



(51) International Patent Classification:

A61B 17/22 (2006.01) A61B 18/24 (2006.01)

A61B 18/26 (2006.01) A61B 18/00 (2006.01)

(21) International Application Number:

PCT/US2022/018030

(22) International Filing Date:

25 February 2022 (25.02.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/154,603 26 February 2021 (26.02.2021) US

63/169,091 31 March 2021 (31.03.2021) US

63/176,156 16 April 2021 (16.04.2021) US

63/193,469 26 May 2021 (26.05.2021) US

17/679,434 24 February 2022 (24.02.2022) US

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(54) Title: INTRAVASCULAR LITHOTRIPSY

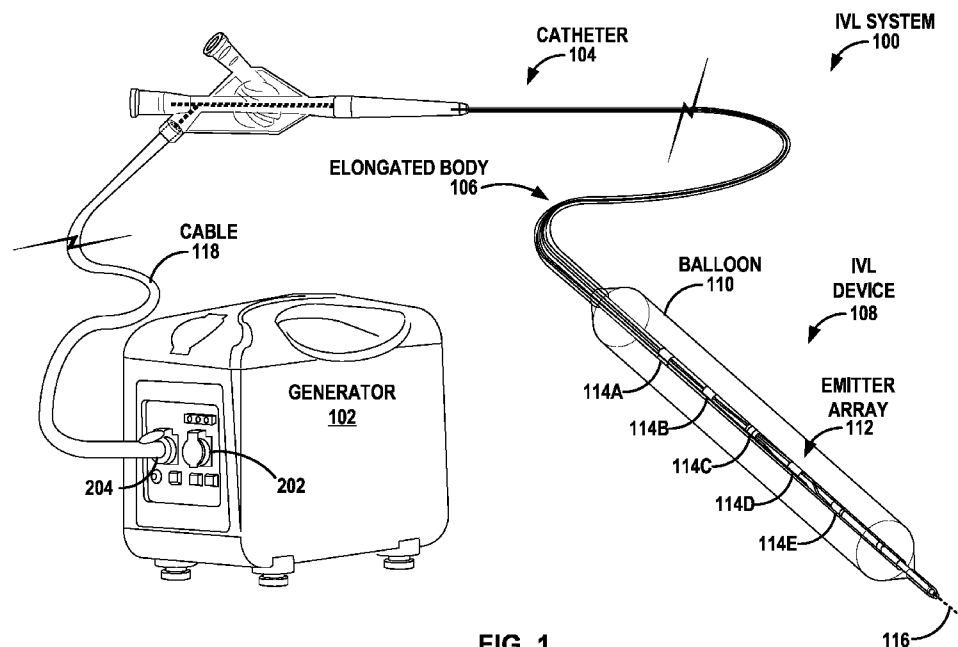


FIG. 1

(57) 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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(81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

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.

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

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

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

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

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

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

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

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

11 In some examples, the first electrode defines an inner radius of about 0.008 inches and
12 an outer radius of about 0.0210 inches. In some examples, the hypotube defines a longitudinal
13 length from about 0.080 inches to about 0.090 inches, and an outer circumference from about
14 0.10 inches to about 0.12 inches. In some examples, the hypotube defines an inner diameter of
15 about 0.029 inches and an outer diameter of about 0.034 inches. In some examples, the first
16 electrode is rectangular-prism shaped, and the first electrode extends at least partially radially
17 inward through an outer surface of the elongated body.

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

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

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

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

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

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

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

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

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

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

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

6 In some examples, the plurality of conductive wires extends generally parallel to the
7 central longitudinal axis. In some examples, the wiring configuration includes a single-coil
8 configuration such that the plurality of conductive wires coil helically around the elongated
9 body, wherein adjacent coil turns of the plurality of conductive wires are spaced longitudinally
10 along the central longitudinal axis. In some examples, the wiring configuration includes a
11 double-coil configuration such that the plurality of conductive wires coil helically around the
12 elongated body, wherein adjacent pairs of coil turns of the plurality of conductive wires are
13 spaced longitudinally along the central longitudinal axis. In some examples, the wiring
14 configuration includes a quadruple-coil configuration such that the plurality of conductive
15 wires coil helically around the elongated body, wherein adjacent groups of four coil turns of
16 the plurality of conductive wires are spaced longitudinally along the central longitudinal axis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

33 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.

Component Index

100 – Intravascular Lithotripsy (IVL) System
102 – Energy Generator
104 – Catheter
106 – Elongated Catheter Body
108 – IVL Device
110 – Interventional Balloon
112 – Pressure-Wave-Emitter Array
114A – First Emitter
114B – Second Emitter
114C – Third Emitter
114D – Fourth Emitter
114E – Fifth Emitter
116 – Central Longitudinal Axis
118 – Removable Cable
202 – Power-Input Connector
204 – Catheter Connector
208 – Internal Power Supplies
210 – High-Voltage DC-DC Converter
212 – High-Voltage Capacitor and Transistor Switch
216 – Voltage-and-Current Measurement Unit
218 – Processor
222 – Device Identification Unit
224 – Power Module
226 – User-Interface (UI) Control Processor
234 – User Interface
302 – Proximal Catheter Portion
304 – Distal Catheter Portion
306 – Catheter Hub
308 – Access Port

- 1 310 – Inflation Port
- 2 312 – Power Port
- 3 314 – Strain Relief
- 4 316 – Outer Elongated Structure
- 5 318 – Inner Elongated Structure
- 6 320 – Inflation Lumen
- 7 322 – Guidewire Lumen
- 8 324 – Distal Port
- 9 326 – Exterior Balloon Coating
- 10 400 – First Electric Emitter Assembly
- 11 402A – First Electrode
- 12 402B – Second Electrode
- 13 402C – Third Electrode
- 14 404A – First Spark Gap
- 15 404B – Second Spark Gap
- 16 406A – First Wire
- 17 406B – Second Wire
- 18 408 – Inflation Fluid
- 19 410 – Hypotube
- 20 412 – Potting Material
- 21 414 – Electrode Edges
- 22 416 – Elastomeric Layer
- 23 418 – Coils
- 24 420 – Polymer Layer
- 25 500 – Second Electric Emitter Assembly
- 26 502A – First Emitter Electrode
- 27 502B – Hypotube Electrode
- 28 502C – Second Emitter Electrode
- 29 504 – Insulating Layer
- 30 506 – Polyimide Inner Elongated Structure
- 31 508A, 508B – Spark Gaps
- 32 600 – Third Electric Emitter Assembly
- 33 602A – First Emitter Electrode

- 1 602B – Hypotube Electrode
- 2 602C – Second Emitter Electrode
- 3 608 – Spark Gap
- 4 700 – First Hypotube Design
- 5 800 – Second Hypotube Design
- 6 802A – First Electrode
- 7 802B – Second Electrode
- 8 802C – Third Electrode
- 9 804A – First Spark Gap
- 10 804B – Second Spark Gap
- 11 806 – Support Structures
- 12 810A – Circumferential Length
- 13 810B – Longitudinal Length
- 14 810C – Electrode Edge Length
- 15 810D – Spark Gap Width
- 16 810E – Support Structure Width
- 17 812 – Hypotube-Array Design
- 18 814 – Coupling Supports
- 19 816 – Removable Supports
- 20 900 – Third Hypotube Design
- 21 902A – First Ring Electrode
- 22 902B – First Disc Electrode
- 23 902C – Second Ring Electrode
- 24 902D – Second Disc Electrode
- 25 904 – Spark Gaps
- 26 906 – Support Structures
- 27 910A – Circumferential Length
- 28 910B – Longitudinal Length
- 29 910C – Support Structure Width
- 30 1000 – Assembly Technique
- 31 1002-1010 – Assembly Steps
- 32 1100 – Flex Circuit
- 33 1102A – First Electrode

- 1 1102B – Second Electrode
- 2 1102C – Third Electrode
- 3 1104 – Spark Gaps
- 4 1108 – Flexible Substrate
- 5 1110A – Circumferential Length
- 6 1110B – Flex Circuit Longitudinal Length
- 7 1110C – Rectangle Longitudinal Length
- 8 1110D – Prong Circumferential Width
- 9 1110E – Prong Longitudinal Length
- 10 1110F – Prong Gap Circumferential Length
- 11 1112 – Prongs
- 12 1200A – First Flex-Circuit Wiring Configuration
- 13 1200B – Second Flex-Circuit Wiring Configuration
- 14 1202 – Top Wire
- 15 1204 – Bottom Wire
- 16 1206 – Top Wire
- 17 1208 – Middle Wire
- 18 1210 – Bottom Wire
- 19 1300A – First Wiring Configuration
- 20 1300B – Second Wiring Configuration
- 21 1302 – Inner Elongated Structure
- 22 1304 – Outer Elongated Structure
- 23 1306 – Outer Structure Inner Layer
- 24 1308 – Outer Structure Outer Layer
- 25 1310 – Outer Structure Outer Layer Termination Point
- 26 1312 – Outer Structure Inner Layer Termination Point
- 27 1400A-D – Wiring Configurations
- 28 1402 – Wire Loop-Back Point
- 29 1404 – Distal Balloon Cone
- 30 1406 – Emitters
- 31 1408 – Exposed Wire Conductor Points
- 32 1500A – First Wiring Configuration
- 33 1500B – Second Wiring Configuration

1	1502A – Four-Emitter Array
2	1502B – Five-Emitter Array
3	1504 – Electric Emitters
4	1506 – Ground Wire
5	1600A – First Wiring Configuration
6	1600B – Second Wiring Configuration
7	1602 – Emitter Array
8	1604 – Emitters
9	1606 – Conductive Wires
10	1700 – IVL Device
11	1702 – Optical Emitters
12	1704 – Optical Fibers
13	1800 – IVL Device
14	1802 – Balloon Outer Layer
15	1804 – Balloon Inner Layer
16	1806 – Balloon Middle Layer
17	1810 – Interventional Balloon
18	1900 – Interventional Device
19	1902 – First Protective Structure
20	1904 – Longitudinal Members
21	1906 – Circumferential Members
22	2000 – IVL Device
23	2002 – Second Protective Structure
24	2100 – IVL Device
25	2102 – Scoring Members
26	2200 – IVL Device
27	2202 – Fracturing Element
28	2204 – Wire
29	2206 – Piezoelectric Elements
30	2300 – IVL Device
31	2302 – Spring
32	2304A – Spring Proximal End
33	2304B – Spring Distal End

1 2400 – IVL Device
2 2402 – Distal Protective Device
3 2404 – Elongated Element
4 2406 – Expandable Basket Member
5 2502 – Sensor
6 2600 – Catheter Handle
7 2602 – Integrated Power Supply
8 2700 – IVL Device
9 2702 – Wave Director
10 2704 – Fluid Pocket
11 2704 – Visual Direction Indicator
12 2800 – IVL Device
13 2814 – Emitter Assemblies
14 2816 – Emitter Units
15 2900 – IVL Device
16 2902 – Sub-Balloons

17
18 During an intravascular lithotripsy (IVL) procedure, and more specifically, during an
19 electrohydraulic lithotripsy (EHL) procedure, a clinician uses high-energy pressure waves to
20 break apart calcified-plaque lesions within a patient's vasculature. Typical IVL systems suffer
21 from a number of disadvantages that limit the efficacy of the treatment. For instance, IVL
22 catheters typically emit pressure waves that propagate around the entire inner circumference of
23 the vessel wall at a target treatment site. In instances in which the calcified lesion is limited to
24 only a portion of the vessel-wall circumference, for example, eccentric, focal, and/or nodular-
25 shaped lesions, pressure waves that propagate in all directions can present less-effective
26 disintegration or a waste of applied energy. As a second example, in addition to directional
27 limitations, typical IVL catheters are designed to deliver a fixed level of energy and/or power,
28 regardless of the particular clinical need (e.g., lesion size and/or density) at the target treatment
29 site, presenting a similar set of difficulties and/or effectiveness limitations.

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

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

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

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

27 FIG. 1 is a conceptual diagram illustrating an example IVL system 100. As shown in
28 FIG. 1, IVL system 100 includes at least an energy generator 102 and an IVL catheter 104
29 removably coupled to energy generator 102, such as via a catheter-connector interface 204. In
30 some examples, a removable cable 118 may be connected between generator 102 and catheter
31 104 to provide energy to catheter 104. As detailed further below, an energy source (e.g., a
32 battery, capacitor, etc.) may additionally or alternatively be integrated into catheter 104.
33 Catheter 102 includes an elongated body 106 and an IVL device 108 positioned at a distal

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

4 As shown in FIG. 1, IVL device 108 includes a fluid-inflatable interventional balloon
5 110 and a pressure-wave-emitter array 112 positioned within balloon 110. Emitter array 112
6 includes one or more individual emitter units 114A–114E. For instance, interventional balloon
7 110, or a distal portion of elongated body 106 passing therethrough, may define a central
8 longitudinal axis 116, and emitter units 114A–114E may be distributed longitudinally along
9 central longitudinal axis 116. It is to be noted that individual emitter units 114A–114E are also
10 referred to throughout this disclosure as “emitters” (e.g., in reference to an emitter unit as a
11 whole), as well as “emitter assemblies” (e.g., in reference to a particular arrangement of sub-
12 components collectively forming the emitter unit).

13 In particular, the example emitter array 112 shown in FIG. 1 includes a first emitter unit
14 114A, a second emitter unit 114B, a third emitter unit 114C, a fourth emitter unit 114D, and a
15 fifth emitter unit 114E. While five emitter units 114 are illustrated in FIG. 1, emitter array 112
16 of IVL device 108 may include as few as one individual emitter unit and up to as many emitter
17 units as could reasonably fit within balloon 110. Each emitter unit 114 is configured to receive
18 energy from energy generator 102 and use the received energy to generate and transmit high-
19 energy pressure waves through balloon 110 and across the target treatment site. As detailed
20 further below, energy generator 102 may generate and transmit energy in the form of electrical
21 energy, optical energy, or a combination thereof. For instance, emitter units 114 may use the
22 received energy to generate a cavitation within the fluid inside balloon 110, propagating one
23 or more high-energy pressure waves radially outward through balloon 110 and the calcified
24 lesion. In some cases, but not all cases, a secondary set of high-energy pressure waves can
25 subsequently result from the collapse of the fluid cavitation, further destabilizing the internal
26 structure of the calcified-plaque lesion. In some examples, one or more of emitters 114 can
27 include an electrical-based emitter configured to receive electrical energy from generator 102,
28 such as via one or more conductive wires, and generate a spark between a pair of electrodes,
29 thereby triggering the initial cavitation. Additionally, or alternatively, one or more of emitters
30 114 can include an optical-based emitter configured to receive a high-energy optical (e.g., light)
31 signal from generator 102, such as via one or more fiber-optic wires or tubes and direct the
32 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.

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

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

13 As described above, catheter 104 is configured to advance through a patient's
14 vasculature (e.g., through an arteriotomy) to position the balloon 110 adjacent to a calcium
15 lesion located at a target treatment site. IVL device 108 may be configured to cause a first
16 pressure-wave (or group of waves) by expanding a volume of liquid resulting from a phase
17 change from a liquid into a liquid-vapor, which may cause a bubble to rapidly expand. A second
18 pressure wave may occur as the bubble subsequently collapses. In some examples, the balloon
19 110 has an exterior coating 326, e.g., made from a polymer and/or other materials, as detailed
20 further below. For instance, exterior coating 326 may include a hydrophilic coating to improve
21 navigability through the patient's vasculature. Additionally, or alternatively, exterior coating
22 326 may include a drug coating, such as an anti-thrombogenic drug or an anti-proliferative
23 medication, as well as an excipient to aid in drug transfer. As detailed further below, balloon
24 110 may be or be porous/semi-permeable (e.g., a "weeping" balloon) for the infusion of drugs
25 into the vessel, as compared to being injected into the vessel through a lumen.

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

1 surrounding inflation fluid 408 to propagate high-energy pressure waves through inflation fluid
2 408.

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

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

15 As illustrated further in FIG. 4B, hypotube 410 of emitter assembly 400 includes two
16 pairs of conductive electrodes and respective spark gaps therebetween - first pair of electrodes
17 402A, 402B (with spark gap 404A therebetween), and second pair of electrodes 402B, 402C
18 (with spark gap 404B therebetween). That is, electrode 402B may be used as a common
19 electrode for both of electrodes 402A, 402C, aligned relative to opposite edges of electrode
20 402B. Put explicitly, first edge 414A of first electrode 402A is aligned relative to second edge
21 414B of second electrode 402B to define first spark gap 404A. Additionally, third edge 414C
22 of second electrode 402B is aligned relative to fourth edge 414D of third electrode 402C to
23 define second spark gap 404B. In some examples, the two pairs of conductive electrodes may
24 be wired to be simultaneously actuatable, or in other examples, may be wired to be separately
25 actuatable, as detailed further below. Such wiring configurations enable the clinician to choose
26 which emitter assemblies, or even particular electrode pairs, to activate for treatment of the
27 calcified-plaque lesion. While a two-electrode-pair system is primarily shown and described
28 herein, it should be noted that greater numbers of electrode pairs may also be incorporated into
29 emitter assembly 400.

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

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

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

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

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

29 FIG. 5A is a perspective view of a second example electronic emitter assembly 500 of
30 the catheter 104 of FIG. 1, and FIG. 5B is a cross-sectional diagram of the emitter assembly
31 500 of FIG. 5A. Specifically, the example emitter assembly 500 of FIGS. 5A and 5B includes
32 two laser-cut “emitter” electrodes 502A, 502C welded to a laser-cut polyimide “coupler” layer

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

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

10 As shown in FIGS. 5A and 5B, in this example, a polyimide inner elongated structure
11 506 extends distally through the core of the emitter assembly 500, as seen on the outside of the
12 assembly in FIG. 5A, or at the innermost circle in FIG. 5B. The portion of the outermost
13 concentric ring above central longitudinal axis 116 is a laser-cut-hypotube electrode 502B that
14 passes energy to the opposing-side mirrored “emitter” electrodes 502A, 502C. The portion of
15 the outermost concentric ring below central longitudinal axis 116 is another emitter electrode
16 502C welded to the wire 406D. The rectangular extensions about the longitudinal axis 116 that
17 carry on away from the emitter assembly on both sides are additional flat wires 406 that lead
18 to and away from the emitters to carry energy for producing the pressure waves and then
19 leading the voltage back to ground. The outer portion of the emitter assembly 500 as seen in
20 FIG. 5A, or the middle core as seen in FIG. 5B, is the first spark gap 508A at which the current
21 from the emitter electrode 502A “jumps” to the hypotube electrode 502B.

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

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

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

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

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

15 The portion of the outermost concentric ring above central longitudinal axis 116 is a
16 laser-cut hypotube electrode 602B that passes energy to the opposing-side emitter electrodes
17 602A, 602C. As described above, below the central longitudinal axis 116 in FIG. 6C are two
18 emitter electrodes 602A, 602C that extend radially inward through both the outer surface and
19 the inner surface of elongated structure 506. As shown particularly in FIG. 6C, a plurality of
20 flat wires 406 are distributed circumferentially around longitudinal axis 116 that lead toward
21 and away from the emitter electrodes 602A, 602C to carry energy for producing the high-
22 energy pressure waves, and then leading proximally back to ground voltage. In FIG. 6B, these
23 flat wires 406 are represented as dashed lines embedded within potting material 412, and as
24 solid components in FIG. 6C, as the potting material 412 has been removed to facilitate
25 visualization of the flat wires 406 in this space.

26 In the example of FIGS. 6A and 6B, the spark gap 608A (e.g., the site at which the
27 electric current from the emitter electrode 602A “jumps” to the hypotube electrode 602B, is
28 shown to be substantially filled with potting material 412. In other examples, the section of
29 potting material 412 within spark gap 608A may be milled out or otherwise removed. The
30 potting material 412, shown just beneath both the laser-cut hypotube 602B and the emitter
31 602A in FIG. 6A, and wrapped around inner elongated structure 506, can include any suitable
32 adhesive or potting material, such as an ultraviolet adhesive, an epoxy, or a reflowing polymer.

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

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

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

18 FIG. 7A is a 2-D representation of a first example design for a laser-cut hypotube 700
19 of an electronic emitter assembly 400 (FIG. 4), and FIG. 7B is a 3-D representation of the first
20 example hypotube 400 of FIG. 7A. For instance, FIG. 7B illustrates what hypotube 400 of FIG.
21 7A would look like when rolled into its final tubular form. As one non-limiting, illustrative
22 example, in the tubular form shown in FIG. 7B, cylindrical hypotube 700 may define an inner
23 diameter of about 0.025 to about 0.035 (e.g., about 0.03 inches), and an outer diameter of about
24 0.03 inches to about 0.04 inches (e.g., about 0.035 inches).

