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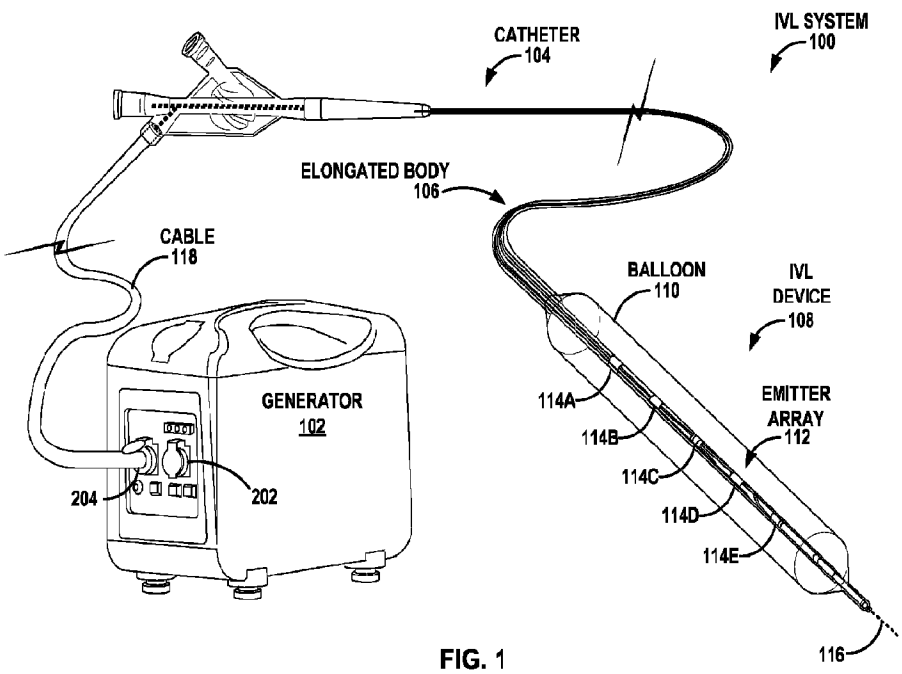

FIG. 1

(57) **Abrégé/Abstract:**
A medical device may include an elongated body, a balloon positioned at a distal portion of the elongated body, and one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon. The one or more pressure- wave emitters may be configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site. The at least one of the one or more pressure-wave emitters may include an electronic emitter comprising a first electrode and a second electrode. The first electrode and the second electrode may be arranged to define a spark gap between the first electrode and the second electrode, and the second electrode may comprise a portion of a hypotube.

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Abstract:

A medical device may include an elongated body, a balloon positioned at a distal portion of the elongated body, and one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon. The one or more pressure- wave emitters may be configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site. The at least one of the one or more pressure-wave emitters may include an electronic emitter comprising a first electrode and a second electrode. The first electrode and the second electrode may be arranged to define a spark gap between the first electrode and the second electrode, and the second electrode may comprise a portion of a hypotube.

INTRAVASCULAR LITHOTRIPSY

Field

The present disclosure relates to treatments for a calcified-plaque lesion in a patient's vasculature.

Description of Related Art

During an intravascular lithotripsy (IVL) procedure, and more specifically, during an electrohydraulic lithotripsy (EHL) procedure, a clinician uses a catheter configured to emit high-energy pressure waves to break apart calcified-plaque lesions within a patient's vasculature.

SUMMARY

The present disclosure describes systems and techniques for producing and directing high-energy intravascular pressure waves for fragmentation and/or disintegration of calcified lesions within a vasculature of a patient. For purposes of illustration, the techniques herein are described primarily with respect to electrical-based systems and respective applications thereof, such as peripheral-vessel applications. However, it is to be understood that the techniques described herein may be assumed to be likewise applicable to similar systems based on other forms of energy, such as optical (e.g., laser) based systems and respective applications, such as coronary-treatment applications, except where explicitly noted below.

In general, the systems described herein include an energy generator removably coupled to a catheter having an array of pressure-wave emitters distributed within an interventional balloon. During a lesion-disintegration procedure, a clinician may advance the interventional balloon to a target treatment site within a patient's vasculature and inflate the balloon with an inflation fluid, such as a saline/contrast fluid mixture, until the balloon contacts at least a portion of the local vessel wall. The clinician may then actuate the energy generator, causing the catheter to generate a cavitation bubble within the fluid-filled balloon, propagating a high-energy pressure wave through the balloon and the calcified lesion. A secondary pressure wave can also result from the subsequent collapse of the fluid cavitation, further destabilizing the internal structure of the lesion.

In some examples, a medical device includes: an elongated body; a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon, the one or more pressure-wave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein at least one of the one or more pressure-wave emitters includes an electronic emitter including a first electrode and a second electrode, wherein the first electrode and the second electrode are arranged to define a spark gap between the first electrode and the second electrode, and wherein the second electrode includes a portion of a hypotube.

In some examples, the first electrode and the second electrode are embedded in an adhesive layer, and the electronic emitter further includes an elastomeric tube disposed radially between the elongated body and the second electrode. In some examples, the electronic emitter further includes a coil layer disposed radially between the elongated body and the elastomeric tube.

In some examples, the first electrode is oriented such that an exterior surface is non-parallel to the central longitudinal axis of the elongated body in the absence of external forces. In some examples, the first electrode is configured to move relative to the elongated body such that the exterior surface of the first electrode is oriented parallel to the central longitudinal axis during insertion and withdrawal of the medical device through the vasculature of the patient.

In some examples, the spark gap includes a first spark gap, the electronic emitter further includes a third electrode, and the third electrode is arranged so as to define a second spark gap between the second electrode and the third electrode. In some examples, the first electrode, the second electrode, and the third electrode are all portions of a common cylindrical surface of the hypotube. In some examples, the first electrode and the third electrode both define rounded triangular shapes, and the second electrode defines a parallelogram shape. In some examples, the first electrode, the second electrode, and the third electrode all define parallelogram shapes.

In some examples, the first electrode, the second electrode, and the third electrode all define rounded rectangular shapes. In some examples, the first electrode and the third electrode both define oval shapes, and the second electrode defines a semi-cylindrical shape. In some examples, the electronic emitter further includes a coupler layer positioned radially between

the elongated body and the second electrode. In some examples, the coupler layer includes polyimide.

In some examples, the electronic emitter is wired such that the first electrode and the third electrode are independently actuatable. In some examples, the first electrode is ring-shaped; the second electrode is disc-shaped; and the first electrode is positioned around the second electrode.

In some examples, the electronic emitter further includes a third electrode and a fourth electrode; the third electrode is ring-shaped and the fourth electrode is disc-shaped; the third electrode is positioned around the fourth electrode; and the first, second, third, and fourth electrodes are all portions of a common cylindrical surface of the hypotube.

In some examples, the first electrode defines an inner radius of about 0.008 inches and an outer radius of about 0.0210 inches. In some examples, the hypotube defines a longitudinal length from about 0.080 inches to about 0.090 inches, and an outer circumference from about 0.10 inches to about 0.12 inches. In some examples, the hypotube defines an inner diameter of about 0.029 inches and an outer diameter of about 0.034 inches. In some examples, the first electrode is rectangular-prism shaped, and the first electrode extends at least partially radially inward through an outer surface of the elongated body.

In some examples, the first electrode extends radially inward through the elongated body and at least partially radially inward into an inner lumen of the elongated body. In some examples, the one or more pressure-wave emitters include five electronic emitters spaced longitudinally along the central longitudinal axis of the elongated body.

In some examples, an intravascular lithotripsy (IVL) system includes an energy generator; and a catheter, as referenced above.

In some examples, the energy generator is configured to control a treatment cycle by causing the electronic emitter to transmit a plurality of pressure-wave pulses, and the plurality of pressure-wave pulses includes about 80 pulses to about 300 pulses.

In some examples, a method of forming an electronic pressure-wave emitter of an intravascular lithotripsy (IVL) catheter includes: laser-cutting a hypotube to define at least a first electrode and a second electrode arranged to define a spark gap therebetween; inserting an elongated body through the laser-cut hypotube; flowing a potting material around the laser-cut hypotube; and removing obsolete support structures from the hypotube.

In some examples, the spark gap includes a first spark gap; and laser-cutting the hypotube further includes laser-cutting the hypotube to define a third electrode arranged so as to define a second spark gap between the second electrode and the third electrode.

In some examples, laser-cutting the hypotube includes laser-cutting the hypotube such that the first electrode and the third electrode both define rounded triangular shapes, and such that the second electrode defines a parallelogram shape. In some examples, laser-cutting the hypotube includes laser-cutting the hypotube such that the first electrode, the second electrode, and the third electrode all define parallelogram shapes.

In some examples, laser-cutting the hypotube includes laser-cutting the hypotube such that the first electrode, the second electrode, and the third electrode all define rounded rectangular shapes. In some examples, laser-cutting the hypotube includes laser-cutting the hypotube such that the first electrode and the third electrode both define oval shapes, and such that the second electrode defines a semi-cylindrical shape. In some examples, the method further includes wiring the first electrode and the third electrode so as to be independently actuatable.

In some examples, the spark gap includes a first spark gap; and laser-cutting the hypotube further includes laser-cutting the hypotube to define a third electrode and a fourth electrode arranged so as to define a second spark gap between the third electrode and the fourth electrode. In some examples, laser-cutting the hypotube further includes laser-cutting the hypotube such that: the first electrode and the third electrode are ring-shaped; the second electrode and the fourth electrode are disc-shaped; the first electrode is positioned around the second electrode; and the third electrode is positioned around the fourth electrode.

In some examples, a medical device includes an elongated body; a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon, the one or more pressure-wave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein at least one of the one or more pressure-wave emitters includes an electronic emitter including a first electrode, a second electrode, and a third electrode arranged to define a first spark gap between the first electrode and the second electrode, and a second spark gap between the second

electrode and the third electrode, and wherein the first electrode, the second electrode, and the third electrode are portions of a common hypotube.

In some examples, the medical device includes a plurality of conductive wires configured to provide electrical energy to the emitter array, the plurality of conductive wires arranged according to a wiring configuration.

In some examples, the plurality of conductive wires extends generally parallel to the central longitudinal axis. In some examples, the wiring configuration includes a single-coil configuration such that the plurality of conductive wires coil helically around the elongated body, wherein adjacent coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis. In some examples, the wiring configuration includes a double-coil configuration such that the plurality of conductive wires coil helically around the elongated body, wherein adjacent pairs of coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis. In some examples, the wiring configuration includes a quadruple-coil configuration such that the plurality of conductive wires coil helically around the elongated body, wherein adjacent groups of four coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis.

In some examples, the plurality of conductive wires includes a plurality of flat wires. In some examples, the plurality of conductive wires includes a plurality of round wires with flattened portions along the emitter array.

In some examples, the elongated body includes an inner body and an outer body; the outer body includes an inner layer and an outer layer; and the plurality of conductive wires coils around an exterior surface of the inner layer. In some examples, the outer layer of the outer body is flowed over the plurality of conductive wires such that the plurality of conductive wires is embedded in the outer layer. In some examples, the outer layer includes a potting layer or a heat-shrink tube. In some examples, the outer layer terminates proximally from the inner layer, such that a distal portion of the plurality of conductive wires is exposed to an interior of the balloon.

In some examples, the elongated body includes an inner body and an outer body, and the plurality of conductive wires coils around an exterior surface of the inner body such that the plurality of conductive wires forms a reinforcement layer for the elongated body.

In some examples, each of the plurality of emitters includes a respective voltage wire such that each of the plurality of emitters is independently actuatable. In some examples, the exterior surface of the balloon includes a polymer coating. In some examples, the exterior

surface of the balloon includes a hydrophilic coating or a drug-based coating, such as an anti-thrombogenic coating or an anti-proliferative medication.

In some examples, the balloon includes two or more nested expandable substrates. In some examples, the two or more nested expandable substrates include at least an outer layer and an inner layer, wherein an interior surface of the outer layer is bonded to an exterior surface of the inner layer so as to form a single multi-layered extrusion. In some examples, the inner layer includes a high-pressure holding layer, and the outer layer includes a urethane layer.

In some examples, the balloon further includes a reinforcing structure. In some examples, the reinforcing structure includes a plurality of longitudinal fibers aligned parallel to the longitudinal axis of the balloon and a plurality of braided fibers. In some examples, the plurality of longitudinal fibers includes four to eight longitudinal fibers.

In some examples, the balloon includes an outer layer, an inner layer nested within the outer layer, and a cage structure nested between the outer layer and the inner layer, and the cage structure includes one or more longitudinal members oriented parallel to the longitudinal axis and one or more circumferential elements oriented perpendicular to the longitudinal axis.

In some examples, the medical device further includes a cage structure at least partially surrounding the exterior surface of the balloon. In some examples, the cage structure is rigidly coupled to the exterior surface of the balloon. In some examples, the cage structure includes a nitinol braid, metal wires, printed metals, radiopaque metal wires, or radiopaque printed metals. In some examples, the balloon includes a porous membrane configured to infuse a drug at the target treatment site.

In some examples, the balloon includes a plurality of longitudinal ribs configured to define folding guides as the balloon folds radially inward. In some examples, the plurality of longitudinal ribs includes an odd number of ribs. In some examples, the medical device includes a spring configured to longitudinally stretch the balloon in an absence of external forces.

In some examples, the medical device includes a fracturing member positioned on an external surface of the balloon. In some examples, the fracturing member includes a conductive wire running along the longitudinal axis of the balloon; and a plurality of piezo-elements positioned along the conductive wire, the plurality of piezo-elements configured to emit additional pressure waves against the calcified lesion. In some examples, the medical device includes a protective device positioned at the distal portion of the elongated body, and the

protective device is configured to at least partially occlude the target treatment site and to collect fragmented lesion portions.

In some examples, the medical device includes a protective device positioned along the elongated body proximal to the balloon, and the protective device is configured to at least partially occlude the target treatment site and to collect fragmented lesion portions.

In some examples, the elongated body defines a lumen configured to receive a 0.0104" to 0.035" guidewire. In some examples, the medical device includes a handle positioned at a proximal end of the elongated body, wherein the handle includes an integral power supply for the emitter array. In some examples, the medical device includes a scoring member configured to contact and abrade the calcified lesion. In some examples, the scoring member defines a serrated exterior surface.

In some examples, the medical device includes means for controlling a primary direction of emission of the pressure waves. In some examples, the medical device includes a wave director positioned against an interior surface of the balloon and along only a portion of a circumference of the balloon, the wave director configured to absorb or reflect the pressure waves from the second portion of the circumference of the balloon. In some examples, the medical device includes a ceramic, porcelain, diamond, polyimide, or polyether ether ketone (PEEK). In some examples, the wave director defines a reflective-fluid pocket or an absorbent-fluid pocket.

In some examples, the medical device includes a radiopaque indicator positioned along the first portion of the circumference of the balloon, and the radiopaque indicator is configured to indicate an emitted direction of the pressure waves. In some examples, the radiopaque indicator includes a radiopaque wire positioned along the exterior surface of the balloon. In some examples, the radiopaque indicator includes a conductive wire of a fracturing element positioned along an exterior surface of the balloon, and the fracturing element further includes a plurality of piezoelectric elements configured to emit additional pressure waves through the calcified lesion.

In some examples, each of the one or more shockwave emitters defines a respective orientation, and the medical device further includes a user-input mechanism to modify the respective orientations of the one or more shockwave emitters. In some examples, each of the one or more shockwave emitters defines a respective fixed orientation, and the medical device further includes a user-input mechanism configured to independently actuate a first subset of the one or more shockwave emitters independently from a second subset of the one or more

shockwave emitters. In some examples, the balloon includes two or more elongated sub-balloons oriented circumferentially around the central longitudinal axis, each sub-balloon including a respective subset of the one or more shockwave emitters.

In some examples, the system further includes a sensor configured to generate sensor data indicative of at least one parameter. In some such examples, the energy generator is configured to vary an amount of energy delivered based on the sensor data. In some examples, to vary the amount of energy, the energy generator is configured to vary a current level, a voltage level, a pulse duration, a pulse frequency, or a light intensity. In some examples, the sensor data includes fluid-pressure data, fluid-rate data, or temperature data. In some examples, the sensor includes an electrical-impedance monitor, an inflation-fluid flow-rate monitor, an inflation-fluid pressure monitor, a vessel-wall surface monitor, a vessel-diameter monitor, an interventional-balloon diameter monitor, or a plaque-fragmentation monitor. In some examples, the sensor includes a resonant-frequency sensor, and the energy monitor is configured to vary a pressure-wave frequency to approximate a resonant frequency of the calcified lesion. In some examples, the energy generator is configured to terminate an applied voltage based on the sensor data.

BRIEF DESCRIPTION OF THE DRAWINGS

Features, aspects, and advantages are described below with reference to the drawings, which are intended to illustrate, but not to limit, the invention. In the drawings, like reference characters denote corresponding features consistently throughout similar examples.

FIG. 1 is a conceptual diagram of an example intravascular lithotripsy (IVL) system, including an energy generator and a catheter having a pressure-wave-emitter array within an interventional balloon.

FIG. 2 is a conceptual block diagram illustrating some example components of the energy generator of FIG. 1.

FIG. 3 is a conceptual diagram illustrating some example components of the catheter of FIG. 1.

FIG. 4A is a perspective view of a first example emitter assembly of the catheter of FIG. 1.

FIG. 4B is a cross-sectional diagram of the emitter assembly of FIG. 4A.

FIG. 5A is a perspective view of a second example emitter assembly of the catheter of FIG. 1.

FIG. 5B is a cross-sectional diagram of the emitter assembly of FIG. 5A.

FIG. 6A illustrates a third example emitter assembly of the catheter of FIG. 1.

FIG. 6B is a cross-sectional diagram of the emitter assembly of FIG. 6A.

FIG. 6C is a cross-sectional diagram of the emitter assembly of FIG. 6A with a potting-material layer removed to illustrate the components embedded therein.

FIG. 7A is a 2-D representation of a first example design for a laser-cut hypotube of an emitter assembly, defining a non-orthogonal spark-gap orientation.

FIG. 7B is a 3-D representation of the first example hypotube design of FIG. 7A.

FIG. 8A is a 2-D representation of a second example design for a laser-cut hypotube of an emitter assembly, defining an orthogonal spark-gap orientation.

FIG. 8B is a 2-D representation of a laser-cut hypotube array that includes the second example hypotube design of FIG. 8A.

FIG. 9 is a 2-D representation of a third example design for a laser-cut hypotube of an emitter assembly, defining a circular spark-gap configuration.

FIG. 10 is a flowchart illustrating an example technique for forming an emitter assembly for an IVL catheter.

FIGS. 11A and 11B illustrate an example flex circuit for an emitter assembly of an IVL catheter.

FIGS. 12A and 12B illustrate two example wiring configurations for the flex circuit of FIGS. 11A and 11B.

FIGS. 13A and 13B illustrate two example wiring configurations for conductively wiring an electronic pressure-wave-emitter array.

FIGS. 14A–14D are conceptual cross-sectional drawings illustrating four example wiring configurations for an electronic emitter array of the catheter of FIG. 1.

FIG. 15A is a conceptual diagram illustrating an example wiring configuration for an electronic-emitter array having four emitter units.

FIG. 15B is a conceptual diagram illustrating an example wiring configuration for an electronic-emitter array having five emitter units.

FIG. 16A is a conceptual diagram illustrating a first example wiring configuration.

FIG. 16B is a conceptual diagram illustrating a second example wiring configuration.

FIG. 17A is a conceptual diagram illustrating an example IVL device having an optical-based emitter array.

FIG. 17B is a cross-sectional view through the IVL device of FIG. 17A.

FIG. 18 is a cross-sectional diagram of an example IVL device having a multiple-layered interventional balloon.

FIGS. 19 and 20 illustrate two example IVL devices having interventional balloons with protective structures.

FIG. 21 illustrates an example IVL device having a pair of scoring members.

FIG. 22 illustrates an example IVL device having a fracturing element.

FIG. 23 illustrates an example IVL device having a spring mechanism.

FIG. 24 illustrates an example IVL device having a distal protective member.

FIG. 25 illustrates the IVL system of FIG. 1 with an example closed-loop energy-delivery feedback mechanism.

FIG. 26 illustrates an example handle for the IVL catheter of FIG. 1.

FIG. 27 is a cross-sectional view through a first example directionally focused IVL device.

FIG. 28A is a perspective view, and FIG. 28B is a cross-sectional view of a second example directionally focused IVL device.

FIG. 29A is a perspective view, and FIG. 29B is a cross-sectional view of a third example directionally focused IVL device.

DETAILED DESCRIPTION

Although specific examples are disclosed below, inventive subject matter extends beyond the specifically disclosed examples to other alternative examples and/or uses and to modifications and equivalents thereof. Thus, the scope of the claims appended hereto is not limited by any of the particular examples described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain examples; however, the order of description should not be construed to imply that these operations are order-dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components.

For purposes of comparing various examples, certain aspects and advantages of these examples are described. Not necessarily all such aspects or advantages are achieved by any particular example. Thus, for example, various examples may be carried out in a manner that

achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.

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During an intravascular lithotripsy (IVL) procedure, and more specifically, during an electrohydraulic lithotripsy (EHL) procedure, a clinician uses high-energy pressure waves to break apart calcified-plaque lesions within a patient's vasculature. Typical IVL systems suffer from a number of disadvantages that limit the efficacy of the treatment. For instance, IVL catheters typically emit pressure waves that propagate around the entire inner circumference of the vessel wall at a target treatment site. In instances in which the calcified lesion is limited to only a portion of the vessel-wall circumference, for example, eccentric, focal, and/or nodular-shaped lesions, pressure waves that propagate in all directions can present less-effective disintegration or a waste of applied energy. As a second example, in addition to directional limitations, typical IVL catheters are designed to deliver a fixed level of energy and/or power, regardless of the particular clinical need (e.g., lesion size and/or density) at the target treatment site, presenting a similar set of difficulties and/or effectiveness limitations.

As a third example, many IVL-catheter designs include a distal interventional balloon for distributing the pressure waves across the surrounding tissue. In some cases, these interventional balloons may rupture in response to an above-threshold wave pressure or when treating heavily calcified lesions. If the balloon tears around its entire circumference, the distal

portion of the balloon may "bunch up" around the distal catheter tip, causing a more difficult and/or more complex withdrawal from the patient, e.g., by removing an outer sheath or other introducer in order to remove the balloon catheter. As a final example, certain features of typical interventional balloons can increase resistance against inserting the catheter into the introducer sheath at the beginning of the procedure, and/or withdrawing the catheter through the introducer sheath at the end of the procedure. For instance, bulky balloon "cones" and ineffective re-wrapping of balloon "pleats" can require the clinician to apply additional undue force to successfully perform the IVL procedure.

The present disclosure describes systems and techniques for producing and directing high-energy intravascular pressure waves for fragmentation and/or disintegration of calcified lesions within a vasculature of a patient. For illustration purposes, the techniques herein are described primarily with respect to electrical-based systems and respective applications thereof, such as peripheral-vessel applications. However, it is to be understood that the techniques described herein may be assumed to be likewise applicable to similar systems based on other forms of energy, such as optical (e.g., laser) based systems and respective applications, such as coronary-treatment applications, except where explicitly noted below.

In general, the systems described herein include an energy source and an IVL catheter having a distal IVL device, including an interventional balloon and a pressure-wave-emitter array. During a lesion-disintegration procedure, a clinician may advance the interventional balloon to a target treatment site within a patient's vasculature and inflate the balloon with an inflation fluid, such as a saline/contrast-fluid mixture, until the balloon contacts at least a portion of the local vessel wall. The clinician may then actuate the energy generator, causing the catheter to generate a cavitation bubble within the fluid-filled balloon, propagating a high-energy pressure wave through the balloon and the calcified lesion. A secondary pressure wave can also result from the subsequent collapse of the fluid cavitation, further destabilizing the internal structure of the lesion.

FIG. 1 is a conceptual diagram illustrating an example IVL system 100. As shown in FIG. 1, IVL system 100 includes at least an energy generator 102 and an IVL catheter 104 removably coupled to energy generator 102, such as via a catheter-connector interface 204. In some examples, a removable cable 118 may be connected between generator 102 and catheter 104 to provide energy to catheter 104. As detailed further below, an energy source (e.g., a battery, capacitor, etc.) may additionally or alternatively be integrated into catheter 104. Catheter 102 includes an elongated body 106 and an IVL device 108 positioned at a distal

portion of elongated body 106. Elongated body 106 is configured to navigate a tortuous vasculature of a patient toward a target treatment site, e.g., a calcified-plaque lesion within a vessel.

As shown in FIG. 1, IVL device 108 includes a fluid-inflatable interventional balloon 110 and a pressure-wave-emitter array 112 positioned within balloon 110. Emitter array 112 includes one or more individual emitter units 114A–114E. For instance, interventional balloon 110, or a distal portion of elongated body 106 passing therethrough, may define a central longitudinal axis 116, and emitter units 114A–114E may be distributed longitudinally along central longitudinal axis 116. It is to be noted that individual emitter units 114A–114E are also referred to throughout this disclosure as "emitters" (e.g., in reference to an emitter unit as a whole), as well as "emitter assemblies" (e.g., in reference to a particular arrangement of sub-components collectively forming the emitter unit).

In particular, the example emitter array 112 shown in FIG. 1 includes a first emitter unit 114A, a second emitter unit 114B, a third emitter unit 114C, a fourth emitter unit 114D, and a fifth emitter unit 114E. While five emitter units 114 are illustrated in FIG. 1, emitter array 112 of IVL device 108 may include as few as one individual emitter unit and up to as many emitter units as could reasonably fit within balloon 110. Each emitter unit 114 is configured to receive energy from energy generator 102 and use the received energy to generate and transmit high-energy pressure waves through balloon 110 and across the target treatment site. As detailed further below, energy generator 102 may generate and transmit energy in the form of electrical energy, optical energy, or a combination thereof. For instance, emitter units 114 may use the received energy to generate a cavitation within the fluid inside balloon 110, propagating one or more high-energy pressure waves radially outward through balloon 110 and the calcified lesion. In some cases, but not all cases, a secondary set of high-energy pressure waves can subsequently result from the collapse of the fluid cavitation, further destabilizing the internal structure of the calcified-plaque lesion. In some examples, one or more of emitters 114 can include an electrical-based emitter configured to receive electrical energy from generator 102, such as via one or more conductive wires, and generate a spark between a pair of electrodes, thereby triggering the initial cavitation. Additionally, or alternatively, one or more of emitters 114 can include an optical-based emitter configured to receive a high-energy optical (e.g., light) signal from generator 102, such as via one or more fiber-optic wires or tubes and direct the optical signal to trigger the initial cavitation.

FIG. 2 is a block diagram illustrating some example components of energy generator 102 of FIG. 1. A power input 202 (e.g., for conductively coupling to a wall port or another electricity source) connects to power module 224 and an internal power supply 208. As shown in FIG. 2, power module 224 can include, as various, non-limiting examples, a high-voltage DC-DC converter 210, a high-voltage capacitor and transistor switch 212, a voltage and/or current measurement unit 216, and a device identification unit 222, configured to determine whether catheter 104 is an authorized device while catheter 104 is connected via catheter connector 204. For instance, energy generator 102 may be configured to disable energy output to catheter connector 204 when an unidentified device is connected.

Generator 102 can include a memory and one or more processors, such as processor 218 and/or user-interface-control processor 226. UI control processor 226 is configured to provide functionality for the user interface 234 of energy generator 102, such as a display screen, touch screen, buttons, or other manual controls enabling a user (e.g., a clinician) to operate the energy generator 102.

Although not illustrated in FIG. 2, additionally or alternatively to electrical-energy-based components, in some examples, energy generator 102 includes an optical signal unit configured to convert electrical power (e.g., from power input 202) into a beam of light, such as a laser beam. The optical signal unit may then direct the optical signal into a carrying cable, such as an optical fiber, either coupled to catheter 104 (FIG. 1) or integrated as part of catheter 104.

FIG. 3 is a conceptual diagram showing some example components of catheter 104 of FIG. 1. As shown in FIG. 3, catheter 104 includes a proximal portion 302 and a distal portion 304 opposite the proximal portion. The proximal portion 302 may include a catheter hub 306 and/or a handle (as detailed further below). Catheter hub 306 defines an access port 308, an inflation port 310, and a power port 312. Access port 308 enables the clinician to manipulate (e.g., maneuver, actuate, etc.) the distal portion 304, including IVL device 108. The clinician may use inflation port 310 to inject an inflation fluid, such as a saline/contrast-fluid solution to inflate interventional balloon 110 to an expanded or inflated state, in which an exterior surface of balloon 110 contacts an interior surface of the vessel wall at the target treatment site. Power port 312 is configured to interconnect with a power cable (not shown) to conductively couple catheter 104 to energy generator 102 (FIGS. 1 and 2). Catheter hub 306 may also include a strain relief portion 314 to reinforce elongated body 106 and reduce kinking.

As shown in FIG. 3, in some examples, but not all examples, elongated body 106 may include an outer elongated structure 316 and an inner elongated structure 318. For instance, outer elongated structure 316 may include a sheath or outer catheter defining an inflation lumen 320. In some examples, outer elongated structure 316 forms a proximal extension of interventional balloon 110, such that inflation lumen 320 fluidically couples inflation port 310 to the interior cavity of interventional balloon 110.

Inner elongated structure 318 may include an inner catheter or other inner structure, positioned within inflation lumen 320, configured to retain emitters 114 of emitter array 112. In some such examples, inner elongated structure 318 may itself define an inner lumen 322, e.g., configured to receive a guidewire via distal port 324. In other examples, such as depicted in subsequent figures, elongated body 106 includes just a single layer defining a single inner lumen.

