. **3**. In particular, FIG. **4** is a simplified cutaway perspective view that shows the first housing member **382**A of the manifold housing **382** being attached to the second housing member **382**B.

[0125] It is appreciated that the attachment between the first housing member **382**A and the second housing member **382**B can be provided in any suitable manner. In certain

embodiments, the attachment between the first housing member **382**A and the second housing member **382**B can be provided via an attachment assembly **492**, which can include a first attachment member **492**A that is coupled to and/or formed into the first housing member **382**A, and a second attachment member **492**B that is coupled to and/or formed into the second housing member **382**B. In various embodiments, the first attachment member **492**A is configured to selectively engage the second attachment member **492**B as the first housing member **382**A is being attached to the second housing member **382**B. In one embodiment, as shown, the first attachment member **492**A can include an attachment channel, and the second attachment member **492**B can include an attachment projection that is configured to fit within the attachment channel of the first attachment member **492**A. In another embodiment, the second attachment member **492**B can include an attachment channel, and the first attachment member **492**A can include an attachment projection that is configured to fit within the attachment channel of the second attachment member **492**B. Alternatively, the first attachment member **492**A and/or the second attachment member **492**B can have another suitable design.

[0126] In alternative embodiments, the attachment between the first attachment member **492**A and the second attachment member **492**B can be secured in any suitable manner. For example, in one embodiment, an adhesive material can be used substantially adjacent to and/or between the first attachment member **492**A and the second attachment member **492**B, such as within the attachment channel. In another embodiment, the first attachment member **492**A and the second attachment member **492**B can be ultrasonically sealed to one another. In still another embodiment, the first attachment member **492**A and the second attachment member **492**B can be held together through friction fit. Alternatively, the first attachment member **492**A and the second attachment member **492**B can be secured together in another suitable manner.

[0127] FIG. **4** also illustrates that the first housing member **382**A and the second housing member **382**B of the manifold housing **382** define a media chamber **494** therebetween. In certain embodiments, it is desired that a volume of the media chamber **494** is minimized (in width and/or height) such that a volume of media within the media chamber **494** is minimized to allow for easier aspiration of the balloon **104** (illustrated in FIG. **1**) during inflation. It is for this reason, in some embodiments, that the media inflation port **358** (illustrated in FIG. **3**), the guidewire lumen port **360** (illustrated in FIG. **3**), the energy guide port **362**, and the catheter shaft port **364** are each coupled to and/or formed into the second housing member **382**B of the manifold housing **382** to keep all lumens on the same axis plane.

[0128] As noted above, the energy guide port **362** is configured to couple the one or more energy guides **222**A (illustrated in FIG. **2**) of the energy guide bundle **222** (illustrated in FIG. **2**) into and/or through the manifold housing **382**, so that the energy guides **222**A can guide energy from the energy source **124** (illustrated in FIG. **1**), through the handle assembly **228** (illustrated in FIG. **2**), and into the balloon interior **146** (illustrated in FIG. **1**) of the balloon **104** (illustrated in FIG. **1**).

[0129] It is appreciated that sealing a plurality of energy guides **222**A, such as optical fibers or other suitable energy guides, into a single hole, such as the energy guide port **362**, can be very challenging due to the small size of the energy guides. The number of energy guides **222**A can also result in glue gaps as the energy guides **222**A of the energy guide bundle **222** are coupled into the energy guide port **362**. One way to solve this issue is to organize the energy guides **222**A into individual channels of a multi-lumen extrusion as shown in FIG. **5**.

[0130] In particular, FIG. **5** is a simplified schematic view illustration of a multi-lumen optical sealing component **596** that is usable for coupling a plurality of energy guides **222**A (illustrated in FIG. **2**) into the source manifold **336** of FIG. **3**, such as via the energy guide port **362** (illustrated in FIG. **3**). In some embodiments, as shown, the optical sealing component **596** includes a seal body **596**A that has a plurality of guide channels **598** formed therethrough.