25 The hypotube design 700 shown in FIGS. 7A and 7B largely corresponds to the
26 hypotube design 410 shown in FIG. 4. For instance, hypotube 700 defines first electrode pair
27 402A/402B with spark gap 404A therebetween, and second electrode pair 402B/402C with
28 spark gap 404B therebetween. FIGS. 7A and 7B. illustrate a generally non-orthogonal
29 hypotube design, in which electrodes 402 are irregularly shaped, such that spark gaps 404A,
30 404B are not oriented parallel to central longitudinal axis 116. In particular, as shown in FIG.
31 7A, electrodes 402A and 402C are generally shaped as rounded triangles (e.g., three-sided
32 shapes with rounded corners), and electrode 402B is generally shaped as a parallelogram.

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

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

7 FIG. 8A is a 2-D representation of a second example design 800 for a laser-cut hypotube
8 of an electronic emitter assembly 400 (FIG. 4). As compared to the hypotube 410 shown in
9 FIGS. 7A and 7B, hypotube design 800 includes a more-orthogonal design, in which spark
10 gaps 804A, 804B are oriented parallel to central longitudinal axis 116. For instance, electrodes
11 802A–802C are more-regularly shaped, such as substantially rectangular, such that spark gaps
12 804A, 804B are substantially parallel to longitudinal axis 116.

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

18 Each of electrodes 802A, 802B, 802C may include emitting edges 414 (FIG. 4), e.g.,
19 defining spark gaps 804A, 804B therebetween, having lengths 810C of about 0.040 inches to
20 about 0.055 inches. The resulting spark gaps, then, may define gap widths from about 0.0025
21 inches to about 0.0040 inches. Hypotube 800A may further include a plurality of support
22 structures 806 configured to at least temporarily retain the primary structures (e.g., electrodes
23 802) in place during fabrication of the emitter assembly 114. These support structures 806 may
24 be subsequently removed, e.g., after electrodes 802 are suspended in place via potting material
25 412 (FIG. 4). Support structures 806 may define widths 810E of about 0.0020 inches.

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

1 substrate as the emitters. The example design 812 shown in FIG. 8B also includes a plurality
2 of removable supports 816. Removable supports 816 may initially be cut into the common
3 substrate with hypotubes 800A–800D and coupling supports 814 to help retain these
4 components in place during fabrication, and then subsequently removed after hypotube array
5 812 is assembled into functioning emitter units.

6 FIG. 9 is a 2-D representation of a third example design 900 for a laser-cut hypotube
7 410 of an electronic emitter assembly 400 (FIG. 4). Similar to hypotube design 800 (FIG. 8),
8 hypotube design 900 (while in the planar configuration shown in FIG. 9) may define a rectangle
9 having a circumferential length 910A of about 0.1 inch. The rectangular width 910B (e.g., the
10 longitudinal length of hypotube 900 along longitudinal axis 116) can range from about 0.080
11 inches to about 0.090 inches.

12 As compared to hypotube designs 700 (FIGS. 7A and 7B) and 800 (FIGS. 8A and 8B),
13 both of which define generally linear spark-gap configurations, electrodes 902A–902D of
14 hypotube design 900 are shaped and oriented so as to define substantially rounded or circular
15 spark gaps 904A–904D. For instance, hypotube design 900 may include two substantially ring-
16 like electrodes 902A, 902C, each defining an outer radius of about 0.0210 inches and an inner
17 radius of about 0.013 inches. In the center of ring electrodes 902A, 902C are disc electrodes
18 902B, 902D, respectively. Disc electrodes 902B, 902D may define outer radii of about 0.0090
19 inches. Accordingly, electrode pairs 902A/902B and 902C/902D may define respective ring-
20 shaped, or semi-ring-shaped spark gaps 904 therebetween, having a gap width of about 0.0040
21 inches. Similar to hypotube 800 (FIG. 8), hypotube 900 may initially include one or more
22 vertical support structures 906, which may be removed once electrodes 902 are adhered in
23 place. Support structures 906 may define widths 910C of about 0.0030 inches, for example.

24 FIG. 10 is a flowchart 1000 illustrating an example technique for forming an electronic
25 emitter assembly for an IVL catheter, for instance, the emitter assembly 400 shown in FIG. 4A.
26 The technique of FIG. 10 includes cutting a hypotube according to an electrode design, e.g.,
27 one of designs 700–900 of FIGS. 7A–9, respectively, so as to define one or more pairs of
28 conductive electrodes aligned so as to define a respective spark gap therebetween (1002). The
29 technique further includes inserting an elongated structure, such as inner elongated structure
30 318 of FIG. 4A, into the lumen of the cut hypotube (1004).

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

1 pressure-reflective material, a thermoplastic elastomer 416, wire coils 418, or a polyimide layer
2 420 may be inserted, if not already present (1006). The technique of FIG. 10 further includes
3 flowing a potting material 412 around the assembled components and causing or allowing the
4 potting-material layer 412 to solidify so as to retain the assembled components in place relative
5 to one another (1108).

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

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

19 FIGS. 11A and 11B illustrate an example flex circuit 1100 for an electronic emitter
20 assembly 400 (FIG. 4) of an IVL catheter 104 (FIG. 1). For instance, conductive electrodes
21 (e.g., copper strips) 1102A–1102C may be printed onto a flexible, planar substrate 1106 so as
22 to define respective spark gaps 1104 therebetween. The flexible substrate 1106 may then be
23 rolled into the tubular shape shown in FIG. 11B, and then wired to the rest of emitter assembly
24 400 (FIG. 4). Such techniques may significantly reduce the manufacturing time of an IVL
25 catheter 104 including such circuits 1100.

26 For purposes of illustration, FIG. 11 includes some non-limiting example dimensions
27 of flex circuit 1100. For instance, flex circuit 1100 may include a circumferential length 1110A
28 of about 0.082 inches, and an axial length 1110B (e.g., parallel to longitudinal axis 116) of
29 about 0.080 inches. The planar substrate may further define a primary rectangular body 1108
30 and two axial prongs 1112A, 1112B. Primary rectangular body 1108 may have dimensions of
31 a circumferential length 1110A of about 0.082 inches by an axial length 1110C of about 0.060
32 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

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

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

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

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

18 By comparison, in the second example wiring configuration 1400B of FIG. 14B,
19 conductive wire(s) 406 coil helically around inner elongated structure 318 according to a
20 “single wrap” configuration. In the single-wrap wiring configuration 1400B, two or more wires
21 406A, 406B are inter-coiled, with respective longitudinal spaces between adjacent coil turns.
22 In these “coiled” configurations shown in FIGS. 14B, 14C, and 14D, the wire coils help provide
23 structural support for inner elongated structure 318, e.g., by forming coil layer 418 of FIG. 4B.
24 In some such examples, the emitter array may be wired according to an “n + 1” configuration,
25 in which the number of conductive wires 406 is one more than the number of emitters 1406,
26 such that each emitter has a unique voltage-supply wire, but all share a common ground wire.

27 In the third example wiring configuration 1400C of FIG. 14C, conductive wire(s) 406
28 coil helically around inner elongated structure 318 according to a “double wrap” configuration.
29 In the double-wrap wiring configuration 1400C, wires 406 are inter-coiled as wire pairs, with
30 longitudinal spaces between adjacent pairs of coil turns. Wire-jacket portions 1408 may be
31 removed (e.g., ablated) as necessary for conductively coupling wires 406 to electrode hypotube
32 410 (FIG. 4).

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

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

19 FIG. 16A is a conceptual diagram illustrating a first example wiring configuration
20 1600A for an electronic emitter array 1602 having four emitter units 1604A–1604D. FIG. 16A,
21 like FIGS. 15A and 15B, shows the emitter units 1604 wired according to the “ $n + 1$ ”
22 configuration, and a configuration in which emitter assemblies 1604 wired in parallel. Some
23 example benefits of a parallel wiring configuration 1600A include the ability to transmit a
24 higher electrical current across the emitter units 1604. A parallel wiring configuration 1600A
25 also enables each individual emitter unit 1604 to be actuated (or “fired”) independently of the
26 other emitter units. Additionally, with a parallel wiring configuration 1600A, the total
27 resistance of the IVL system 100 (FIG. 1) may be reduced. For instance, by individually
28 powering a single emitter unit 1604, a greater electrical current may be generated across the
29 spark gap 404 (FIG. 4), thereby reducing the necessary number of resistors in the corresponding
30 electrical circuit.

31 Configuration 1600A may also allow for a reduction in the overall voltage through the
32 system, e.g., translating to a reduction in energy consumption. The ability to individually power
33 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 activate: (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

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

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

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

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

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

6 The cage-like structures 1902, 2002 may be or may include a metal, such as SST or
7 nitinol, or a polymer. In a multi-nested-layer balloon (e.g., balloon 1800 of FIG. 18), the
8 protective structure 1902, 2002 could be disposed between the outer and inner balloon layers
9 1802, 1804. In some examples, the cage-like structure 1902, 2002 includes multiple
10 longitudinal members, e.g., extending parallel to central longitudinal axis 116. In some such
11 examples, protective structure 1902, 2002 may be selected to include an odd number of
12 longitudinal members, such as three longitudinal members or five longitudinal members, in
13 order to promote re-wrap of the respective balloon prior to withdrawal of IVL device 108 from
14 the patient's vasculature. These longitudinal members or bars may be interconnected as a stent-
15 like structure, such that the structure has a predetermined size and shape that does not vary (or
16 varies by a relatively small amount) during inflation of balloon 110.

17 According to some examples, the protective structure 1902, 2002 is rigidly coupled to
18 the exterior surface of the balloon 110. In some such examples, the protective structure 1902,
19 2002 is rigidly coupled to the proximal and distal end portions of balloon 100, but not to a
20 longitudinally central balloon portion.

21 The example of FIG. 19 shows a less-comprehensive protective structure 1902, as
22 compared to the example protective structure 2002 of FIG. 20. For instance, protective structure
23 1902 includes, as non-limiting examples, two (top and bottom) longitudinal elements 1904,
24 and about thirteen circumferential elements 1906. By comparison, protective structure 2002 is
25 shown to include a more-continuous wire-mesh configuration or window-screen configuration
26 having dozens or hundreds of interwoven longitudinal and circumferential elements.

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

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

1 In some examples, balloon 110 may include a single scoring member 2102. In other examples,
2 multiple scoring members 2102 may be distributed, rotationally symmetrically or
3 asymmetrically, about the circumference of balloon 110. During the IVL procedure, balloon
4 110 may be circumferentially rotated to apply a particular scoring member or members 2102
5 against the calcified lesion. In some examples, scoring members 2102 may be formed from a
6 metal, such as an SST or a nickel-titanium alloy (e.g., Nitinol), a metal wire, a printed metal
7 ink (which may contain a very small amount of polymer binder from processing), tungsten, or
8 a polymer.

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

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

18 Fracturing element 2202 provides at least two advantages. First, when conductive wire
19 2204 is aligned against the calcified-plaque lesion, the narrow-cross sectional area of
20 conductive wire 2204 substantially increases a pressure applied to the lesion along the axis of
21 the wire, enabling the clinician to control the particular location at which the lesion begins to
22 fragment. Second, when an alternating current (AC) is applied through conductive wire 2204,
23 piezoelectric elements 2206 are configured to rapidly expand and contract, thereby generating
24 additional pressure waves that are focused directly against the exterior surface of the lesion.

25 In some examples, fracturing element 2200 includes a distal protective element, such
26 as an embolic protection element, as described further below with respect to FIG. 24A. For
27 instance, the distal protective element may be coupled to a distal portion of conductive wire
28 2204. Additionally, or alternatively to wire 2204, fracturing element 2200 can include a braided
29 layer, such as a Nitinol braid. Piezoelectric elements 2206 may be rigidly coupled to an exterior
30 surface of the braid, and the braid may be coupled to the exterior surface of balloon 110. This
31 braid may perform similar functions as those described above with respect to wire 2204.

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

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

9 Another technique for reducing the profile of balloon 110, which is illustrated in FIG.
10 23, is to incorporate a spring 2302 within inner elongated structure 318. The spring 2302 should
11 be longitudinally compressed when bonded (e.g., at proximal end 2304A and distal end 2304B)
12 to inner elongated structure 318. Balloon 110 may then be bonded to inner elongated structure
13 318

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

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

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

3 FIG. 24 illustrates an example IVL device 2400 (e.g., IVL device 108 of FIG. 1)
4 including a distal protective device 2402. According to some examples, a distal protective
5 device 2402 may be positioned at a distal end portion of IVL device 2400. In some examples
6 (but not all examples), the distal protective device 2402 includes an elongated element 2404
7 (e.g., a guidewire) that extends, e.g., through guidewire lumen 322 of inner elongated structure
8 318, and a distal expandable member 2406. In some such examples, expandable member 2406
9 is configured to extend distally outward from distal port 324 and expand radially outward into
10 the expanded configuration shown in FIG. 24. The inner lumen 322 of inner elongated structure
11 318 surrounding the extended distal protective device 2402 may be compatible for guidewires
12 from 0.010" to 0.035". Therefore, the guidewire lumen size can range from 0.011" up to 0.038"
13 to allow for free guidewire movement.

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

23 Distal protective device 2402 could also be rapidly exchanged on the balloon catheter
24 104. A rapid exchange port may be proximal of the balloon 110 or distal of the balloon 110.
25 The distal protective device 2402 may enter or exit the balloon catheter at the hub 306 (FIG.
26 3), proximal of the balloon 110, or distal of the balloon 110. This distal protective device 2402
27 may also be modular (e.g., removable) in nature, so that it is only present on the IVL device
28 2400 when needed for a procedure.

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

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

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

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

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

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

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

1 include a transducer protector, such as a valve or membrane, configured to prevent the inflation
2 fluid 408, e.g., a saline/contrast-fluid mixture, from entering components of energy generator
3 102.

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

13 In other examples, rather than dynamically modifying energy levels (e.g., applied
14 voltage levels, or the like), system 100 may be configured to apply the energy level (e.g.,
15 voltage level) as an “all or nothing” (e.g., binary 0 or 1). For instance, system 100 may only
16 transmit energy, at a predetermined level, through catheter 104 while certain conditions are
17 determined to be met, as indicated by data from sensor 2502. Additionally, or alternatively,
18 system 100 may be configured to adjust other parameters. For instance, system 100 may be
19 configured to dynamically adjust a longitudinal length and/or an inflation diameter of balloon
20 110, as needed.

21 FIG. 26 illustrates an example handle 2600 that may be coupled at the proximal portion
22 302 (FIG. 3) of IVL catheter 104 of FIG. 1. Catheter 104 may include handle 2600 in addition
23 to, or instead of, catheter hub 306 (FIG. 1). In instances in which both hub 306 and handle 2600
24 are present, handle 2600 may couple to a portion of elongated body 106 extending proximally
25 through hub access port 308.

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

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

3 Typical IVL systems and devices are configured to emit high-energy pressure waves
4 that propagate across all spatial dimensions. This attribute may be relatively effective for ring-
5 like calcified-plaque lesions, e.g., that appear around the entire inner circumference of the
6 vessel wall. However, other lesion configurations are not as effectively treated, or alternatively
7 may waste significant amounts of energy due to the inefficient application of the energy.
8 Accordingly, a number of features and techniques are disclosed herein, enabling IVL device
9 108 (FIG. 1) to focus the emitted high-energy pressure waves in a particular spatial direction
10 or limited range of directions.

11 For instance, FIG. 27 is a cross-sectional view of an IVL device 2700 (e.g., IVL device
12 108 of FIG. 1) having a first example wave director 2702. In some examples, wave director
13 2702 includes a layer of material oriented along just a portion of the inner circumference of
14 balloon 110 and extending longitudinally (e.g., proximally and distally) through balloon 110.
15 The material is configured to substantially absorb and/or reflect pressure waves that contact the
16 material, thereby reducing energy that is wasted by being channeled in arbitrary directions. As
17 described above, this acoustically opaque material can include, e.g., a ceramic, porcelain,
18 diamond, polyimide, polyether ether ketone (PEEK), a similar material, or any suitable
19 combination thereof.

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

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

32 Additionally, or alternatively to an absorbent and/or reflective material, wave director
33 2702 of FIG. 27 may be or may include at least one of the pair of electrodes 402 (FIG. 4) of an

1 electronic emitter unit 400. For instance, the half-moon-shaped director 2702 may include one
2 or both of the electrodes 402 to directionally focus the emitted pressure waves to fragment a
3 target calcification. In examples in which wave director 2702 includes both a reflective
4 material as well as one or both electrodes 402, the electrode(s) 402 may be positioned radially
5 inward from the reflective material, which may be adhered to the interior surface of balloon
6 110.

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

14 In some examples, a fluoroscopic wire (e.g., conductive wire 2204, as described above
15 with respect to FIG. 22) or other visual indicator 2704 may be positioned opposite wave
16 director 2702. The visual indicator 2704 helps the clinician orient (e.g., rotate) IVL device 2700
17 toward the target calcification prior to beginning targeted fragmentation. Also, as described
18 above with respect to FIG. 22, in some examples, piezo elements 2206 can be mounted or
19 expanded to an off-center location (e.g., asymmetrically distributed) onto or within balloon
20 110, providing an increase in energy to that side. In such examples, the tissue region adjacent
21 the piezo elements 2206 would receive a greater amount of energy, thus enabling directionally
22 targeted lesion fragmentation.

23 FIG. 28A is a perspective view, and FIG. 28B is a cross-sectional view of a second
24 example directionally focused IVL device 2800 (e.g., IVL device 108 of FIG. 1). IVL device
25 2800 includes an array of emitter assemblies 2814, wherein each emitter assembly 2814
26 includes two or more individual emitter units 2816 distributed circumferentially around inner
27 elongated structure 318. Each individual emitter unit 2816 can include an electrode pair, a piezo
28 element, or an optical emitter.

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

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

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

10 FIG. 29A is a perspective view, and FIG. 29B is a cross-sectional view of a third
11 example directionally focused IVL device 2900 (e.g., IVL device 108 of FIG. 1). IVL device
12 2900 is an example of IVL device 2800 of FIG. 28, except for the differences noted herein. In
13 particular, interventional balloon 110 of IVL device 2900 includes two or more elongated sub-
14 balloons 2902 distributed circumferentially around inner elongated structure 318. Each sub-
15 balloon 2902 is configured to retain a subset of emitter units 2816 that are oriented along a
16 common longitudinal axis. Each emitter-unit subset is configured to be independently
17 actuatable from the other emitter-unit subsets, and the respective sub-balloon 2902 is
18 configured to help apply the emitted pressure waves to a particular portion of the circumference
19 of the interior surface of the target vessel.

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

26 As described above, the emitters 2618 can tilt away from the inner elongated structure
27 318 to be closer to the inner diameter wall of the balloon 110 (e.g., instead of being adjacent to
28 the inner elongated structure 318). Accordingly, the energy delivered by these emitters 2816
29 can be more focused on the wall of the vessel to which they are positioned closest. This, in
30 combination with a cutting wire (e.g., conductive wire 2204 of fracturing element 2202 of FIG.
31 22), can create a high-stress focal point to more-efficiently and/or more-effectively break up a
32 nodular calcified lesion.

1 Additionally, in the examples of FIGS. 28A and 29B, energy generator 102 (FIG. 1)
2 may independently and selectively control the emitters 2816 that reside about the
3 circumference of IVL device 2900. This means that, even without tilting or moving the emitters
4 2816 in any way, the energy delivery may be controlled by only firing the emitters 2816 closest
5 to the calcified lesion. Additionally, if the treatment presented requires full-circumference
6 energy delivery, all emitters 2816 may still be fired, allowing for a more traditional style of
7 treatment to occur.

8 It should be noted that these emitters 2816 can all be located within the same balloon
9 110, as is shown in FIGS. 28A and 28B, or within their own, separate sub-balloons 2902, as
10 shown in FIGS. 29A and 29B. Additionally, while the relative alignments shown in FIGS. 28B
11 and 29B allow for just one array of emitter units, it should be noted that these emitters 2816
12 can be placed about the catheter throughout the balloon 110, and the quantity of possible
13 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.