As described above, catheter 104 is configured to advance through a patient's vasculature (e.g., through an arteriotomy) to position the balloon 110 adjacent to a calcium lesion located at a target treatment site. IVL device 108 may be configured to cause a first pressure-wave (or group of waves) by expanding a volume of liquid resulting from a phase change from a liquid into a liquid-vapor, which may cause a bubble to rapidly expand. A second pressure wave may occur as the bubble subsequently collapses. In some examples, the balloon 110 has an exterior coating 326, e.g., made from a polymer and/or other materials, as detailed further below. For instance, exterior coating 326 may include a hydrophilic coating to improve navigability through the patient's vasculature. Additionally, or alternatively, exterior coating 326 may include a drug coating, such as an anti-thrombogenic drug or an anti-proliferative medication, as well as an excipient to aid in drug transfer. As detailed further below, balloon 110 may be or be porous/semi-permeable (e.g., a "weeping" balloon) for the infusion of drugs into the vessel, as compared to being injected into the vessel through a lumen.

FIG. 4A is a perspective view of a first example emitter assembly 400 (e.g., emitter assembly 114A of FIG. 1) of catheter 104 of FIG. 1, and FIG. 4B is a cross-sectional diagram of emitter 400 of FIG. 4A. In particular, FIGS. 4A and 4B illustrate an electronic emitter 400, including a pair of conductive electrodes 402A, 402B defining a first spark gap 404A therebetween. In such examples, electrodes 402A, 402B are configured to receive electrical energy (e.g., an electric current) from energy generator 102 (FIGS. 1 and 2) via conductive wires 406A, 406B. The resulting spark across spark gap 404 is configured to cavitate the

surrounding inflation fluid 408 to propagate high-energy pressure waves through inflation fluid 408.

In accordance with techniques of this disclosure, one or both electrodes 402A, 402B are subsections or portions of a cylindrical surface of a common hypotube 410. As used herein, a "hypotube" refers to a metallic tube with micro-engineered features along its length.

That is, particular sections of a cylindrical hypotube 410 may be removed (e.g., laser-cut) so as to form one or both electrodes 402A, 402B, and the spark gap 404A therebetween. In some such examples, a potting material 412, such as an adhesive layer, may be flowed overtop of the remaining portions of the cylindrical hypotube (e.g., electrodes 402A, 402B) and then either hardened, or allowed to harden, to retain the hypotube portions in place. Some examples of potting materials 412 include a polyurethane base, an acrylic base, a silicone base, or any other suitable material with sufficient dielectric strength. In some examples, but not all examples, excess potting material 412 may be subsequently removed (e.g., scored, ablated, or milled-out) from between electrodes 402A, 402B to re-establish spark gap 404A, as necessary.

As illustrated further in FIG. 4B, hypotube 410 of emitter assembly 400 includes two pairs of conductive electrodes and respective spark gaps therebetween - first pair of electrodes 402A, 402B (with spark gap 404A therebetween), and second pair of electrodes 402B, 402C (with spark gap 404B therebetween). That is, electrode 402B may be used as a common electrode for both of electrodes 402A, 402C, aligned relative to opposite edges of electrode 402B. Put explicitly, first edge 414A of first electrode 402A is aligned relative to second edge 414B of second electrode 402B to define first spark gap 404A. Additionally, third edge 414C of second electrode 402B is aligned relative to fourth edge 414D of third electrode 402C to define second spark gap 404B. In some examples, the two pairs of conductive electrodes may be wired to be simultaneously actuatable, or in other examples, may be wired to be separately actuatable, as detailed further below. Such wiring configurations enable the clinician to choose which emitter assemblies, or even particular electrode pairs, to activate for treatment of the calcified-plaque lesion. While a two-electrode-pair system is primarily shown and described herein, it should be noted that greater numbers of electrode pairs may also be incorporated into emitter assembly 400.

In some examples, hypotube 410 may similarly define a three-electrode system, but rather than defining two emitter-electrode pairs, the three electrodes may consist of a working electrode, a counter electrode, and a reference electrode. For instance, while the working electrode and the counter electrode are configured to create the pressure-wave, the reference

electrode's role is to act as a reference in measuring and controlling the working-electrode potential without passing any current itself.

As further illustrated in FIG. 4B, electronic emitter assembly 400 includes a plurality of nested layers (e.g., to define elongated body 106 therein). For instance, within hypotube 410 and potting material 412, emitter assembly 400 includes an elastomeric layer 416, such as a thermoplastic elastomer. One such example includes polyether block amide (e.g., PEBAX® from Arkema S.A. of Colombes, France). In some examples, but not all examples, within elastomeric layer 416, emitter assembly 400 may include coils 418, e.g., coiled turns of conductive wires 408, or coils of a spring associated with interventional balloon 110 (FIG. 1), as detailed further below with respect to FIG. 23. Finally, the most internal layer of emitter assembly 400 is a secondary polymer layer 420, such as polyimide. Polymer layer 420 may be tubular-shaped, defining a portion of guidewire lumen 322 therein.

According to some examples, emitter assembly 400 is configured to implement a relatively high, redundant voltage. Accordingly, composing materials should be selected for low degradation, such that the IVL device 108 lasts the duration of the IVL treatment. In some examples, catheter 104 is configured to be single-use-only, while energy generator 102 is considered to be theoretically infinitely reusable. In some examples, the number of pressure-wave "cycles" of an IVL treatment may range from about 80 wave pulses to about 300 wave pulses, but treatments may include more or fewer wave pulses, depending on the unique clinical parameters presented.

In some examples, the electrode pairs 402A/402B and 402B/402C may be made of narrow copper strips that are fixated on inner elongated structure 318 inside of interventional balloon 110 (FIGS. 1, 3). In some examples, but not all examples, each electrode 402 may be cut, bent, or otherwise formed to define an angle relative to central longitudinal axis 116. That is, electrodes 402 may be configured to "tilt" away from central longitudinal axis 116 in the absence of outside forces. During delivery through the patient's vasculature, a radially inward compressive force from the deflated balloon 110 may cause the electrodes to "flatten" toward the central longitudinal axis 116.

FIG. 5A is a perspective view of a second example electronic emitter assembly 500 of the catheter 104 of FIG. 1, and FIG. 5B is a cross-sectional diagram of the emitter assembly 500 of FIG. 5A. Specifically, the example emitter assembly 500 of FIGS. 5A and 5B includes two laser-cut "emitter" electrodes 502A, 502C welded to a laser-cut polyimide "coupler" layer

504. In this example, emitter electrodes 502A, 502C are shown to be generally oval-shaped, but other geometric shapes are contemplated.

A laser-cut "hypotube" electrode 502B is also attached to the coupler layer 504 in between emitter electrodes 502A, 502C, so as to define respective spark gaps 508A, 508B. In this example, hypotube-electrode 502B is shown to be generally semi-cylindrical-shaped, but other geometric shapes are contemplated. A series of flat wires 406A–406D may be utilized to deliver energy from the energy generator 102 (FIGS. 1 and 2) to the emitter electrodes 502A and 502C; from the emitter electrodes 502A, 502C to additional emitter units 114 (FIG. 1) within the IVL device 108; and from the additional emitter units 114 back to ground voltage.

As shown in FIGS. 5A and 5B, in this example, a polyimide inner elongated structure 506 extends distally through the core of the emitter assembly 500, as seen on the outside of the assembly in FIG. 5A, or at the innermost circle in FIG. 5B. The portion of the outermost concentric ring above central longitudinal axis 116 is a laser-cut-hypotube electrode 502B that passes energy to the opposing-side mirrored "emitter" electrodes 502A, 502C. The portion of the outermost concentric ring below central longitudinal axis 116 is another emitter electrode 502C welded to the wire 406D. The rectangular extensions about the longitudinal axis 116 that carry on away from the emitter assembly on both sides are additional flat wires 406 that lead to and away from the emitters to carry energy for producing the pressure waves and then leading the voltage back to ground. The outer portion of the emitter assembly 500 as seen in FIG. 5A, or the middle core as seen in FIG. 5B, is the first spark gap 508A at which the current from the emitter electrode 502A "jumps" to the hypotube electrode 502B.

In some examples, but not all examples, a reflective surface or coating may be applied to the surface within the spark gaps 508, in order to reflect the emitted pressure waves radially outward toward the interventional balloon 110 (FIG. 1). The reflective surface or coating may be, for instance, an acoustically opaque and non-conductive (e.g., insulative) material, such as a ceramic, porcelain, diamond, polyimide, polyether ether ketone (PEEK), another similar material, or any suitable combination thereof.

The penultimate core that lies just beneath both the laser-cut hypotube 502B and the emitter electrode 502A in FIG. 5A, and which can be seen wrapped around the middle core in FIG. 5B, is a coupler or insulating material 504 that creates space between the inner lumen and the emitter electrode 502A.

FIG. 6A illustrates a third example electronic emitter assembly 600 of catheter 104 of FIG. 1, FIG. 6B is a cross-sectional diagram of emitter assembly 600, and FIG. 6C is a cross-

sectional diagram of emitter assembly 600 with potting material 412 removed to illustrate the components embedded therein. In particular, emitter assembly 600 includes two laser-cut "emitter" electrodes 602A, 602C positioned opposite a hypotube electrode 602B. As shown in FIG. 6C, in some examples, but not all examples, emitter electrodes 602A, 602C are configured to breach the exterior surface of inner elongated structure 506, e.g., to help retain the emitter electrodes 602A, 602B in place. In some such examples, emitter electrodes 602A, 602B extend radially inward through the entire wall of inner elongated structure 506 and extend partially radially inward into guidewire lumen 322. Emitter electrodes 602A, 602B may additionally be potted in place, e.g., embedded within potting material 412.

The third example emitter assembly 600 shown in FIGS. 6A, 6B, and 6C shares similarities with the second example emitter assembly 500 shown in FIGS. 5A and 5B, except for the differences noted herein. For instance, in both examples, a polyimide inner elongated structure 506 extends distally through the core of the emitter assembly, as seen on the outside of the assembly 600 in FIG. 6A, or at the radially innermost circle in FIGS. 6B and 6C.

The portion of the outermost concentric ring above central longitudinal axis 116 is a laser-cut hypotube electrode 602B that passes energy to the opposing-side emitter electrodes 602A, 602C. As described above, below the central longitudinal axis 116 in FIG. 6C are two emitter electrodes 602A, 602C that extend radially inward through both the outer surface and the inner surface of elongated structure 506. As shown particularly in FIG. 6C, a plurality of flat wires 406 are distributed circumferentially around longitudinal axis 116 that lead toward and away from the emitter electrodes 602A, 602C to carry energy for producing the high-energy pressure waves, and then leading proximally back to ground voltage. In FIG. 6B, these flat wires 406 are represented as dashed lines embedded within potting material 412, and as solid components in FIG. 6C, as the potting material 412 has been removed to facilitate visualization of the flat wires 406 in this space.

In the example of FIGS. 6A and 6B, the spark gap 608A (e.g., the site at which the electric current from the emitter electrode 602A "jumps" to the hypotube electrode 602B, is shown to be substantially filled with potting material 412. In other examples, the section of potting material 412 within spark gap 608A may be milled out or otherwise removed. The potting material 412, shown just beneath both the laser-cut hypotube 602B and the emitter 602A in FIG. 6A, and wrapped around inner elongated structure 506, can include any suitable adhesive or potting material, such as an ultraviolet adhesive, an epoxy, or a reflowing polymer.

In some examples, a pressure-reflective material may be appended within and/or around spark gap 608A, the reflective material configured to redirect the radially inward pressure waves to travel radially outward toward interventional balloon 110 (FIGS. 1, 3).

FIGS. 7A–9 illustrate three example electrode-design configurations for a laser-cut hypotube 410 (FIG. 4B) defining two or more conductive electrodes for an electronic emitter assembly 400 (FIG. 4). These hypotube designs may be cut (e.g., laser-cut) from a common 2-D surface. In some examples, the electrode designs may be cut from a planar 2-D surface, which may subsequently be formed into a cylindrical hypotube. In other examples, the electrode designs may be cut directly from a cylindrical hypotube.

Example materials that may be used to cut the conductive electrodes from the common planar surface or cylindrical hypotube include 304 SST, titanium, cobalt chromium, 316SST, or a nickel-titanium alloy (e.g., Nitinol), though other options are suitable, as long as they have low degradation, low resistivity, ductility, and are machinable through use of a laser. Additionally, the electrodes may be cut directly out of stents, so a flat sheet of material is not strictly necessary. In some examples, all emitters 114 of emitter array 112 (FIG. 1) may be cut from a single continuous hypotube. This has the advantage of removing the need to weld individual emitters 114 to wires, thus facilitating the manufacturing process.

FIG. 7A is a 2-D representation of a first example design for a laser-cut hypotube 700 of an electronic emitter assembly 400 (FIG. 4), and FIG. 7B is a 3-D representation of the first example hypotube 400 of FIG. 7A. For instance, FIG. 7B illustrates what hypotube 400 of FIG. 7A would look like when rolled into its final tubular form. As one non-limiting, illustrative example, in the tubular form shown in FIG. 7B, cylindrical hypotube 700 may define an inner diameter of about 0.025 to about 0.035 (e.g., about 0.03 inches), and an outer diameter of about 0.03 inches to about 0.04 inches (e.g., about 0.035 inches).

The hypotube design 700 shown in FIGS. 7A and 7B largely corresponds to the hypotube design 410 shown in FIG. 4. For instance, hypotube 700 defines first electrode pair 402A/402B with spark gap 404A therebetween, and second electrode pair 402B/402C with spark gap 404B therebetween. FIGS. 7A and 7B. illustrate a generally non-orthogonal hypotube design, in which electrodes 402 are irregularly shaped, such that spark gaps 404A, 404B are not oriented parallel to central longitudinal axis 116. In particular, as shown in FIG. 7A, electrodes 402A and 402C are generally shaped as rounded triangles (e.g., three-sided shapes with rounded corners), and electrode 402B is generally shaped as a parallelogram.

However, other configurations are contemplated, such as all three electrodes 402A–402C being shaped as parallelograms.

The relative angle between spark gaps 404A, 404B and central longitudinal axis 116 may be varied across different emitters 114 (FIG. 1) to provide differing directions of propagation of the emitted pressure waves. In some such examples, the clinician may independently actuate different emitters to control this aspect of the IVL treatment.

FIG. 8A is a 2-D representation of a second example design 800 for a laser-cut hypotube of an electronic emitter assembly 400 (FIG. 4). As compared to the hypotube 410 shown in FIGS. 7A and 7B, hypotube design 800 includes a more-orthogonal design, in which spark gaps 804A, 804B are oriented parallel to central longitudinal axis 116. For instance, electrodes 802A–802C are more-regularly shaped, such as substantially rectangular, such that spark gaps 804A, 804B are substantially parallel to longitudinal axis 116.

For purposes of illustration, some non-limiting examples of various dimensions of hypotube 800 are shown in FIG. 8. For instance, hypotube 800 (while in the flat configuration shown in FIG. 8) may define a rectangle having a circumferential length 810A of about 0.1 inch. The rectangular width 810B (e.g., the longitudinal length of hypotube 800 along longitudinal axis 116) can range from about 0.080 inches to about 0.090 inches.

Each of electrodes 802A, 802B, 802C may include emitting edges 414 (FIG. 4), e.g., defining spark gaps 804A, 804B therebetween, having lengths 810C of about 0.040 inches to about 0.055 inches. The resulting spark gaps, then, may define gap widths from about 0.0025 inches to about 0.0040 inches. Hypotube 800A may further include a plurality of support structures 806 configured to at least temporarily retain the primary structures (e.g., electrodes 802) in place during fabrication of the emitter assembly 114. These support structures 806 may be subsequently removed, e.g., after electrodes 802 are suspended in place via potting material 412 (FIG. 4). Support structures 806 may define widths 810E of about 0.0020 inches.

FIG. 8B is a 2-D representation of a hypotube-array design 812 that includes multiple instances 800A–800D of the second hypotube design 800 of FIG. 8A. As referenced above, in some examples, two or more emitter units 114 (FIG. 1) of an emitter array 112 may be cut from a single continuous hypotube, or alternatively, cut from a common planar surface and then formed into a cylindrical hypotube. This technique removes the need to weld individual emitters 114 to wires, thus facilitating the manufacturing process. That is, in place of conductively coupled wires 406 (FIG. 4), individual hypotubes 800A–800D may be conductively coupled via conductive-coupling supports 814 that are cut from the same

substrate as the emitters. The example design 812 shown in FIG. 8B also includes a plurality of removable supports 816. Removable supports 816 may initially be cut into the common substrate with hypotubes 800A–800D and coupling supports 814 to help retain these components in place during fabrication, and then subsequently removed after hypotube array 812 is assembled into functioning emitter units.

FIG. 9 is a 2-D representation of a third example design 900 for a laser-cut hypotube 410 of an electronic emitter assembly 400 (FIG. 4). Similar to hypotube design 800 (FIG. 8), hypotube design 900 (while in the planar configuration shown in FIG. 9) may define a rectangle having a circumferential length 910A of about 0.1 inch. The rectangular width 910B (e.g., the longitudinal length of hypotube 900 along longitudinal axis 116) can range from about 0.080 inches to about 0.090 inches.

As compared to hypotube designs 700 (FIGS. 7A and 7B) and 800 (FIGS. 8A and 8B), both of which define generally linear spark-gap configurations, electrodes 902A–902D of hypotube design 900 are shaped and oriented so as to define substantially rounded or circular spark gaps 904A–904D. For instance, hypotube design 900 may include two substantially ring-like electrodes 902A, 902C, each defining an outer radius of about 0.0210 inches and an inner radius of about 0.013 inches. In the center of ring electrodes 902A, 902C are disc electrodes 902B, 902D, respectively. Disc electrodes 902B, 902D may define outer radii of about 0.0090 inches. Accordingly, electrode pairs 902A/902B and 902C/902D may define respective ring-shaped, or semi-ring-shaped spark gaps 904 therebetween, having a gap width of about 0.0040 inches. Similar to hypotube 800 (FIG. 8), hypotube 900 may initially include one or more vertical support structures 906, which may be removed once electrodes 902 are adhered in place. Support structures 906 may define widths 910C of about 0.0030 inches, for example.

FIG. 10 is a flowchart 1000 illustrating an example technique for forming an electronic emitter assembly for an IVL catheter, for instance, the emitter assembly 400 shown in FIG. 4A. The technique of FIG. 10 includes cutting a hypotube according to an electrode design, e.g., one of designs 700–900 of FIGS. 7A–9, respectively, so as to define one or more pairs of conductive electrodes aligned so as to define a respective spark gap therebetween (1002). The technique further includes inserting an elongated structure, such as inner elongated structure 318 of FIG. 4A, into the lumen of the cut hypotube (1004).

In some examples, but not all examples, additional layers may be inserted between hypotube 410 and the inner elongated structure 318 to help provide structural support, improve thermal conductance or increase energy efficiency, as illustrated in FIG. 4B. For instance, a

pressure-reflective material, a thermoplastic elastomer 416, wire coils 418, or a polyimide layer 420 may be inserted, if not already present (1006). The technique of FIG. 10 further includes flowing a potting material 412 around the assembled components and causing or allowing the potting-material layer 412 to solidify so as to retain the assembled components in place relative to one another (1108).

In some examples, but not all examples, the technique of FIG. 10 includes removing a portion of the potting material 412 from between the conductive electrodes of the hypotube, so as to re-establish the spark gap(s) (1010). For instance, step 1010 may include milling out the potting material between electrodes or removing the potting material via laser ablation, variable-speed-rotary-tool removal, or other machine removal. In other examples, prior to flowing the potting layer (1008), the technique of FIG. 10 may further include filling the spark gap(s) with an easily removable material to block the potting material, and then subsequently removing the material. In other examples, the hypotube may be over-molded onto an existing potting layer, such that the spark gap is not filled-in in the first place.

In some examples, the technique of FIG. 10 further includes removing obsolete structural components from hypotube 410. For instance, as shown in FIG. 8A, temporary support structures 806 may be removed from between electrodes 802 once the electrodes 802 are secured in place.

FIGS. 11A and 11B illustrate an example flex circuit 1100 for an electronic emitter assembly 400 (FIG. 4) of an IVL catheter 104 (FIG. 1). For instance, conductive electrodes (e.g., copper strips) 1102A–1102C may be printed onto a flexible, planar substrate 1106 so as to define respective spark gaps 1104 therebetween. The flexible substrate 1106 may then be rolled into the tubular shape shown in FIG. 11B, and then wired to the rest of emitter assembly 400 (FIG. 4). Such techniques may significantly reduce the manufacturing time of an IVL catheter 104 including such circuits 1100.

For purposes of illustration, FIG. 11 includes some non-limiting example dimensions of flex circuit 1100. For instance, flex circuit 1100 may include a circumferential length 1110A of about 0.082 inches, and an axial length 1110B (e.g., parallel to longitudinal axis 116) of about 0.080 inches. The planar substrate may further define a primary rectangular body 1108 and two axial prongs 1112A, 1112B. Primary rectangular body 1108 may have dimensions of a circumferential length 1110A of about 0.082 inches by an axial length 1110C of about 0.060 inches. Axial prongs 1112 may similarly be substantially rectangular, defining circumferential

widths 1110D of about 0.012 inches by axial lengths 1110E of about 0.020 inches. Axial prongs 1112A, 1112B may be circumferentially separated by a gap 1110F of about 0.046 inches.

FIGS. 12A and 12B illustrate two example wiring configurations 1200A, 1200B, respectively, for an emitter array 112 (FIG. 1) of an IVL device 108 including two flex circuits 1100A, 1100B (e.g., flex circuit 1100 of FIGS. 11A and 11B). In particular, FIG. 12A shows an example wiring configuration 1200A in which the flex circuits 1102A, 1102B are wired in parallel. The top conductive wire 1202 (solid line) leads to a voltage input, and the bottom conductive wire 1204 (dashed line) leads to ground voltage.

FIG. 12B shows another example wiring configuration 1200B in which the flex circuits 1102A, 1102B are wired so as to be independently actuatable. For instance, the top conductive wire 1206 provides a connection between a voltage input and flex circuit 1102B, and the middle conductive wire 1208 (solid lines) provides a connection between the voltage input and flex circuit 1102A. The bottom conductive wire 1210 provides a common connection to ground voltage for both of flex circuits 1102.

FIGS. 13A and 13B illustrate two example wiring configurations 1300A, 1300B, respectively for conductively wiring an electronic emitter array 400 (FIG. 4). In the example 1300A shown in FIG. 13A, elongated body includes an inner elongated structure 1302 (e.g., polyimide inner layer 420 of FIG. 4), and an outer elongated structure 1304 having two nested layers: an inner layer 1306 and an outer layer 1308. A plurality of conductive wires 406, such as "flat" or "rectangular" wires, coil axially along an exterior surface of the inner layer 1306 of outer elongated structure 1304. The outer layer 1308 of outer elongated structure 1304, such as a heat-shrink tube, thermoplastic tube, or potting material 412 (FIG. 4) may then be reflowed overtop of the conductive wires 406, such that the conductive wires 406 are embedded in the outer layer 1308 of outer elongated structure 1304.

In some examples, outer layer 1308 of outer elongated structure 1304 may terminate a predetermined distance 1310 proximally from the distal end 1312 of inner layer 1306, such that distal portion of conductive wires 406 are exposed and may be adjusted underneath the interventional balloon 110 (FIG. 1). Conductive wires 406 may include flat wires, round wires, or a combination thereof. For instance, in some examples, conductive wires 406 include round wires with "flattened" portions near the emitters 114.

In wiring configuration 1300A, the adhesive outer layer 1308 is "tacked" to the inner layer 1306 to reinforce the structure of interventional balloon 110 (FIG. 1). This may help

prevent the balloon 110 from "accordioning" during insertion or removal of the IVL device 108. The wires may also serve as a reinforcing member for the outer elongated structure 1304.

By comparison, FIG. 13B shows a different configuration 1300B, in which the conductive wires 406 are coiled directly around the inner elongated structure 1302. In some examples, the use of flat wires (e.g., round wires with flattened portions near the emitters) helps reduce the overall radial profile of the IVL device 108. In this configuration 1300B, conductive wires 406 could also serve as a reinforcing member for the inner elongated structure 1302 (e.g., coil layer 418 of FIG. 4B).

FIGS. 14A–14D are conceptual cross-sectional drawings illustrating four example wiring configurations 1400A–1400D, respectively, for an electronic emitter array 112 of catheter 104 of FIG. 1. In each of these four examples, conductive wires 406 run distally along an outer surface of inner elongated structure 318 but are not rigidly coupled to inner elongated structure 318.

In the first example wiring configuration 1400A of FIG. 14A, conductive wire(s) 406 extend generally linearly along the distal direction, e.g., along to central longitudinal axis 116. In this configuration, the emitters 1406 may be wired in series, or in other examples, a combination of parallel and serial wiring.

By comparison, in the second example wiring configuration 1400B of FIG. 14B, conductive wire(s) 406 coil helically around inner elongated structure 318 according to a "single wrap" configuration. In the single-wrap wiring configuration 1400B, two or more wires 406A, 406B are inter-coiled, with respective longitudinal spaces between adjacent coil turns. In these "coiled" configurations shown in FIGS. 14B, 14C, and 14D, the wire coils help provide structural support for inner elongated structure 318, e.g., by forming coil layer 418 of FIG. 4B. In some such examples, the emitter array may be wired according to an "n + 1" configuration, in which the number of conductive wires 406 is one more than the number of emitters 1406, such that each emitter has a unique voltage-supply wire, but all share a common ground wire.

In the third example wiring configuration 1400C of FIG. 14C, conductive wire(s) 406 coil helically around inner elongated structure 318 according to a "double wrap" configuration. In the double-wrap wiring configuration 1400C, wires 406 are inter-coiled as wire pairs, with longitudinal spaces between adjacent pairs of coil turns. Wire-jacket portions 1408 may be removed (e.g., ablated) as necessary for conductively coupling wires 406 to electrode hypotube 410 (FIG. 4).

In the fourth example wiring configuration 1400D of FIG. 14D, conductive wires 406 coil helically around inner elongated structure 318 according to a "quadruple wrap" configuration. In the quadruple-wrap wiring configuration 1400D, wires 406 are inter-coiled as groups of four wires, with longitudinal spaces between adjacent groups of four coil turns. Wire-jacket portions 1408 may be removed (e.g., ablated) as necessary for conductively coupling wires 406 to electrode hypotube 410 (FIG. 4). In other examples, wires may be grouped and coiled in numbers greater than four.

FIG. 15A is a conceptual diagram illustrating an example wiring configuration 1500A for an electronic emitter array 1502A having four emitter units 1504A–1504D, and FIG. 15B is a conceptual diagram illustrating an example wiring configuration 1500B for an electronic emitter array 1502B having five emitters 1504A–1504E. While only four-emitter and five-emitter assemblies 1502 are shown, it is to be understood that any suitable and practical number of emitter units 1504 may be implemented within IVL device 108. As referenced above, both wiring configurations 1500A, 1500B are examples of an "n + 1" configurations, in which the number of conductive wires is one more than the number of emitters 1504, such that each emitter 1504 has a unique voltage-supply wire, but all emitters 1504 share a common ground wire 1506. In such configurations, individual emitters 1504 are independently actuatable providing enhanced control over the IVL therapy for the clinician.

FIG. 16A is a conceptual diagram illustrating a first example wiring configuration 1600A for an electronic emitter array 1602 having four emitter units 1604A–1604D. FIG. 16A, like FIGS. 15A and 15B, shows the emitter units 1604 wired according to the "n + 1" configuration, and a configuration in which emitter assemblies 1604 wired in parallel. Some example benefits of a parallel wiring configuration 1600A include the ability to transmit a higher electrical current across the emitter units 1604. A parallel wiring configuration 1600A also enables each individual emitter unit 1604 to be actuated (or "fired") independently of the other emitter units. Additionally, with a parallel wiring configuration 1600A, the total resistance of the IVL system 100 (FIG. 1) may be reduced. For instance, by individually powering a single emitter unit 1604, a greater electrical current may be generated across the spark gap 404 (FIG. 4), thereby reducing the necessary number of resistors in the corresponding electrical circuit.

Configuration 1600A may also allow for a reduction in the overall voltage through the system, e.g., translating to a reduction in energy consumption. The ability to individually power each emitter 1604, and the ability to choose a sequence of order of firing of each emitter unit

1604, allows for greater overall control of the IVL device 108, including how and where the applied energy is directed, as detailed further below.

FIG. 16B is a conceptual diagram illustrating a second example wiring configuration 1600B for the electronic emitter array 1602 of FIG. 16A. In wiring configuration 1600B, a combination of both parallel and serial wiring techniques may be implemented, enabling advantages of both configurations. For instance, emitters 1604A and 1604B are connected in series, whereas other emitters 1604 are connected in parallel. In particular, wiring configuration 1600B enables the clinician to simultaneously acuate: (1) emitters 1604A–1604D (e.g., using wires 1606A and 1606C); (2) emitters 1604C and 1604D (e.g., using wires 1606B and 1606C); or (3) emitters 1604A and 1604B (e.g., using wires 1606A and 1606B). However, FIG. 16B is not intended to be limiting - any suitable wiring combination for emitters 1604 is contemplated and encompassed herein.

FIG. 17A is a conceptual diagram, and FIG. 17B is a cross-sectional view, illustrating an IVL device 1700 having an array (e.g., emitter array 112 of FIG. 1) of optical-based pressure-wave emitters 1702A–1702C. As used herein, optical-based emitters 1702 can include the distal ends or distal portions of respective optical fibers or tubes 1704A-1704C, which IVL device 108 of FIG. 1 may include in addition to, or alternatively to, one or more electronic emitter units, as described above.