[0131] In one embodiment, the seal body **596**A can be substantially circular disk-shaped to match a substantially circular cross-section of the energy guide port **362** (illustrated in FIG. **3**). Alternatively, the seal body **596**A and/or the energy guide port **362** can have another suitable shape.

[0132] The number of guide channels **598** formed into and/or through the seal body **596**A can be varied, and can be configured to suit the number of energy guides **222**A included within the energy guide bundle **222** (illustrated in FIG. **2**). In one embodiment, as shown in FIG. **5**, the seal body **596**A can include ten guide channels **598** to accommodate up to ten energy guides **222**A. Alternatively, the seal body **596**A can include greater than ten or less than ten guide channels **598**.

[0133] In certain embodiments, once the energy guides **222**A are all seated in their respective guide channels **598**, the energy guides **222**A can be reliably adhered to the optical sealing component **596** with a wicking adhesive. In one embodiment, the optical sealing component **596** and/or the seal body **596**A can be formed from a transparent material so that UV glue can be used to promote curing. In one embodiment, the optical sealing component **596** and/or the seal body **596**A can be adhered as a subassembly prior to bonding into the energy guide port **362** in the source manifold **336** (illustrated in FIG. **3**).

[0134] In certain embodiments, the catheter systems and related methods utilize an energy source, e.g., a light source such as a laser source or another suitable energy source, which provides energy that is guided by one or more energy guides, e.g., light guides such as optical fibers, which are disposed along the catheter shaft and within the balloon interior of the balloon to create a localized plasma in the catheter fluid that is retained within the balloon interior of the balloon. The energy guide can be used in conjunction with a plasma generator that is positioned at or near a guide distal end of the energy guide within the balloon interior of the balloon located at the treatment site. The creation of the localized plasma can initiate a pressure wave and can initiate the rapid formation of one or more bubbles that can rapidly expand to a maximum size and then dissipate through a cavitation event that can launch a pressure wave upon collapse. The rapid expansion of the plasma-induced bubbles can generate one or more pressure waves in the catheter fluid retained within the balloon interior of the balloon and thereby impart pressure waves onto and induce fractures in the vascular lesions at the treatment site within or adjacent to the blood vessel wall within the body of the patient. In some embodiments, the energy source can be configured to provide sub-millisecond pulses of energy, e.g., light energy, to initiate the plasma formation in the catheter

fluid within the balloon to cause the rapid bubble formation and to impart the pressure waves upon the balloon wall at the treatment site. Thus, the pressure waves can transfer mechanical energy through an incompressible catheter fluid to the treatment site to impart a fracture force on the intravascular lesion. Without wishing to be bound by any particular theory, it is believed that the rapid change in catheter fluid momentum upon the balloon wall that is in contact with the intravascular lesion is transferred to the intravascular lesion to induce fractures to the lesion.

[0135] The catheter systems and related methods disclosed herein further include a handle assembly that is attached to the catheter shaft and that is handled and used by the user or operator to operate, position and control the catheter. In various embodiments, the handle assembly has a source manifold incorporated and/or integrated therein. In such embodiments, the source manifold can include one or more of a manifold housing, a pressure sensor that is coupled to and/or integrated into the manifold housing, and a media inflation port, a guidewire lumen port, an energy guide port, and a catheter shaft port that are formed into and/or coupled to the manifold housing. The pressure sensor is configured to sense a fluid pressure of the catheter fluid within the catheter system. For example, in certain embodiments, the pressure sensor can be configured to sense a fluid pressure within the balloon interior or at any desired location along an inflation conduit. The media inflation port is configured to couple the inflation conduit into and/or through the manifold housing so that the catheter fluid can be directed as desired through the handle assembly and into the balloon interior. The guidewire lumen port is configured to couple a guidewire lumen, which defines a conduit through which a guidewire extends, into, from and/or through the manifold housing, so that the guidewire lumen can thus extend from the handle assembly into and/or through the balloon interior. The energy guide port is configured to couple the one or more energy guides into and/or through the manifold housing, so that the energy guides can guide energy from the energy source, through the handle assembly, and into the balloon interior. The catheter shaft port is configured to couple the catheter shaft to the manifold housing so that the user can effectively control positioning of the catheter shaft, with the balloon attached thereto, substantially adjacent to the vascular lesion(s) at the treatment site via manipulation of the handle assembly.