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

4 7. The medical device of claim 1, wherein the electronic emitter further comprises a
5 coupler layer positioned radially between the elongated body and the second electrode.
6

7 8. The medical device of claim 1,
8 wherein the first electrode is ring-shaped;
9 wherein the second electrode is disc-shaped; and
10 wherein the first electrode is positioned around the second electrode.
11

12 9. The medical device of claim 8,
13 wherein the electronic emitter further comprises a third electrode and a fourth electrode;
14 wherein the third electrode is ring shaped and the fourth electrode is disc-shaped;
15 wherein the third electrode is positioned around the fourth electrode; and
16 wherein the first, second, third, and fourth electrodes are all portions of a common
17 cylindrical surface of the hypotube.
18

19 10. The medical device of claim 1, wherein the hypotube defines a longitudinal length from
20 about 0.080 inches to about 0.090 inches, and an outer circumference from about 0.10 inches
21 to about 0.12 inches.
22

23 11. The medical device of claim 1, wherein the first electrode is rectangular-prism shaped,
24 and wherein the first electrode extends at least partially radially inward through an outer surface
25 of the elongated body.
26

27 12. The medical device of claim 11, wherein the first electrode extends radially inward
28 through the elongated body and at least partially radially inward into an inner lumen of the
29 elongated body.
30

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

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

3 an elongated body;

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

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

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

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

16 wherein the second electrode comprises a portion of a hypotube.
17

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

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

22 inserting an elongated body through the laser-cut hypotube;

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

24 removing obsolete support structures from the hypotube.
25

26 15. The method of claim 14,

27 wherein the spark gap comprises a first spark gap; and

28 wherein laser-cutting the hypotube further comprises laser-cutting the hypotube to
29 define a third electrode arranged so as to define a second spark gap between the second
30 electrode and the third electrode.
31

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

1 a first spark gap between the first electrode and the second electrode, and a second spark gap
2 between the second electrode and the third electrode, and
3 wherein the first electrode, the second electrode, and the third electrode are portions of
4 a common hypotube.
5

6 21. A medical device comprising:

7 an elongated body;

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

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

16 a plurality of conductive wires configured to provide electrical energy to the emitter
17 array, the plurality of conductive wires arranged according to a wiring configuration.
18

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

22 23. The medical device of claim 21, wherein the wiring configuration comprises a single-
23 coil configuration such that the plurality of conductive wires coil helically around the
24 elongated body, wherein adjacent coil turns of the plurality of conductive wires are spaced
25 longitudinally along the central longitudinal axis.
26

27 24. The medical device of claim 21, wherein the wiring configuration comprises a double-
28 coil configuration such that the plurality of conductive wires coil helically around the
29 elongated body, wherein adjacent pairs of coil turns of the plurality of conductive wires are
30 spaced longitudinally along the central longitudinal axis.
31

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

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

3
4 26. The medical device of claim 21, wherein the plurality of conductive wires comprises a
5 plurality of flat wires.

6
7 27. The medical device of claim 21, wherein the plurality of conductive wires comprises a
8 plurality of round wires with flattened portions along the emitter array.

9
10 28. The medical device of claim 21, wherein:
11 the elongated body comprises an inner body and an outer body;
12 the outer body comprises an inner layer and an outer layer; and
13 the plurality of conductive wires coils around an exterior surface of the inner layer.

14
15 29. The medical device of claim 28, wherein the outer layer of the outer body is flowed
16 over the plurality of conductive wires such that the plurality of conductive wires is embedded
17 in the outer layer.

18
19 30. The medical device of claim 28, wherein the outer layer comprises a potting layer or a
20 heat-shrink tube.

21
22 31. The medical device of claim 28, wherein the outer layer terminates proximally from the
23 inner layer, such that a distal portion of the plurality of conductive wires is exposed to an
24 interior of the balloon.

25
26 32. The medical device of claim 21, wherein the elongated body comprises an inner body
27 and an outer body, and wherein the plurality of conductive wires coils around an exterior
28 surface of the inner body such that the plurality of conductive wires forms a reinforcement
29 layer for the elongated body.

30
31 33. The medical device of claim 21, wherein each of the plurality of emitters comprises a
32 respective voltage wire such that each of the plurality of emitters is independently actuatable.

1 34. A medical device comprising:
2 an elongated body;
3 a balloon positioned at a distal portion of the elongated body, the balloon configured to
4 receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an
5 interior surface of a target treatment site within a vasculature of a patient; and
6 an emitter array positioned along a central longitudinal axis of the elongated body
7 within the balloon, the emitter array configured to propagate pressure waves radially outward
8 through the fluid to fragment a calcified lesion at the target treatment site, wherein the emitter
9 array comprises a plurality of electrode pairs including at least one electrode formed from a
10 portion of a hypotube.

11
12 35. The medical device of Claim 34, wherein the exterior surface of the balloon comprises
13 a polymer coating.

14
15 36. The medical device of Claim 34, wherein the exterior surface of the balloon comprises
16 a hydrophilic coating.

17
18 37. The medical device of Claim 34, wherein the exterior surface of the balloon comprises
19 a drug-based coating.

20
21 38. The medical device of Claim 37, wherein the drug-based coating comprises an anti-
22 thrombogenic coating or an anti-proliferative medication.

23
24 39. The medical device of Claim 34, wherein the balloon comprises two or more nested
25 expandable substrates.

26
27 40. The medical device of Claim 39, wherein the two or more nested expandable substrates
28 comprise at least an outer layer and an inner layer, wherein an interior surface of the outer layer
29 is bonded to an exterior surface of the inner layer so as to form a single multi-layered extrusion.

30
31 41. The medical device of Claim 40, wherein the inner layer comprises a high-pressure
32 holding layer, and wherein the outer layer comprises a urethane layer.

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

3
4 43. The medical device of Claim 42, wherein the reinforcing structure comprises a plurality
5 of longitudinal fibers aligned parallel to the longitudinal axis of the balloon, and a plurality of
6 braided fibers.

7
8 44. The medical device of Claim 43, wherein the plurality of longitudinal fibers comprises
9 from four to eight longitudinal fibers.

10
11 45. The medical device of Claim 34, wherein the balloon comprises an outer layer, an inner
12 layer nested within the outer layer, and a cage structure nested between the outer layer and the
13 inner layer, and wherein the cage structure comprises one or more longitudinal members
14 oriented parallel to the longitudinal axis and one or more circumferential elements oriented
15 perpendicular to the longitudinal axis.

16
17 46. The medical device of Claim 34, further comprising a cage structure at least partially
18 surrounding the exterior surface of the balloon.

19
20 47. The medical device of Claim 46, wherein the cage structure is rigidly coupled to the
21 exterior surface of the balloon.

22
23 48. The medical device of Claim 46, wherein the cage structure comprises a nitinol braid,
24 metal wires, printed metals, radiopaque metal wires, or radiopaque printed metals.

25
26 49. The medical device of Claim 34, wherein the balloon comprises a porous membrane
27 configured to infuse a drug at the target treatment site.

28
29 50. The medical device of Claim 34, wherein the balloon comprises a plurality of
30 longitudinal ribs configured to define folding guides as the balloon folds radially inward.

31
32 51. The medical device of Claim 50, wherein the plurality of longitudinal ribs comprises
33 an odd number of ribs.

1
2 52. The medical device of Claim 34, further comprising a spring configured to
3 longitudinally stretch the balloon in an absence of external forces.
4

5 53. A medical device comprising:

6 an elongated body;

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

10 an emitter array positioned along a central longitudinal axis of the elongated body
11 within the balloon, the emitter array configured to propagate pressure waves radially outward
12 through the fluid to fragment a calcified lesion at the target treatment site, wherein the emitter
13 array comprises a plurality of electrode pairs including at least one electrode formed from a
14 portion of a hypotube.
15

16 54. The medical device of Claim 53, further comprising a fracturing member positioned
17 on an external surface of the balloon.
18

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

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

21 a plurality of piezo-elements positioned along the conductive wire, the plurality of
22 piezo-elements configured to emit additional pressure waves against the calcified lesion.
23

24 56. The medical device of Claim 53, further comprising a protective device positioned at
25 the distal portion of the elongated body, the protective device configured to at least partially
26 occlude the target treatment site and to collect fragmented lesion portions.
27

28 57. The medical device of Claim 53, further comprising a protective device positioned
29 along the elongated body proximal to the balloon, the protective device configured to at least
30 partially occlude the target treatment site and to collect fragmented lesion portions.
31

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

1
2 59. The medical device of Claim 58, further comprising the guidewire, wherein the
3 guidewire has an inner diameter range from 0.011" to 0.038".
4

5 60. The medical device of Claim 53, further comprising a handle positioned at a proximal
6 end of the elongated body, wherein the handle comprises an integral power supply for the
7 emitter array.
8

9 61. The medical device of claim 53, further comprising a scoring member configured to
10 contact and abrade the calcified lesion.
11

12 62. The medical device of Claim 61, wherein the scoring member defines a serrated
13 exterior surface.
14

15 63. A medical device comprising:
16 an elongated body;
17 a balloon positioned at a distal portion of the elongated body, the balloon configured to
18 receive a fluid and thereby inflate such that an exterior surface of the balloon contacts an
19 interior surface of a target treatment site within a vasculature of a patient; and
20 an emitter array positioned along a central longitudinal axis of the elongated body
21 within the balloon, the emitter array configured to propagate pressure waves radially outward
22 through the fluid to fragment a calcified lesion at the target treatment site,
23 wherein the emitter array comprises a plurality of electrode pairs including at least
24 one electrode formed from a portion of a hypotube, and
25 means for controlling a primary direction of emission of the pressure waves.
26

27 64. The medical device of claim 63, further comprising a wave director positioned against
28 an interior surface of the balloon and along only a portion of a circumference of the balloon,
29 the wave director configured to absorb or reflect the pressure waves away from the second
30 portion of the circumference of the balloon.
31

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

1
2 66. The medical device of claim 64, wherein the wave director defines a fluid pocket
3 configured to receive a pressure-reflective fluid or a pressure-absorbent fluid.
4

5 67. The medical device of Claim 63, further comprising a radiopaque indicator positioned
6 along the first portion of the circumference of the balloon, the radiopaque indicator configured
7 to indicate an emitted direction of the pressure waves.
8

9 68. The medical device of Claim 67, wherein the radiopaque indicator comprises a
10 radiopaque wire positioned along the exterior surface of the balloon.
11

12 69. The medical device of Claim 67, wherein the radiopaque indicator comprises a
13 conductive wire of a fracturing element positioned along an exterior surface of the balloon, and
14 wherein the fracturing element further comprises a plurality of piezoelectric elements
15 configured to emit additional pressure waves through the calcified lesion.
16

17 70. The medical device of Claim 63, wherein each of the one or more shockwave emitters
18 defines a respective orientation, and wherein the medical device further comprises a user-input
19 mechanism to modify the respective orientations of the one or more shockwave emitters.
20

21 71. The medical device of Claim 63, wherein each of the one or more shockwave emitters
22 defines a respective fixed orientation, and wherein the medical device further comprises a user-
23 input mechanism configured to independently actuate a first subset of the one or more
24 shockwave emitters independently from a second subset of the one or more shockwave
25 emitters.
26

27 72. The medical device of Claim 63, wherein the balloon comprises two or more
28 elongated sub-balloons oriented circumferentially around the central longitudinal axis, each
29 sub-balloon comprising a respective subset of the one or more shockwave emitters.
30

31 73. A system comprising:
32 an energy generator; and
33 a catheter comprising:

1 an elongated body;
2 a balloon positioned at a distal portion of the elongated body, the balloon
3 configured to receive a fluid to inflate such that an exterior surface of the balloon
4 contacts an interior surface of a target treatment site within a vasculature of a patient;
5 an emitter array positioned along a central longitudinal axis within the balloon,
6 the emitter array comprising one or more shockwave emitters configured to propagate
7 pressure waves radially outward through the fluid to fragment a calcified lesion at the
8 target treatment site; and
9 a sensor configured to generate sensor data indicative of at least one
10 parameter.
11

12 74. The system of claim 73, wherein the energy generator is configured to vary an amount
13 of energy delivered based on the sensor data.
14

15 75. The system of claim 74, wherein, to vary the amount of energy, the energy generator
16 is configured to vary a current level, a voltage level, a pulse duration, a pulse
17 frequency, or a light intensity.
18

19 76. The system of claim 73, wherein the sensor data comprises fluid-pressure data, fluid-
20 rate data, or temperature data.
21

22 77. The system of claim 73, wherein the sensor comprises an electrical-impedance
23 monitor, an inflation-fluid flow-rate monitor, an inflation-fluid pressure monitor, a
24 vessel-wall surface monitor, a vessel-diameter monitor, an interventional-balloon
25 diameter monitor, or a plaque-fragmentation monitor.
26

27 78. The system of claim 73, wherein the sensor comprises a resonant-frequency sensor,
28 and wherein the energy monitor is configured to vary a pressure-wave frequency to
29 approximate a resonant frequency of the calcified lesion.
30

31 79. The system of claim 73, wherein the energy generator is configured to terminate an
32 applied voltage based on the sensor data.
33

- 1 80. A medical device comprising:
2 an elongated body;
3 a balloon positioned at a distal portion of the elongated body, the balloon configured
4 to receive a fluid to inflate such that an exterior surface of the balloon contacts an interior
5 surface of a target treatment site within a vasculature of a patient; and
6 an emitter array positioned along a central longitudinal axis within the balloon, the
7 emitter array comprising one or more shockwave emitters configured to propagate pressure
8 waves radially outward through the fluid to fragment a calcified lesion at the target treatment
9 site, wherein at least one of the one or more shockwave emitters comprises an optical-based
10 emitter.
11
- 12 81. The medical device of claim 80, further comprising an optical fiber running parallel to
13 the central longitudinal axis along a distal direction, wherein the at optical-based emitter
14 comprises a distal-most portion of the optical fiber.
15
- 16 82. The medical device of claim 81, wherein the optical fiber is configured to transmit a
17 laser signal into the balloon, wherein the laser signal is configured to cavitate the fluid upon
18 contact with the fluid at the distal-most portion of the optical fiber to generate the shockwave.
19

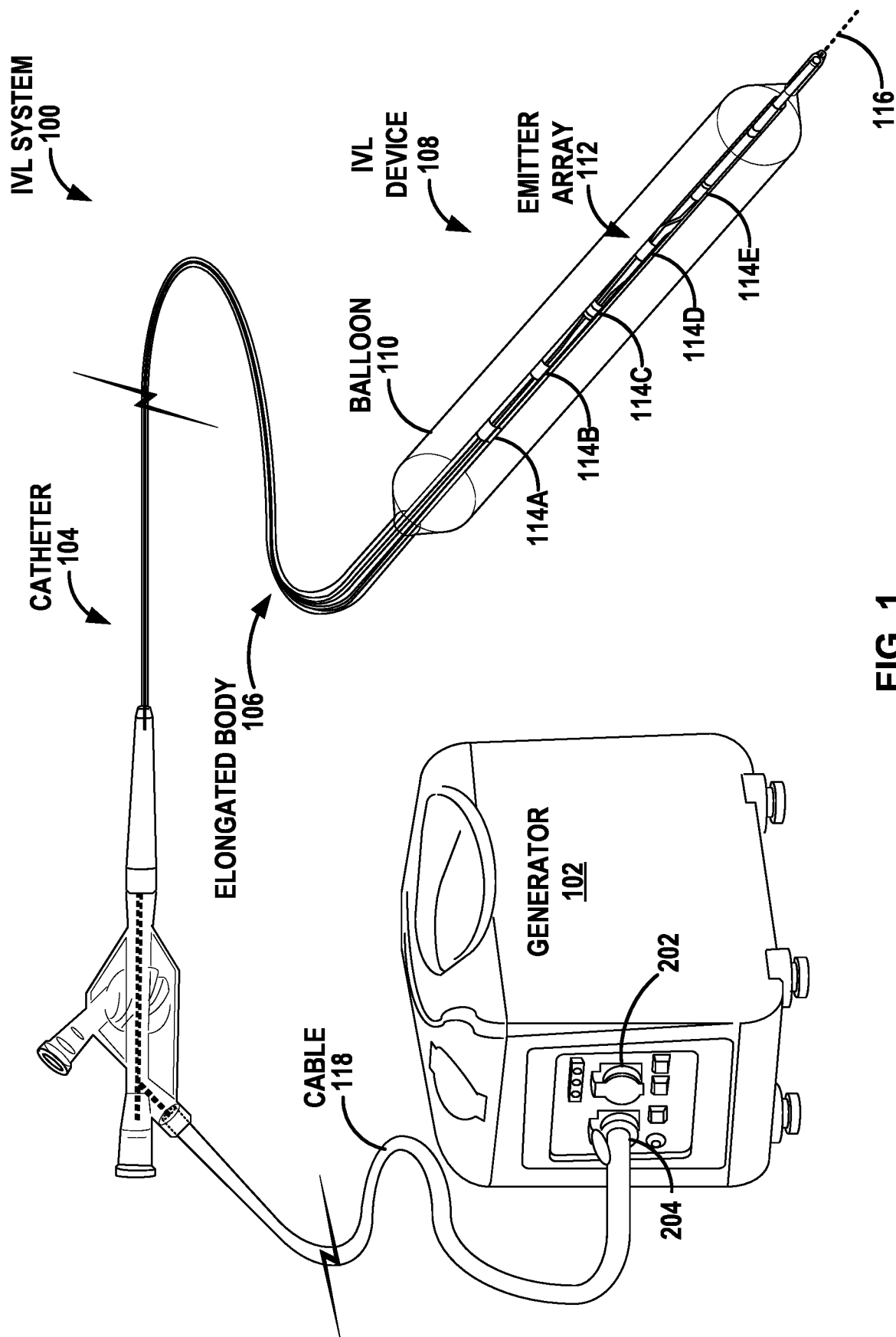


FIG. 1

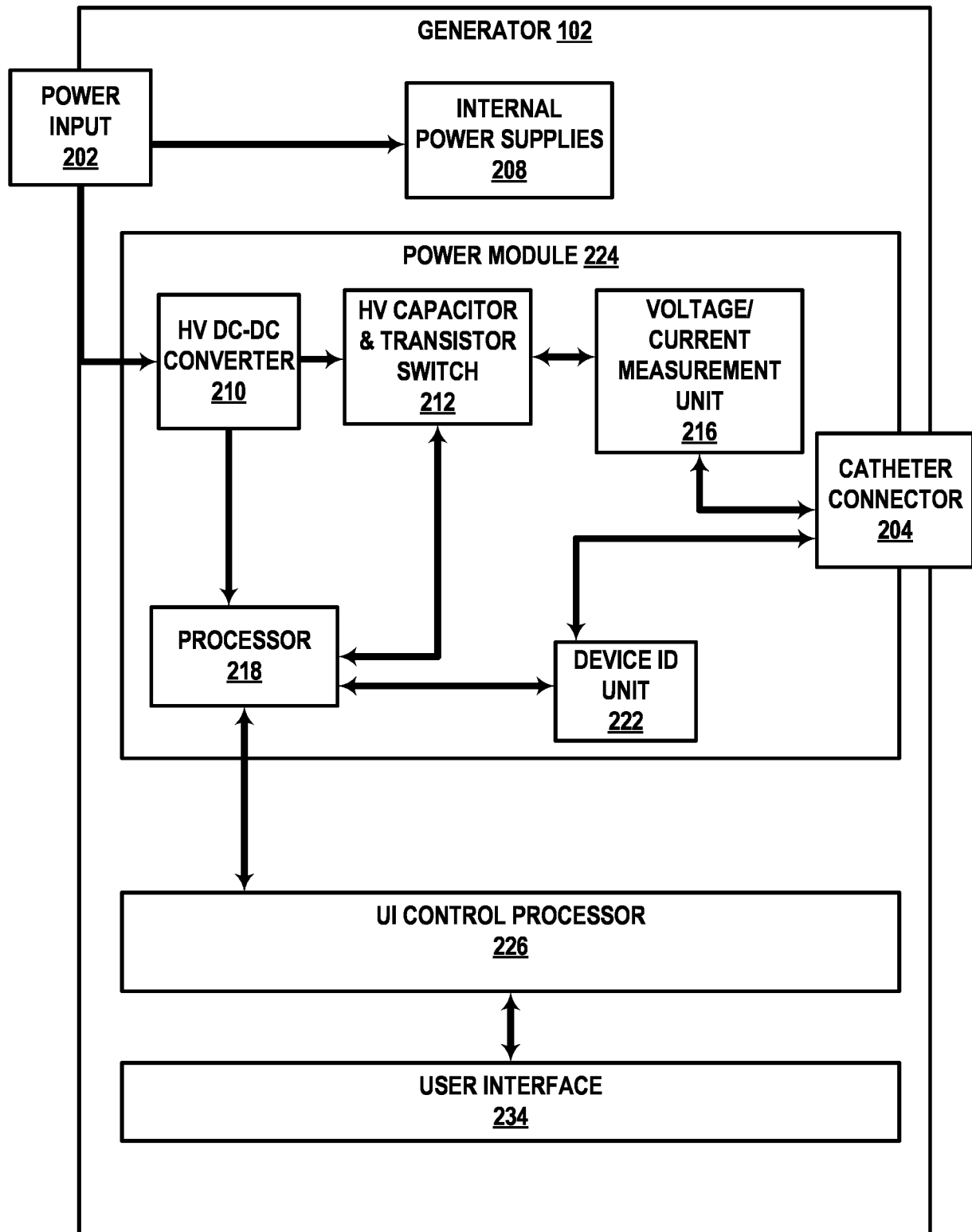
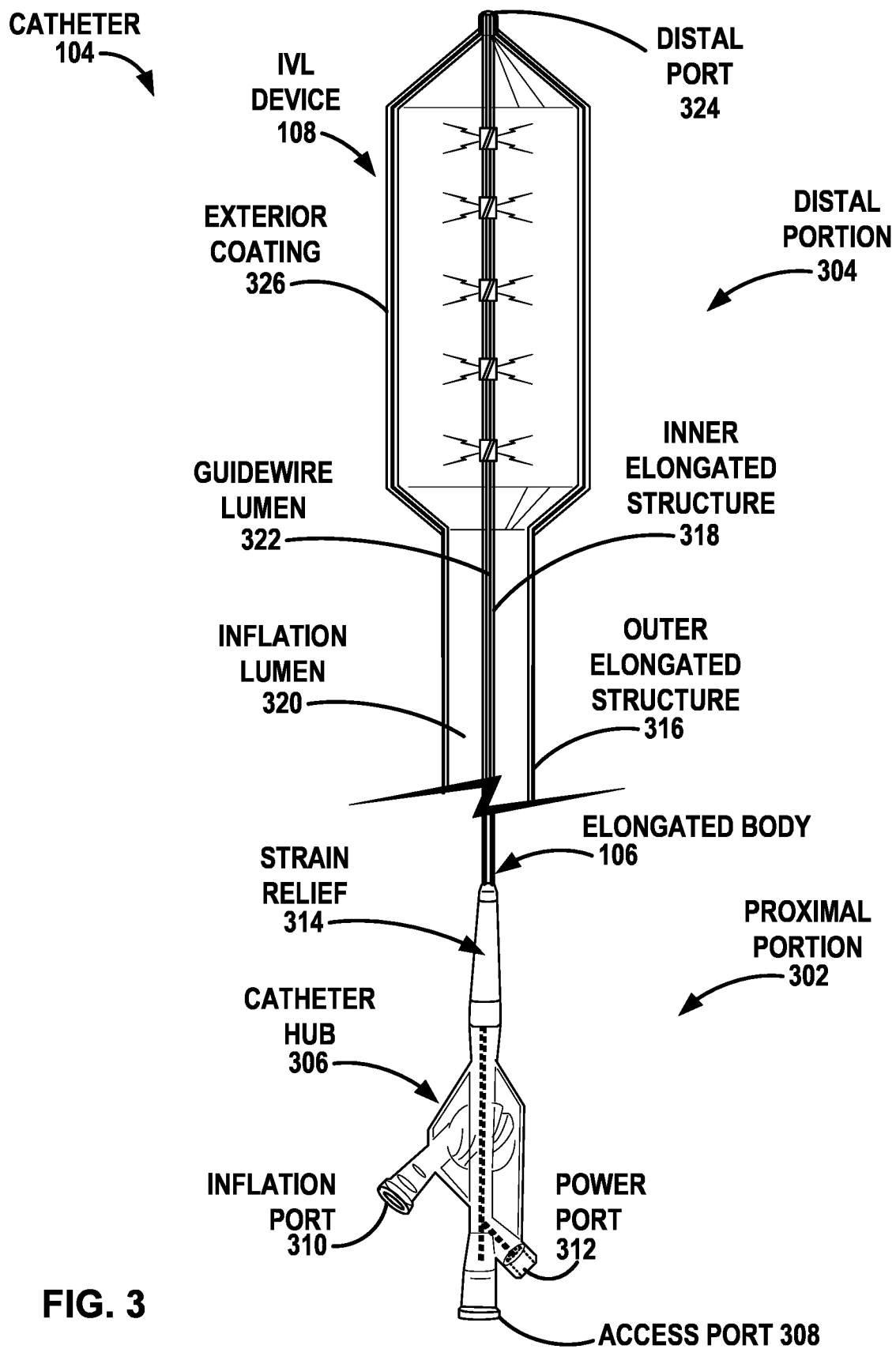