According to some non-limiting examples, optical fibers 1704 may deliver, e.g., about 20-100 millijoules of energy within about one millisecond into the inflation fluid 408, such as water, a saline/contrast-fluid mixture, another fluid, or a combination thereof, within interventional balloon 110 in order to generate and propagate high-energy pressure waves. However, these values are merely illustrative, and the amounts of energy and/or time may be adjusted for a particular clinical application. In some examples, an emitted optical pulse width (e.g., emitted-light duration) may be 5 nanoseconds or more.

Based on varying clinical needs, IVL device 1700 may include any suitable number of optical fibers 1704. In some examples, IVL device 1700 is configured to transmit a laser signal having a wavelength from about 1064 nanometers (nm) to about 1460 nm, though shorter wavelengths may be similarly effective. Example diameters for optical fibers 1704 can range from about 50 microns or less to about 200 microns or greater, depending on the particular clinical application.

As shown in FIG. 17A, in some examples, the distal emitter portion 1702A of optical fiber 1704A may be oriented at a predetermined angle "θ" relative to central longitudinal axis

116. For instance, to protect inner elongated structure 318, distal emitter portion 1702A may be oriented at an angle θ of greater than 90 degrees, such as greater than about 114 degrees (e.g., greater than about 24 degrees from a vertical tangent. For optical fiber 1704A, only a distal-most surface or distal-most end of emitter portion 1702A is angled away from inner elongated structure 318. In other examples, such as the example of optical fiber 1704B, an entire distal portion 1702B may be bent or angled away from inner elongated structure 318. In some such examples, the optical fiber distal portion 1702B can diverge by an angle "φ" from about 0 degrees to about 24 degrees.

Optical emitters 1702 of optical fibers 1704 may be positioned either circumferentially around inner elongated structure 318 (e.g., as shown in FIG. 17B), or in other examples, longitudinally along inner elongated structure 318, or in still other examples, a combination thereof to emit and deliver high-energy pressure waves. For instance, optical fibers 1704 may be adjacent to inner elongated structure 318 (e.g., 1704A) for circumferential lesion treatments, or radially off-centered (e.g., 1704B) for non-circumferential lesion treatments. Some example benefits of using more than one optical fiber 1704 include reducing the overall cross-sectional profile of IVL device 1700 by positioning optical fibers 1704 around the proximal portion of the catheter elongated body 106 (FIG. 1). Additionally, a greater number of optical fibers 1704 allows for a more controlled pressure wave. In addition to directing the energy based on where the optical fibers 1704 are placed about the IVL catheter 104, the size of the cavitation bubble may be controlled based on a selected diameter (e.g., cross-sectional area) of optical fibers 1704. These optical fibers 1704 may be individually or simultaneously actuated based on the needs of the treatment, e.g., allowing for a single IVL device 108 that can treat both circumferential calcified lesions as well as nodular calcified lesions.

FIG. 18 is a cross-sectional diagram of an example IVL device 1800 (e.g., IVL device 108 of FIG. 1) with an interventional balloon 1810 (e.g., balloon 110 of FIG. 1) having a multiple-layered construction for enhanced durability. As shown, balloon 1810 may have an outer layer 1802 and an inner layer 1804, for the purposes of reinforcement. Either or both of reinforcing layers 1802, 1804 may include a separate extrusion that goes over the top of the balloon 1810, with another layer over the top of this pressure-holding layer.

The example shown in FIG. 18 represents just one of multiple solutions to the potential risk of balloon rupture. For instance, balloon 1810 may be formed from a single multi-layered extrusion, wherein a thin, more-compliant layer 1802 on the outside of the balloon is softer and less prone to tearing than an inner, high-pressure, non-compliant (or "less compliant") holding

layer 1804. For instance, one example structure could comprise a high-pressure inner holding layer 1804 that makes up, e.g., between 70% and 100% of the thickness of the balloon wall, such as Nylon-12, or Pebax-72D. The outside layer 1802 is made from a more-compliant substance such as urethane, Pebax, or any other suitable material with a medium-to-low durometer measurement, e.g., of about 63D or lower.

Another solution is to form the balloon from two separate extrusions 1802, 1804, e.g., a separate extrusion layer 1802 on the outside of the balloon placed upon the exterior surface of an inner non-compliant or semi-compliant balloon 1804. Another solution is to form the balloon 1810 from a thin polymer inner layer 1804 covered by reinforcing layers 1806 such as polymer fibers, like Aramid or UHMWPE, with a top coating 1802 for fiber encapsulation. The outer layer 1802 may be a plurality of reinforcing layers, for instance, a set of sixteen braided fibers, and four to eight (inclusive) longitudinal fibers, as one non-limiting example. Other variations of braid patterns are similarly viable, such as those including thirty-two fibers or forty-eight fibers. Additionally, the reinforcing fibers may be arranged in an orthogonal textile pattern, such as a mesh sheet cut into pieces, as opposed to (or in addition to) being braided directly onto the balloon 1810.

While not shown in FIG. 18, another solution against potential balloon rupture is to coat the balloon with an abrasion-resistant coating, such as exterior coating 326 of FIG. 3. This solution may be accomplished by applying the coating to the balloon 1800 through a dip, a spray, or a roll-cast. According to some examples, this coating may be or may include a polymer, such as urethane, parylene, silicone, or a thermoplastic polyurethane (TPU). These coatings may allow for a balloon 1810 that holds a high pressure while protecting the balloon structure from damage due to contact with the calcified lesions within the target vessel. Although not illustrated, another technique includes implementing a compliant balloon body to allow conformance to plaque and puncture resistance. In the example of this solution, non-compliant cones on either end of the balloon would be implemented to prevent the pressure wave from propagating proximal to, or distal from, the balloon 110.

FIGS. 19 and 20 illustrate two example IVL devices 1900, 2000, respectively, having interventional balloons 110 with protective structures 1902, 2002, or "protective cages." Specifically, FIG. 19 is a profile view of a first example IVL device 1900 having a first-such protective structure 1902, and FIG. 20 is a side view of a second example IVL device 2000 having a second-such protective structure 2002.

These protective structures 1902, 2002 are configured to provide similar rupture-protection to the more-continuous balloon outer layer or coating 1802 described above with respect to FIG. 18. According to either of these examples, balloon 110 can have a cage-like structure overtop of it, thereby reducing direct physical contact (e.g., friction) between the exterior surface of the balloon and the calcified-plaque lesion appended to the vessel wall.

The cage-like structures 1902, 2002 may be or may include a metal, such as SST or nitinol, or a polymer. In a multi-nested-layer balloon (e.g., balloon 1800 of FIG. 18), the protective structure 1902, 2002 could be disposed between the outer and inner balloon layers 1802, 1804. In some examples, the cage-like structure 1902, 2002 includes multiple longitudinal members, e.g., extending parallel to central longitudinal axis 116. In some such examples, protective structure 1902, 2002 may be selected to include an odd number of longitudinal members, such as three longitudinal members or five longitudinal members, in order to promote re-wrap of the respective balloon prior to withdrawal of IVL device 108 from the patient's vasculature. These longitudinal members or bars may be interconnected as a stent-like structure, such that the structure has a predetermined size and shape that does not vary (or varies by a relatively small amount) during inflation of balloon 110.

According to some examples, the protective structure 1902, 2002 is rigidly coupled to the exterior surface of the balloon 110. In some such examples, the protective structure 1902, 2002 is rigidly coupled to the proximal and distal end portions of balloon 100, but not to a longitudinally central balloon portion.

The example of FIG. 19 shows a less-comprehensive protective structure 1902, as compared to the example protective structure 2002 of FIG. 20. For instance, protective structure 1902 includes, as non-limiting examples, two (top and bottom) longitudinal elements 1904, and about thirteen circumferential elements 1906. By comparison, protective structure 2002 is shown to include a more-continuous wire-mesh configuration or window-screen configuration having dozens or hundreds of interwoven longitudinal and circumferential elements.

FIG. 21 illustrates an example IVL device 2100 (e.g., IVL device 108 of FIG. 1) including a pair of scoring members 2102A, 2102B. Scoring members 2102 are configured to physically contact and abrade (e.g., through friction applied across a substantially small surface area, corresponding to a substantially high stress-pressure at that point) an interior surface of a calcified-plaque lesion to help fragment and disintegrate the lesion.

In some examples, scoring members 2102 may be coupled to a protective structure (e.g., protective cages 1902, 2002 of FIGS. 19 and 20, respectively) within or over the balloon 110.

In some examples, balloon 110 may include a single scoring member 2102. In other examples, multiple scoring members 2102 may be distributed, rotationally symmetrically or asymmetrically, about the circumference of balloon 110. During the IVL procedure, balloon 110 may be circumferentially rotated to apply a particular scoring member or members 2102 against the calcified lesion. In some examples, scoring members 2102 may be formed from a metal, such as an SST or a nickel-titanium alloy (e.g., Nitinol), a metal wire, a printed metal ink (which may contain a very small amount of polymer binder from processing), tungsten, or a polymer.

In some examples, such as the example shown in FIG. 21, scoring members 2102 may include generally flat or planar external surfaces. In other examples, scoring members 2102 may include toothed or serrated external surfaces, e.g., to increase kinetic friction when contacting the calcified-plaque lesion.

FIG. 22 illustrates an example IVL device 2200 (e.g., IVL device 108 of FIG. 1) including a fracturing element 2202 configured to help fragment the calcified-plaque lesion during the IVL procedure. As shown in FIG. 22, fracturing element 2202 includes an elongated conductive wire 2204, and a plurality of piezoelectric elements 2206 distributed longitudinally along the wire 2204.

Fracturing element 2202 provides at least two advantages. First, when conductive wire 2204 is aligned against the calcified-plaque lesion, the narrow-cross sectional area of conductive wire 2204 substantially increases a pressure applied to the lesion along the axis of the wire, enabling the clinician to control the particular location at which the lesion begins to fragment. Second, when an alternating current (AC) is applied through conductive wire 2204, piezoelectric elements 2206 are configured to rapidly expand and contract, thereby generating additional pressure waves that are focused directly against the exterior surface of the lesion.

In some examples, fracturing element 2200 includes a distal protective element, such as an embolic protection element, as described further below with respect to FIG. 24A. For instance, the distal protective element may be coupled to a distal portion of conductive wire 2204. Additionally, or alternatively to wire 2204, fracturing element 2200 can include a braided layer, such as a Nitinol braid. Piezoelectric elements 2206 may be rigidly coupled to an exterior surface of the braid, and the braid may be coupled to the exterior surface of balloon 110. This braid may perform similar functions as those described above with respect to wire 2204.

FIG. 23 illustrates an IVL device 2300 (e.g., IVL device 108 of FIG. 1) with an example spring mechanism 2302. With some previous devices, the interventional balloon 110 can

become difficult to insert into and remove from an introducer sheath (not shown) during an IVL procedure. This may be caused, for example, by excessively bulky proximal and/or distal balloon cones (as compared to, e.g., distal balloon cone 1404 of FIG. 14A), or a lack of effective folding or wrapping of balloon 110 during and/or after deflation. In some examples, this problem may be addressed by reducing the balloon's radial profile (e.g., cross-sectional area) while it is in an uninflated or deflated state. This could be accomplished by longitudinally stretching the balloon 110 while bonding the proximal and distal ends of the balloon to inner elongated structure 318.

Another technique for reducing the profile of balloon 110, which is illustrated in FIG. 23, is to incorporate a spring 2302 within inner elongated structure 318. The spring 2302 should be longitudinally compressed when bonded (e.g., at proximal end 2304A and distal end 2304B) to inner elongated structure 318. Balloon 110 may then be bonded to inner elongated structure 318

such that, when spring 2302 is allowed to expand back to its rest length, inner elongated structure 318 and balloon 110 similarly expand along the longitudinal direction 116 and compress radially inward. Balloon 110 may also be stretched longitudinally about the tube 318 (as described above) during the bonding process to further facilitate this technique. During inflation, balloon 110 will still expand to its pre-formed shape, while the inner elongated structure 318 will slightly compress along the longitudinal direction. That is, the proximal and distal points at which balloon 110 is bonded to inner elongated structure 318 may slightly compress toward one another as balloon 110 expands radially outward.

Another technique for reducing the cross-sectional profile of balloon 110 is to improve balloon re-wrap after deflation during a procedure. This can be accomplished in a number of ways, such as by incorporating or embedding a plurality of longitudinal wires into the balloon body. These longitudinal wires may help define pleats or pre-determined folding locations for balloon 110, rather than allowing the balloon material to "bunch up" in a disordered fashion. While any number of longitudinal wires may be incorporated, an odd number of longitudinal wires can help prevent the balloon from collapsing into a symmetrical plane, such as a "paddle" or "pancake" configuration of the balloon. Additionally, the longitudinal members may be radiopaque so that they can be used to visualize the inflated balloon 110 and its apposition relative to the vessel wall during the IVL procedure. Such configurations can obviate the use of a separate fluid contrast medium, thereby potentially reducing an overall duration of the IVL procedure. In some examples, these longitudinal wires could consist of metal wires (e.g., flat,

round, or irregular-shaped, such as pentagonal), a printed ink (e.g., a metal or polymer ink), or a polymer structure.

FIG. 24 illustrates an example IVL device 2400 (e.g., IVL device 108 of FIG. 1) including a distal protective device 2402. According to some examples, a distal protective device 2402 may be positioned at a distal end portion of IVL device 2400. In some examples (but not all examples), the distal protective device 2402 includes an elongated element 2404 (e.g., a guidewire) that extends, e.g., through guidewire lumen 322 of inner elongated structure 318, and a distal expandable member 2406. In some such examples, expandable member 2406 is configured to extend distally outward from distal port 324 and expand radially outward into the expanded configuration shown in FIG. 24. The inner lumen 322 of inner elongated structure 318 surrounding the extended distal protective device 2402 may be compatible for guidewires from 0.010" to 0.035". Therefore, the guidewire lumen size can range from 0.011" up to 0.038" to allow for free guidewire movement.

The distal protective device 2402 is configured to capture calcified particulates that are generated during the IVL procedure. Expandable member 2406 may include a basket-frame design, as shown in FIG. 24A, but other suitable designs are contemplated as well. In some such examples, the basket frame 2406 may be or may include a Nitinol cut-tube (similar to a stent) or a Nitinol wireframe. The material that makes up the basket 2406 may be a thin polymer with ablated holes or a fiber mesh. According to some examples, the basket frame 2406 could be placed outside the balloon catheter 104 and is designed so that the distal protective member's shaft 2404 is compatible with the balloon dilation (wherein the balloon 110 presses up against the shaft 2404 of the filter device 2402).

Distal protective device 2402 could also be rapidly exchanged on the balloon catheter 104. A rapid exchange port may be proximal of the balloon 110 or distal of the balloon 110. The distal protective device 2402 may enter or exit the balloon catheter at the hub 306 (FIG. 3), proximal of the balloon 110, or distal of the balloon 110. This distal protective device 2402 may also be modular (e.g., removable) in nature, so that it is only present on the IVL device 2400 when needed for a procedure.

FIG. 25 illustrates an example of IVL system 100 of FIG. 1, including a closed-loop energy-delivery feedback mechanism. In some current IVL systems, the amount of delivered energy is fixed and not tailored to the clinical need. This disclosure allows for the automatic delivery of energy based on the clinical scenario presented, in order to improve treatment efficacy and efficiency, via a sensor 2502 that measures, e.g., fluid pressure, fluid amount/rate,

and/or temperature. Any combination or sole use of the monitoring provided by the controls as disclosed herein may provide input to determine a maximum pressure-wave intensity and/or heat level to be generated by the emitters.

According to some examples, system 100 may include one or more sensors 2502, e.g., incorporated within energy generator 102, catheter 104, or both. Based on data received from sensor 2502, system 100 (e.g., processing circuitry of generator 102, or a separate computing device associated with system 100) is configured to dynamically (e.g., in real-time) adjust energy levels output by generator 102.

For instance, sensor(s) 2502 may include as non-limiting examples: an inflation-fluid flow-rate monitor, an inflation-fluid pressure monitor, a vessel-wall surface monitor, a vessel-diameter monitor, a balloon-diameter monitor, a plaque-fragmentation monitor, or any other type of sensor configured to provide insight regarding a current progress of the IVL procedure. In some examples, sensor 2502 is configured to detect the resonant frequency (e.g., natural frequency or harmonic frequency) of the calcium in the lesion.

Based on real-time monitoring of the sensor data from sensor(s) 2502, system 100 may be configured to dynamically adjust one or more of: an electric-current level, a voltage level, an electric pulse duration or frequency, a light intensity, a light-pulse duration, a light-pulse frequency, or any other suitable parameter affecting an amount or rate of energy delivered via emitter array 112. For the specific example of plaque-lesion resonant frequency, system 100 may be configured to automatically adjust the emitter sonic frequency to match the detected resonant frequency of the lesion to more-effectively fragment the lesion.

In some examples additionally or alternatively to dynamically adjusting energy levels, system 100 is configured to automatically terminate an applied voltage in response to certain conditions being met, including (but not limited to) a threshold fragmentation of the calcified-plaque lesion being achieved or a detected system parameter being outside threshold levels (e.g., a suspected malfunction of balloon 110 or another component).

As one illustrative example, IVL system 100 may be configured to monitor a fluid pressure of balloon 110. For instance, sensor 2502 can include a pressure transducer configured to interact with the inflation lumen 320. Accordingly, system 100 can further include a three-way fluid connector (e.g., catheter hub 306 of FIG. 3) configured to fluidically couple an inflation syringe (e.g., inflation port 310), inflation lumen 320, and a pressure line running back to energy generator 102. The pressure transducer may be integrated into energy generator 102 and fluidically coupled along the pressure line. In some such examples, the fluid line may also

include a transducer protector, such as a valve or membrane, configured to prevent the inflation fluid 408, e.g., a saline/contrast-fluid mixture, from entering components of energy generator 102.

As another illustrative example, IVL system 100 (e.g., processing circuitry of energy generator 102 or of another computing device associated with system 100) may be configured to monitor an electrical impedance of one or more components of system 100. When plasma is created within the spark gap 404 between the electrode pair 402 (FIG. 4), the local electrical impedance will drop, thus causing system 100 (upon detection) to terminate the applied voltage. Additionally, or alternatively, system 100 (e.g., measurement unit 216 of FIG. 2) may be configured to monitor an electrical-current level produced by generator 102 as it is output and automatically terminate the applied voltage in response to an above-threshold change in the monitored current.

In other examples, rather than dynamically modifying energy levels (e.g., applied voltage levels, or the like), system 100 may be configured to apply the energy level (e.g., voltage level) as an "all or nothing" (e.g., binary 0 or 1). For instance, system 100 may only transmit energy, at a predetermined level, through catheter 104 while certain conditions are determined to be met, as indicated by data from sensor 2502. Additionally, or alternatively, system 100 may be configured to adjust other parameters. For instance, system 100 may be configured to dynamically adjust a longitudinal length and/or an inflation diameter of balloon 110, as needed.

FIG. 26 illustrates an example handle 2600 that may be coupled at the proximal portion 302 (FIG. 3) of IVL catheter 104 of FIG. 1. Catheter 104 may include handle 2600 in addition to, or instead of, catheter hub 306 (FIG. 1). In instances in which both hub 306 and handle 2600 are present, handle 2600 may couple to a portion of elongated body 106 extending proximally through hub access port 308.

Existing IVL catheters require a costly generator to power the catheter. In the example shown in FIG. 26, catheter handle 2600 includes an integrated power supply 2602. Power supply 2602 may include a battery, capacitor, or any other suitable integrated power source configured to deliver sufficient power levels to actuate emitter array 112 (FIG. 1). That is, in some examples, system 100 (FIG. 1) may include handle 2600 in place of energy generator 102. In other examples, handle 2600 may be configured to supply supplemental or auxiliary power to emitter array 112. In some examples, catheter 104 may be configured to removably

couple to energy generator 102 and function while either connected or disconnected, similar to a laptop or other mobile device.

Typical IVL systems and devices are configured to emit high-energy pressure waves that propagate across all spatial dimensions. This attribute may be relatively effective for ring-like calcified-plaque lesions, e.g., that appear around the entire inner circumference of the vessel wall. However, other lesion configurations are not as effectively treated, or alternatively may waste significant amounts of energy due to the inefficient application of the energy. Accordingly, a number of features and techniques are disclosed herein, enabling IVL device 108 (FIG. 1) to focus the emitted high-energy pressure waves in a particular spatial direction or limited range of directions.

For instance, FIG. 27 is a cross-sectional view of an IVL device 2700 (e.g., IVL device 108 of FIG. 1) having a first example wave director 2702. In some examples, wave director 2702 includes a layer of material oriented along just a portion of the inner circumference of balloon 110 and extending longitudinally (e.g., proximally and distally) through balloon 110. The material is configured to substantially absorb and/or reflect pressure waves that contact the material, thereby reducing energy that is wasted by being channeled in arbitrary directions. As described above, this acoustically opaque material can include, e.g., a ceramic, porcelain, diamond, polyimide, polyether ether ketone (PEEK), a similar material, or any suitable combination thereof.

In the example shown in FIG. 27, wave director 2702 is shown to have a half-moon-shape cross-sectional profile, although other configurations are contemplated. For instance, wave director 2702 may define a substantially semi-circular cross-sectional profile, or alternatively, include a relatively thin reflective layer coated onto the portion of the inner surface of balloon 110.

In some examples, wave director 2702 includes a distinct lumen "pocket" 2704 that can be inflated or deflated as needed with typical balloon angioplasty. In some examples, a fluid pocket 2704 separate from inflation lumen 320 (FIG. 3) is configured to deliver a gas to inflate the pocket 2704 so as not to interfere with inflation of the balloon 110 itself. During use of IVL device 2700, the pressure waves emitted from spark gap 404A will be unable to penetrate the fluid pocket 2704 and will therefore be absorbed and or reflected toward the opposite circumferential direction.

Additionally, or alternatively to an absorbent and/or reflective material, wave director 2702 of FIG. 27 may be or may include at least one of the pair of electrodes 402 (FIG. 4) of an

electronic emitter unit 400. For instance, the half-moon-shaped director 2702 may include one or both of the electrodes 402 to directionally focus the emitted pressure waves to fragment a target calcification. In examples in which wave director 2702 includes both a reflective material as well as one or both electrodes 402, the electrode(s) 402 may be positioned radially inward from the reflective material, which may be adhered to the interior surface of balloon 110.

Additionally, or alternatively to the reflective material, in some examples, the compositional material of balloon 110 may be strategically varied to provide for directionally targeted wave emission. For instance, the material of balloon 110 may be configured to be thicker along some portions of the circumference than along other portions. In some examples, the balloon 110 may incorporate a more-transmissive material along a first portion of its circumference and a more-absorbent and/or more-reflective material along a second portion of its circumference.

In some examples, a fluoroscopic wire (e.g., conductive wire 2204, as described above with respect to FIG. 22) or other visual indicator 2704 may be positioned opposite wave director 2702. The visual indicator 2704 helps the clinician orient (e.g., rotate) IVL device 2700 toward the target calcification prior to beginning targeted fragmentation. Also, as described above with respect to FIG. 22, in some examples, piezo elements 2206 can be mounted or expanded to an off-center location (e.g., asymmetrically distributed) onto or within balloon 110, providing an increase in energy to that side. In such examples, the tissue region adjacent the piezo elements 2206 would receive a greater amount of energy, thus enabling directionally targeted lesion fragmentation.

FIG. 28A is a perspective view, and FIG. 28B is a cross-sectional view of a second example directionally focused IVL device 2800 (e.g., IVL device 108 of FIG. 1). IVL device 2800 includes an array of emitter assemblies 2814, wherein each emitter assembly 2814 includes two or more individual emitter units 2816 distributed circumferentially around inner elongated structure 318. Each individual emitter unit 2816 can include an electrode pair, a piezo element, or an optical emitter.

As shown in FIGS. 28A and 28B, emitter units 2816 may be configured to mount or expand to an off-center location within the cross-sectional area of balloon 110, thereby providing an increase in energy delivered to the respective side of balloon 110. In some examples, each individual emitter unit 2816 is configured to be independently actuatable. In other examples, all individual emitter units 2816 of different emitter assemblies 2814 that are

aligned along a common longitudinal axis are configured to be commonly actuatable. Additionally, or alternatively, individual emitter units 2816, as mounted on stalks 2818, can be configured to tilt or angle toward and away from inner elongated structure 318, to further control directional energy transmission.

Also, as shown in FIGS. 28A and 28B, IVL device 2800 can include one or more radiopaque visual indicators 2704 to help with device orientation relative to the target treatment site. However, as shown in FIG. 28B, visual indicators 2704 should be asymmetrically distributed about the circumference of balloon 110 to prevent ambiguous balloon-orientation determinations.

FIG. 29A is a perspective view, and FIG. 29B is a cross-sectional view of a third example directionally focused IVL device 2900 (e.g., IVL device 108 of FIG. 1). IVL device 2900 is an example of IVL device 2800 of FIG. 28, except for the differences noted herein. In particular, interventional balloon 110 of IVL device 2900 includes two or more elongated sub-balloons 2902 distributed circumferentially around inner elongated structure 318. Each sub-balloon 2902 is configured to retain a subset of emitter units 2816 that are oriented along a common longitudinal axis. Each emitter-unit subset is configured to be independently actuatable from the other emitter-unit subsets, and the respective sub-balloon 2902 is configured to help apply the emitted pressure waves to a particular portion of the circumference of the interior surface of the target vessel.

In some examples, each sub-balloon 2902 is configured to be individually inflatable, e.g., according to a different inflation rate or amount than the other sub-balloons. In this way, IVL device may be positioned off-center toward a particular portion of the vessel wall (e.g., the calcified lesion). Such examples enable the respective subset of emitter units 2816, including a corresponding scoring member 2102 (FIG. 21), if present, to be positioned even closer to the target treatment site.

As described above, the emitters 2618 can tilt away from the inner elongated structure 318 to be closer to the inner diameter wall of the balloon 110 (e.g., instead of being adjacent to the inner elongated structure 318). Accordingly, the energy delivered by these emitters 2816 can be more focused on the wall of the vessel to which they are positioned closest. This, in combination with a cutting wire (e.g., conductive wire 2204 of fracturing element 2202 of FIG. 22), can create a high-stress focal point to more-efficiently and/or more-effectively break up a nodular calcified lesion.

Additionally, in the examples of FIGS. 28A and 29B, energy generator 102 (FIG. 1) may independently and selectively control the emitters 2816 that reside about the circumference of IVL device 2900. This means that, even without tilting or moving the emitters 2816 in any way, the energy delivery may be controlled by only firing the emitters 2816 closest to the calcified lesion. Additionally, if the treatment presented requires full-circumference energy delivery, all emitters 2816 may still be fired, allowing for a more traditional style of treatment to occur.

It should be noted that these emitters 2816 can all be located within the same balloon 110, as is shown in FIGS. 28A and 28B, or within their own, separate sub-balloons 2902, as shown in FIGS. 29A and 29B. Additionally, while the relative alignments shown in FIGS. 28B and 29B allow for just one array of emitter units, it should be noted that these emitters 2816 can be placed about the catheter throughout the balloon 110, and the quantity of possible emitters is only dictated by the length of the balloon 110 being used.

WHAT IS CLAIMED IS:

1. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid to inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon, the one or more pressure-wave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site,

wherein at least one of the one or more pressure-wave emitters comprises an electronic emitter comprising a first electrode and a second electrode,

wherein the first electrode and the second electrode are arranged to define a spark gap between the first electrode and the second electrode, and

wherein the second electrode comprises a portion of a hypotube.

2. The medical device of claim 1,

wherein the spark gap comprises a first spark gap;

wherein the electronic emitter further comprises a third electrode; and

wherein the third electrode is arranged so as to define a second spark gap between the second electrode and the third electrode.

3. The medical device of claim 2, wherein the first electrode, the second electrode, and the third electrode are all portions of a common cylindrical surface of the hypotube.

4. The medical device of claim 3, wherein the first electrode and the third electrode both define rounded triangular shapes, and wherein the second electrode defines a parallelogram shape.

5. The medical device of claim 3, wherein the first electrode, the second electrode, and the third electrode all define rounded rectangular shapes.

6. The medical device of claim 3, wherein the first electrode and the third electrode both define oval shapes, and wherein the second electrode defines a semi-cylindrical shape.

7. The medical device of claim 1, wherein the electronic emitter further comprises a coupler layer positioned radially between the elongated body and the second electrode.

8. The medical device of claim 1,
wherein the first electrode is ring-shaped;
wherein the second electrode is disc-shaped; and
wherein the first electrode is positioned around the second electrode.

9. The medical device of claim 8,
wherein the electronic emitter further comprises a third electrode and a fourth electrode;
wherein the third electrode is ring shaped and the fourth electrode is disc-shaped;
wherein the third electrode is positioned around the fourth electrode; and
wherein the first, second, third, and fourth electrodes are all portions of a common cylindrical surface of the hypotube.

10. The medical device of claim 1, wherein the hypotube defines a longitudinal length from about 0.080 inches to about 0.090 inches, and an outer circumference from about 0.10 inches to about 0.12 inches.

11. The medical device of claim 1, wherein the first electrode is rectangular-prism shaped, and wherein the first electrode extends at least partially radially inward through an outer surface of the elongated body.

12. The medical device of claim 11, wherein the first electrode extends radially inward through the elongated body and at least partially radially inward into an inner lumen of the elongated body.