[0136] In some embodiments, the handle assembly can further include at least a portion of a system controller, such as in the form of a printed circuit board (PCB) that is attached to the pressure sensor, and an energy activation button.

[0137] The present technology is also directed toward methods for treating a treatment site within or adjacent to a vessel wall, with such methods utilizing the devices disclosed herein.

[0138] It should be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content and/or context clearly dictates otherwise. It should also be noted that the term "or" is generally employed in its sense including "and/or" unless the content or context clearly dictates otherwise.

[0139] It should also be noted that, as used in this specification and the appended claims, the phrase "configured" describes a system, apparatus, or other structure that is constructed or configured to perform a particular task or adopt a particular configuration. The phrase "configured" can be used interchangeably with other similar phrases such as arranged and configured, constructed and arranged, constructed, manufactured and arranged, and the like.

[0140] It is recognized that the figures shown and described are not necessarily drawn to scale, and that they are provided for ease of reference and understanding, and for relative positioning of the structures.

[0141] The headings used herein are provided for consistency with suggestions under **37** CFR **1.77** or otherwise to provide organizational cues. These headings shall not be viewed to limit or characterize the invention(s) set out in any claims that may issue from this disclosure. As an example, a description of a technology in the "Background" is not an admission that technology is prior art to any invention(s) in this disclosure. Neither is the "Summary" or "Abstract" to be considered as a characterization of the invention(s) set forth in issued claims.

[0142] The embodiments described herein are not intended to be exhaustive or to limit the invention to the precise forms disclosed in the following detailed description. Rather, the embodiments are chosen and described so that others skilled in the art can appreciate and understand the principles and practices. As such, aspects have been described with reference to various specific and preferred embodiments and techniques. However, it should be understood that many variations and modifications may be made while remaining within the spirit and scope herein.

[0143] It is understood that although a number of different embodiments of the catheter systems have been illustrated and described herein, one or more features of any one embodiment can be combined with one or more features of one or more of the other embodiments, provided that such combination satisfies the intent of the present invention.

[0144] While a number of exemplary aspects and embodiments of the catheter systems have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope, and no limitations are intended to the details of construction or design herein shown.

What is claimed is:

1. A catheter system for disrupting calcification at a treatment site within or adjacent to a vessel wall or heart valve, the catheter system comprising:

an energy source that generates energy;

a balloon that is positionable substantially adjacent to the treatment site, the balloon having a balloon wall that defines a balloon interior, the balloon interior being configured to receive a balloon fluid;

an energy guide that is configured to receive energy from the energy source, the energy guide guiding the energy into the balloon interior;

an inflation conduit that is in fluid communication with the balloon interior, the inflation conduit being configured to convey the balloon fluid into the balloon interior; and

a pressure sensor assembly that is configured to sense a balloon pressure of the balloon fluid within the balloon

interior, the pressure sensor assembly being in fluid communication with the balloon interior and the inflation conduit.

2. The catheter system of claim **1** further comprising a handle assembly that is coupled to the balloon, the handle assembly being positioned spaced apart from the balloon, the handle assembly being usable by a user to operate the catheter system, the pressure sensor assembly being positioned within the handle assembly.

3. The catheter system of claim **2** wherein further comprising a manifold assembly that is coupled to the handle assembly, the manifold assembly being in fluid communication with (i) the balloon fluid within the balloon interior, (ii) the pressure sensor assembly, and (iii) the inflation conduit.

4. The catheter system of claim **3** wherein the inflation fluid is configured to flow first through the inflation conduit and subsequently through the manifold assembly before entering the balloon interior.