FIG. 2



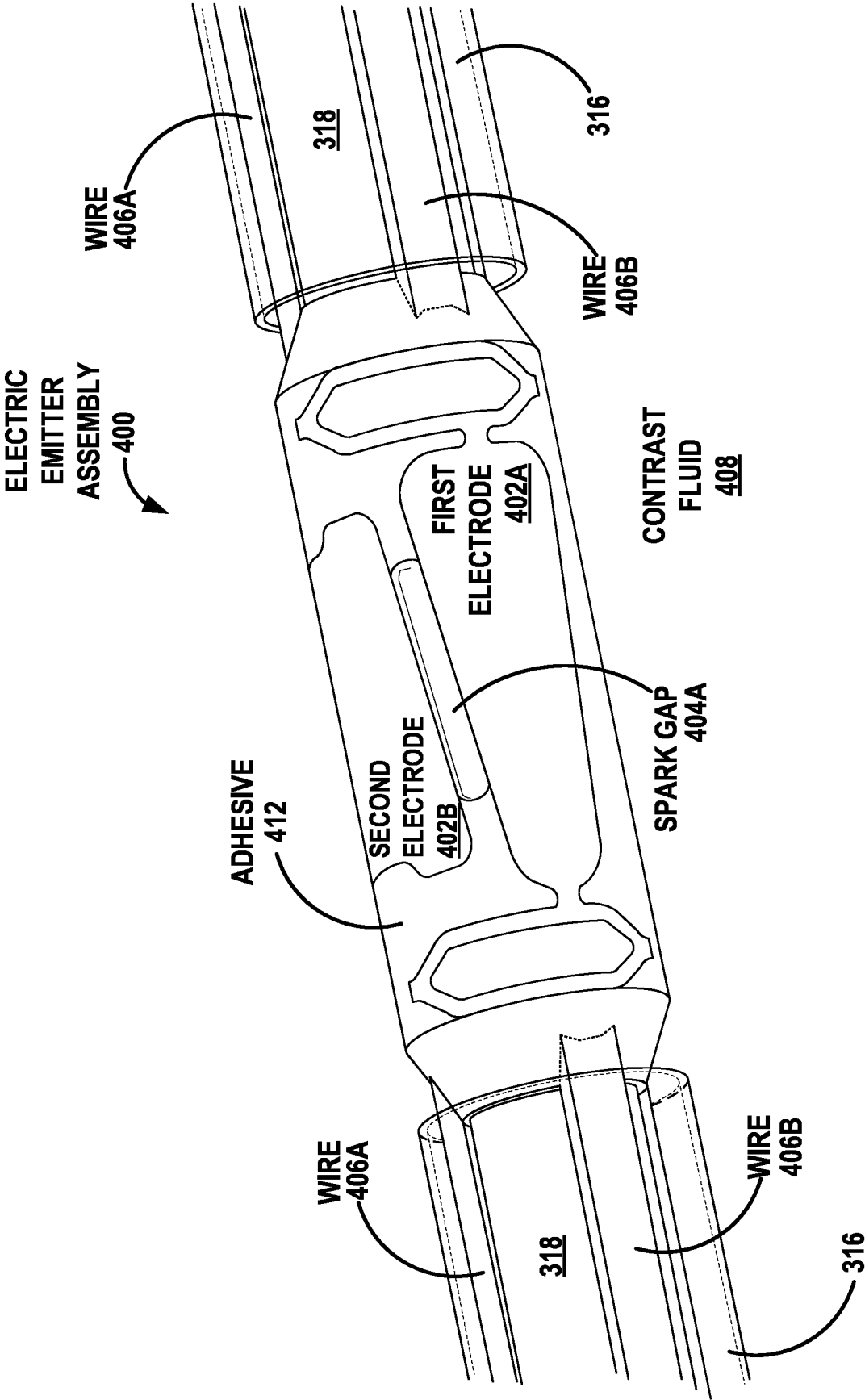


FIG. 4A

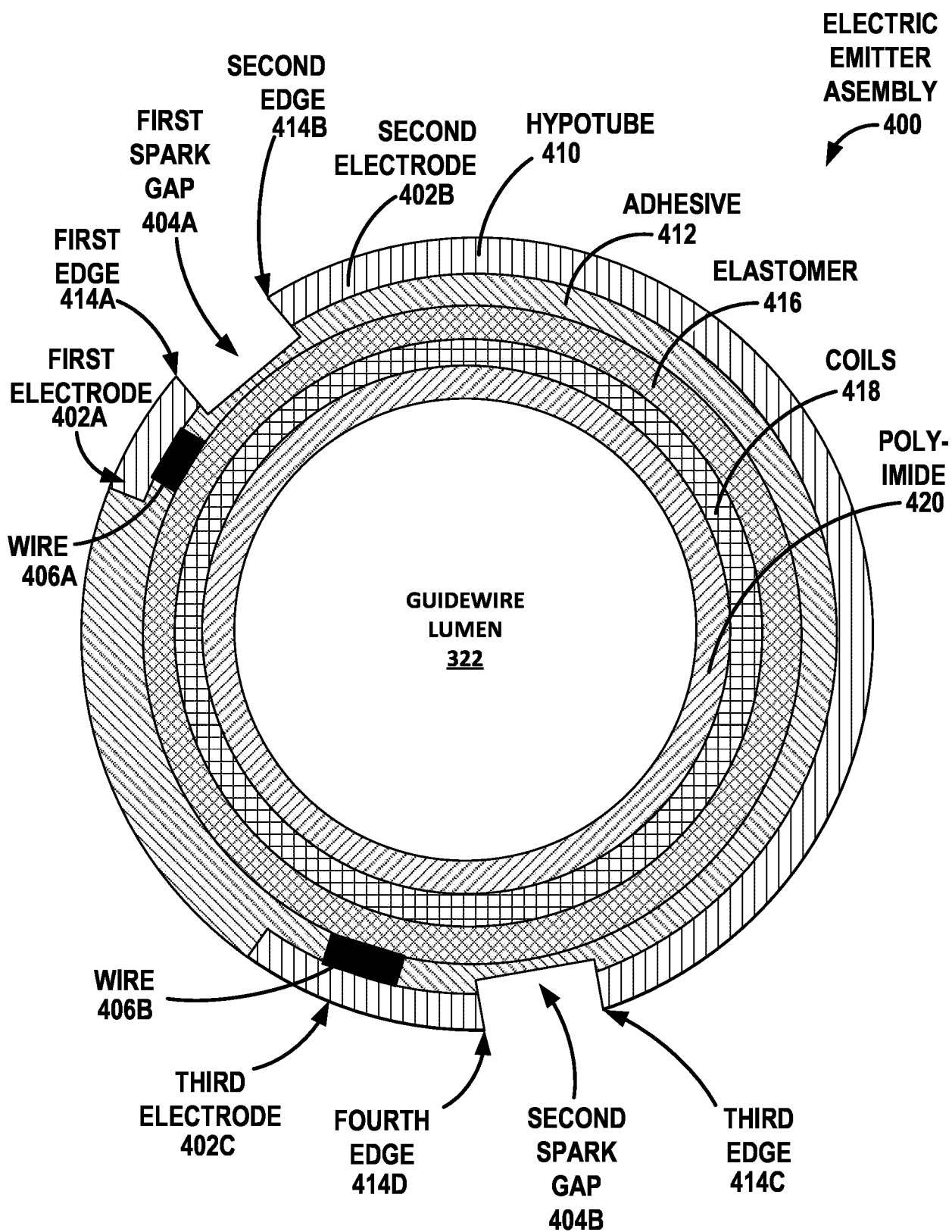


FIG. 4B

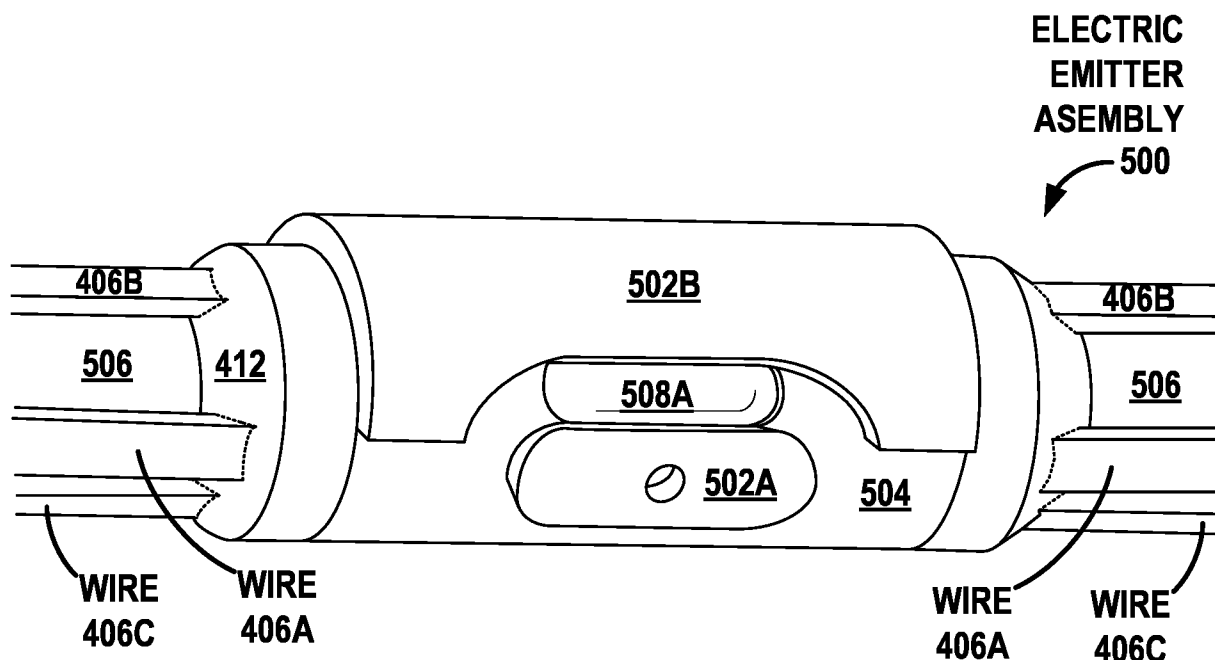


FIG. 5A

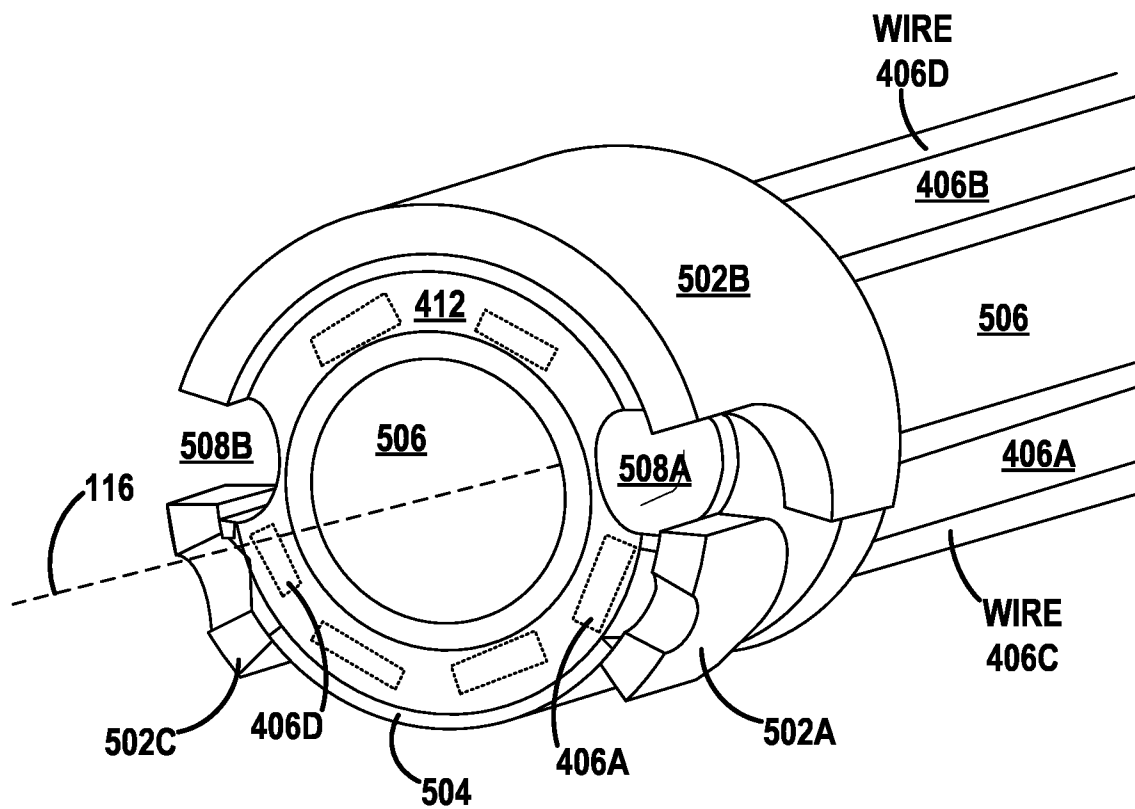
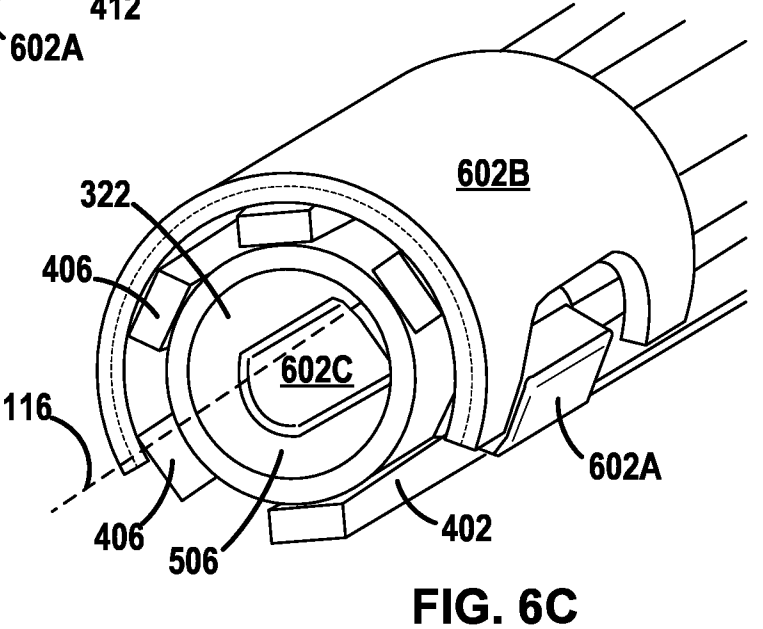
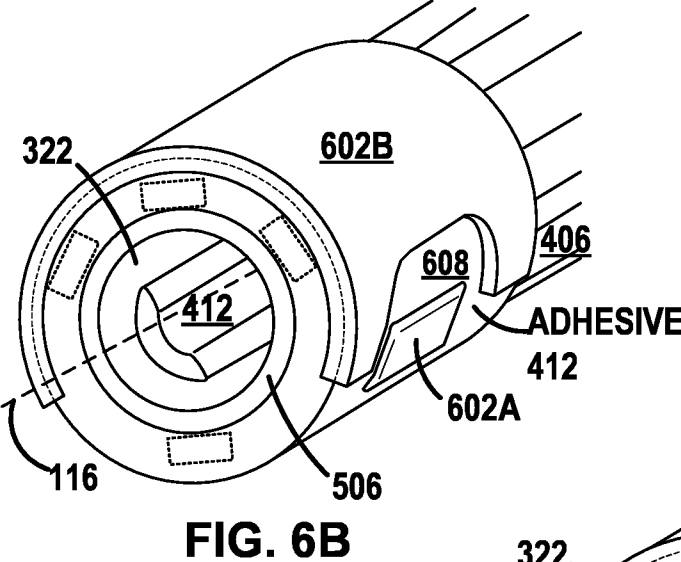
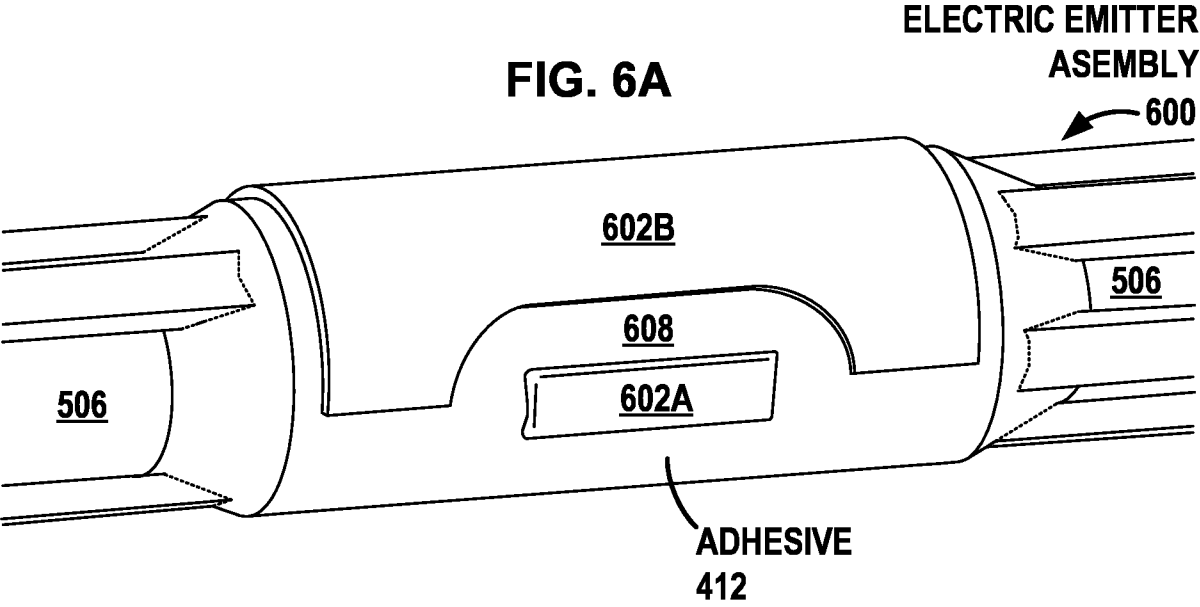