13. An intravascular lithotripsy (IVL) system comprising:
an energy generator; and

a catheter removably and conductively coupled to the energy generator, the catheter comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid to inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon, the one or more pressure-wave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site,

wherein at least one of the one or more pressure-wave emitters comprises an electronic emitter comprising a first electrode and a second electrode,

wherein the first electrode and the second electrode are arranged to define a spark gap between the first electrode and the second electrode, and

wherein the second electrode comprises a portion of a hypotube.

14. A method of forming an electronic pressure-wave emitter of an intravascular lithotripsy (IVL) catheter, the method comprising:

laser-cutting a hypotube to define at least a first electrode and a second electrode arranged to define a spark gap therebetween;

inserting an elongated body through the laser-cut hypotube;

flowing a potting material around the laser-cut hypotube; and

removing obsolete support structures from the hypotube.

15. The method of claim 14,

wherein the spark gap comprises a first spark gap; and

wherein laser-cutting the hypotube further comprises laser-cutting the hypotube to define a third electrode arranged so as to define a second spark gap between the second electrode and the third electrode.

16. The method of claim 15, wherein laser-cutting the hypotube comprises laser-cutting the hypotube such that the first electrode and the third electrode both define rounded triangular shapes, and such that the second electrode defines a parallelogram shape.

17. The method of claim 15, wherein laser-cutting the hypotube comprises laser-cutting the hypotube such that the first electrode, the second electrode, and the third electrode all define rounded rectangular shapes.

18. The method of claim 15, wherein laser-cutting the hypotube comprises laser-cutting the hypotube such that the first electrode and the third electrode both define oval shapes, and such that the second electrode defines a semi-cylindrical shape.

19. The method of claim 14,

wherein the spark gap comprises a first spark gap; and

wherein laser-cutting the hypotube further comprises laser-cutting the hypotube to define a third electrode and a fourth electrode arranged so as to define a second spark gap between the third electrode and the fourth electrode, and wherein:

the first electrode and the third electrode are ring-shaped;

the second electrode and the fourth electrode are disc-shaped;

the first electrode is positioned around the second electrode; and

the third electrode is positioned around the fourth electrode.

20. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

one or more pressure-wave emitters positioned along a central longitudinal axis of the elongated body within the balloon, the one or more pressure-wave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site,

wherein at least one of the one or more pressure-wave emitters comprises an electronic emitter comprising a first electrode, a second electrode, and a third electrode arranged to define

a first spark gap between the first electrode and the second electrode, and a second spark gap between the second electrode and the third electrode, and

wherein the first electrode, the second electrode, and the third electrode are portions of a common hypotube.

21. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient;

an emitter array positioned along a central longitudinal axis of the elongated body within the balloon, the emitter array configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein the emitter array comprises a plurality of emitters including at least one electrode formed from a portion of a hypotube; and

a plurality of conductive wires configured to provide electrical energy to the emitter array, the plurality of conductive wires arranged according to a wiring configuration.

22. The medical device of claim 21, wherein the plurality of conductive wires extends generally parallel to the central longitudinal axis.

23. The medical device of claim 21, wherein the wiring configuration comprises a single-coil configuration such that the plurality of conductive wires coil helically around the elongated body, wherein adjacent coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis.

24. The medical device of claim 21, wherein the wiring configuration comprises a double-coil configuration such that the plurality of conductive wires coil helically around the elongated body, wherein adjacent pairs of coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis.

25. The medical device of claim 21, wherein the wiring configuration comprises a quadruple-coil configuration such that the plurality of conductive wires coil helically around

the elongated body, wherein adjacent groups of four coil turns of the plurality of conductive wires are spaced longitudinally along the central longitudinal axis.

26. The medical device of claim 21, wherein the plurality of conductive wires comprises a plurality of flat wires.

27. The medical device of claim 21, wherein the plurality of conductive wires comprises a plurality of round wires with flattened portions along the emitter array.

28. The medical device of claim 21, wherein:
the elongated body comprises an inner body and an outer body;
the outer body comprises an inner layer and an outer layer; and
the plurality of conductive wires coils around an exterior surface of the inner layer.

29. The medical device of claim 28, wherein the outer layer of the outer body is flowed over the plurality of conductive wires such that the plurality of conductive wires is embedded in the outer layer.

30. The medical device of claim 28, wherein the outer layer comprises a potting layer or a heat-shrink tube.

31. The medical device of claim 28, wherein the outer layer terminates proximally from the inner layer, such that a distal portion of the plurality of conductive wires is exposed to an interior of the balloon.

32. The medical device of claim 21, wherein the elongated body comprises an inner body and an outer body, and wherein the plurality of conductive wires coils around an exterior surface of the inner body such that the plurality of conductive wires forms a reinforcement layer for the elongated body.

33. The medical device of claim 21, wherein each of the plurality of emitters comprises a respective voltage wire such that each of the plurality of emitters is independently actuatable.

34. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

an emitter array positioned along a central longitudinal axis of the elongated body within the balloon, the emitter array configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein the emitter array comprises a plurality of electrode pairs including at least one electrode formed from a portion of a hypotube.

35. The medical device of Claim 34, wherein the exterior surface of the balloon comprises a polymer coating.

36. The medical device of Claim 34, wherein the exterior surface of the balloon comprises a hydrophilic coating.

37. The medical device of Claim 34, wherein the exterior surface of the balloon comprises a drug-based coating.

38. The medical device of Claim 37, wherein the drug-based coating comprises an anti-thrombogenic coating or an anti-proliferative medication.

39. The medical device of Claim 34, wherein the balloon comprises two or more nested expandable substrates.

40. The medical device of Claim 39, wherein the two or more nested expandable substrates comprise at least an outer layer and an inner layer, wherein an interior surface of the outer layer is bonded to an exterior surface of the inner layer so as to form a single multi-layered extrusion.

41. The medical device of Claim 40, wherein the inner layer comprises a high-pressure holding layer, and wherein the outer layer comprises a urethane layer.

42. The medical device of Claim 39, wherein the balloon further comprises a reinforcing structure.

43. The medical device of Claim 42, wherein the reinforcing structure comprises a plurality of longitudinal fibers aligned parallel to the longitudinal axis of the balloon, and a plurality of braided fibers.

44. The medical device of Claim 43, wherein the plurality of longitudinal fibers comprises from four to eight longitudinal fibers.

45. The medical device of Claim 34, wherein the balloon comprises an outer layer, an inner layer nested within the outer layer, and a cage structure nested between the outer layer and the inner layer, and wherein the cage structure comprises one or more longitudinal members oriented parallel to the longitudinal axis and one or more circumferential elements oriented perpendicular to the longitudinal axis.

46. The medical device of Claim 34, further comprising a cage structure at least partially surrounding the exterior surface of the balloon.

47. The medical device of Claim 46, wherein the cage structure is rigidly coupled to the exterior surface of the balloon.

48. The medical device of Claim 46, wherein the cage structure comprises a nitinol braid, metal wires, printed metals, radiopaque metal wires, or radiopaque printed metals.

49. The medical device of Claim 34, wherein the balloon comprises a porous membrane configured to infuse a drug at the target treatment site.

50. The medical device of Claim 34, wherein the balloon comprises a plurality of longitudinal ribs configured to define folding guides as the balloon folds radially inward.

51. The medical device of Claim 50, wherein the plurality of longitudinal ribs comprises an odd number of ribs.

52. The medical device of Claim 34, further comprising a spring configured to longitudinally stretch the balloon in an absence of external forces.

53. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

an emitter array positioned along a central longitudinal axis of the elongated body within the balloon, the emitter array configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein the emitter array comprises a plurality of electrode pairs including at least one electrode formed from a portion of a hypotube.

54. The medical device of Claim 53, further comprising a fracturing member positioned on an external surface of the balloon.

55. The medical device of claim 54, wherein the fracturing member comprises:

a conductive wire running along the longitudinal axis of the balloon; and

a plurality of piezo-elements positioned along the conductive wire, the plurality of piezo-elements configured to emit additional pressure waves against the calcified lesion.

56. The medical device of Claim 53, further comprising a protective device positioned at the distal portion of the elongated body, the protective device configured to at least partially occlude the target treatment site and to collect fragmented lesion portions.

57. The medical device of Claim 53, further comprising a protective device positioned along the elongated body proximal to the balloon, the protective device configured to at least partially occlude the target treatment site and to collect fragmented lesion portions.

58. The medical device of Claim 53, wherein the elongated body defines a lumen configured to receive a 0.0104" to 0.035" guidewire.

59. The medical device of Claim 58, further comprising the guidewire, wherein the guidewire has an inner diameter range from 0.011" to 0.038".

60. The medical device of Claim 53, further comprising a handle positioned at a proximal end of the elongated body, wherein the handle comprises an integral power supply for the emitter array.

61. The medical device of claim 53, further comprising a scoring member configured to contact and abrade the calcified lesion.

62. The medical device of Claim 61, wherein the scoring member defines a serrated exterior surface.

63. A medical device comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

an emitter array positioned along a central longitudinal axis of the elongated body within the balloon, the emitter array configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site,

wherein the emitter array comprises a plurality of electrode pairs including at least one electrode formed from a portion of a hypotube, and

means for controlling a primary direction of emission of the pressure waves.

64. The medical device of claim 63, further comprising a wave director positioned against an interior surface of the balloon and along only a portion of a circumference of the balloon, the wave director configured to absorb or reflect the pressure waves away from the second portion of the circumference of the balloon.

65. The medical device of claim 64, wherein the wave director comprises a ceramic, porcelain, diamond, polyimide, or polyether ether ketone (PEEK).

66. The medical device of claim 64, wherein the wave director defines a fluid pocket configured to receive a pressure-reflective fluid or a pressure-absorbent fluid.

67. The medical device of Claim 63, further comprising a radiopaque indicator positioned along the first portion of the circumference of the balloon, the radiopaque indicator configured to indicate an emitted direction of the pressure waves.

68. The medical device of Claim 67, wherein the radiopaque indicator comprises a radiopaque wire positioned along the exterior surface of the balloon.

69. The medical device of Claim 67, wherein the radiopaque indicator comprises a conductive wire of a fracturing element positioned along an exterior surface of the balloon, and wherein the fracturing element further comprises a plurality of piezoelectric elements configured to emit additional pressure waves through the calcified lesion.

70. The medical device of Claim 63, wherein each of the one or more shockwave emitters defines a respective orientation, and wherein the medical device further comprises a user-input mechanism to modify the respective orientations of the one or more shockwave emitters.

71. The medical device of Claim 63, wherein each of the one or more shockwave emitters defines a respective fixed orientation, and wherein the medical device further comprises a user-input mechanism configured to independently actuate a first subset of the one or more shockwave emitters independently from a second subset of the one or more shockwave emitters.

72. The medical device of Claim 63, wherein the balloon comprises two or more elongated sub-balloons oriented circumferentially around the central longitudinal axis, each sub-balloon comprising a respective subset of the one or more shockwave emitters.

73. A system comprising:

an energy generator; and

a catheter comprising:

an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid to inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient;

an emitter array positioned along a central longitudinal axis within the balloon, the emitter array comprising one or more shockwave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site; and

a sensor configured to generate sensor data indicative of at least one parameter.

74. The system of claim 73, wherein the energy generator is configured to vary an amount of energy delivered based on the sensor data.

75. The system of claim 74, wherein, to vary the amount of energy, the energy generator is configured to vary a current level, a voltage level, a pulse duration, a pulse frequency, or a light intensity.

76. The system of claim 73, wherein the sensor data comprises fluid-pressure data, fluid-rate data, or temperature data.

77. The system of claim 73, wherein the sensor comprises an electrical-impedance monitor, an inflation-fluid flow-rate monitor, an inflation-fluid pressure monitor, a vessel-wall surface monitor, a vessel-diameter monitor, an interventional-balloon diameter monitor, or a plaque-fragmentation monitor.

78. The system of claim 73, wherein the sensor comprises a resonant-frequency sensor, and wherein the energy monitor is configured to vary a pressure-wave frequency to approximate a resonant frequency of the calcified lesion.

79. The system of claim 73, wherein the energy generator is configured to terminate an applied voltage based on the sensor data.

80. A medical device comprising:

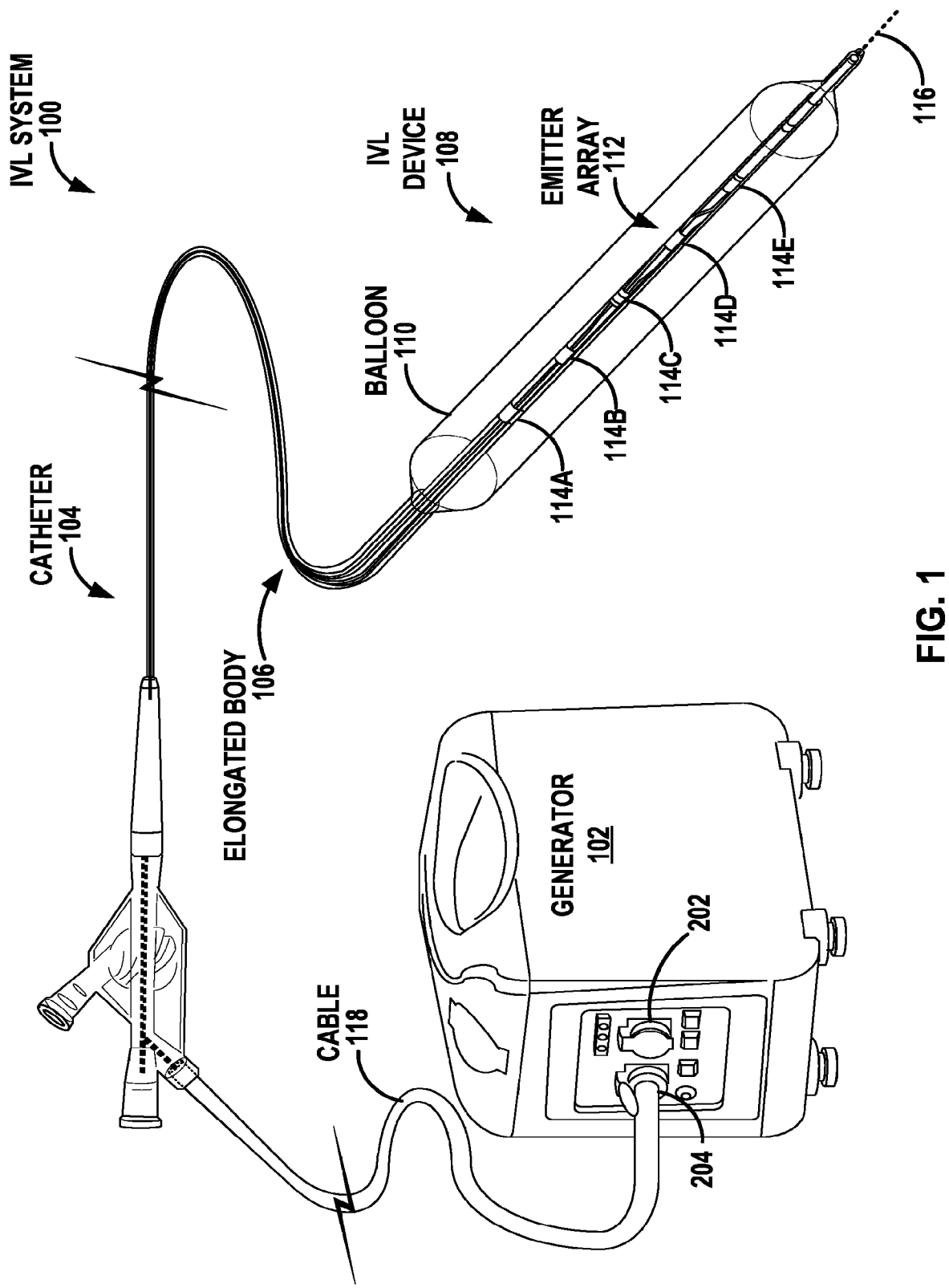
an elongated body;

a balloon positioned at a distal portion of the elongated body, the balloon configured to receive a fluid to inflate such that an exterior surface of the balloon contacts an interior surface of a target treatment site within a vasculature of a patient; and

an emitter array positioned along a central longitudinal axis within the balloon, the emitter array comprising one or more shockwave emitters configured to propagate pressure waves radially outward through the fluid to fragment a calcified lesion at the target treatment site, wherein at least one of the one or more shockwave emitters comprises an optical-based emitter.

81. The medical device of claim 80, further comprising an optical fiber running parallel to the central longitudinal axis along a distal direction, wherein the at optical-based emitter comprises a distal-most portion of the optical fiber.

82. The medical device of claim 81, wherein the optical fiber is configured to transmit a laser signal into the balloon, wherein the laser signal is configured to cavitate the fluid upon contact with the fluid at the distal-most portion of the optical fiber to generate the shockwave.


IVL SYSTEM
100
CATHETER
104
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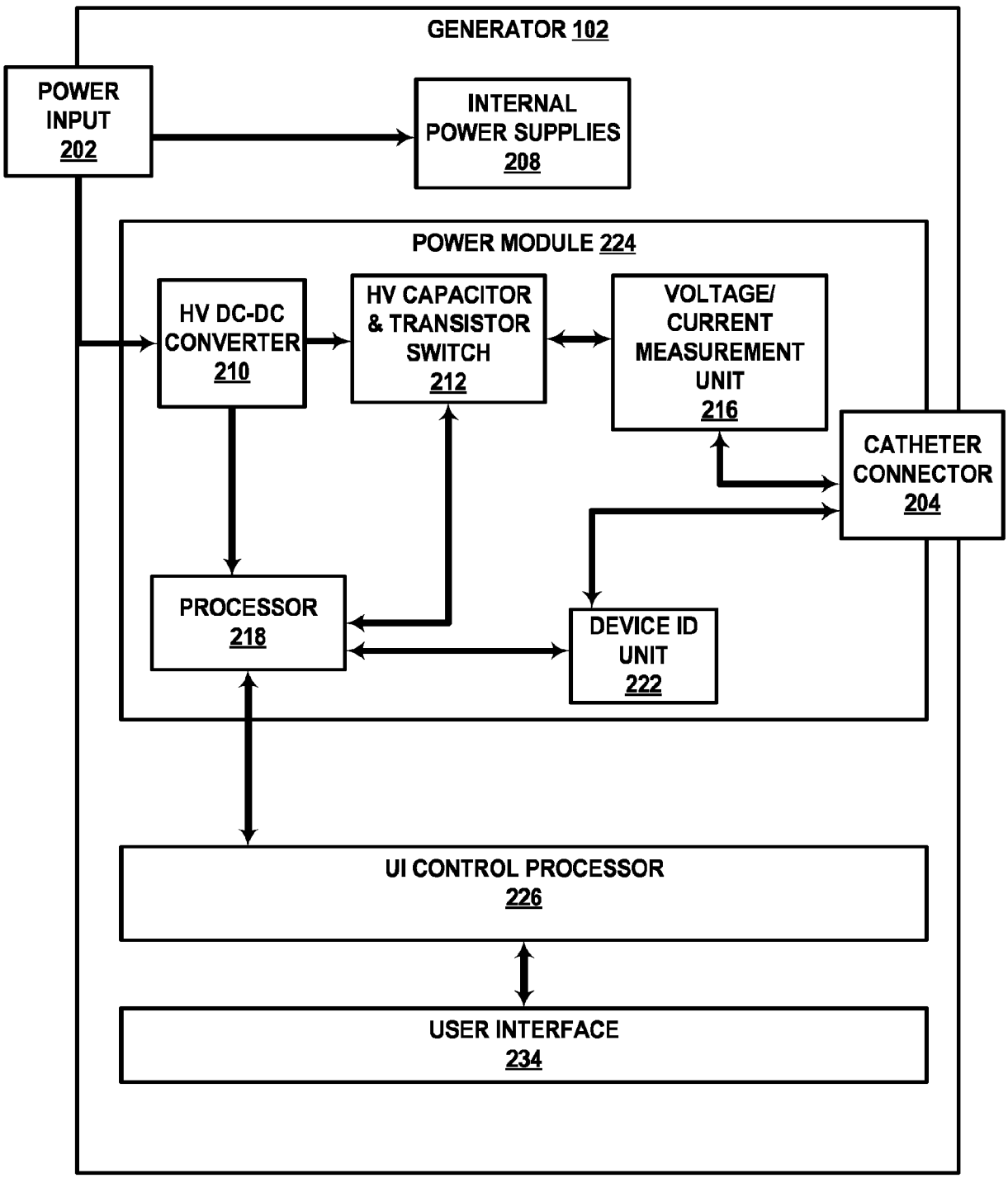
106
CABLE
118
GENERATOR
102
202
204
IVL
DEVICE
108
BALLOON
110
EMITTER
ARRAY
112
114A
114B
114C
114D
114E
116

FIG. 1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INTERNAL POWER SUPPLIES 208
POWER MODULE 224
HV DC-DC CONVERTER 210
HV CAPACITOR & TRANSISTOR SWITCH 212
VOLTAGE/ CURRENT MEASUREMENT UNIT 216
CATHETER CONNECTOR 204
PROCESSOR 218
DEVICE ID UNIT 222
UI CONTROL PROCESSOR 226
USER INTERFACE 234

FIG. 2

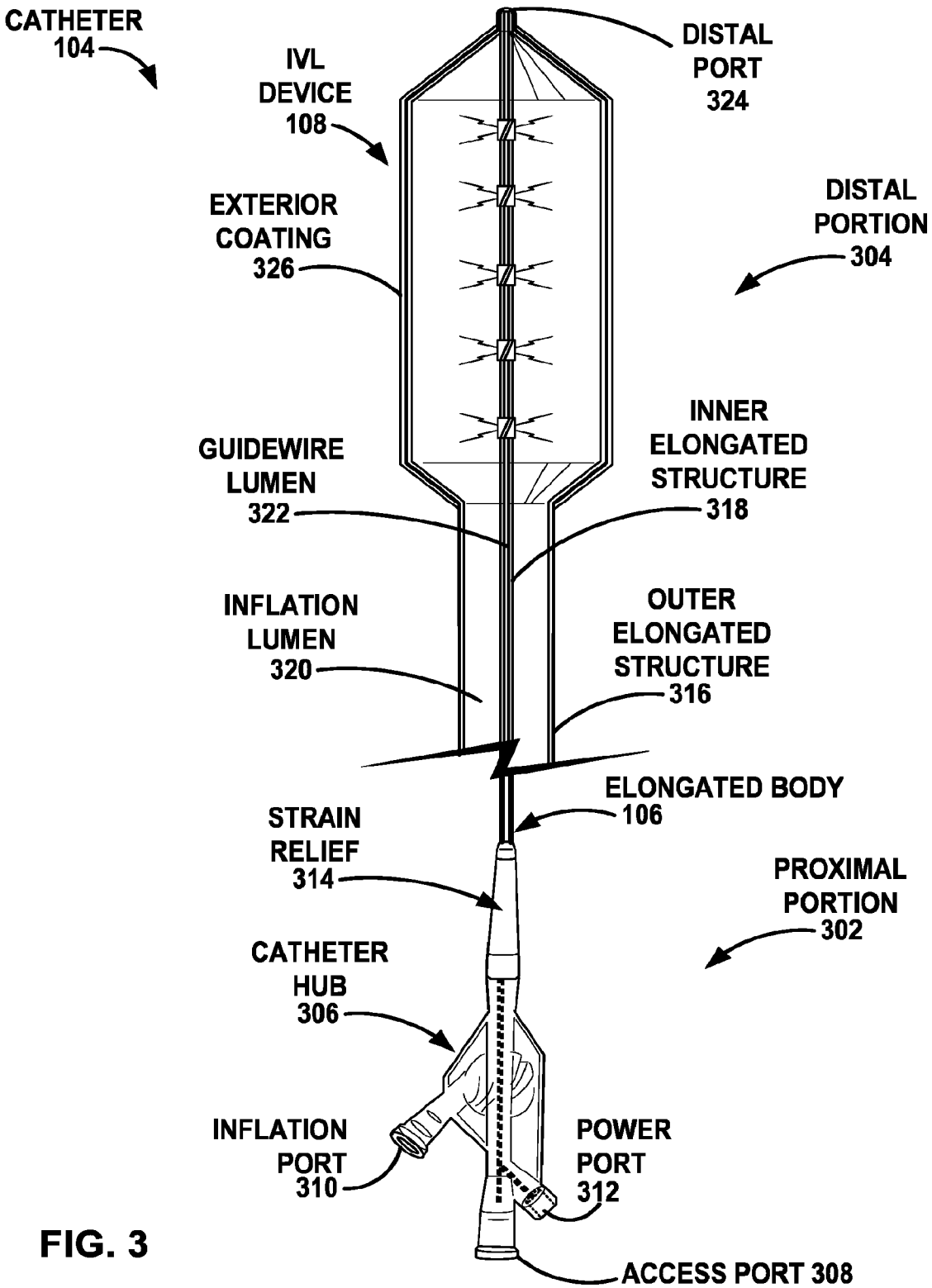

CATHETER
104
IVL
DEVICE
108
DISTAL
PORT
324
EXTERIOR
COATING
326
DISTAL
PORTION
304
GUIDEWIRE
LUMEN
322
INNER
ELONGATED
STRUCTURE
318
INFLATION
LUMEN
320
OUTER
ELONGATED
STRUCTURE
316
ELONGATED BODY
106
STRAIN
RELIEF
314
PROXIMAL
PORTION
302
CATHETER
HUB
306
INFLATION
PORT
310
POWER
PORT
312
ACCESS PORT 308

FIG. 3

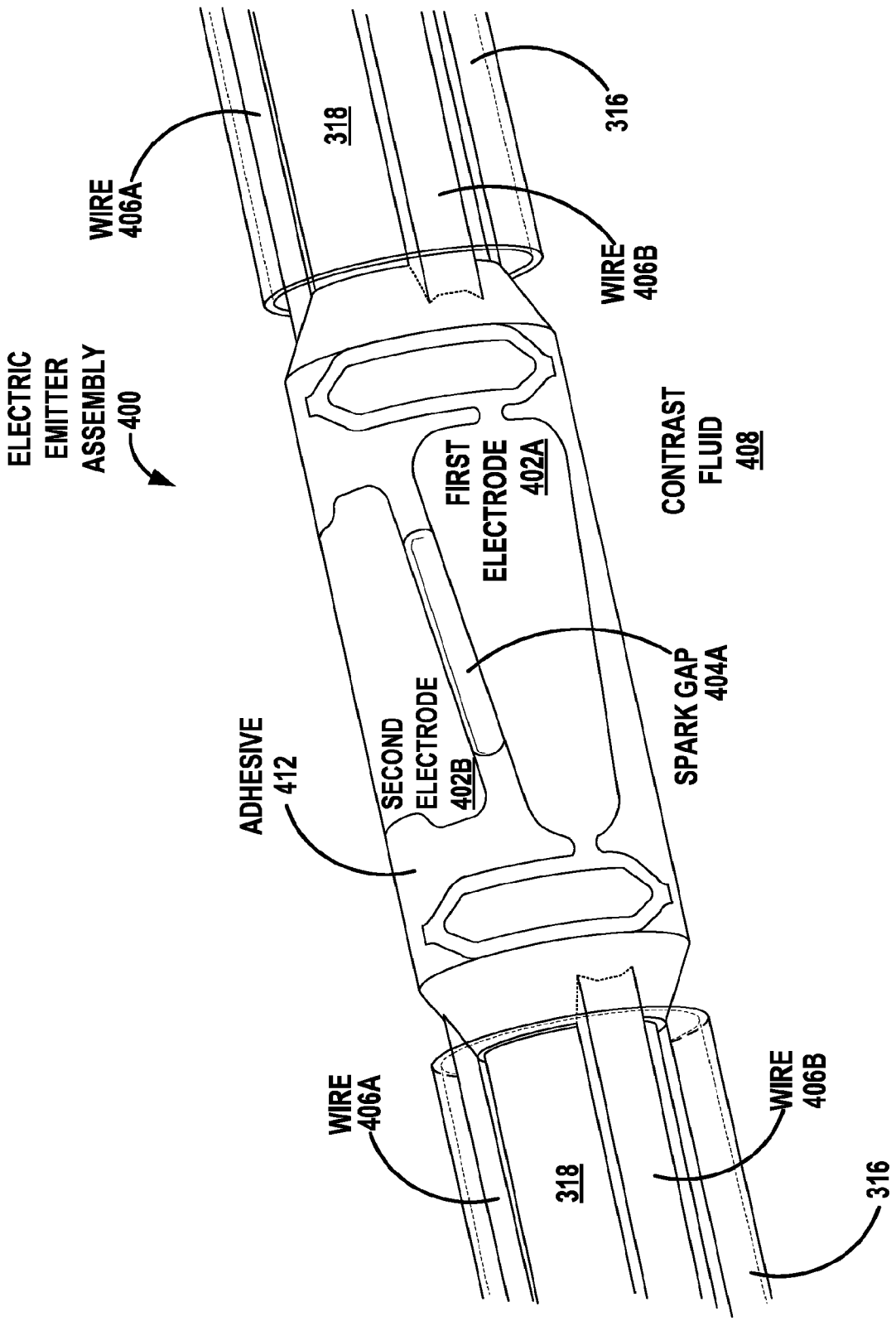
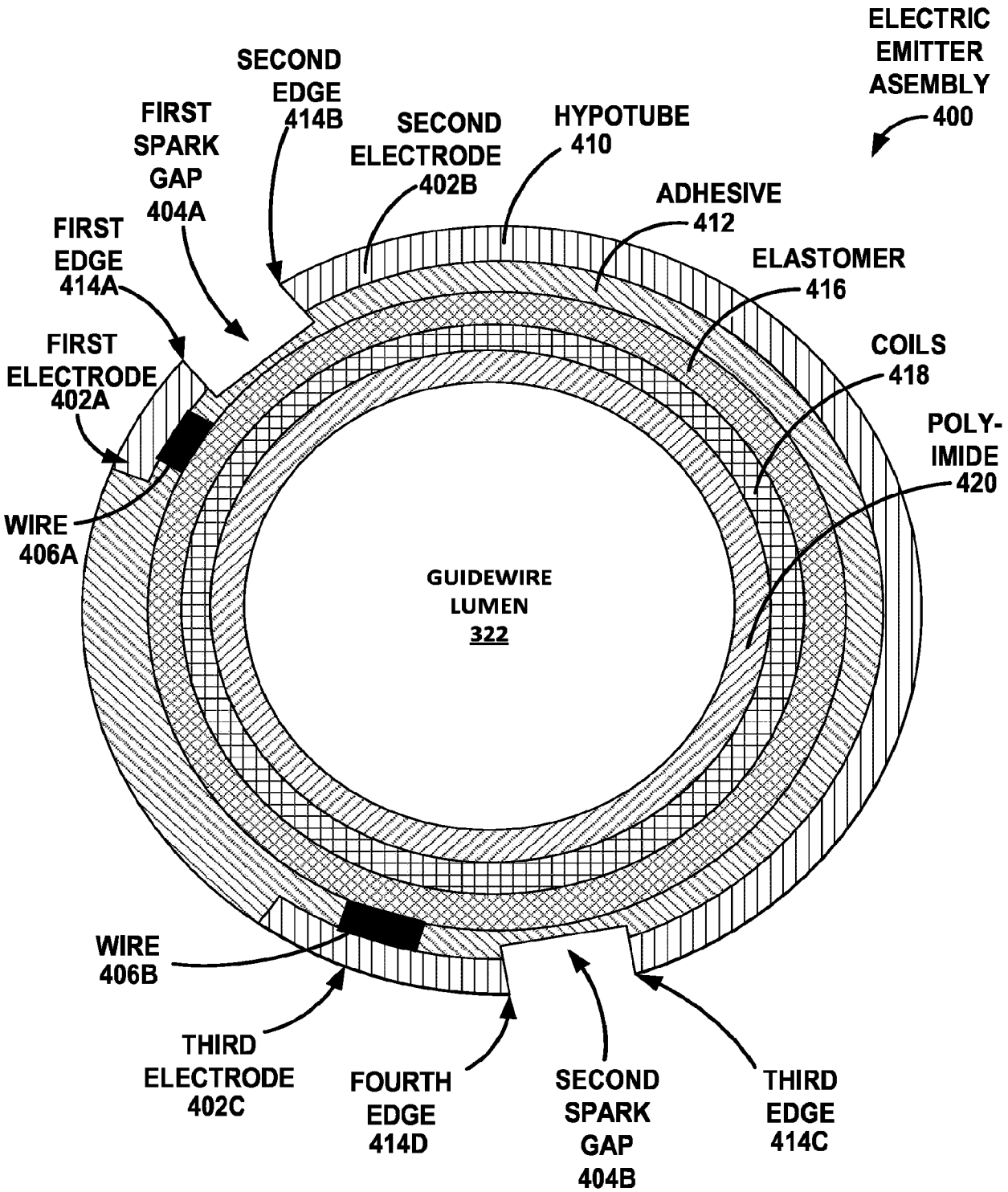