5. The catheter system of claim **3** wherein the manifold assembly includes a manifold retainer that is configured to receive and retain the balloon fluid.

6. The catheter system of claim **5** wherein the pressure sensor assembly includes a pressure sensor that contacts the manifold retainer so that the pressure sensor can sense the balloon pressure of the balloon fluid based on the balloon fluid retained within the manifold retainer.

7. The catheter system of claim **1** wherein the pressure sensor assembly includes a pressure sensor, the pressure sensor including a printed circuit board.

8. The catheter system of claim **7** wherein the manifold assembly includes a manifold body, the pressure sensory assembly being coupled to the manifold body so that the pressure sensor extends within the manifold body.

9. The catheter system of claim **8** wherein the pressure sensor assembly includes a pressure sensor sealer that forms a seal between the pressure sensor and the manifold body.

10. The catheter system of claim **8** wherein the manifold body includes a pressure sensor aperture that is configured to receive the pressure sensor.

11. A catheter system for disrupting calcification at a treatment site within or adjacent to a vessel wall or heart valve, the catheter system comprising:

a balloon that is positionable substantially adjacent to the treatment site, the balloon having a balloon wall that defines a balloon interior, the balloon interior being configured to receive a balloon fluid;

an inflation conduit that is in fluid communication with the balloon interior, the inflation conduit being configured to convey the balloon fluid into the balloon interior; and

a pressure sensor assembly that is configured to sense a balloon pressure of the balloon fluid within the balloon interior, the pressure sensor assembly being in fluid communication with the balloon interior and the inflation conduit.

12. The catheter system of claim **11** further comprising a handle assembly that is coupled to the balloon, the handle assembly being positioned spaced apart from the balloon, the handle assembly being usable by a user to operate the catheter system, the pressure sensor assembly being positioned within the handle assembly.

13. The catheter system of claim **12** further comprising a manifold assembly that is coupled to the handle assembly, the manifold assembly being in fluid communication with (i) the balloon fluid within the balloon interior, (ii) the pressure sensor assembly, and (iii) the inflation conduit.

14. The catheter system of claim **13** wherein the inflation fluid is configured to flow first through the inflation conduit and subsequently through the manifold assembly before entering the balloon interior.

15. The catheter system of claim **13** wherein the manifold assembly includes a manifold retainer that is configured to receive and retain the balloon fluid.

16. The catheter system of claim **15** wherein the pressure sensor assembly includes a pressure sensor that contacts the manifold retainer so that it can sense the balloon pressure of the balloon fluid based on the balloon fluid retained within the manifold retainer.

17. The catheter system of claim **11** wherein the pressure sensor assembly includes a pressure sensor, the pressure sensor including a printed circuit board.

18. The catheter system of claim **17** wherein the manifold assembly includes a manifold body, the pressure sensory assembly being coupled to the manifold body so that the pressure sensor extends within the manifold body.

19. The catheter system of claim **18** wherein the pressure sensor assembly includes a pressure sensor sealer that forms a seal between the pressure sensor and the manifold body.

20. A catheter system for disrupting calcification at a treatment site within or adjacent to a vessel wall or heart valve, the catheter system comprising:

an energy source that generates energy;

a balloon that is positionable substantially adjacent to the treatment site, the balloon having a balloon wall that defines a balloon interior, the balloon interior being configured to receive a balloon fluid;

an energy guide that is configured to receive energy from the energy source, the energy guide guiding the energy into the balloon interior;

a handle assembly that is coupled to the balloon, the handle assembly being positioned spaced apart from the balloon, the handle assembly being usable by a user to operate the catheter system;

an inflation conduit that is in fluid communication with the balloon interior, the inflation conduit being coupled to the handle assembly, the inflation conduit being configured to convey the balloon fluid into the balloon interior; and

a pressure sensor assembly that is configured to sense a balloon pressure of the balloon fluid within the balloon interior, the pressure sensor assembly being in fluid communication with the balloon interior and the inflation conduit, the pressure sensor assembly being positioned within the handle assembly.

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