FIG. 5B



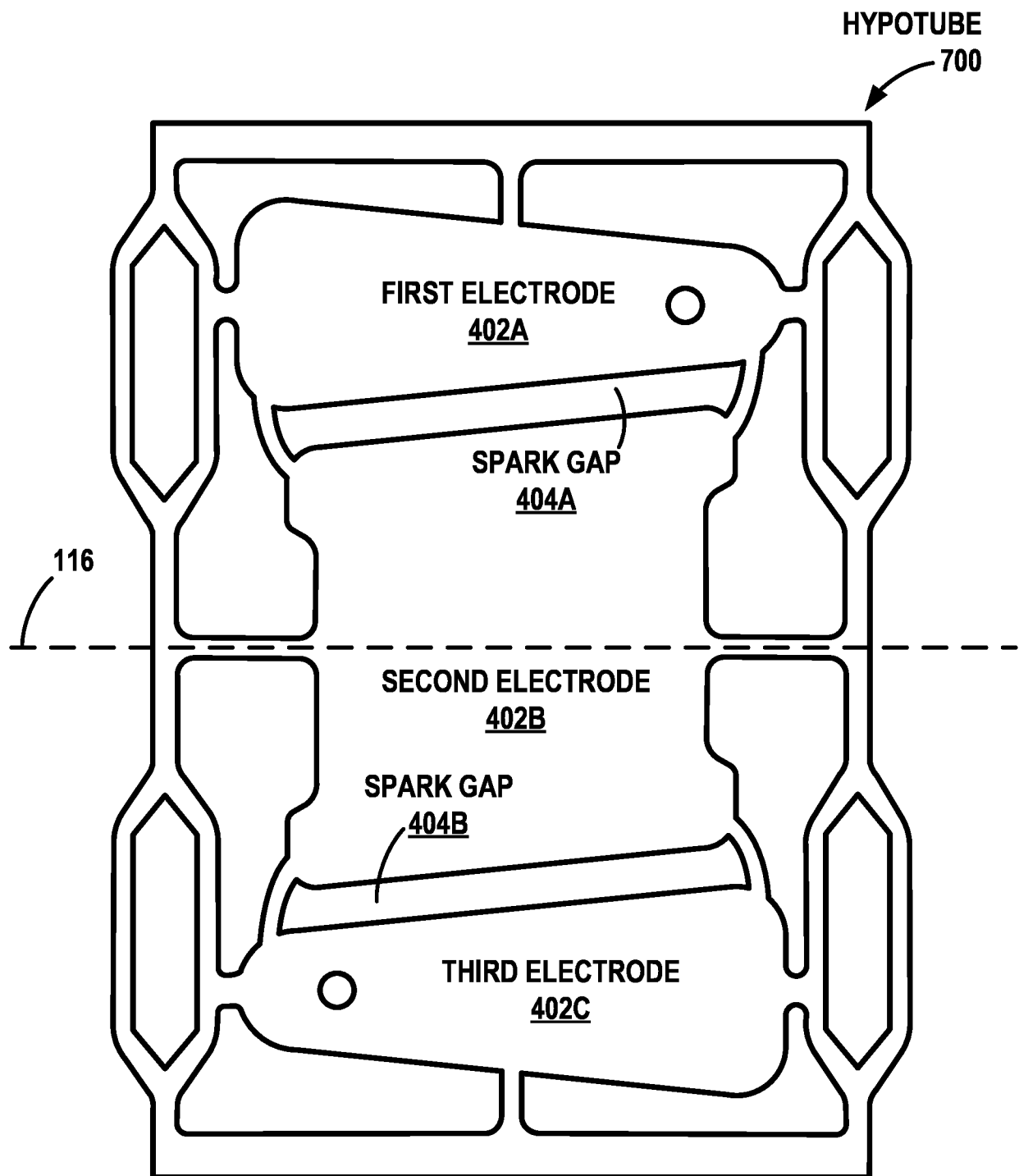


FIG. 7A

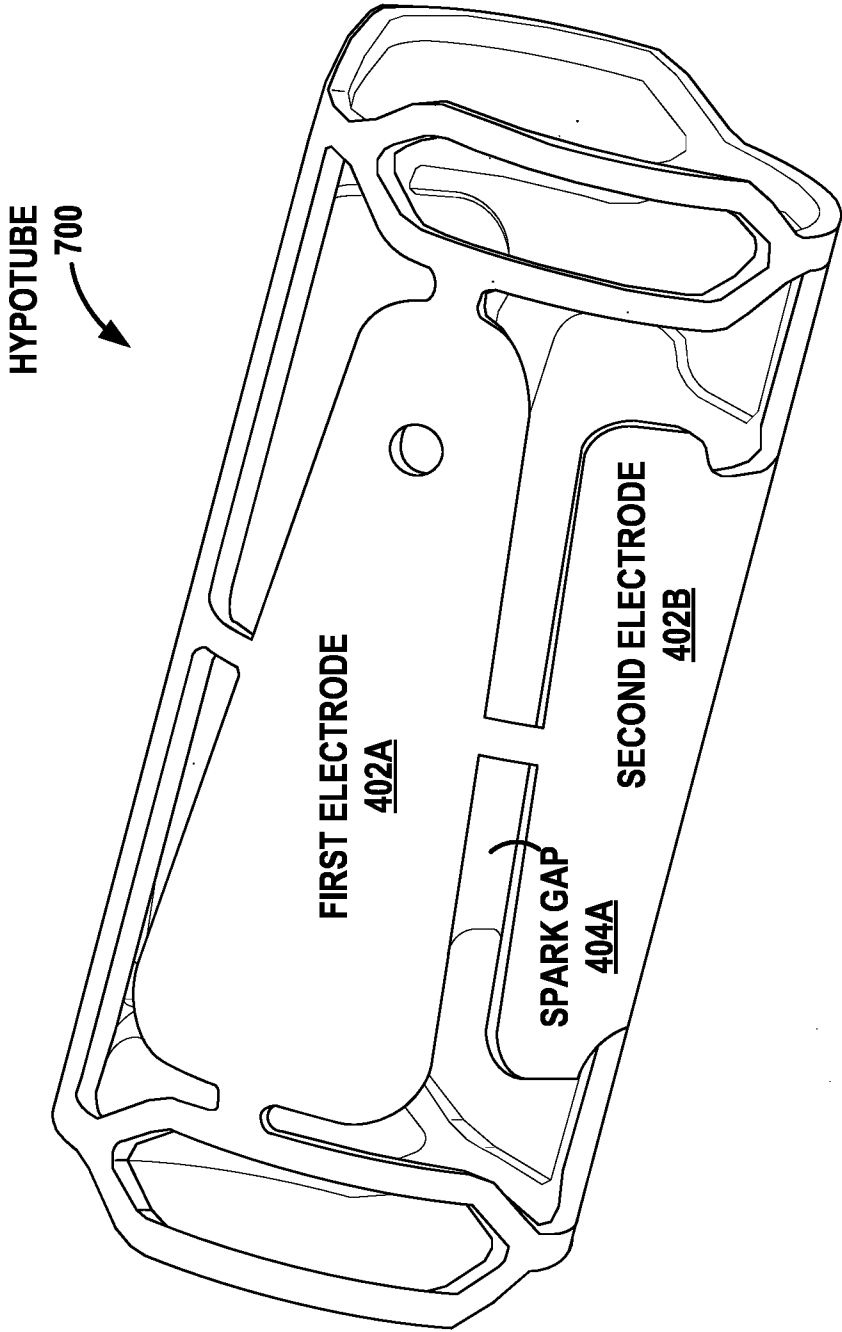


FIG. 7B

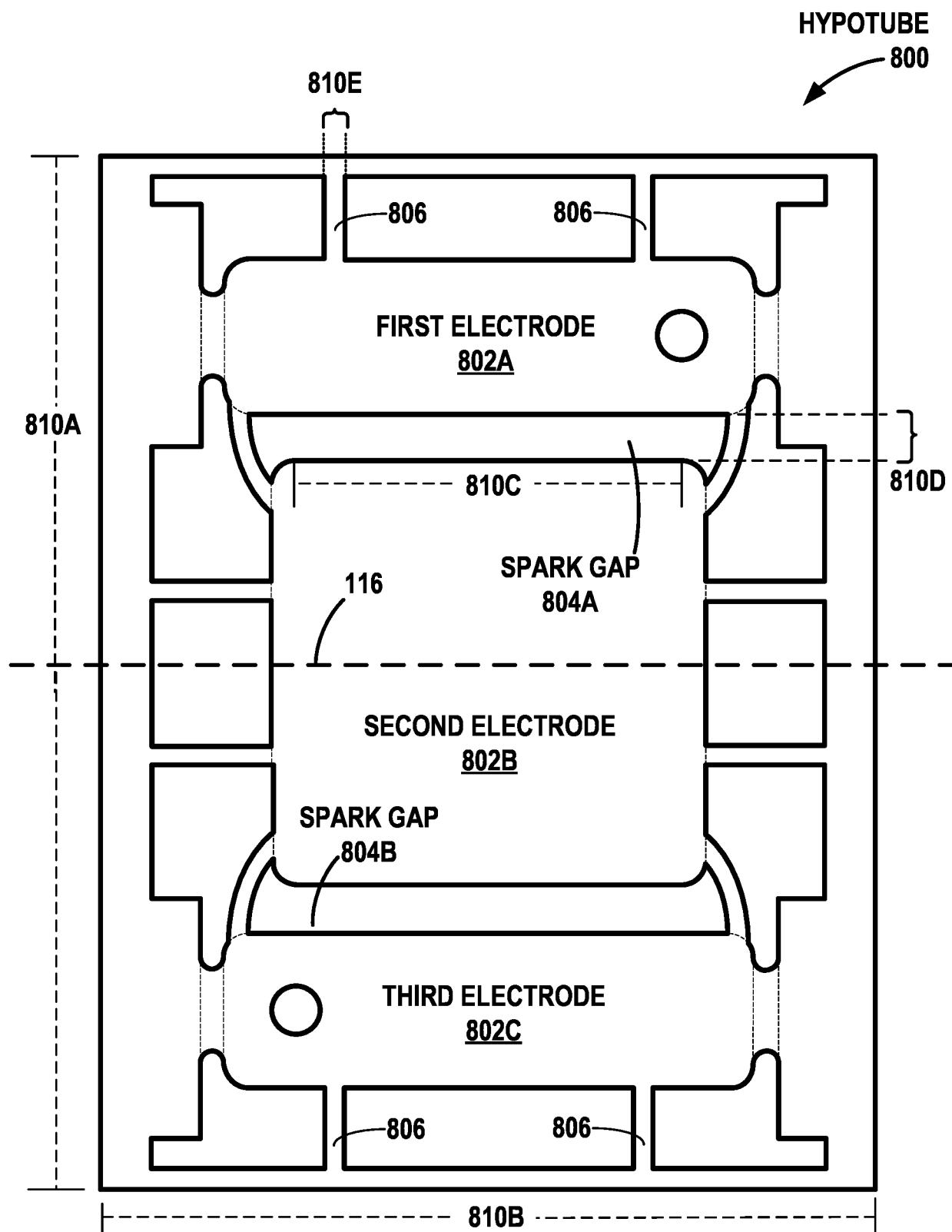


FIG. 8A

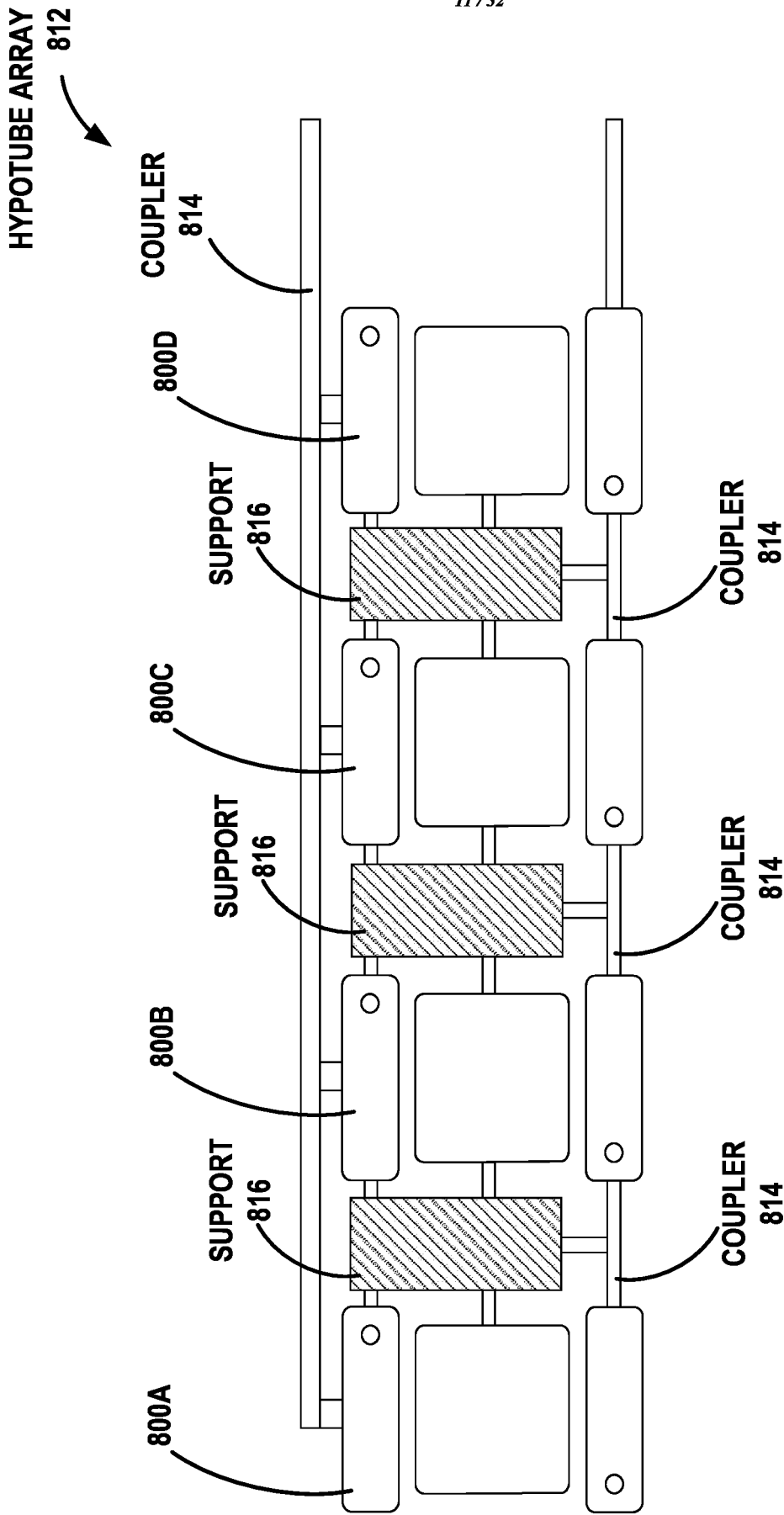
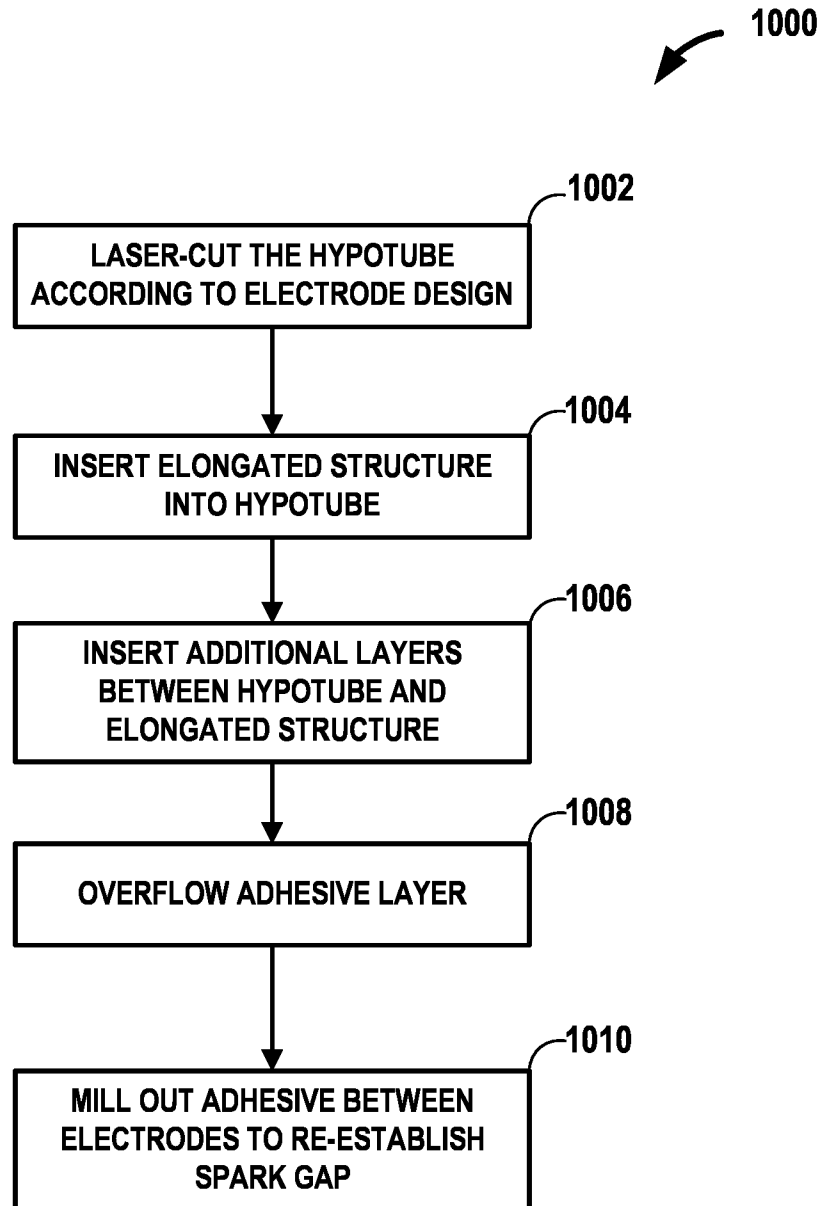