ELECTRIC EMITTER ASSEMBLY 400
WIRE 406A
318
316
WIRE 406B
FIRST ELECTRODE 402A
CONTRAST FLUID 408
ADHESIVE 412
SECOND ELECTRODE 402B
SPARK GAP 404A
WIRE 406A
318
WIRE 406B
316

FIG. 4A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SECOND EDGE 414B
FIRST SPARK GAP 404A
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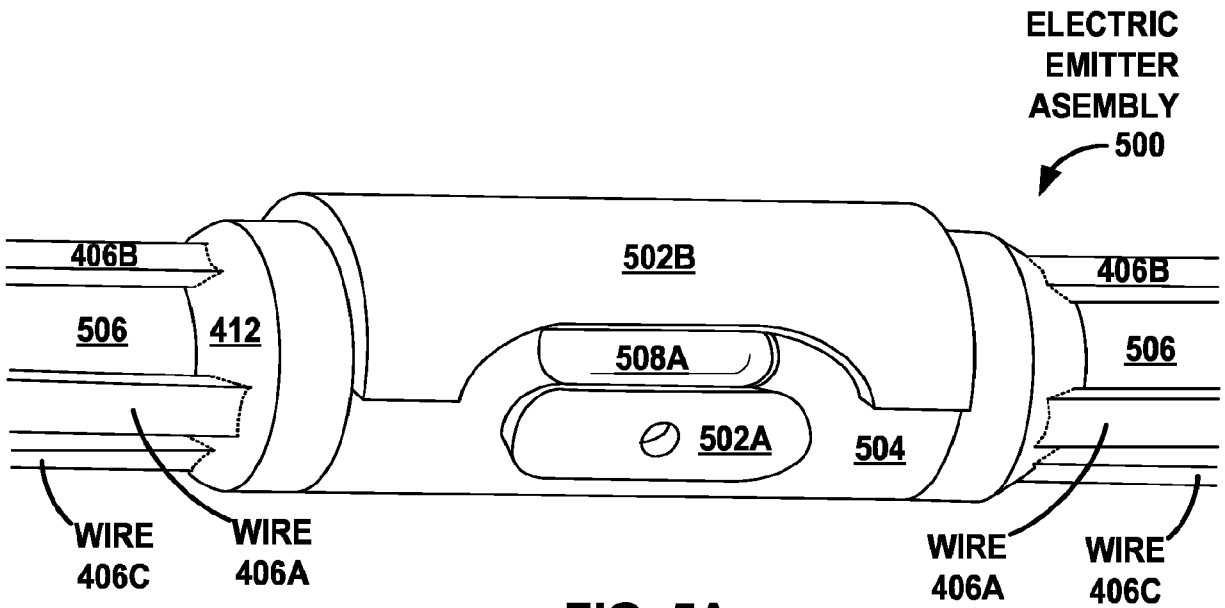
FIRST EDGE 414A
ELASTOMER 416
FIRST ELECTRODE 402A
COILS 418
POLY-IMIDE 420
WIRE 406A
GUIDEWIRE LUMEN 322
WIRE 406B
THIRD ELECTRODE 402C
FOURTH EDGE 414D
SECOND SPARK GAP 404B
THIRD EDGE 414C

FIG. 4B


ELECTRIC
EMITTER
ASEMBLY
500
406B
502B
406B
506
412
508A
506
502A
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WIRE
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WIRE
406A
WIRE
406A
WIRE
406C

FIG. 5A

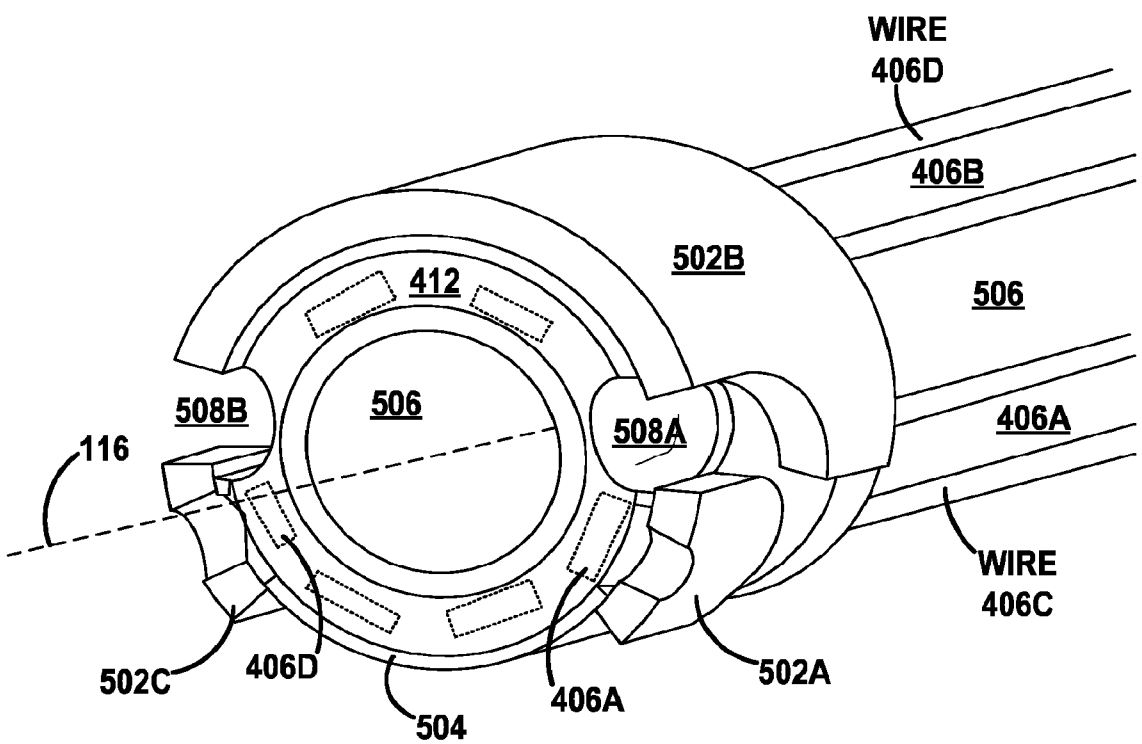
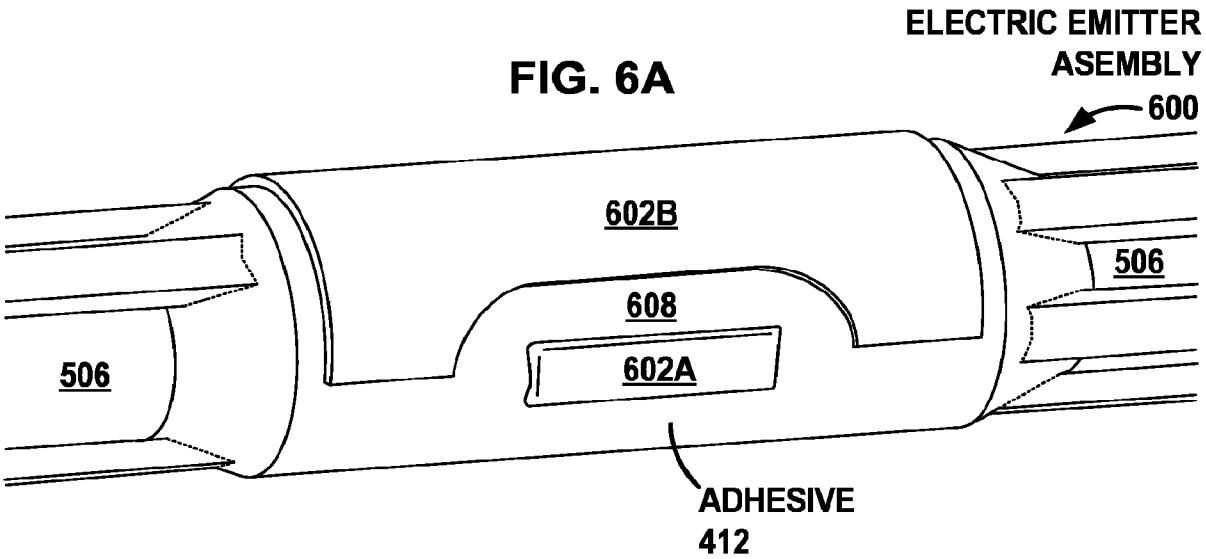

WIRE
406D
406B
502B
412
506
508B
506
508A
406A
116
WIRE
406C
502C
406D
504
406A
502A

FIG. 5B

FIG. 6A



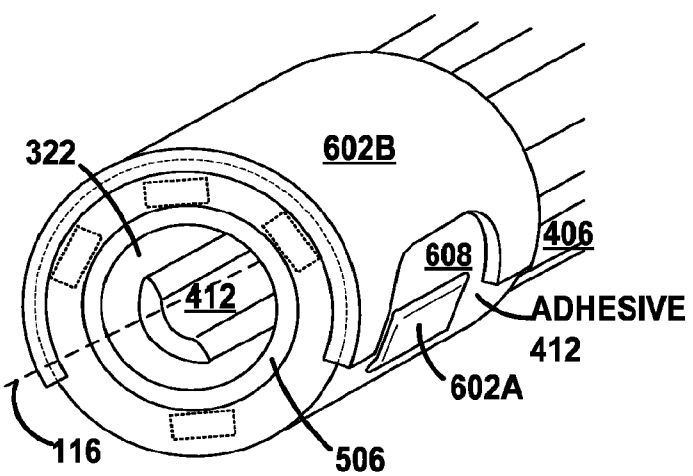


FIG. 6B

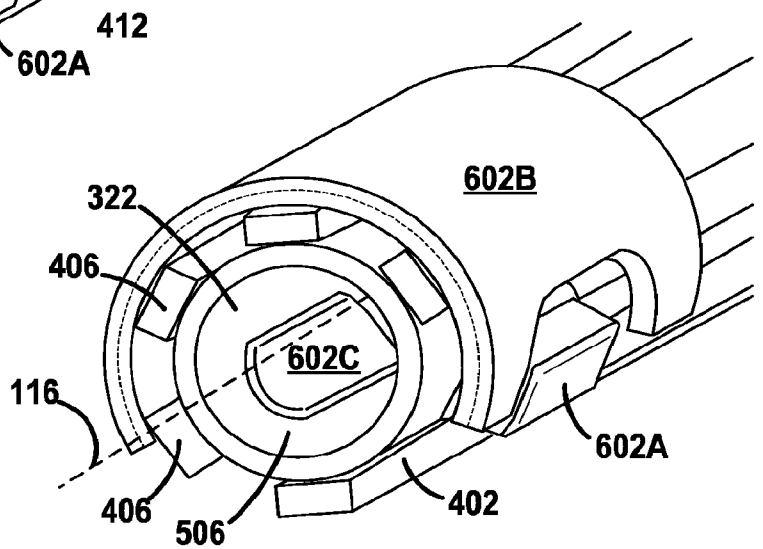


FIG. 6C

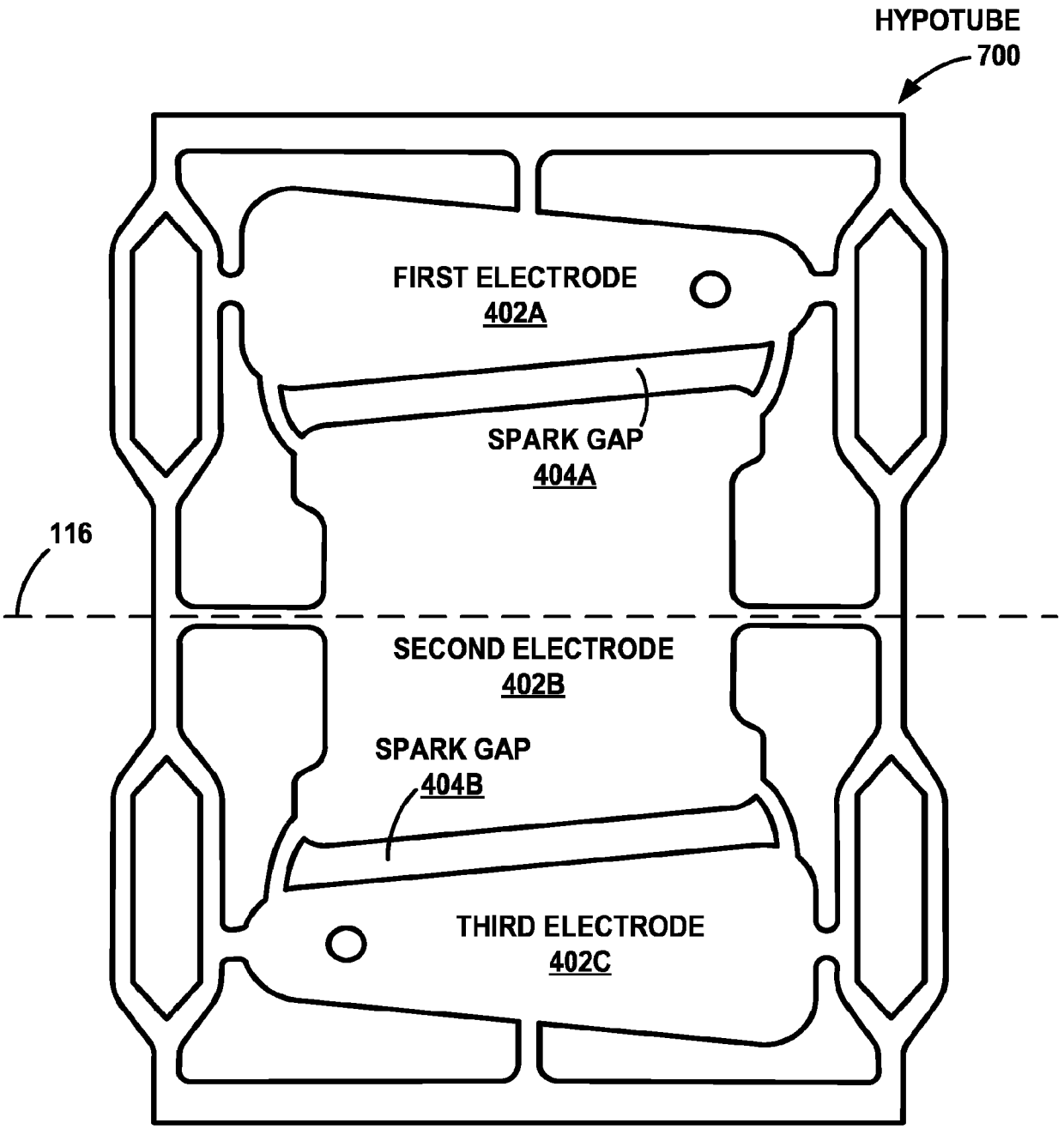

HYPOTUBE
700
FIRST ELECTRODE
402A
SPARK GAP
404A
116
SECOND ELECTRODE
402B
SPARK GAP
404B
THIRD ELECTRODE
402C

FIG. 7A

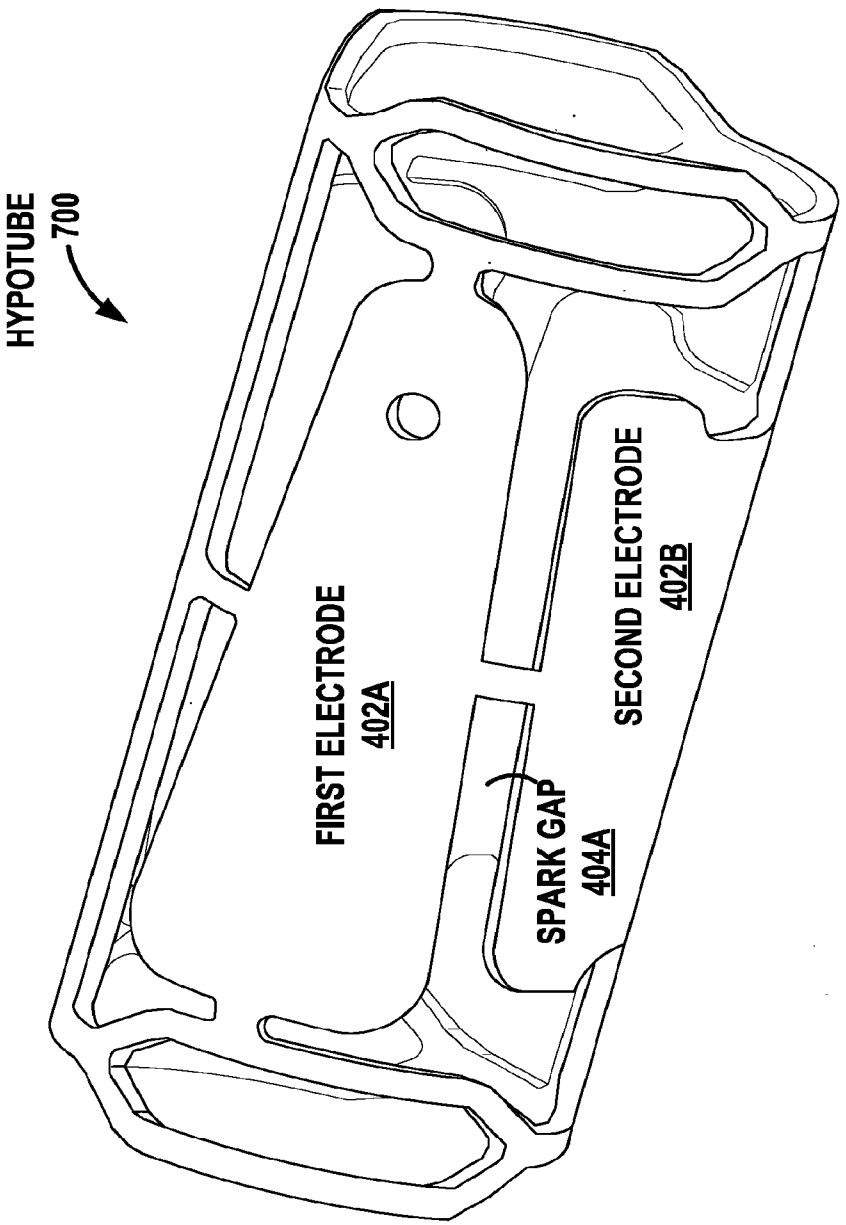

HYPOTUBE
700
FIRST ELECTRODE
402A
SECOND ELECTRODE
402B
SPARK GAP
404A

FIG. 7B

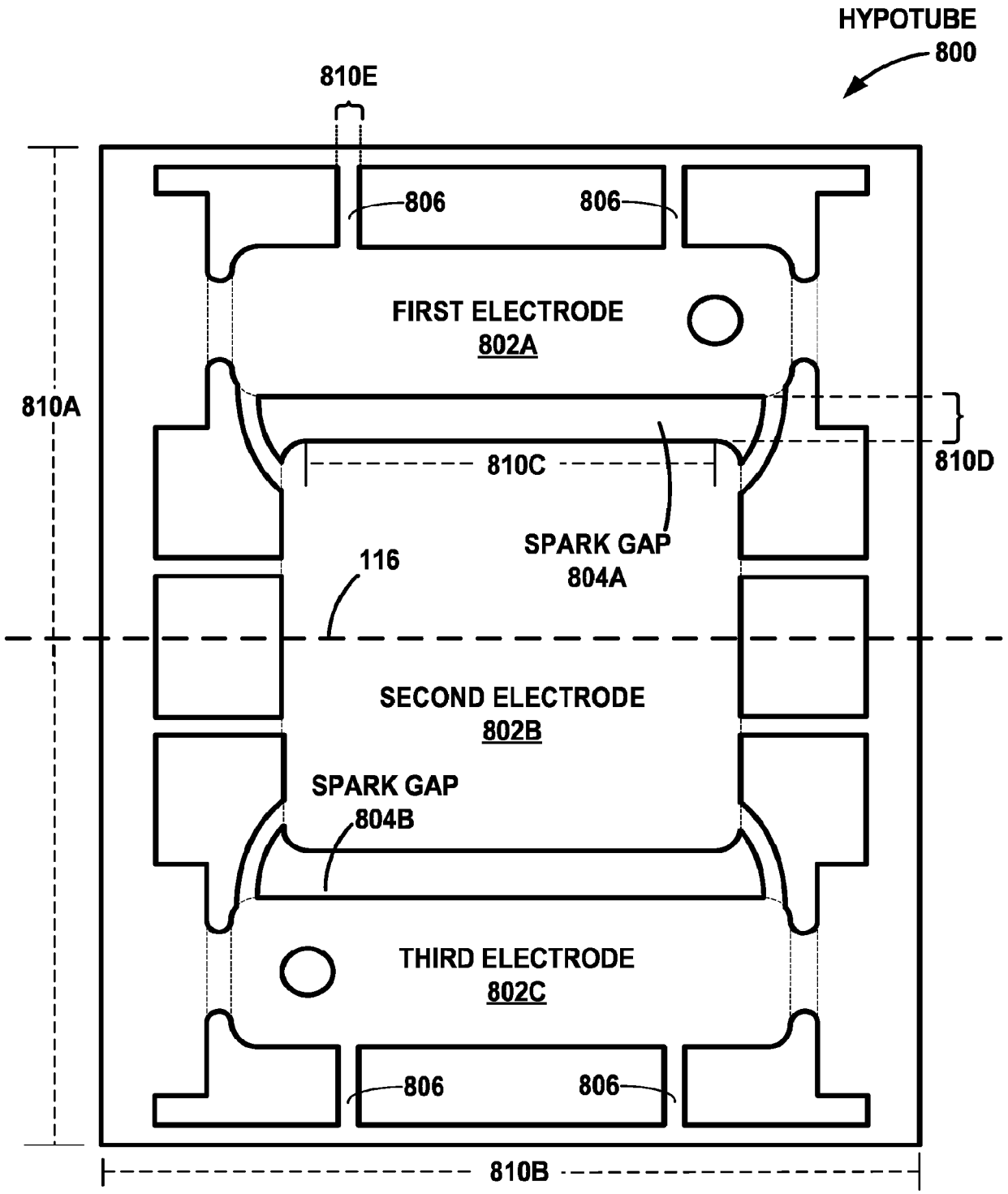

HYPOTUBE
800
810E
806
806
FIRST ELECTRODE
802A
810A
810C
810D
SPARK GAP
804A
116
SECOND ELECTRODE
802B
SPARK GAP
804B
THIRD ELECTRODE
802C
806
806
810B

FIG. 8A

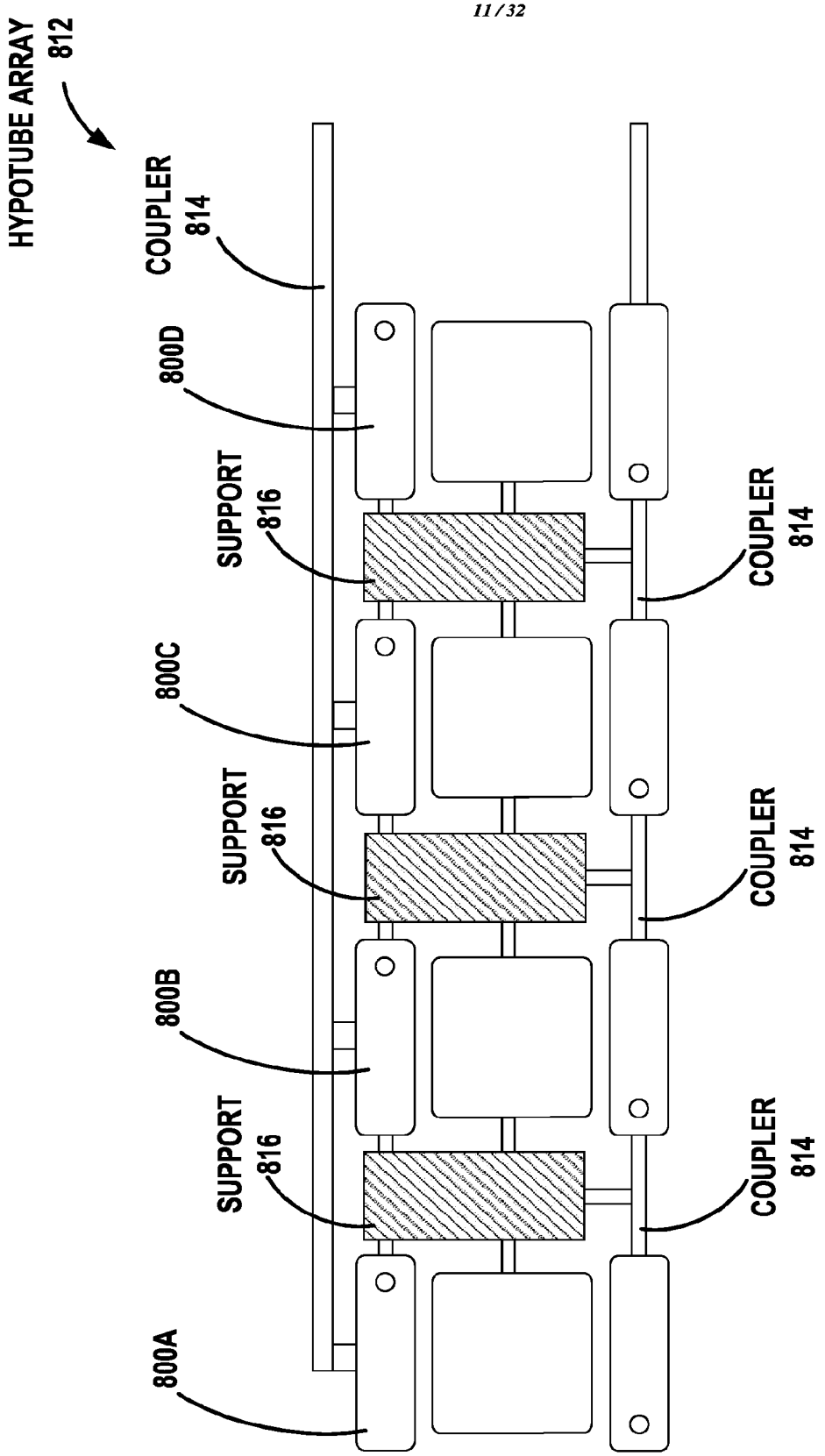

HYPOTUBE ARRAY
812
COUPLER
814
800D
SUPPORT
816
800C
SUPPORT
816
800B
SUPPORT
816
800A
COUPLER
814
COUPLER
814
COUPLER
814

FIG. 8B

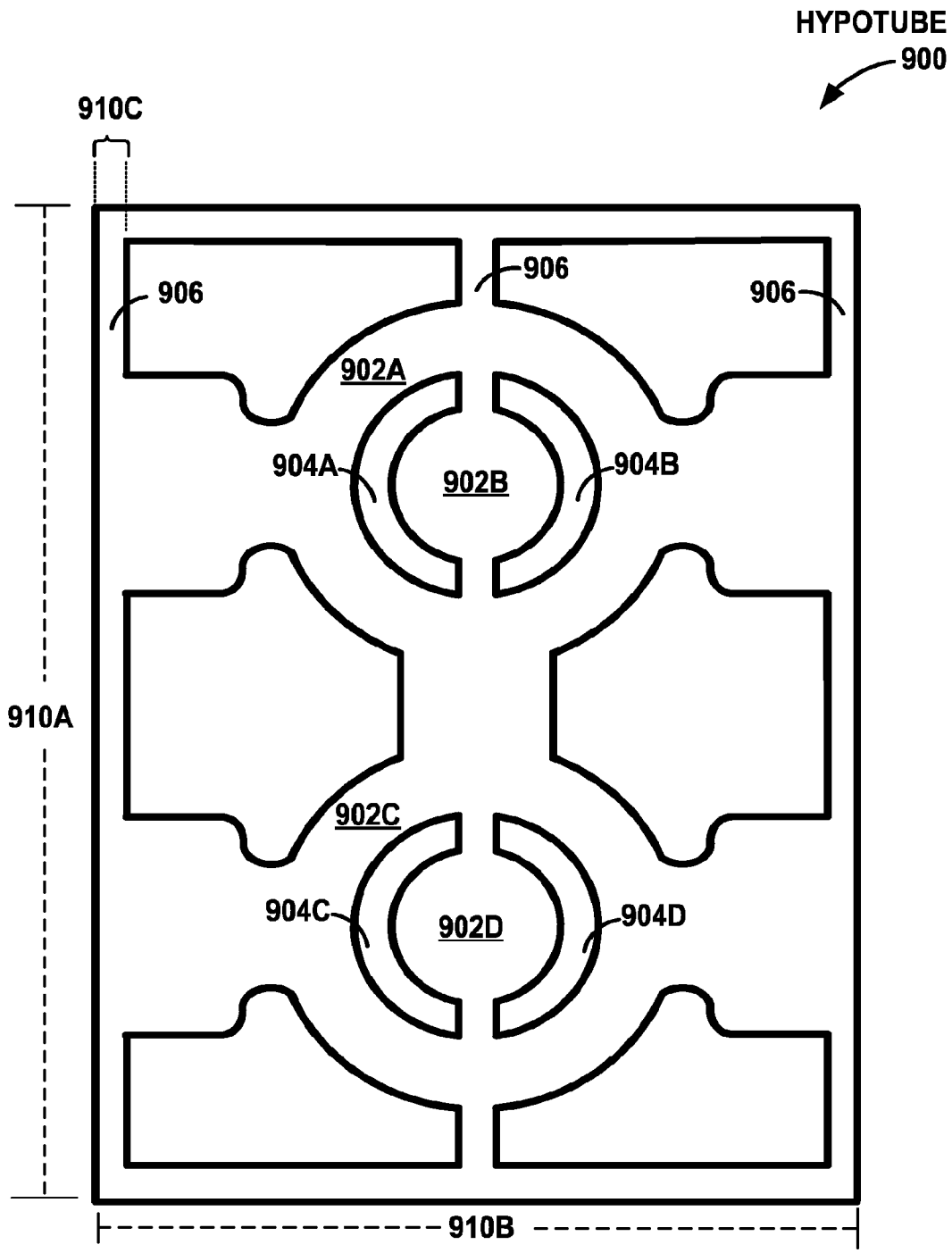

HYPOTUBE
900
910C
906
906
906
902A
904A
902B
904B
910A
902C
904C
902D
904D
910B

FIG. 9

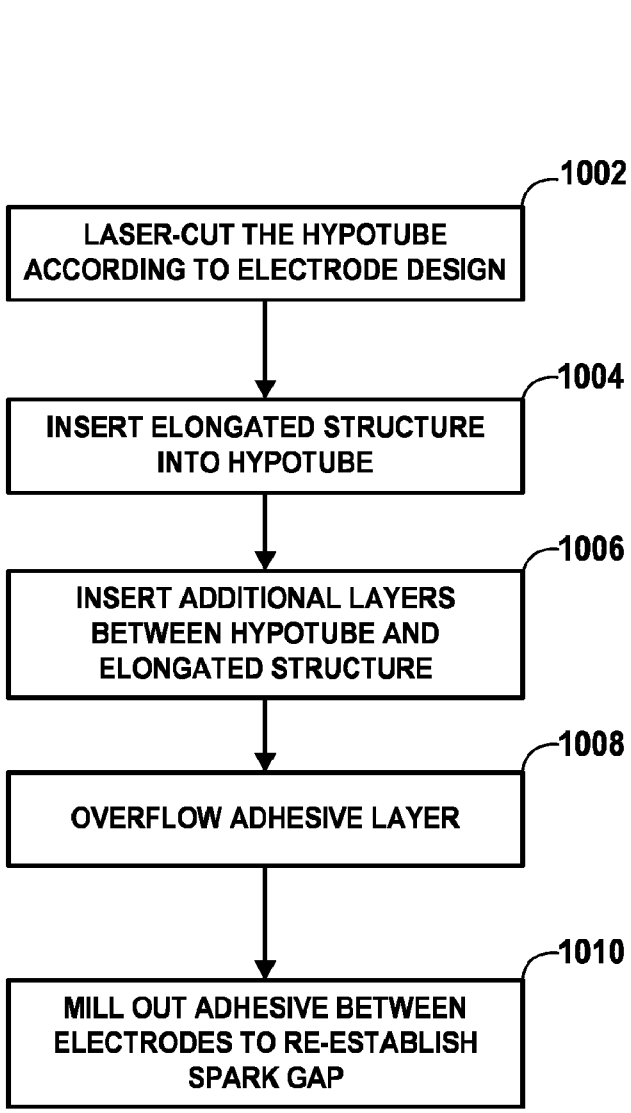

1000
1002
LASER-CUT THE HYPOTUBE ACCORDING TO ELECTRODE DESIGN
1004
INSERT ELONGATED STRUCTURE INTO HYPOTUBE
1006
INSERT ADDITIONAL LAYERS BETWEEN HYPOTUBE AND ELONGATED STRUCTURE
1008
OVERFLOW ADHESIVE LAYER
1010
MILL OUT ADHESIVE BETWEEN ELECTRODES TO RE-ESTABLISH SPARK GAP