FIG. 8B

**FIG. 10**

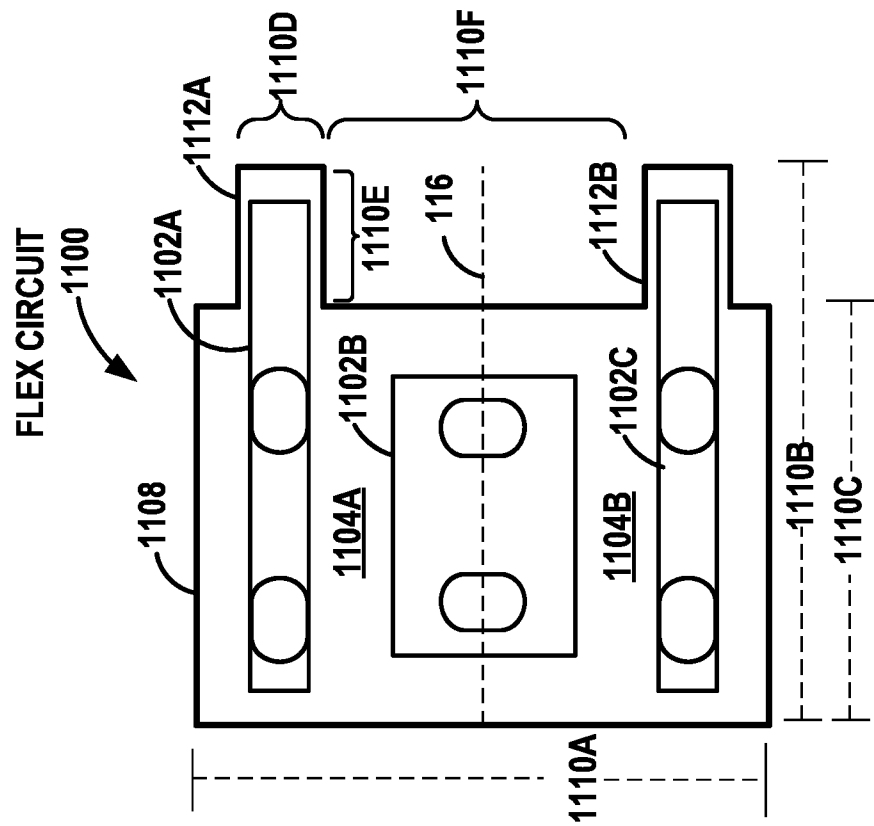


FIG. 11A

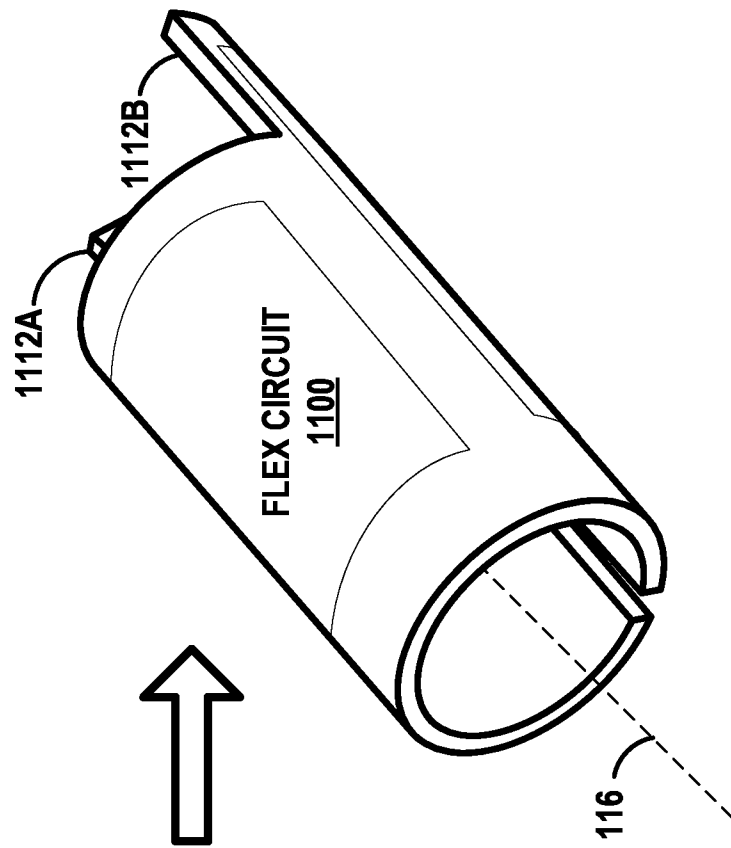
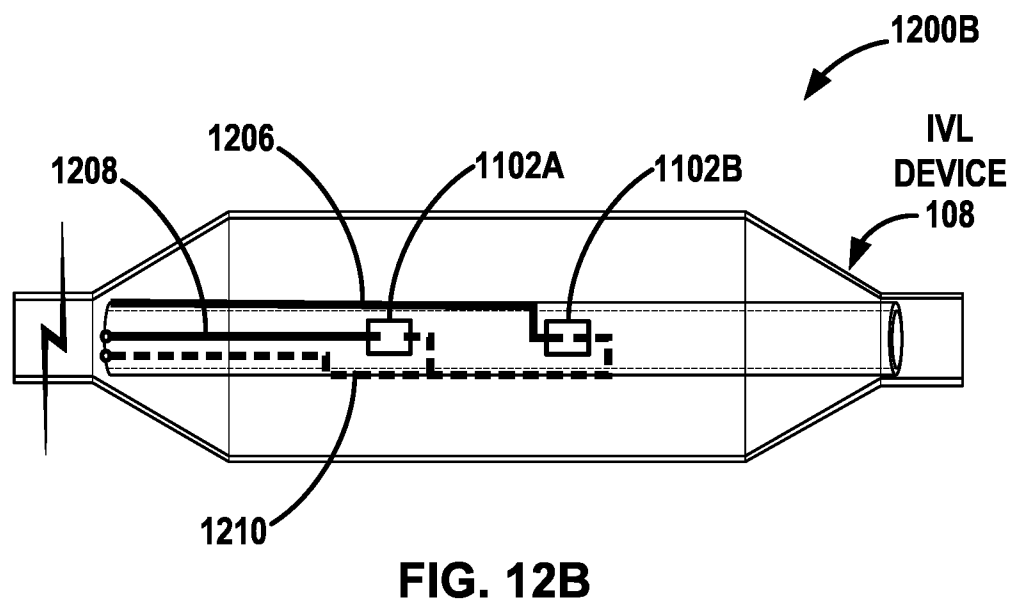
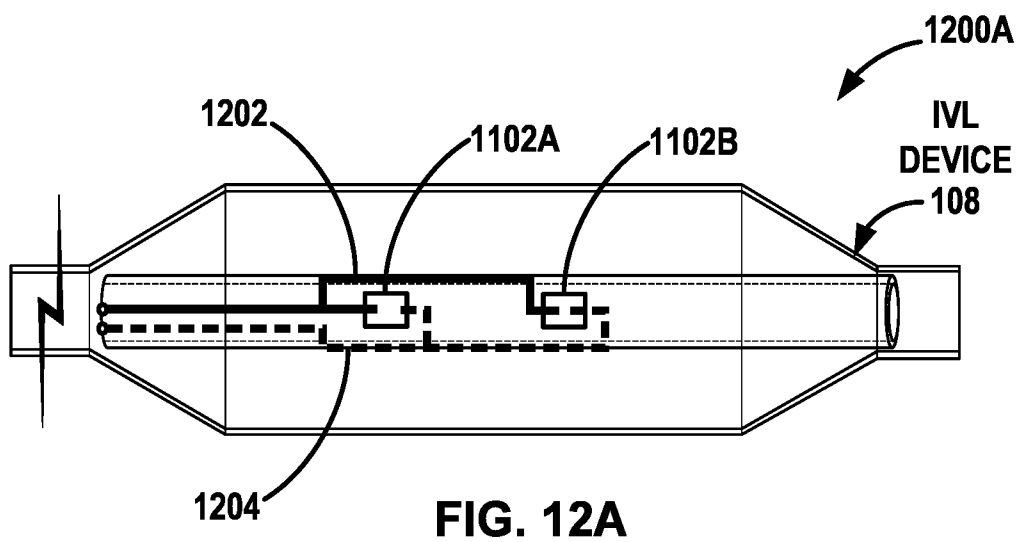
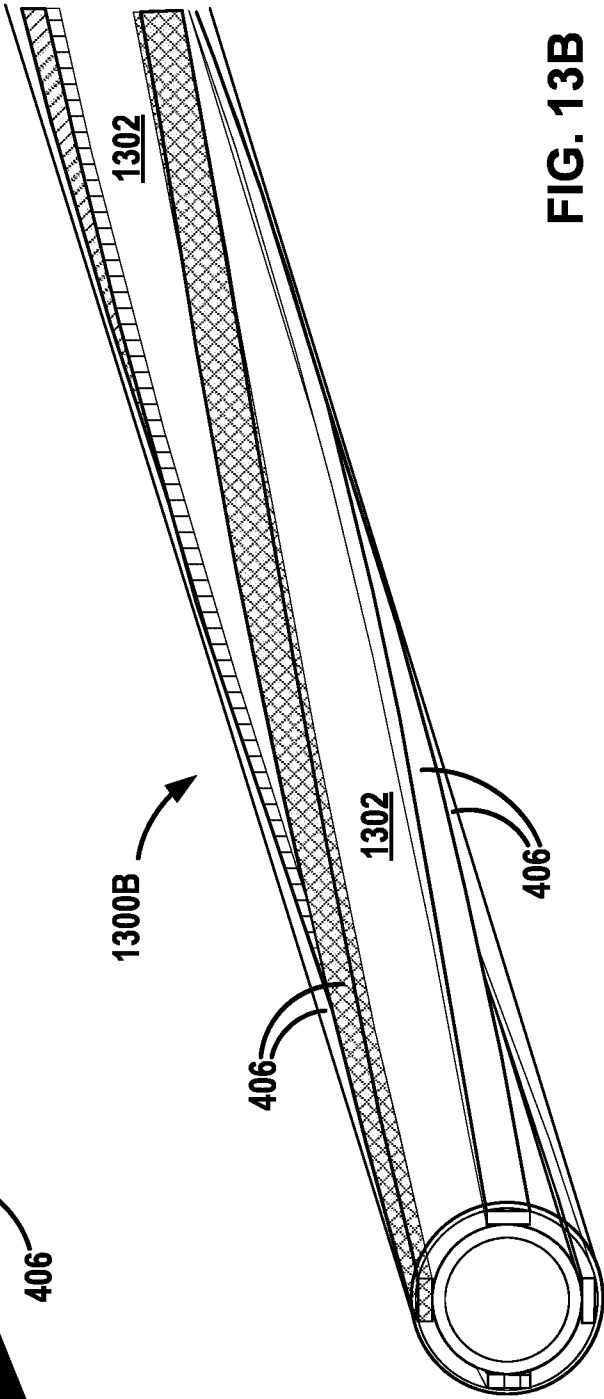
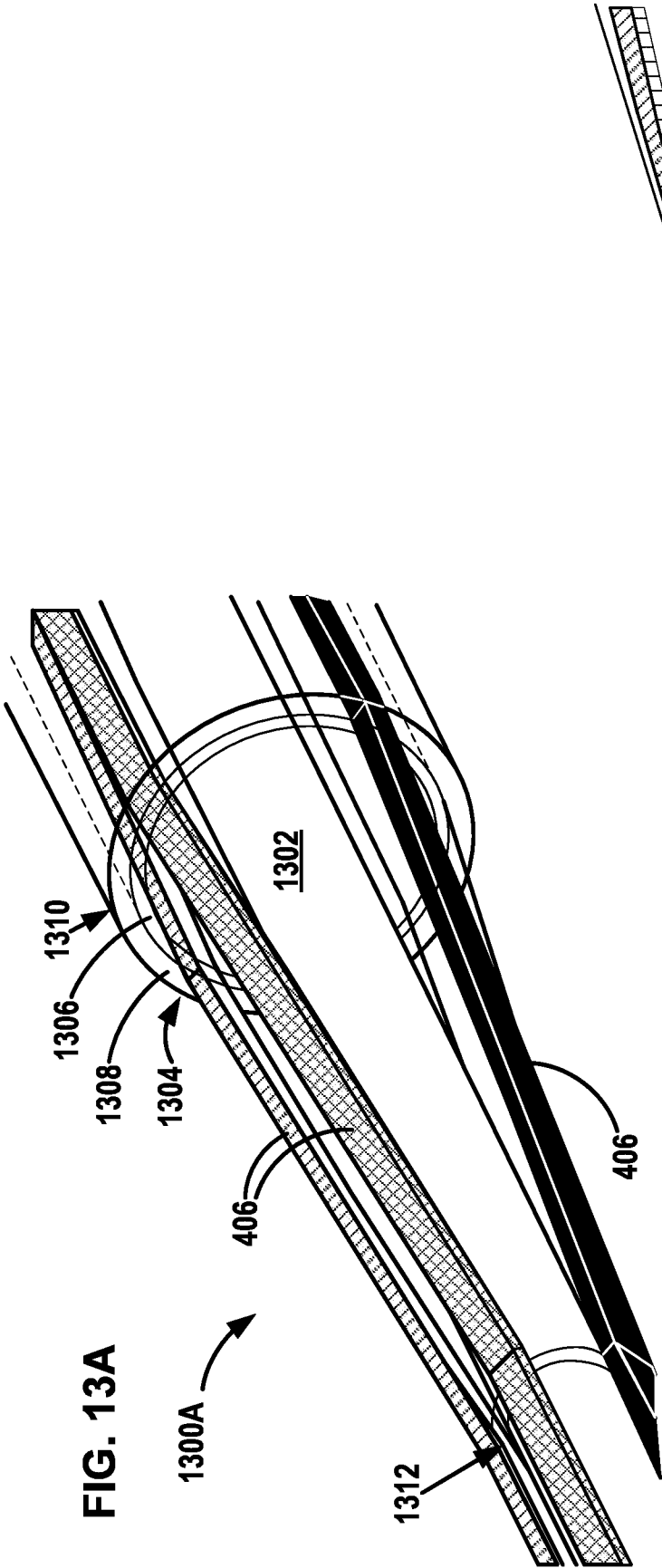


FIG. 11B





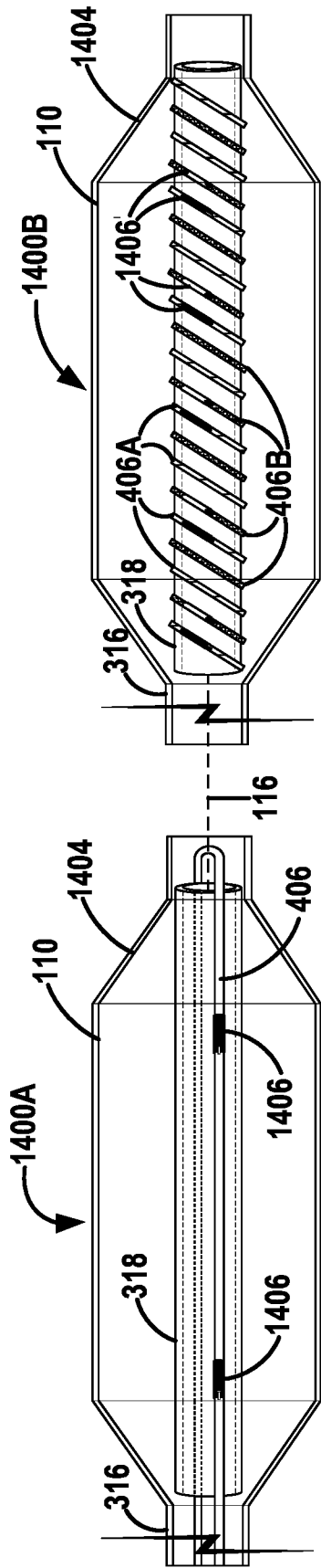


FIG. 14B

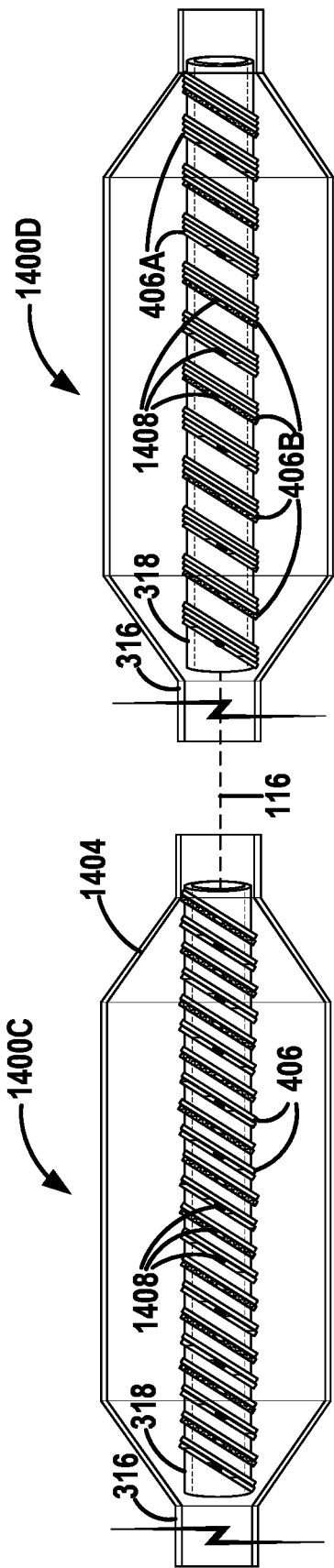
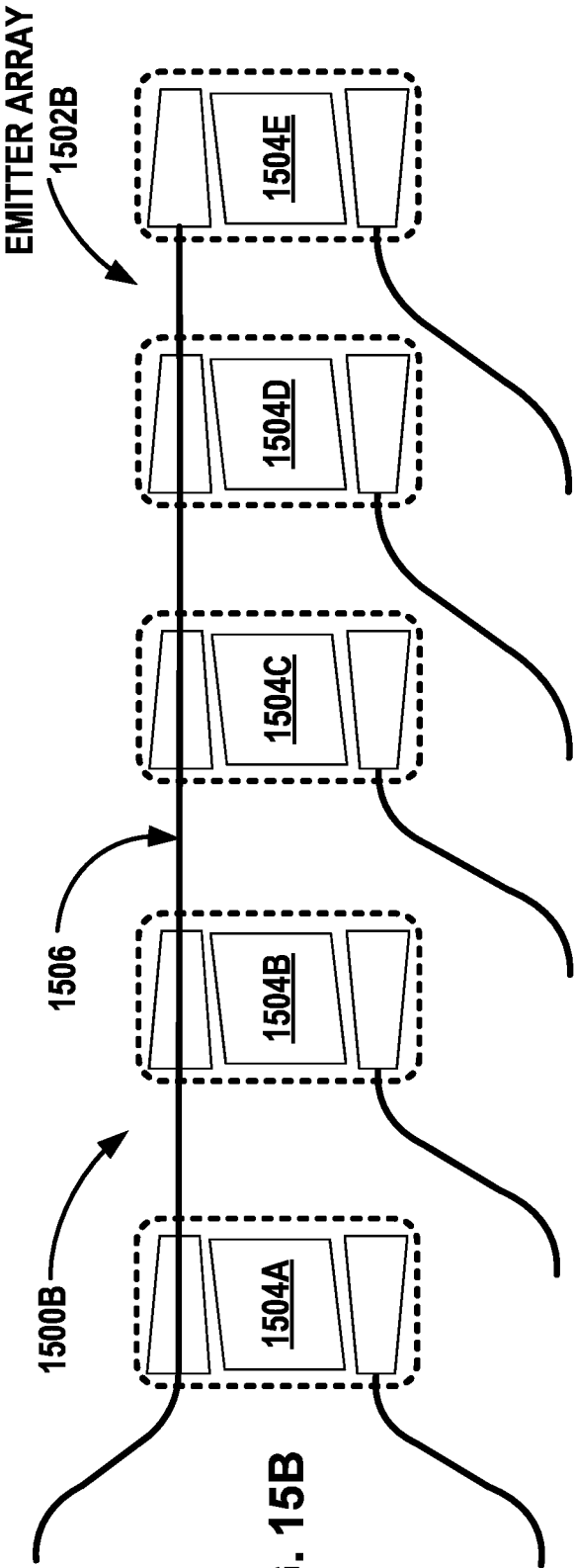
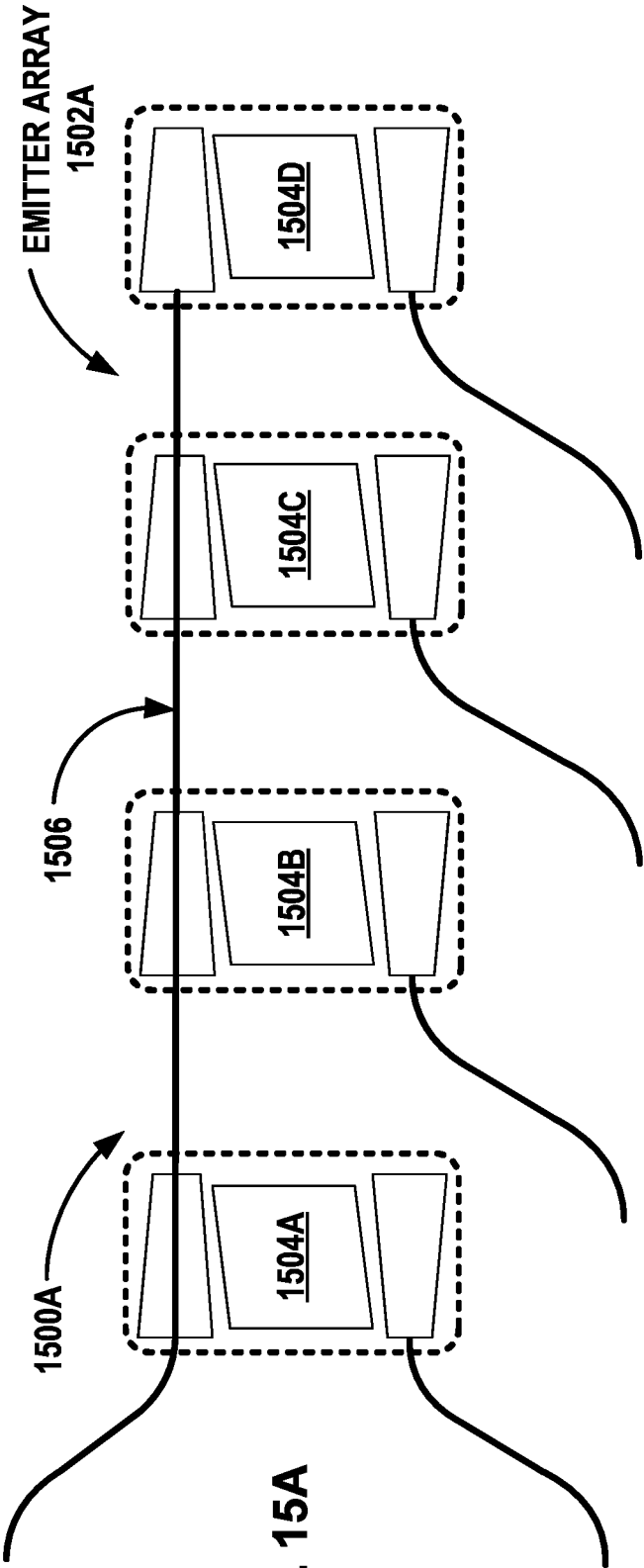


FIG. 14D

FIG. 14A

FIG. 14C



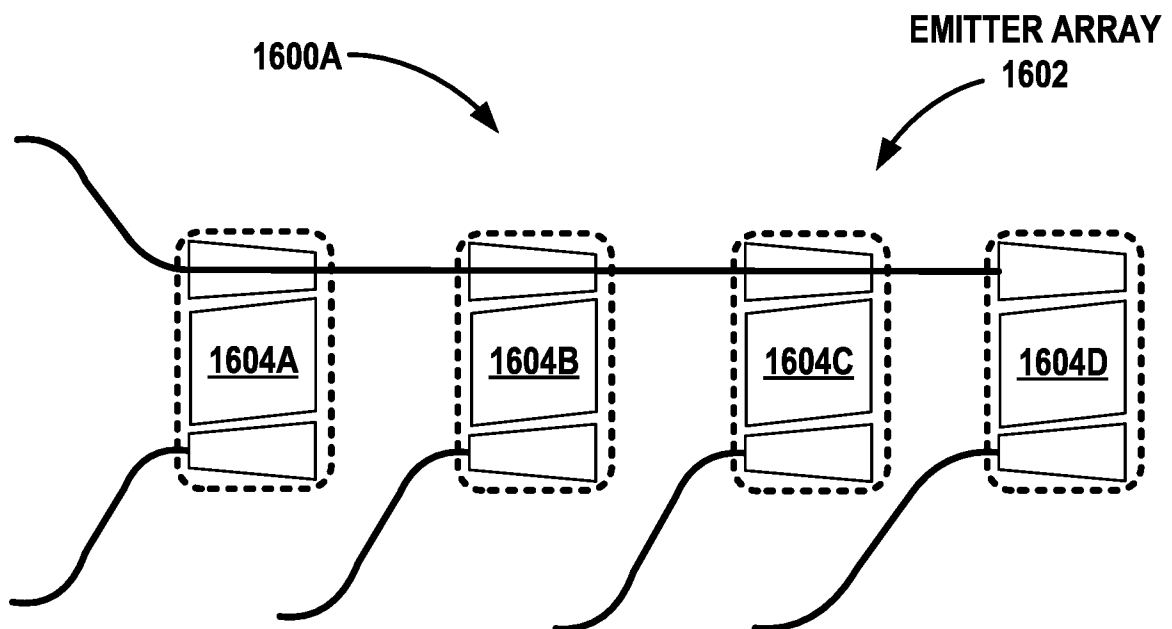


FIG. 16A

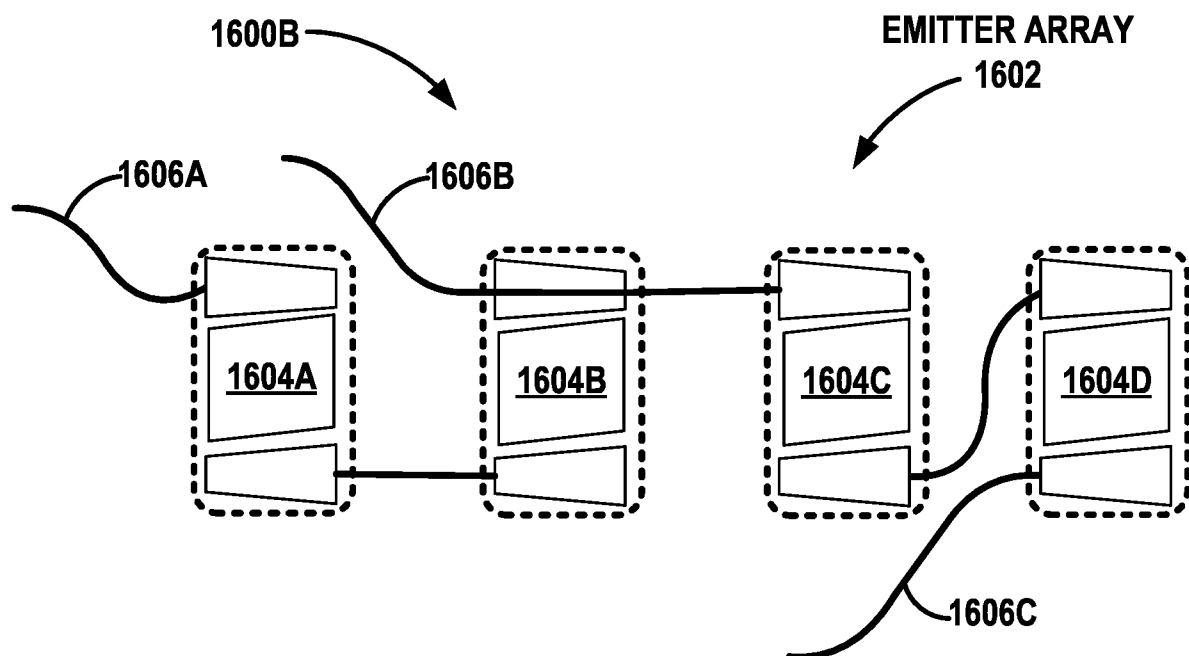
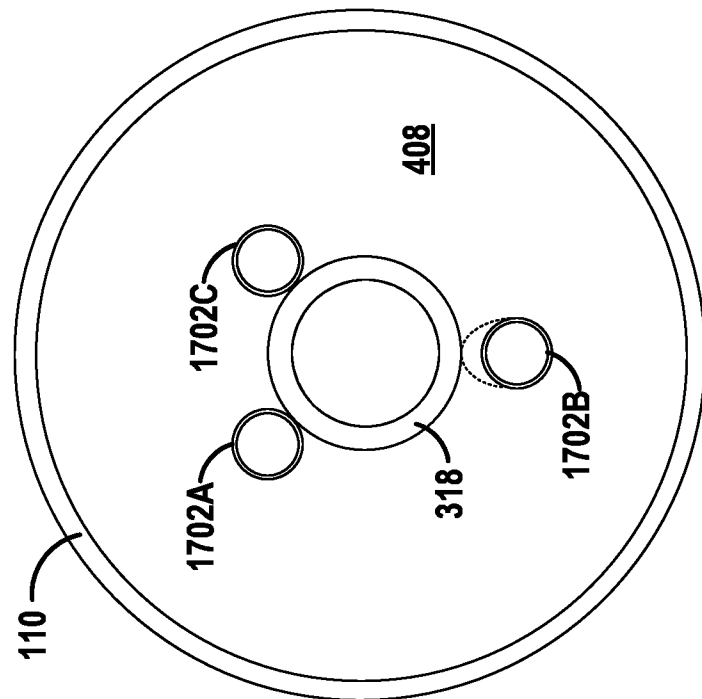
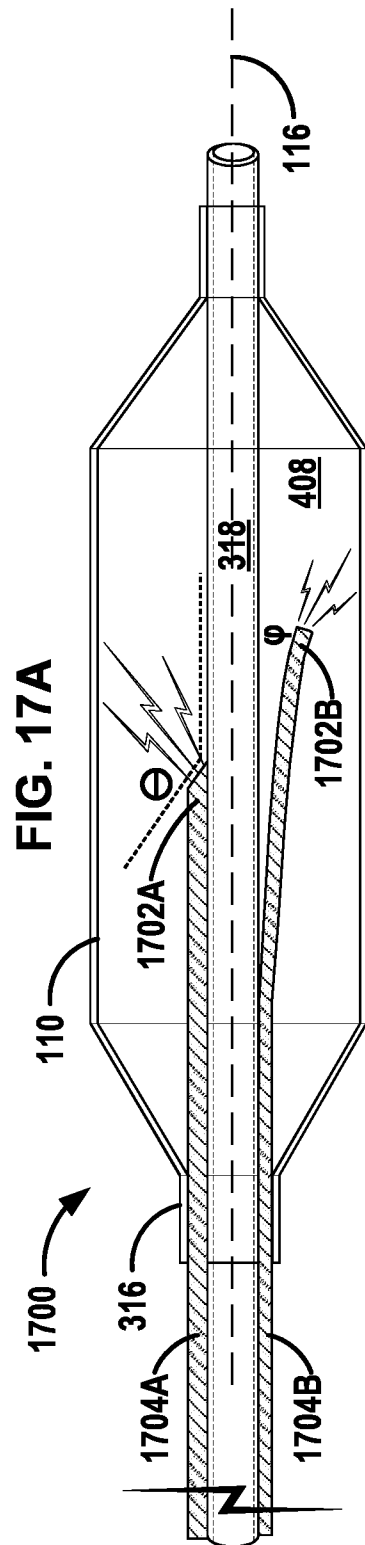