FIG. 10

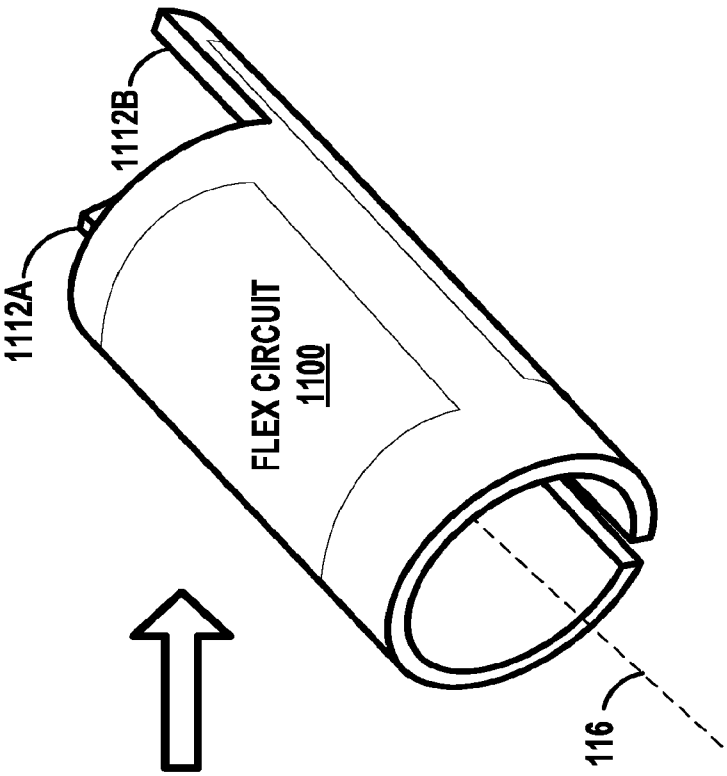


FIG. 11B

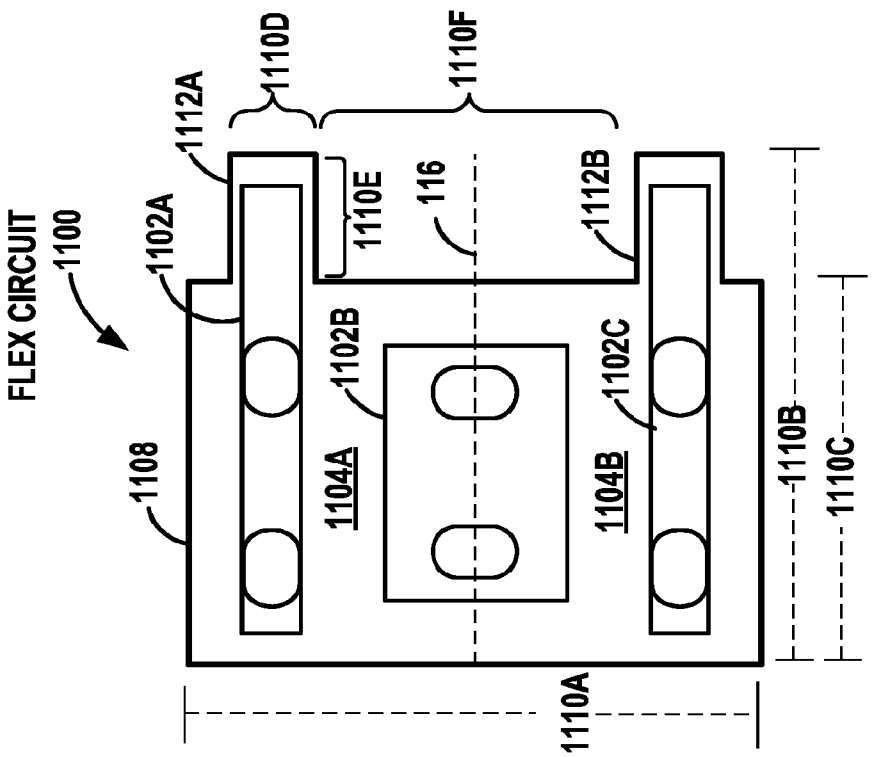


FIG. 11A

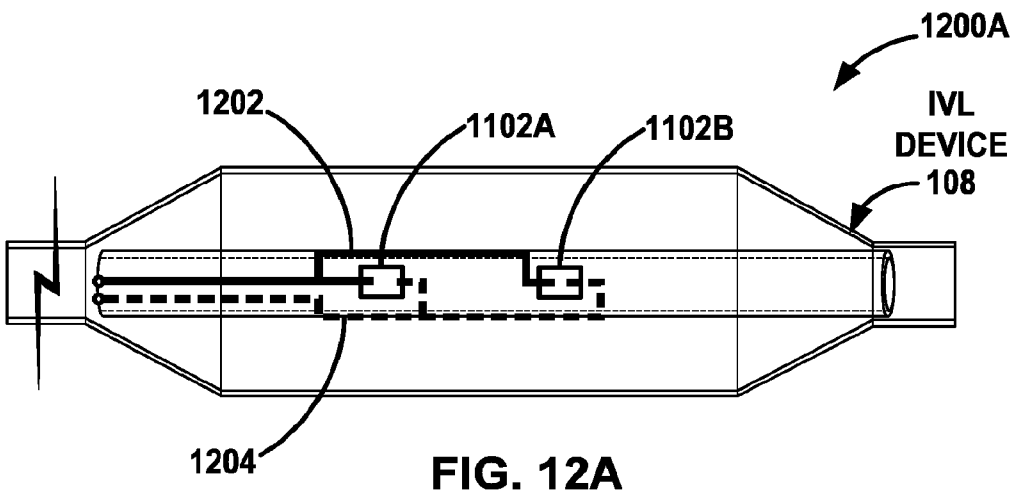


FIG. 12A

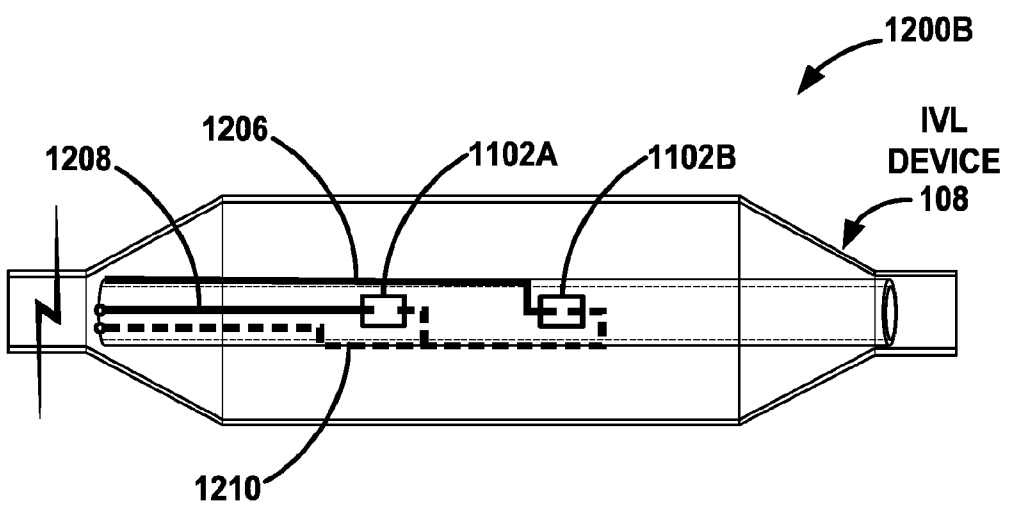


FIG. 12B

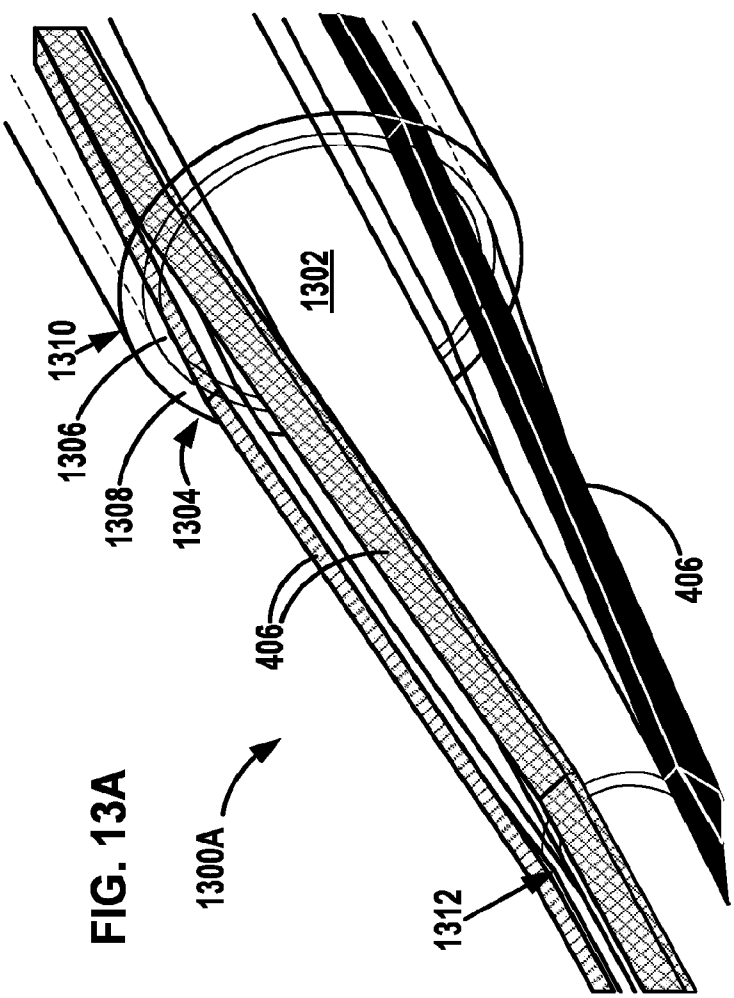


FIG. 13A

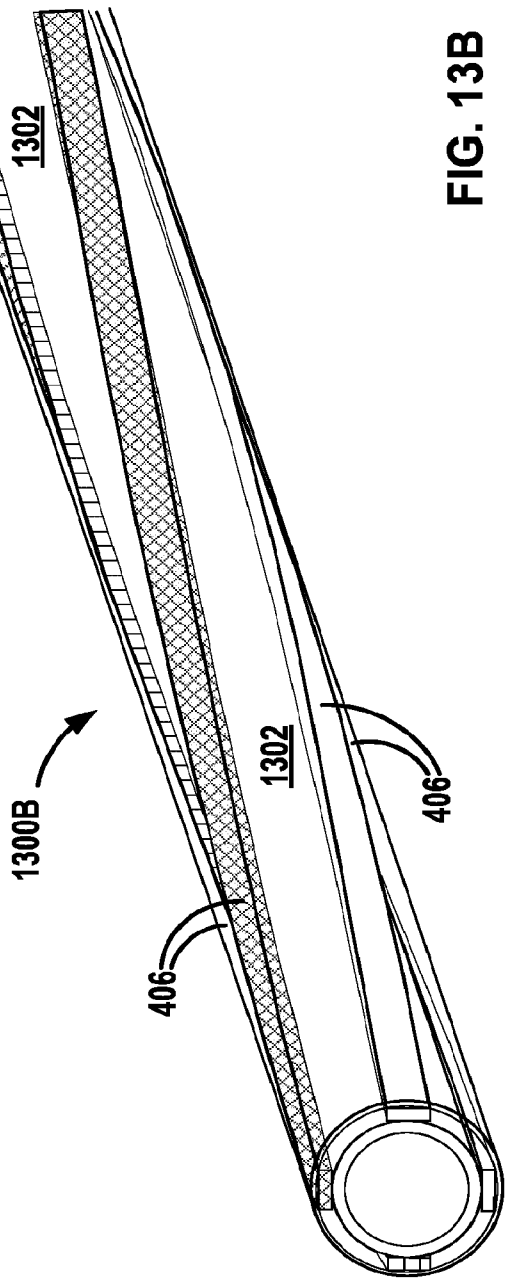


FIG. 13B

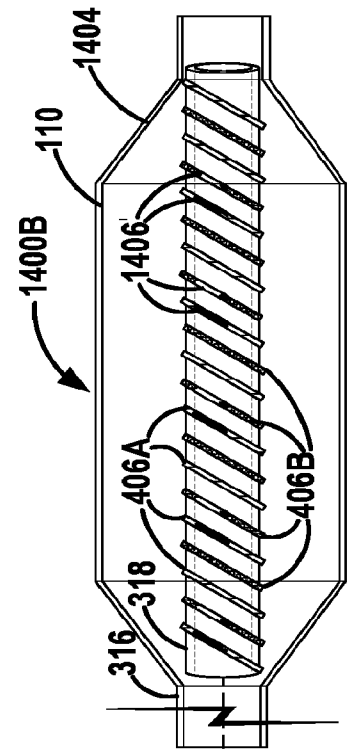


FIG. 14B

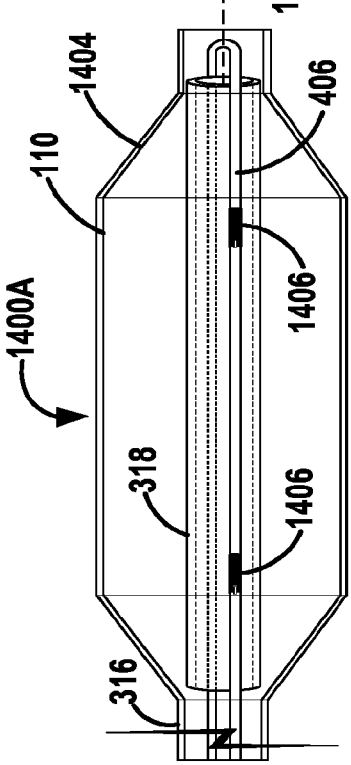


FIG. 14A

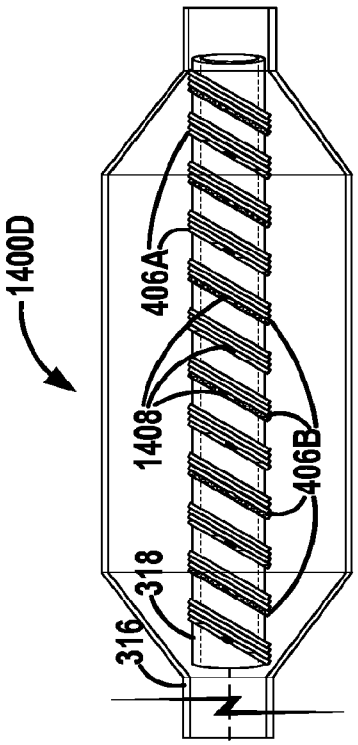


FIG. 14D

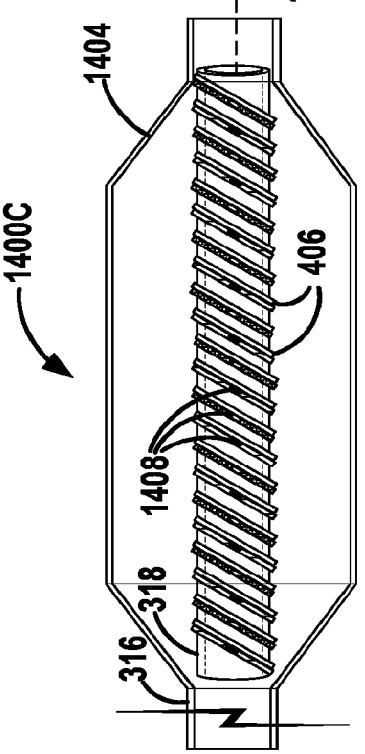


FIG. 14C

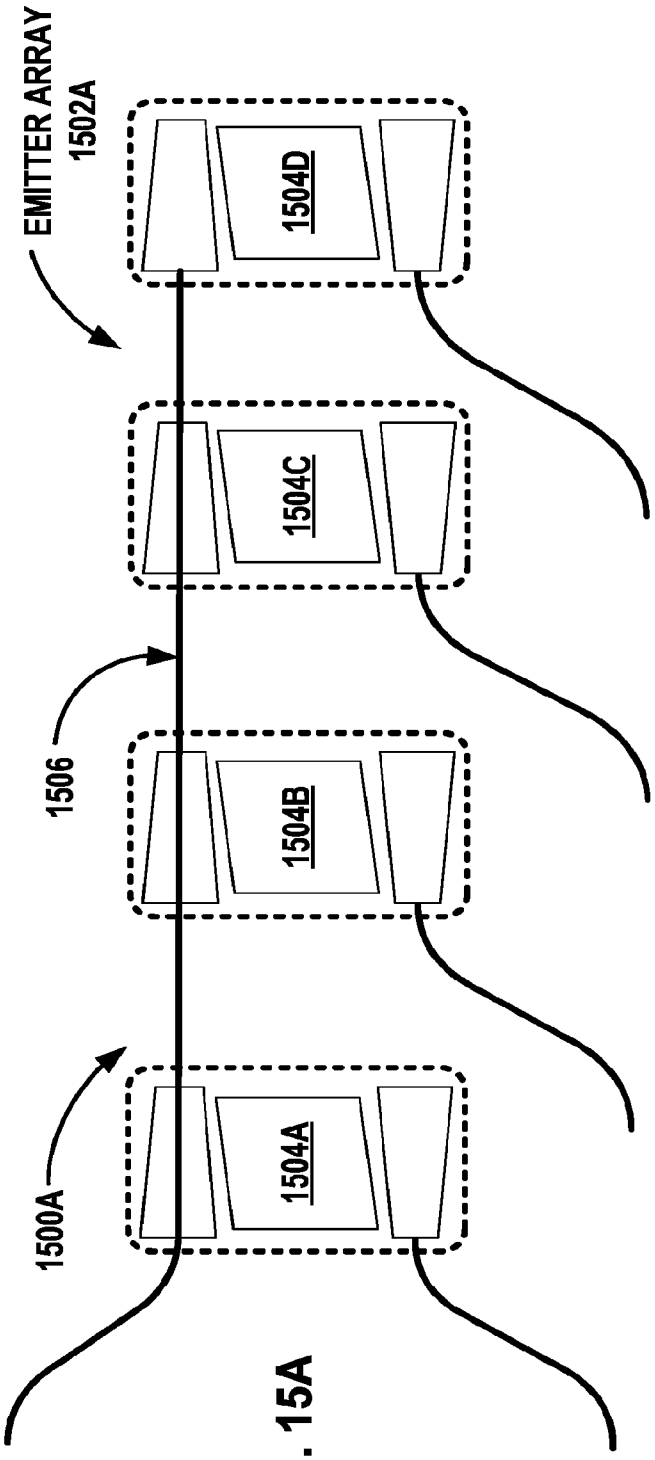


FIG. 15A

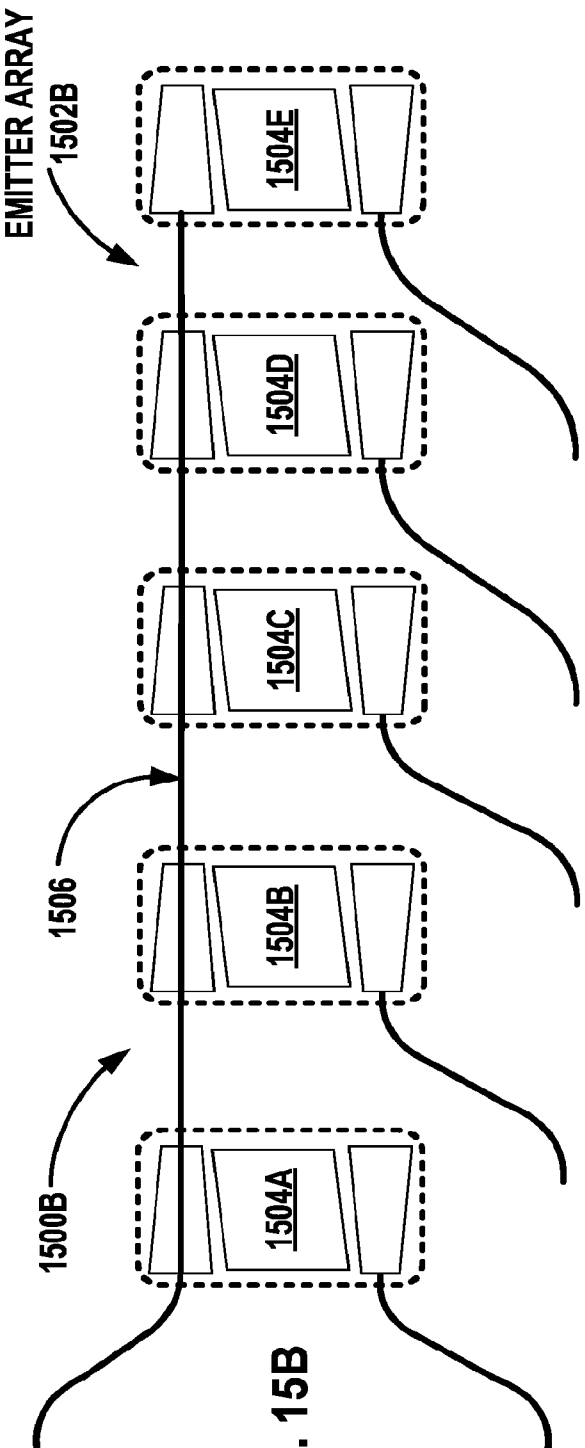


FIG. 15B

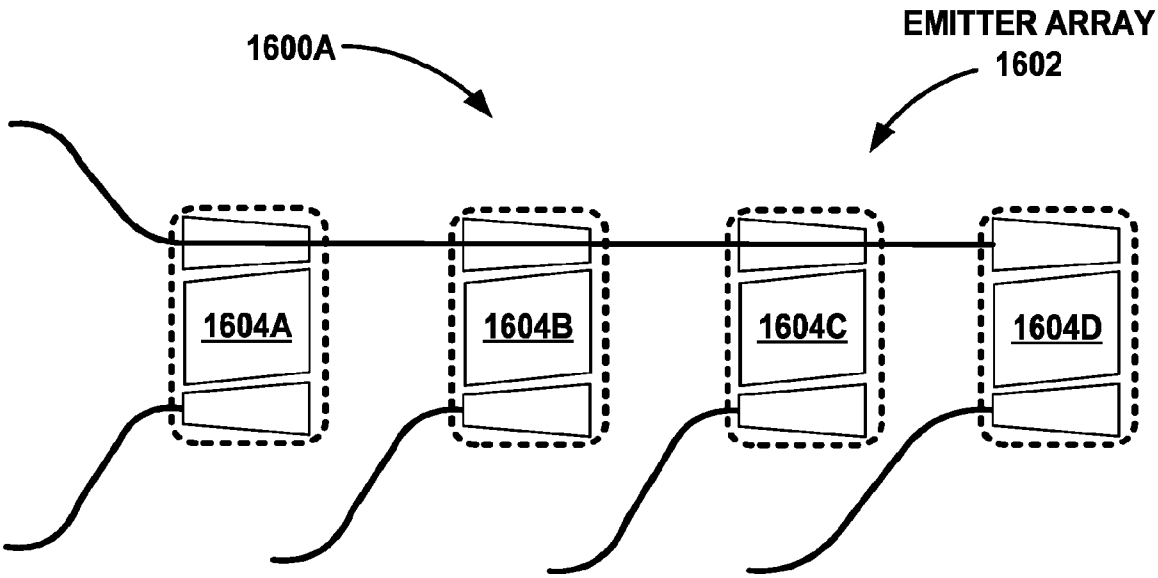


FIG. 16A

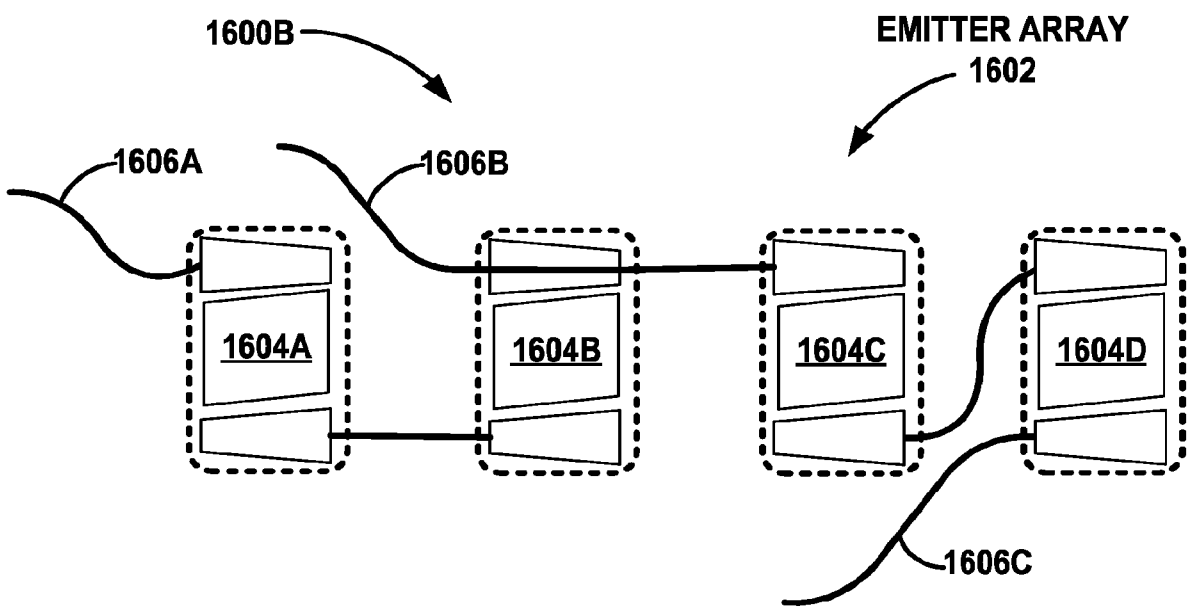


FIG. 16B

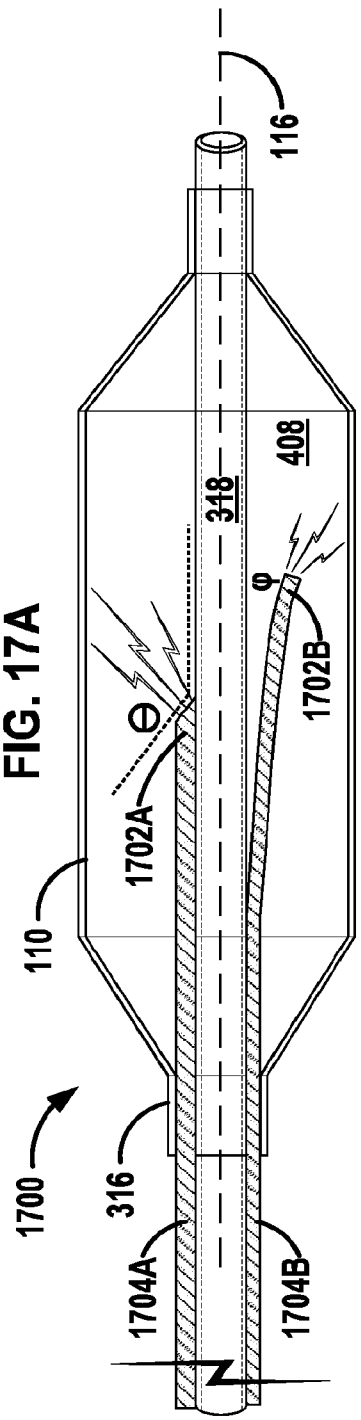


FIG. 17A

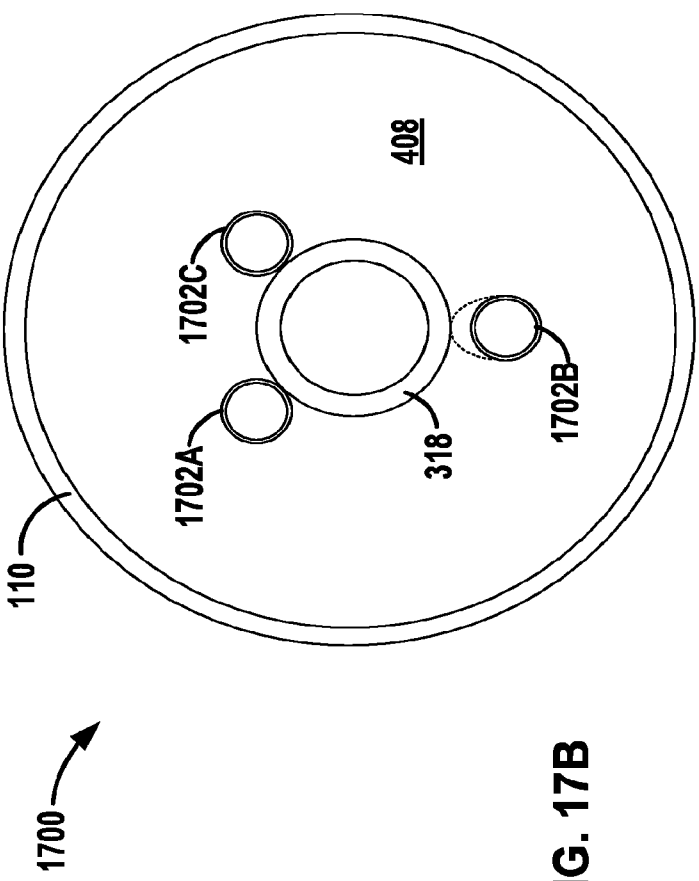


FIG. 17B

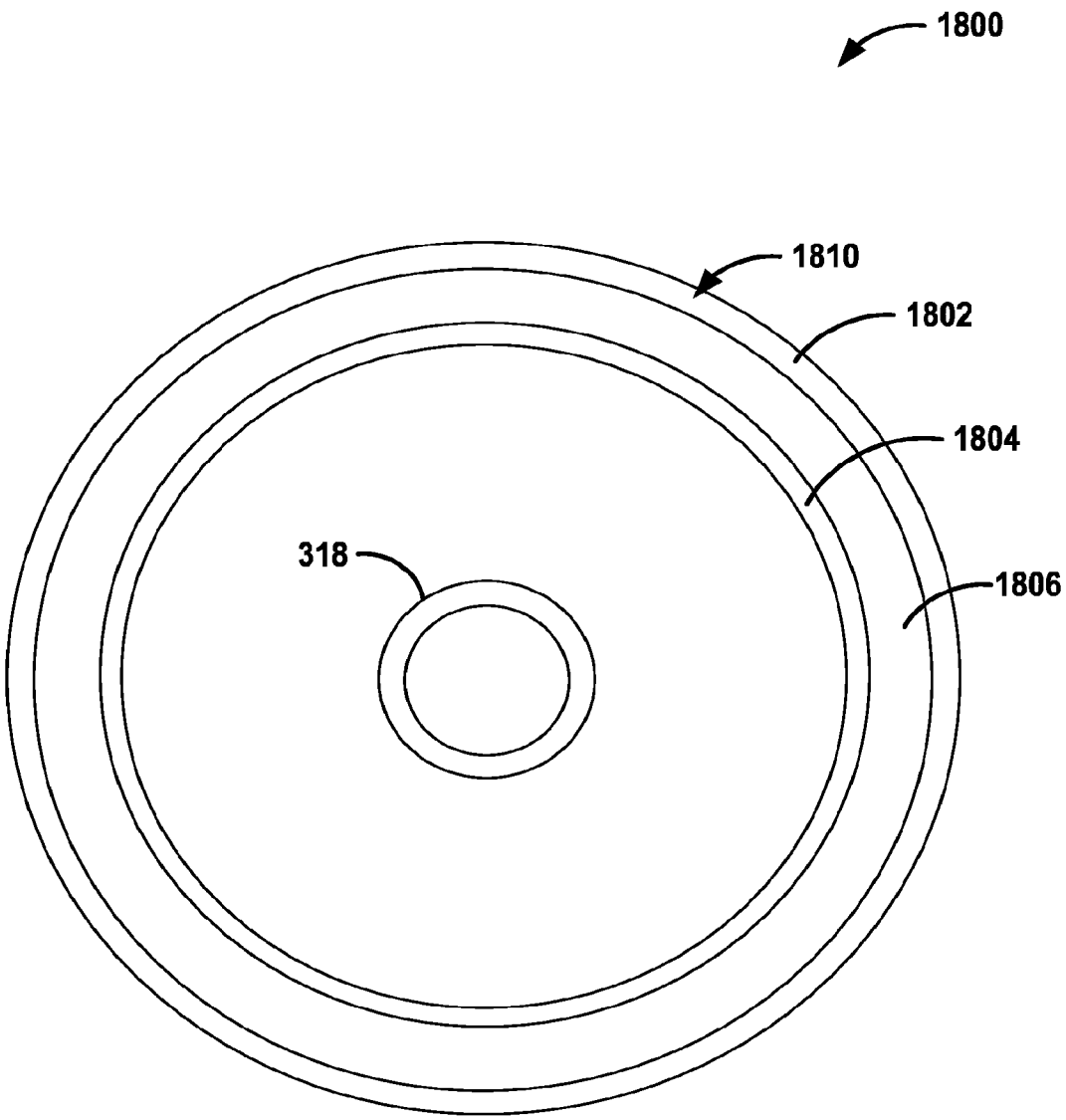


FIG. 18

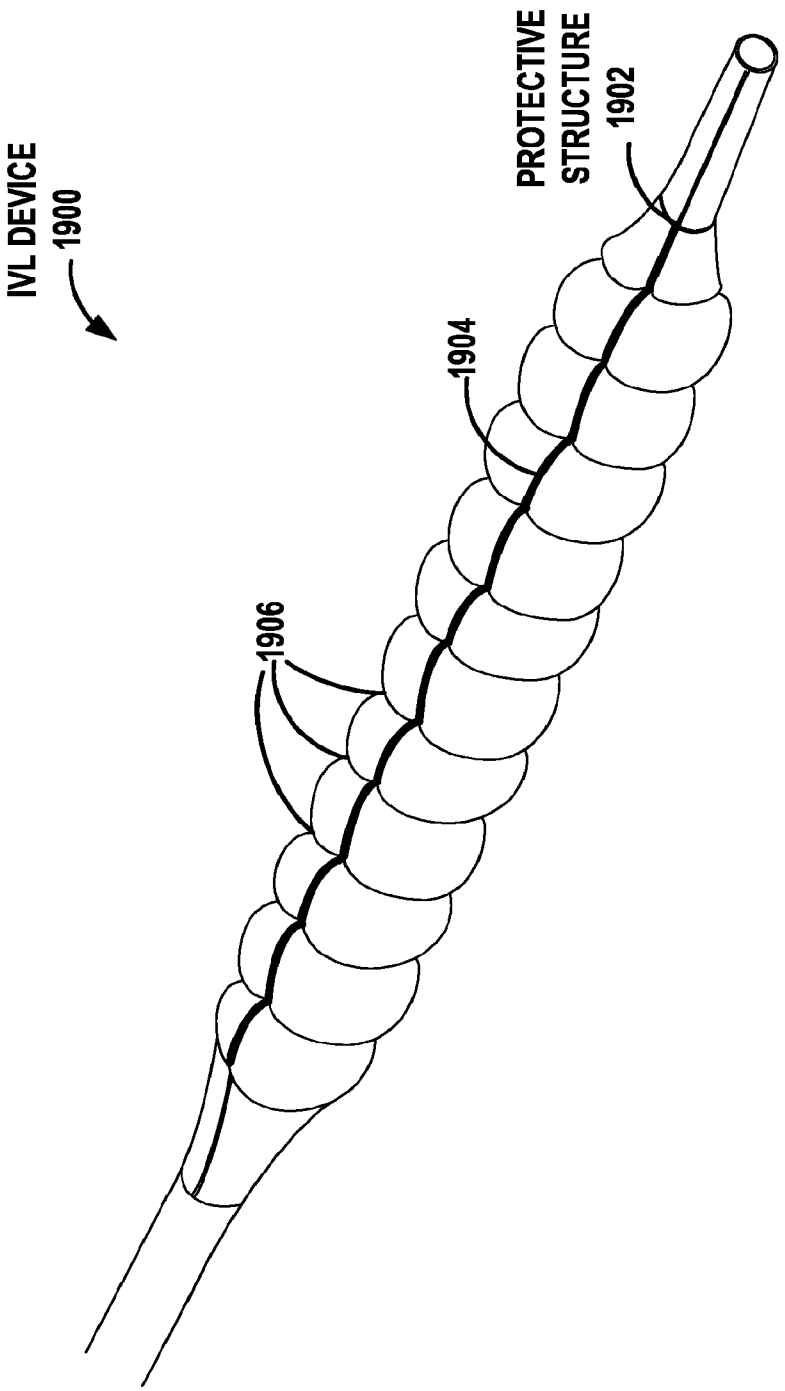


FIG. 19

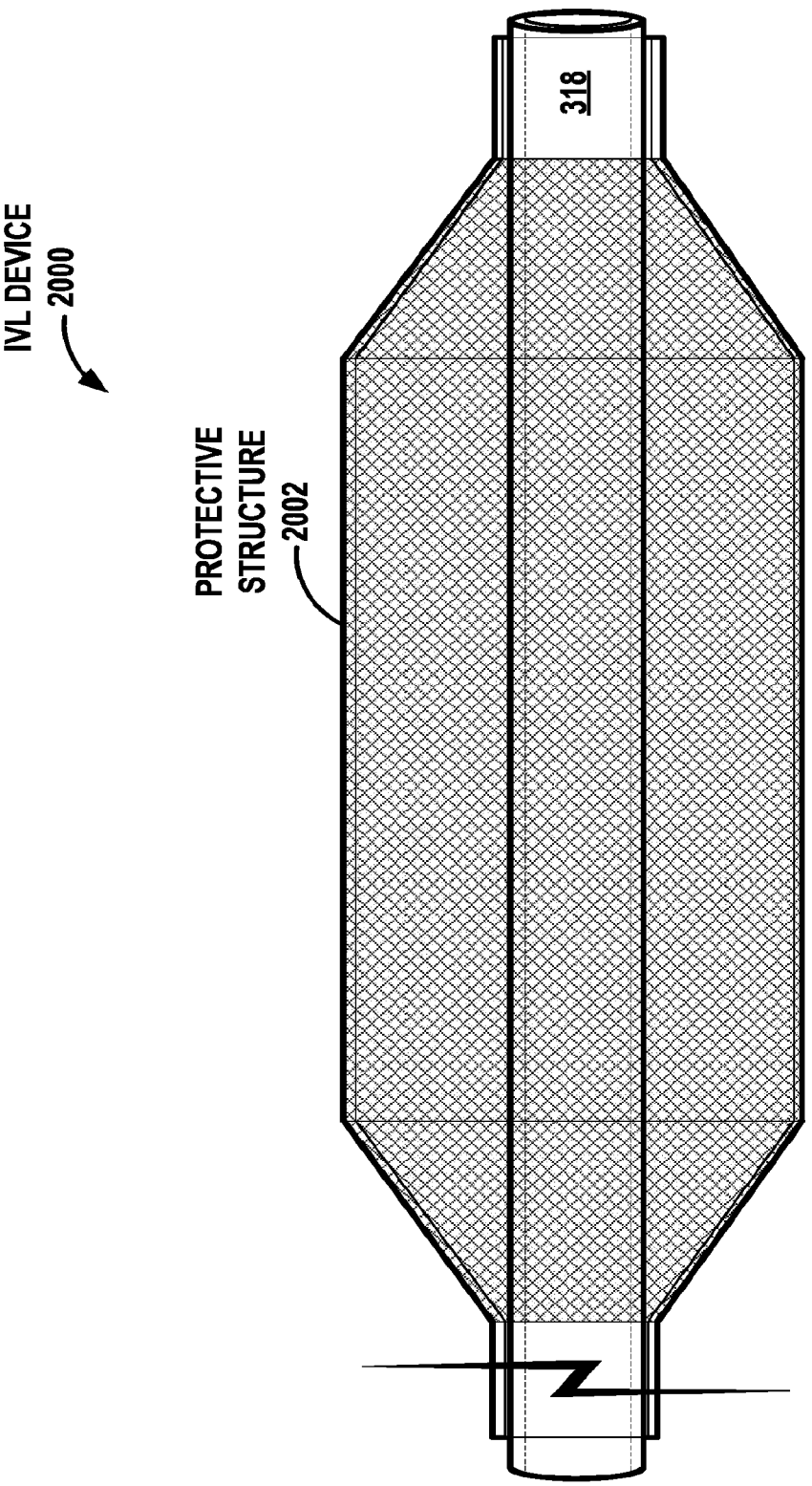


FIG. 20

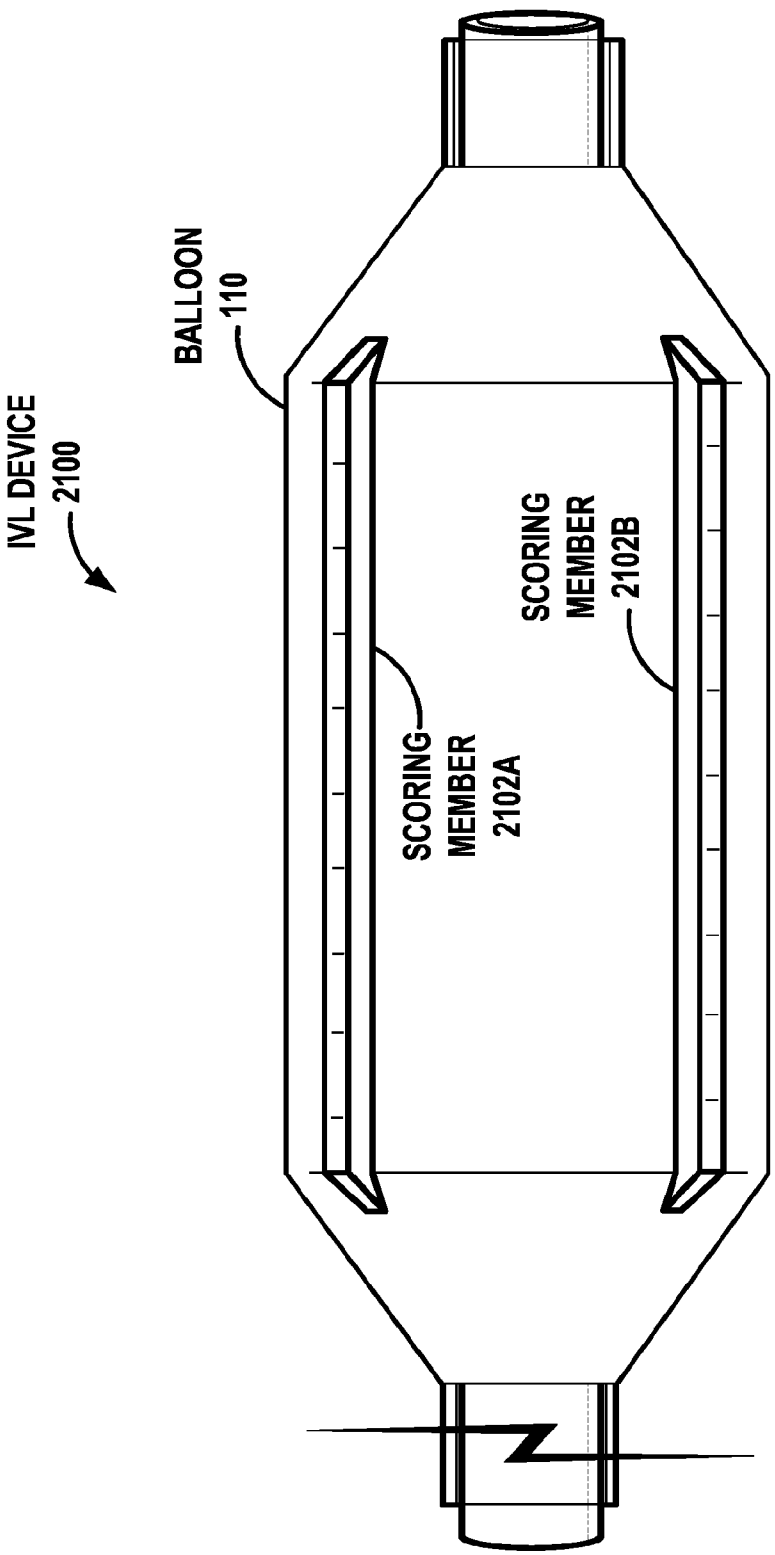

IVL DEVICE
2100
BALLOON
110
SCORING
MEMBER
2102A
SCORING
MEMBER
2102B

FIG. 21

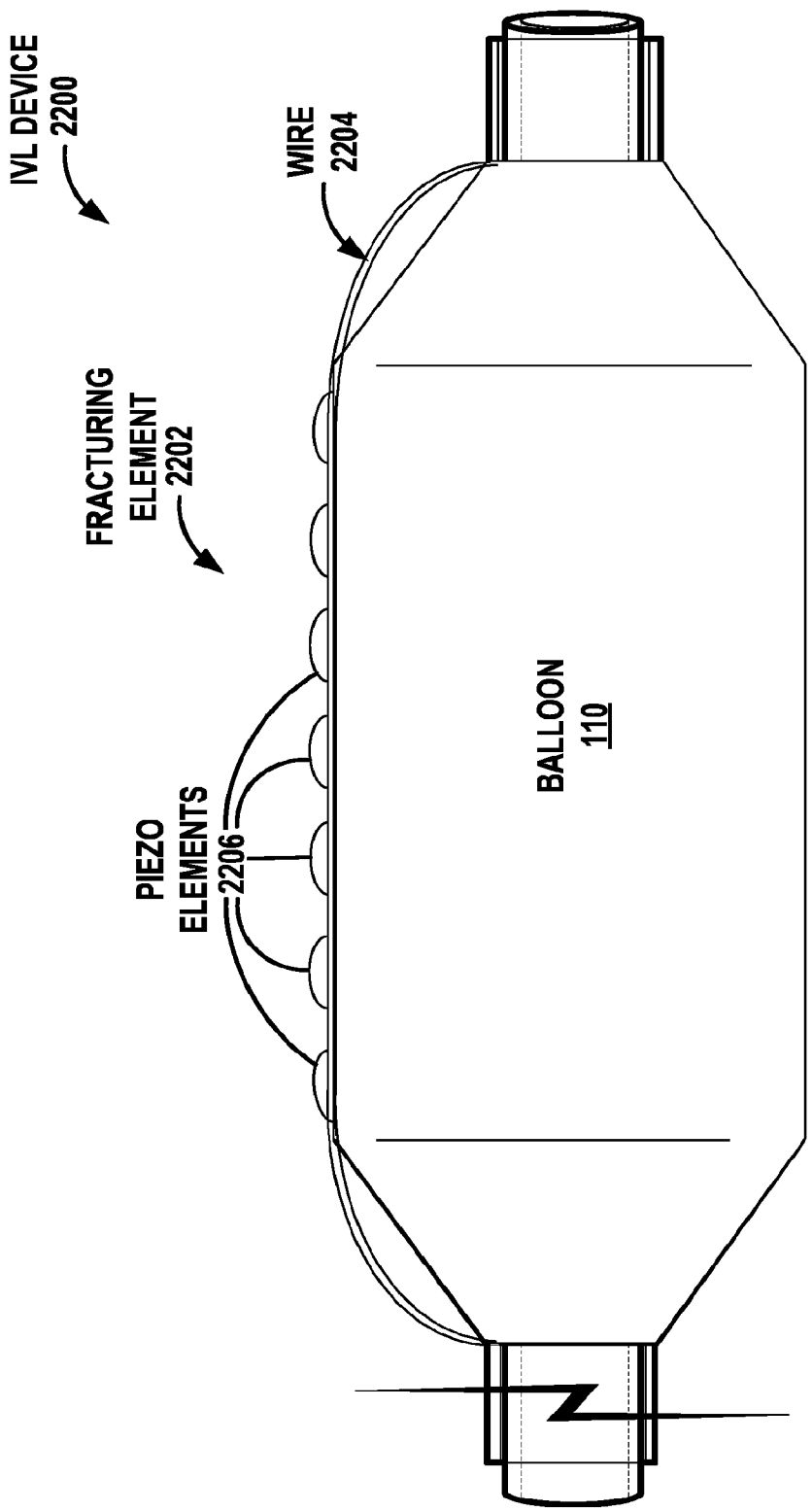

IVL DEVICE
2200
WIRE
2204
FRACTURING
ELEMENT
2202
PIEZO
ELEMENTS
2206
BALLOON
110

FIG. 22

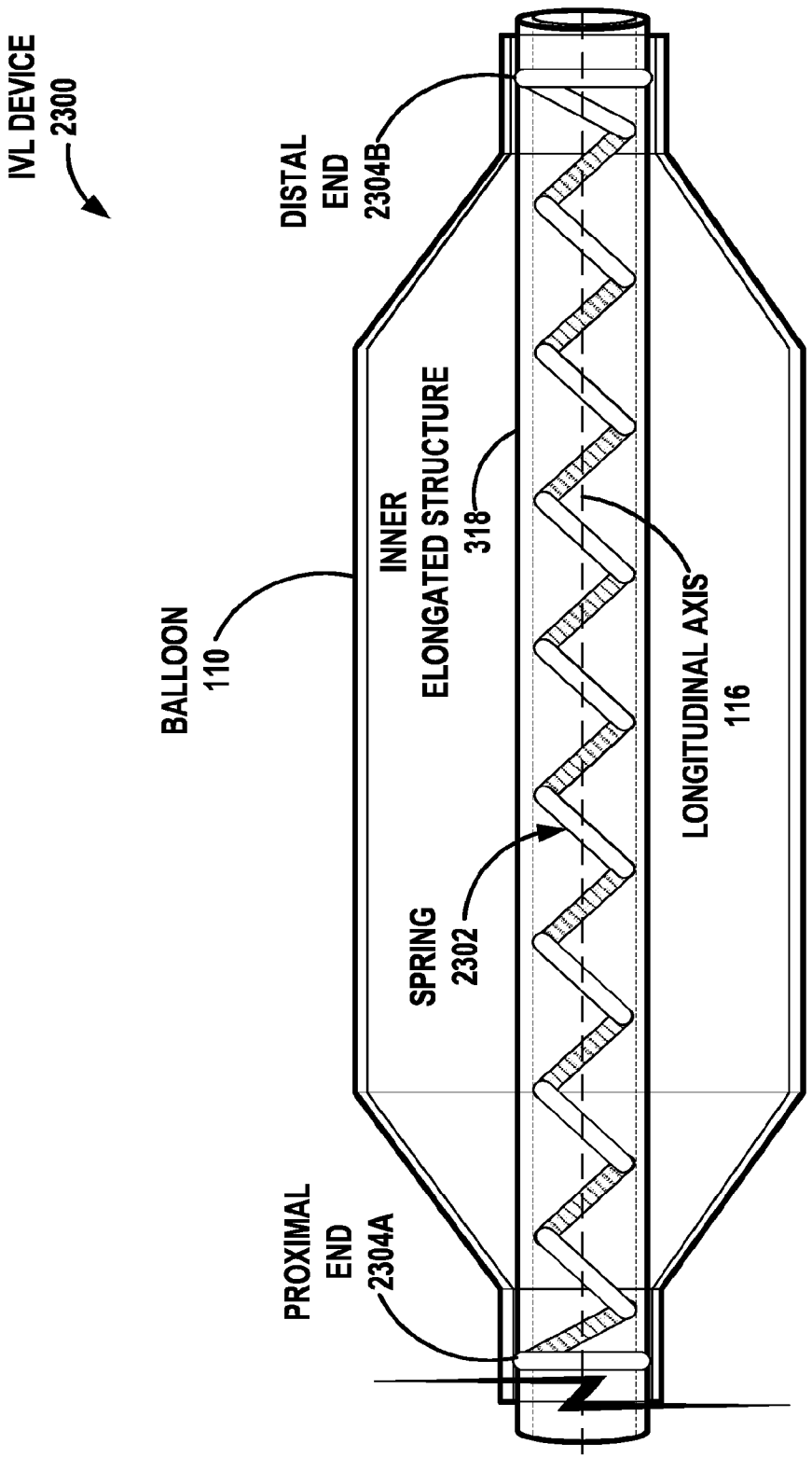

IVL DEVICE
2300
DISTAL
END
2304B
INNER
ELONGATED STRUCTURE
318
BALLOON
110
LONGITUDINAL AXIS
116
SPRING
2302
PROXIMAL
END
2304A

FIG. 23

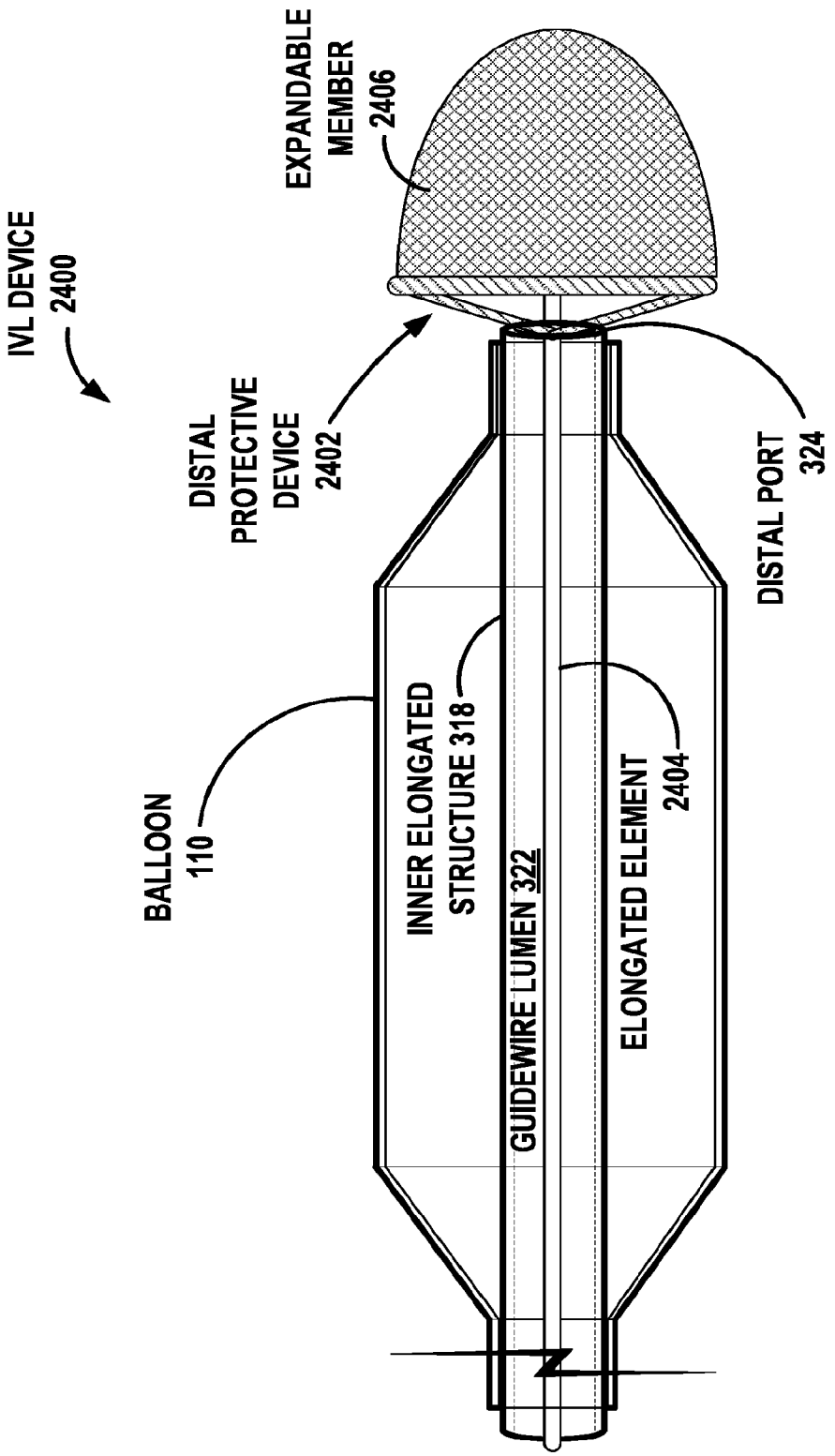

IVL DEVICE
2400
EXPANDABLE
MEMBER
2406
DISTAL
PROTECTIVE
DEVICE
2402
DISTAL PORT
324
BALLOON
110
INNER ELONGATED
STRUCTURE 318
GUIDEWIRE LUMEN 322
ELONGATED ELEMENT
2404

FIG. 24

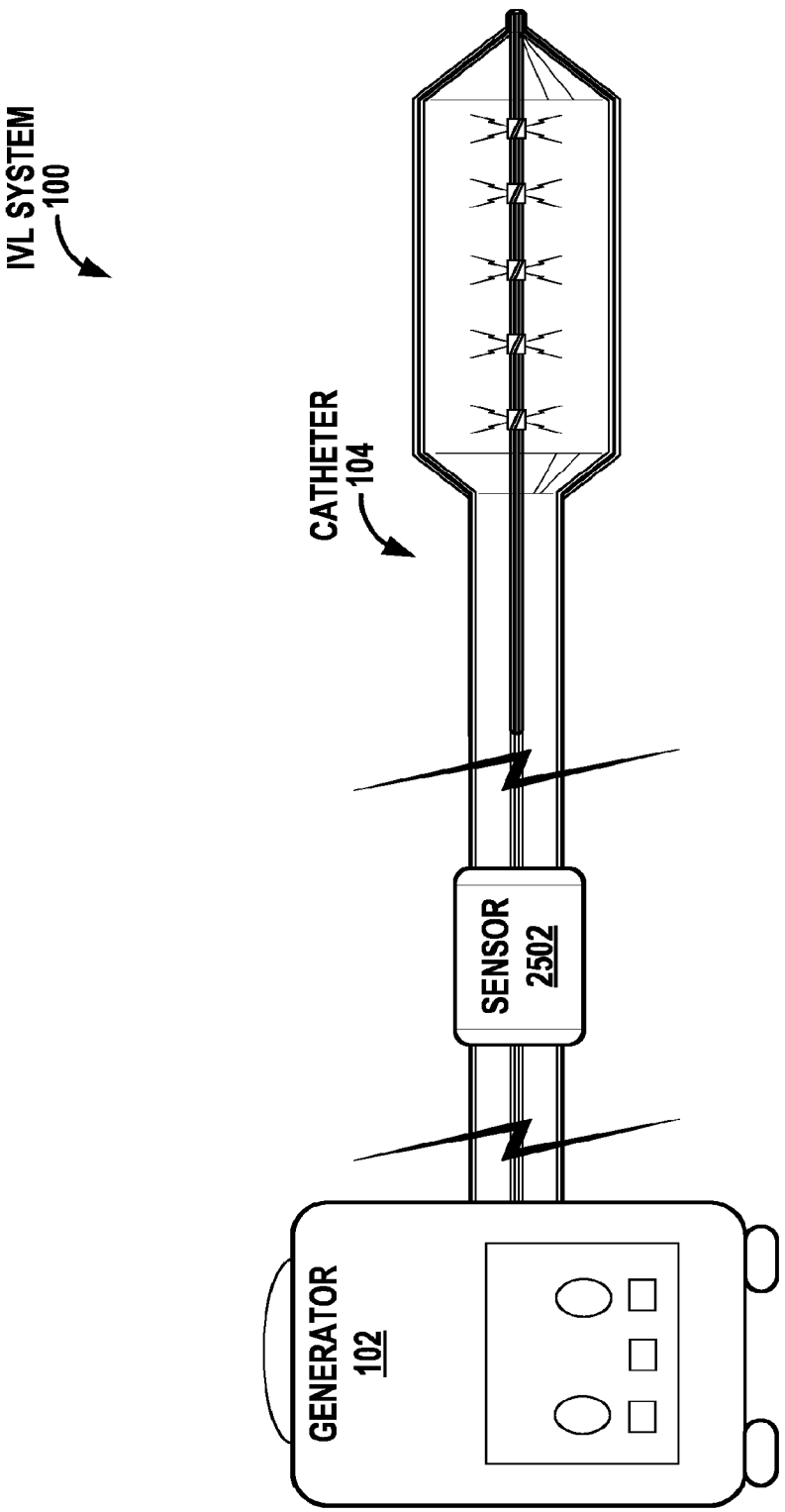


FIG. 25

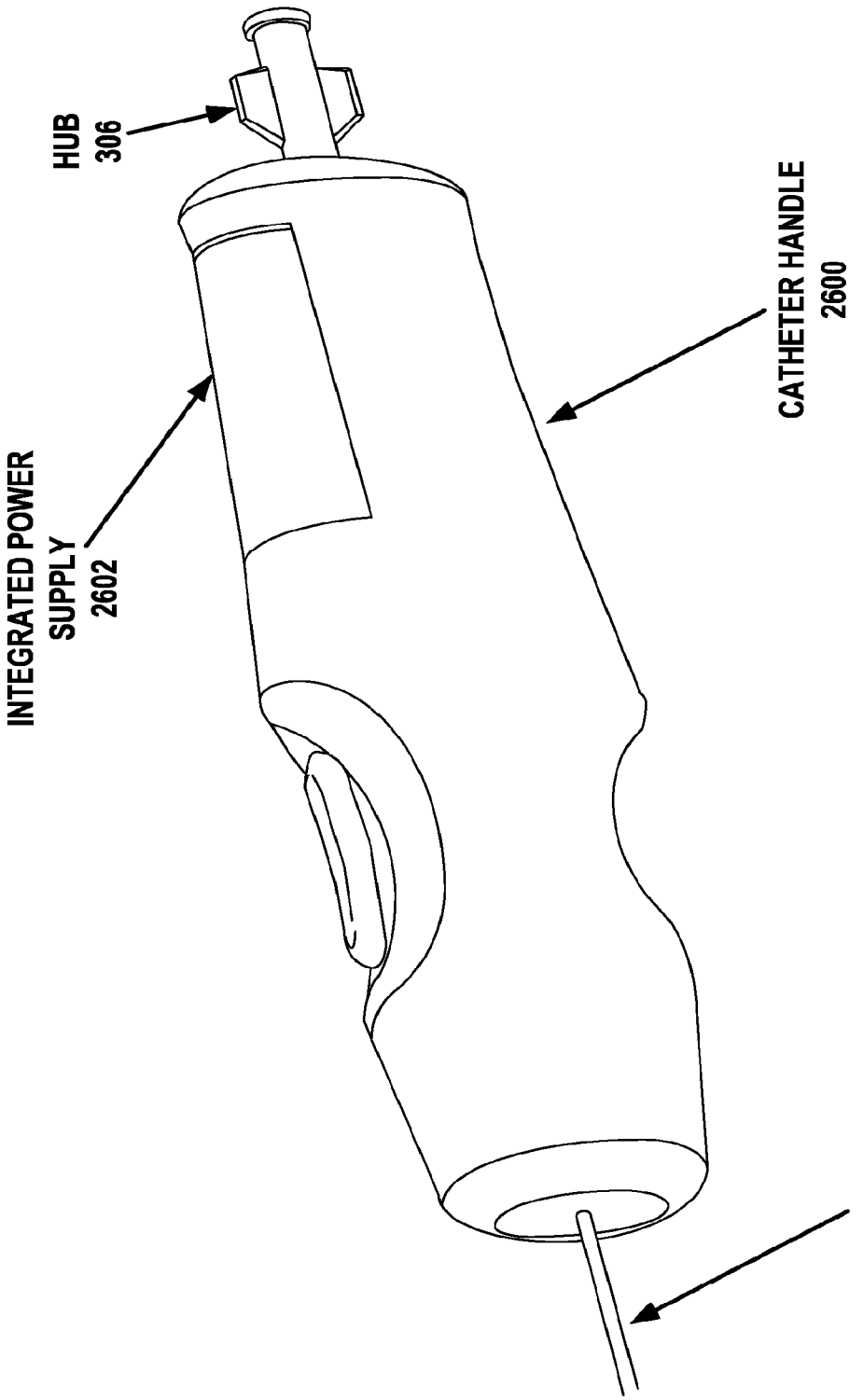

HUB
306
CATHETER HANDLE
2600
INTEGRATED POWER
SUPPLY
2602
ELONGATED BODY
106

FIG. 26

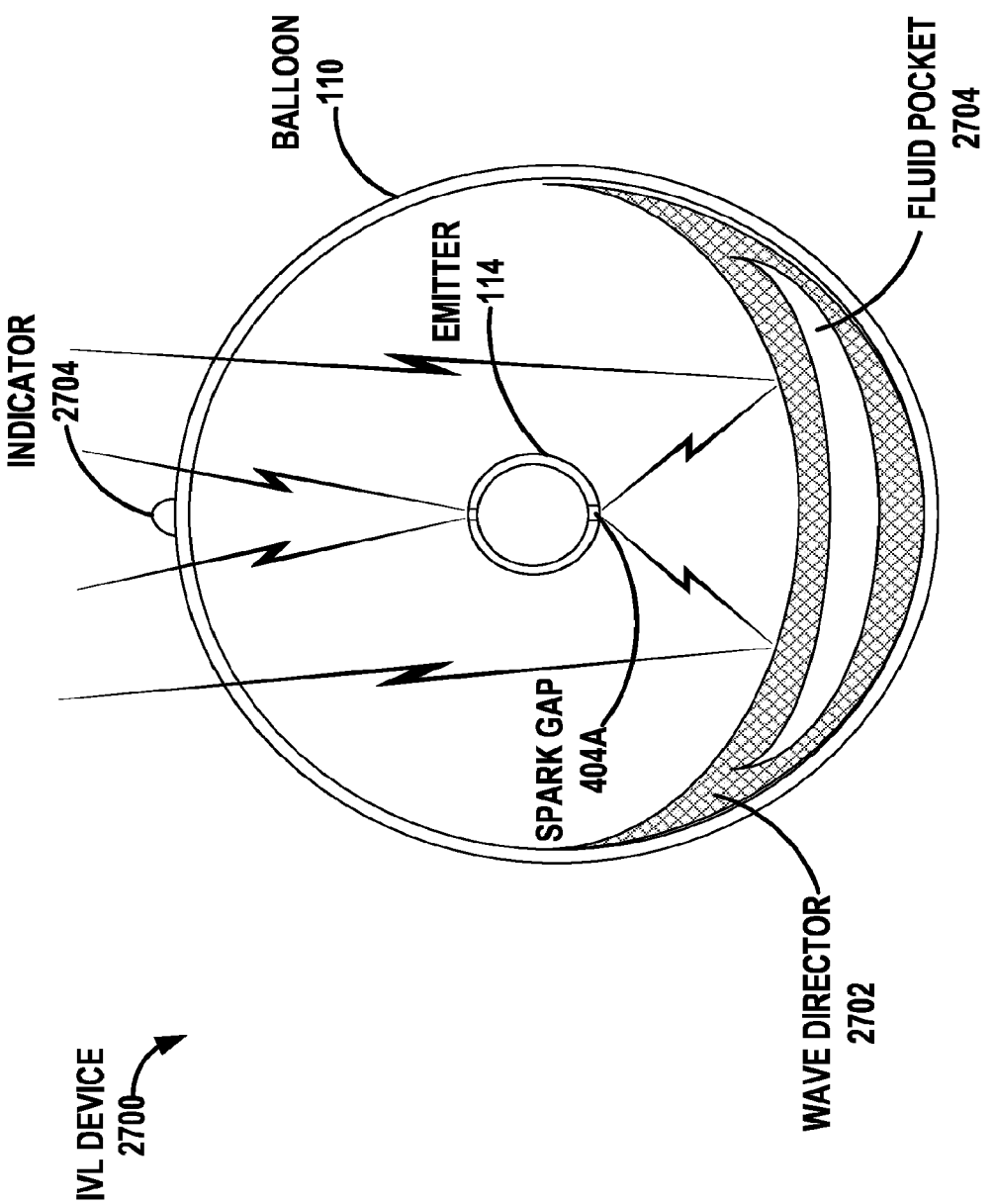

IVL DEVICE
2700
INDICATOR
2704
BALLOON
110
EMITTER
114
SPARK GAP
404A
WAVE DIRECTOR
2702
FLUID POCKET
2704

FIG. 27

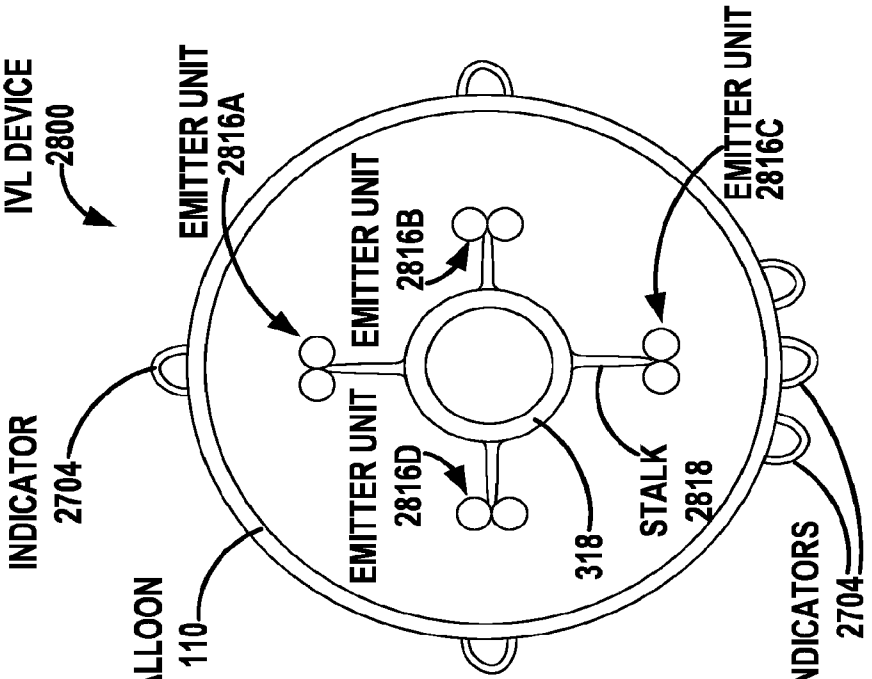


FIG. 28B

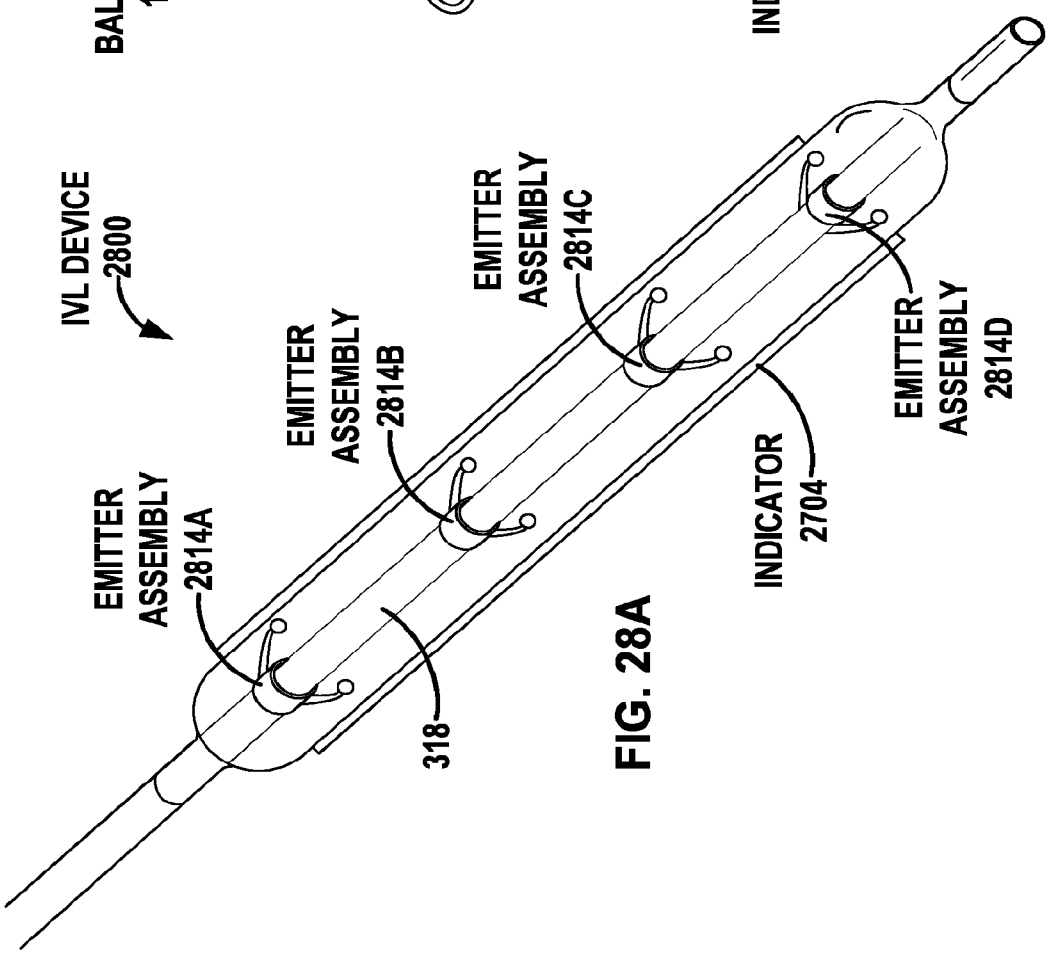


FIG. 28A

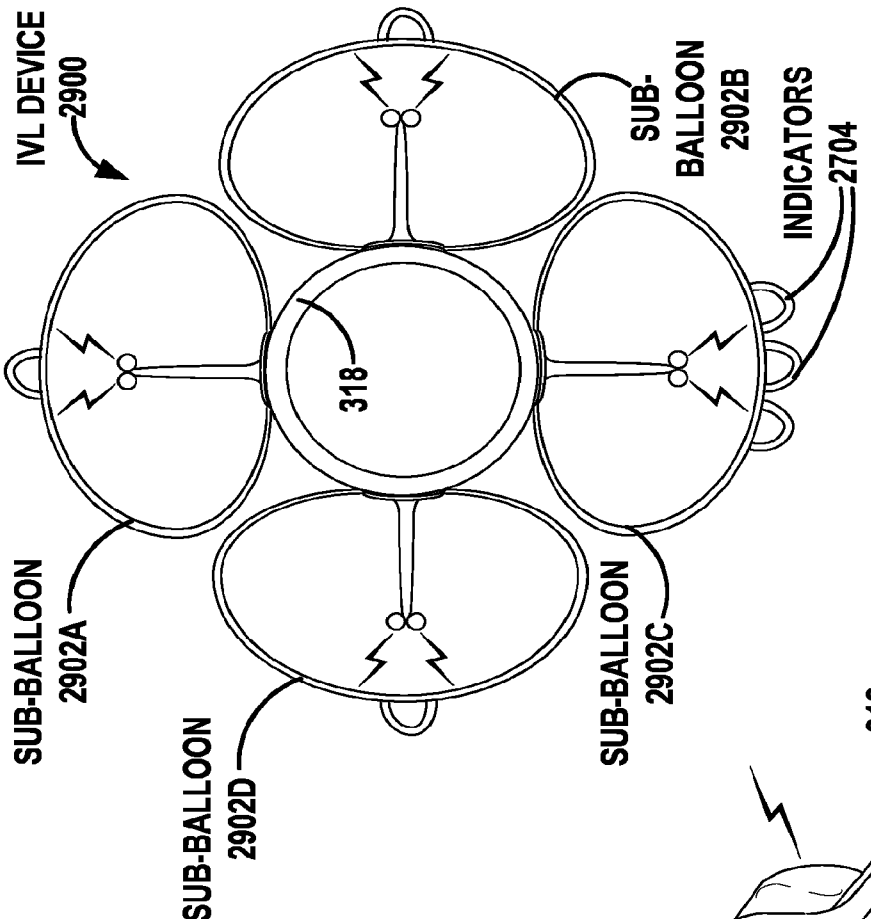


FIG. 29B

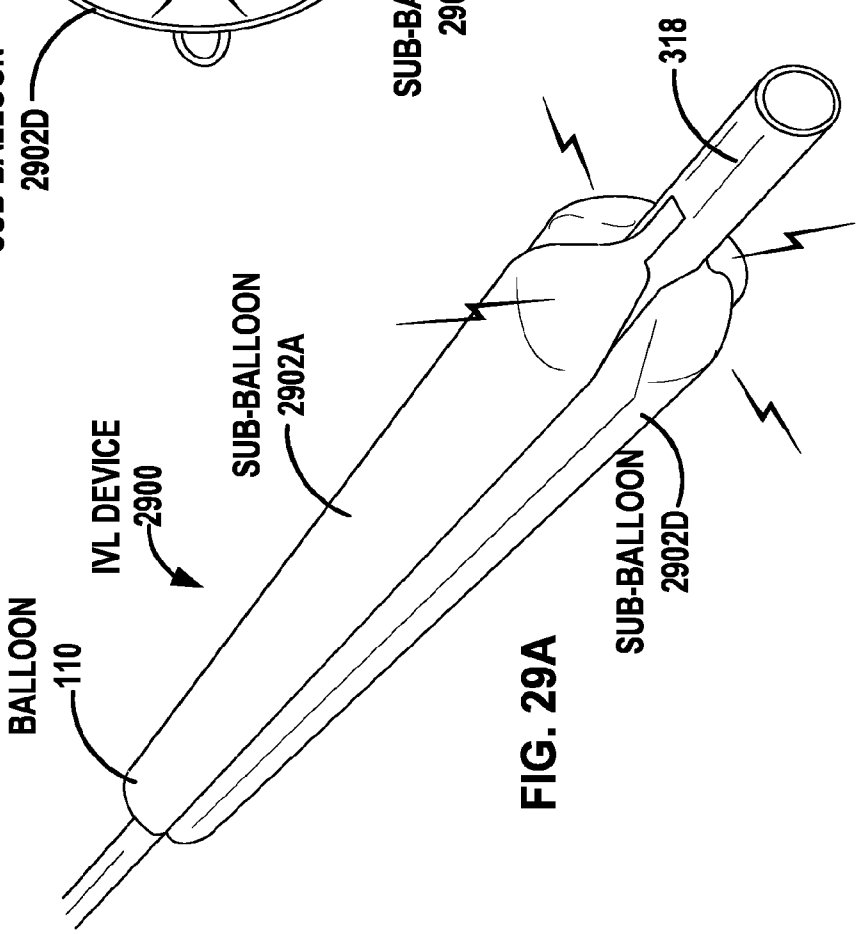


FIG. 29A

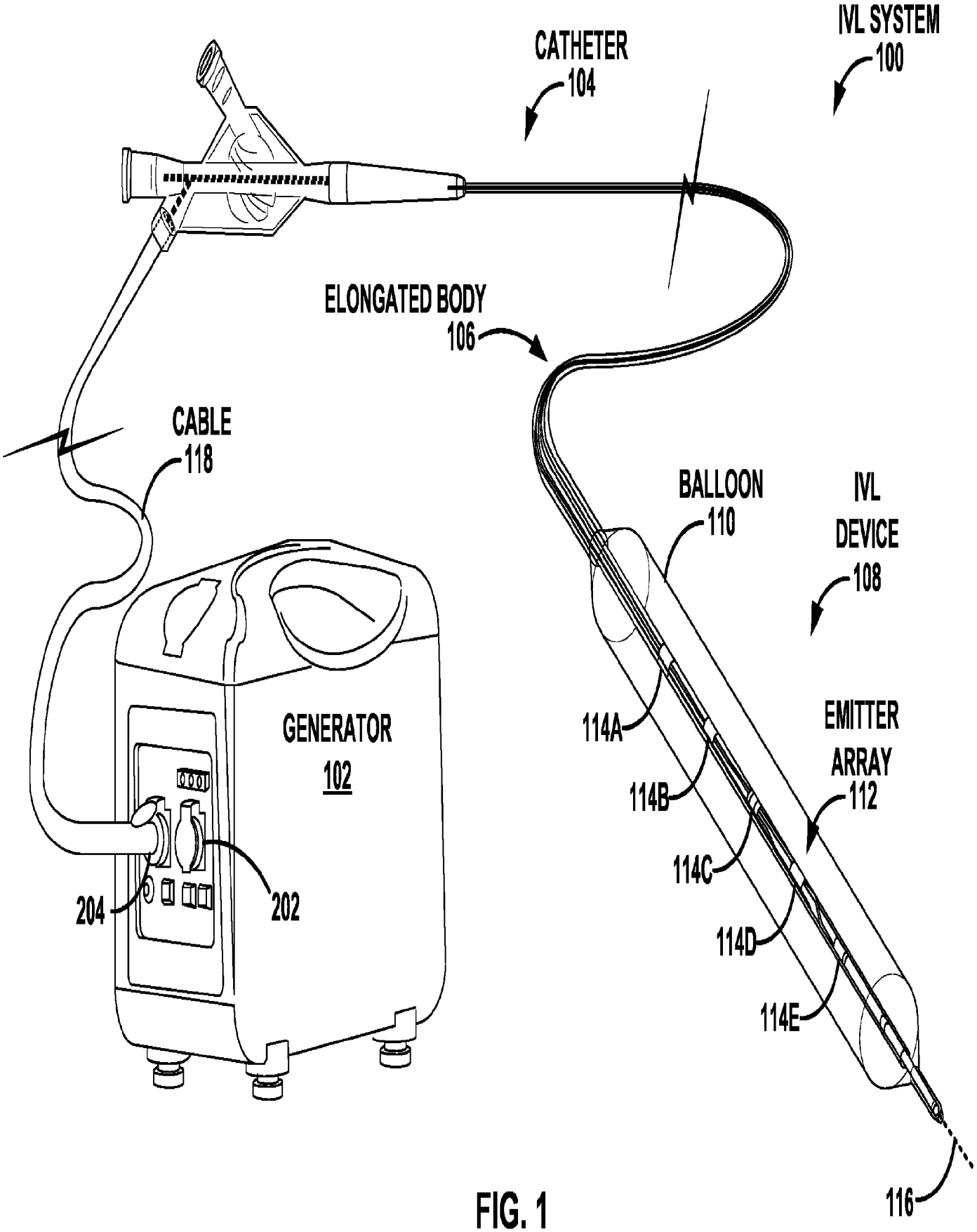

IVL SYSTEM
100
CATHETER
104
ELONGATED BODY
106
CABLE
118
BALLOON
110
IVL
DEVICE
108
GENERATOR
102
EMITTER
ARRAY
112
114A
114B
114C
114D
114E
204
202
116

FIG. 1