FIG. 16B



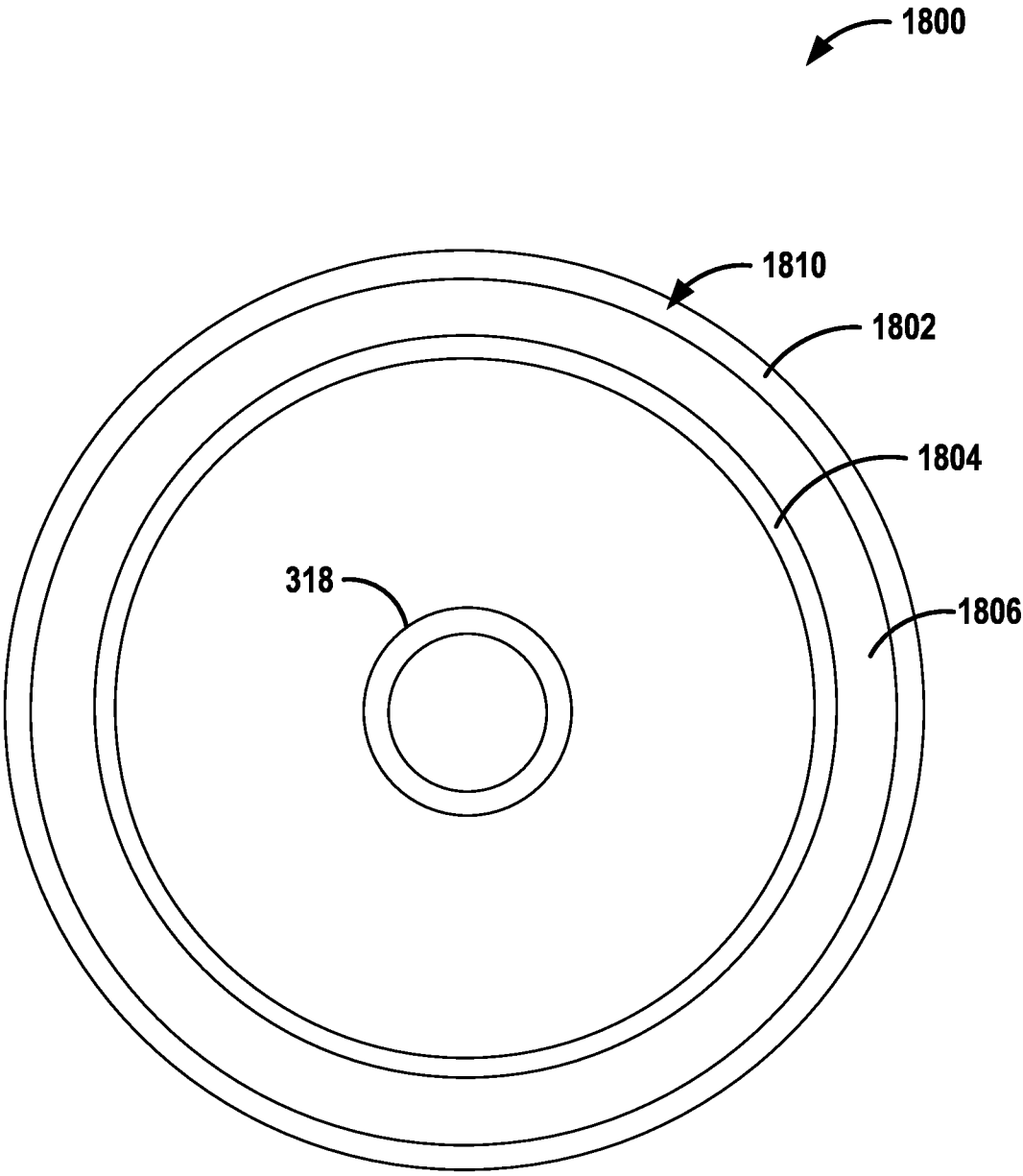


FIG. 18

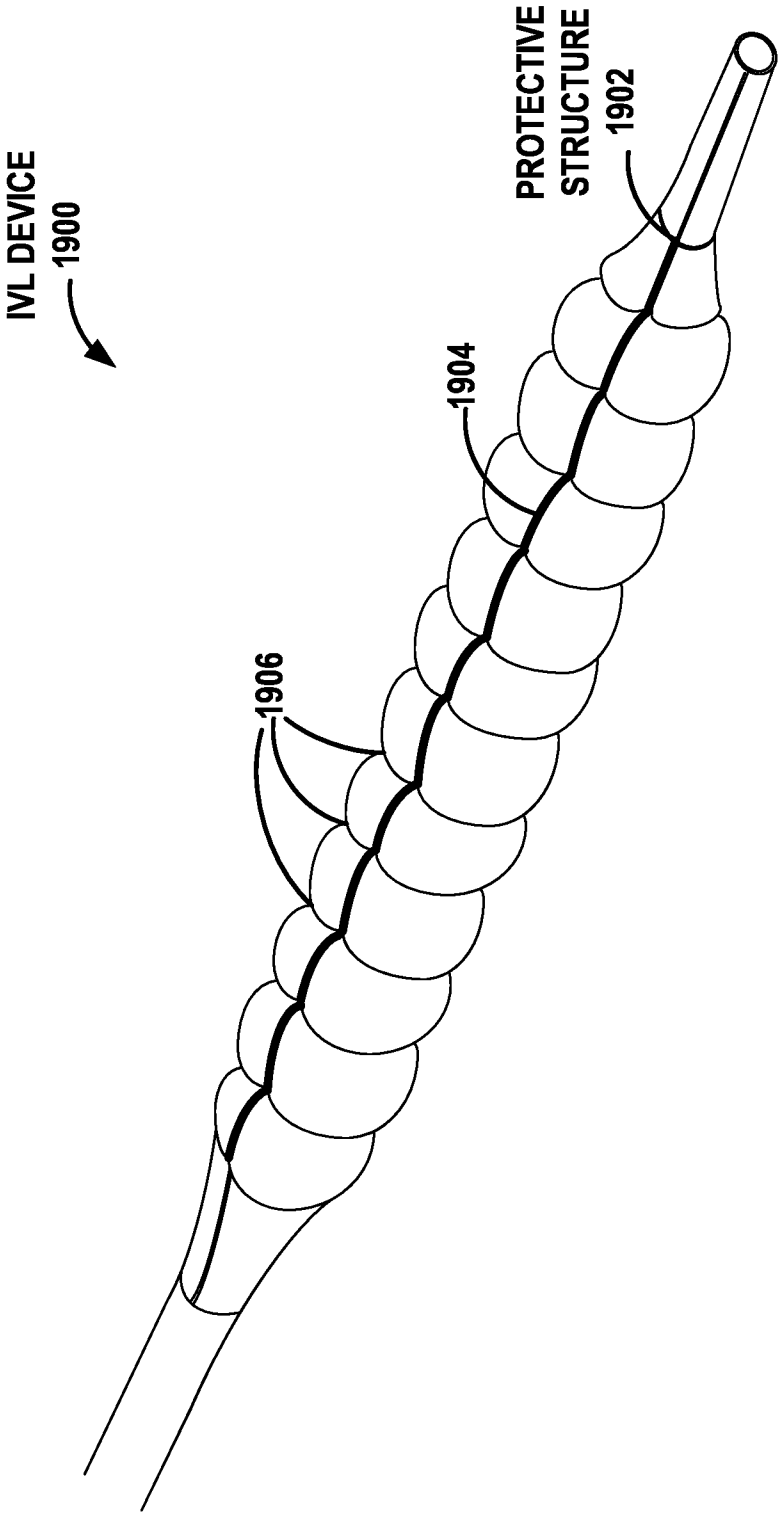


FIG. 19

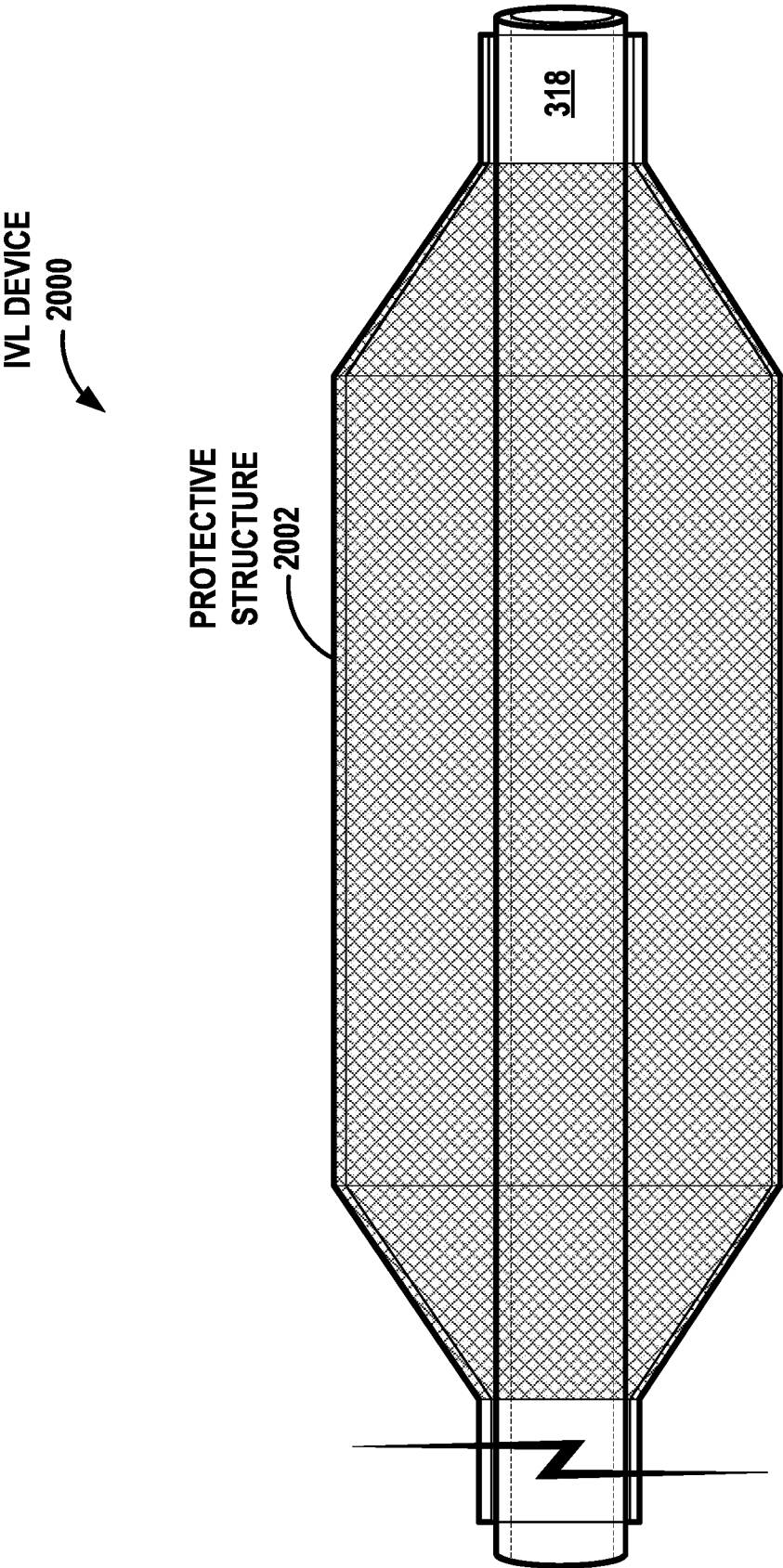


FIG. 20

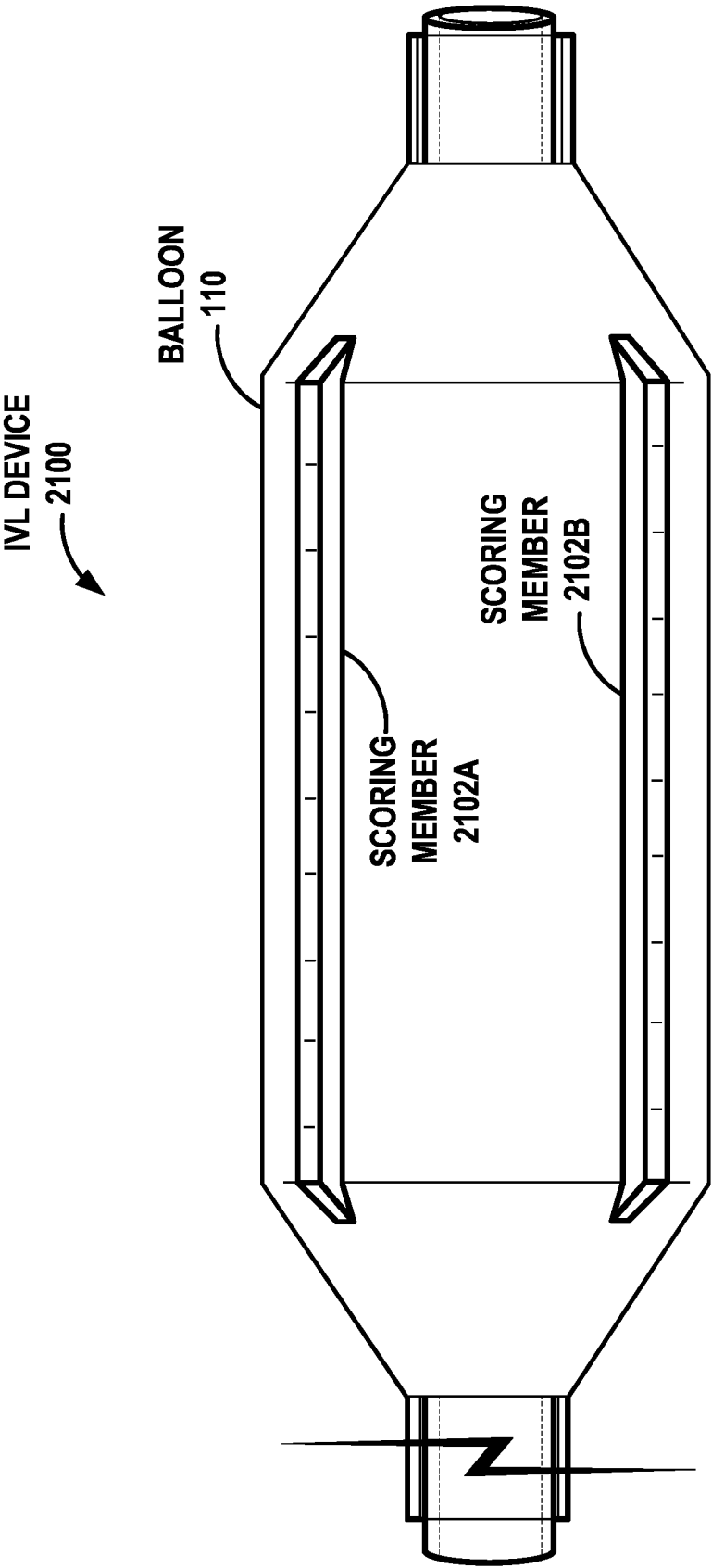


FIG. 21

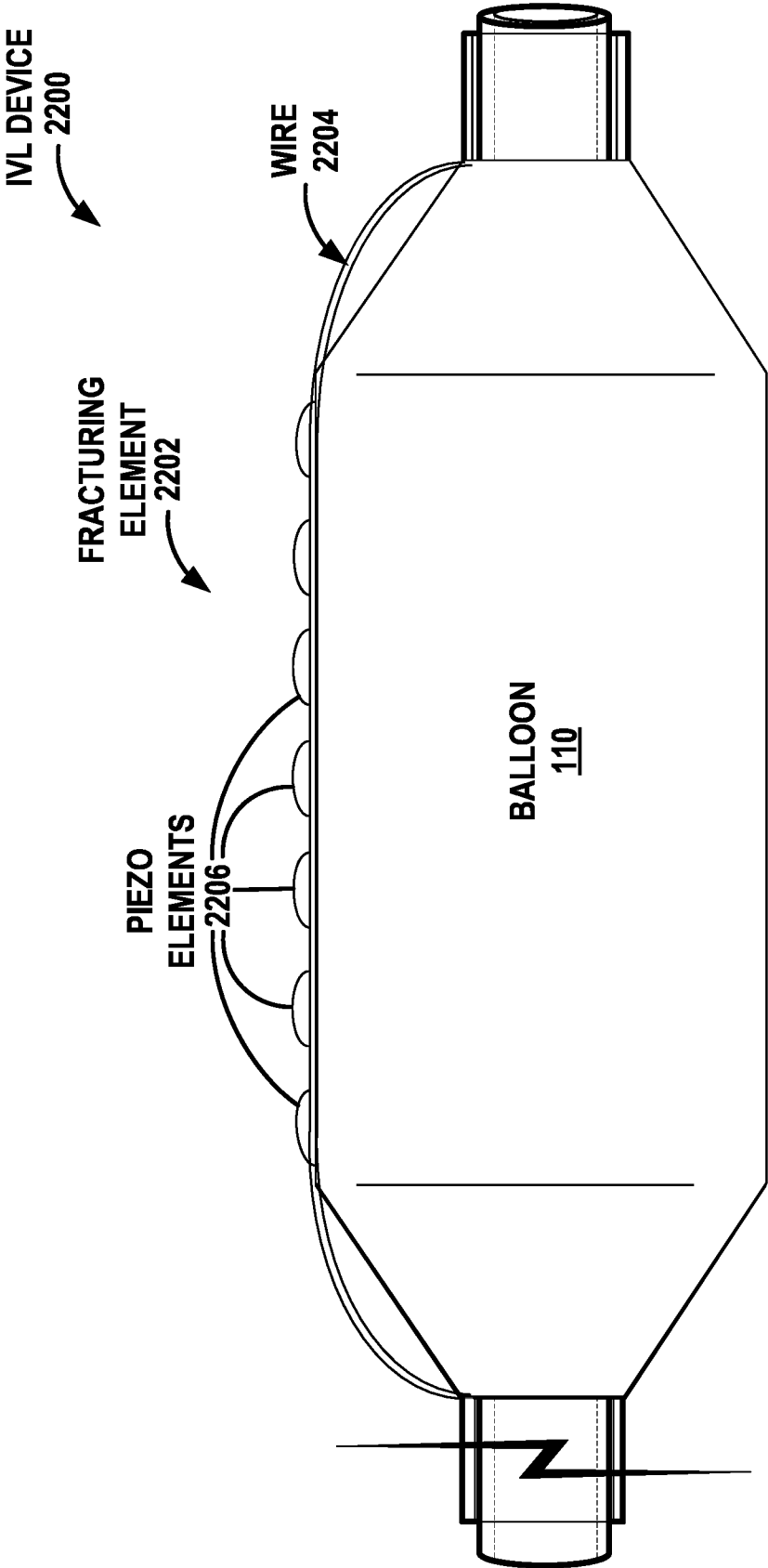


FIG. 22

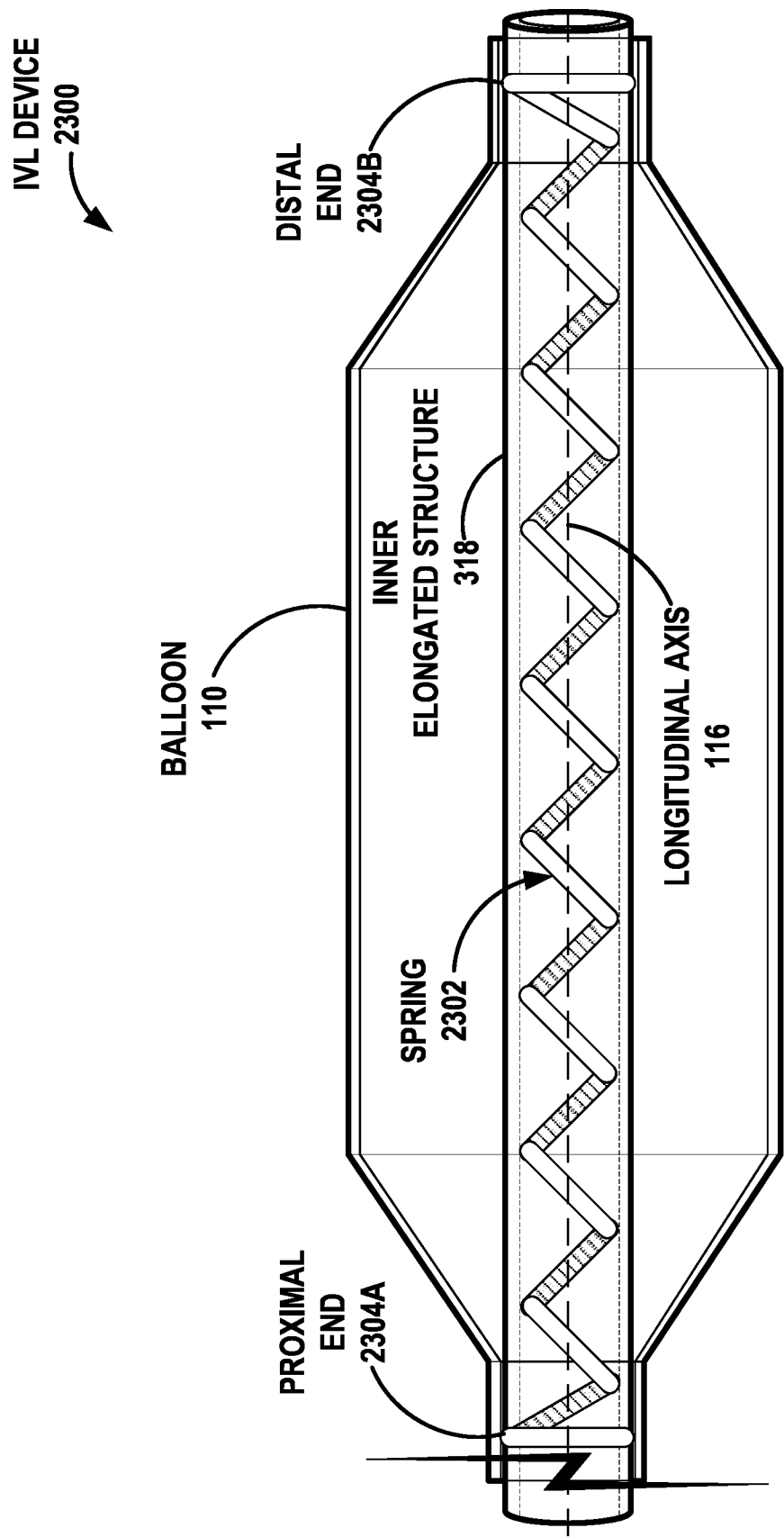


FIG. 23

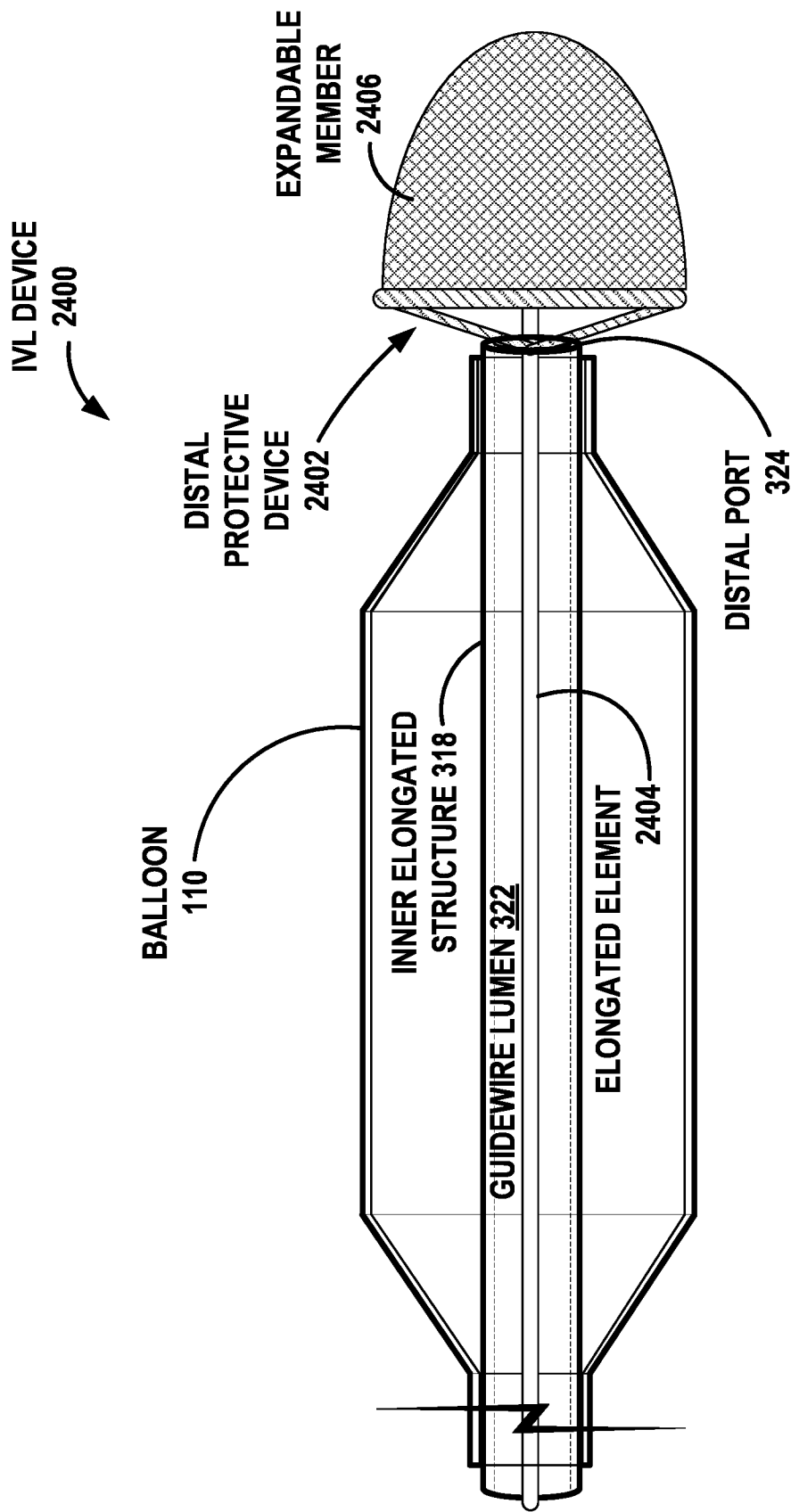


FIG. 24

IVL SYSTEM
100

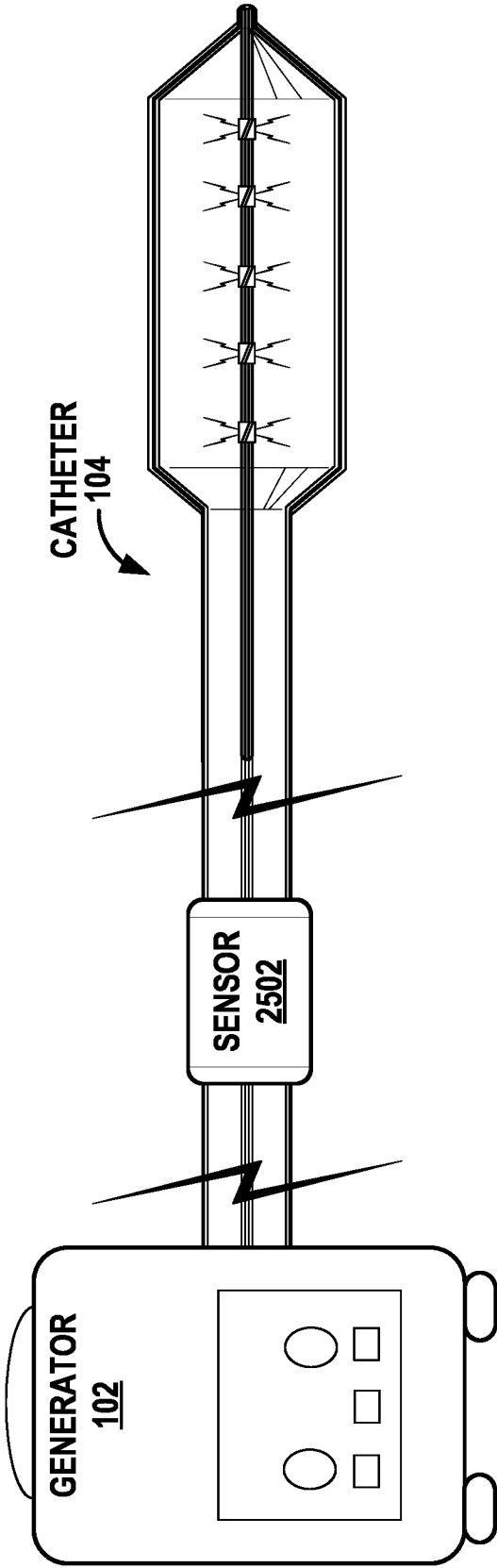


FIG. 25

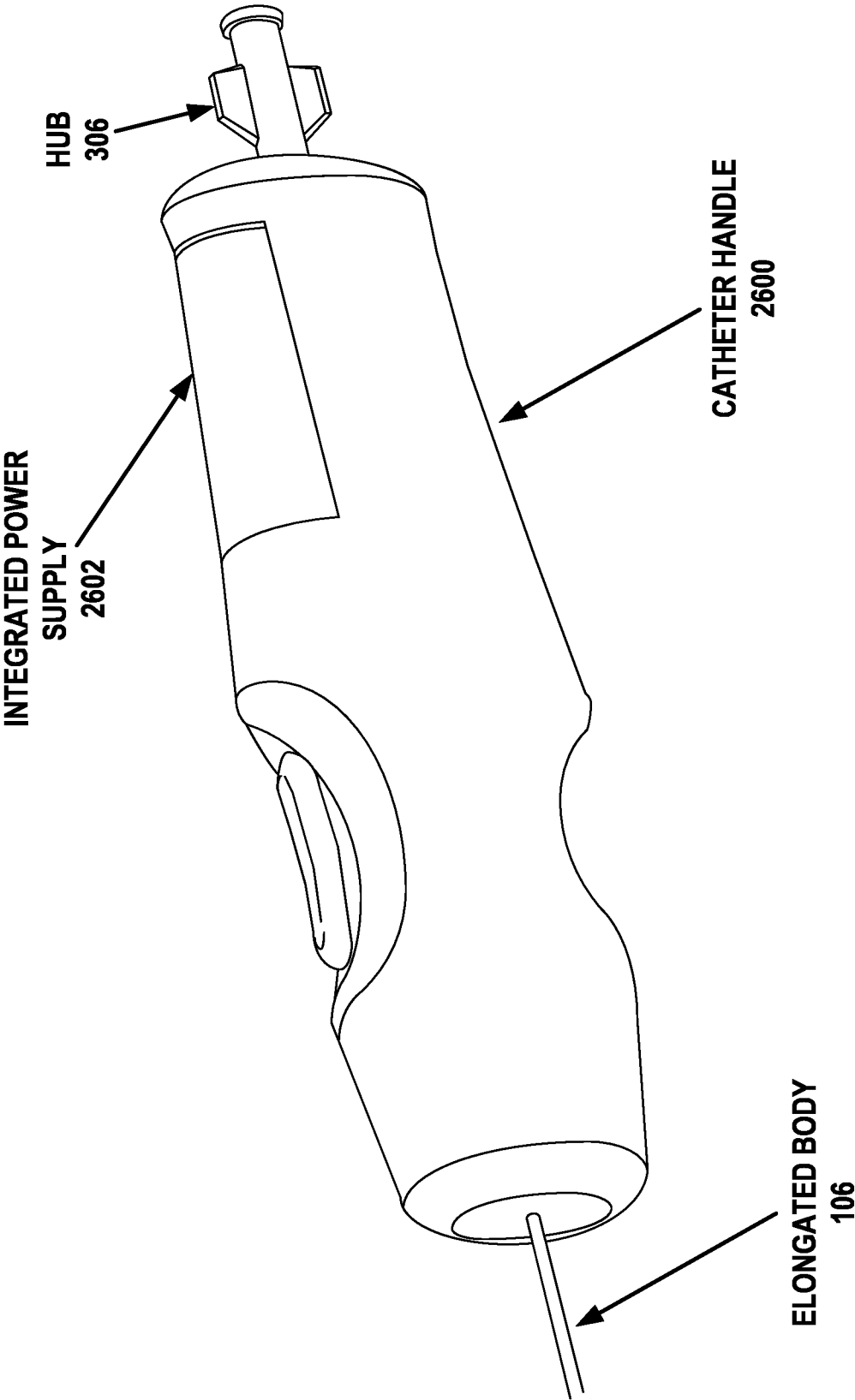


FIG. 26

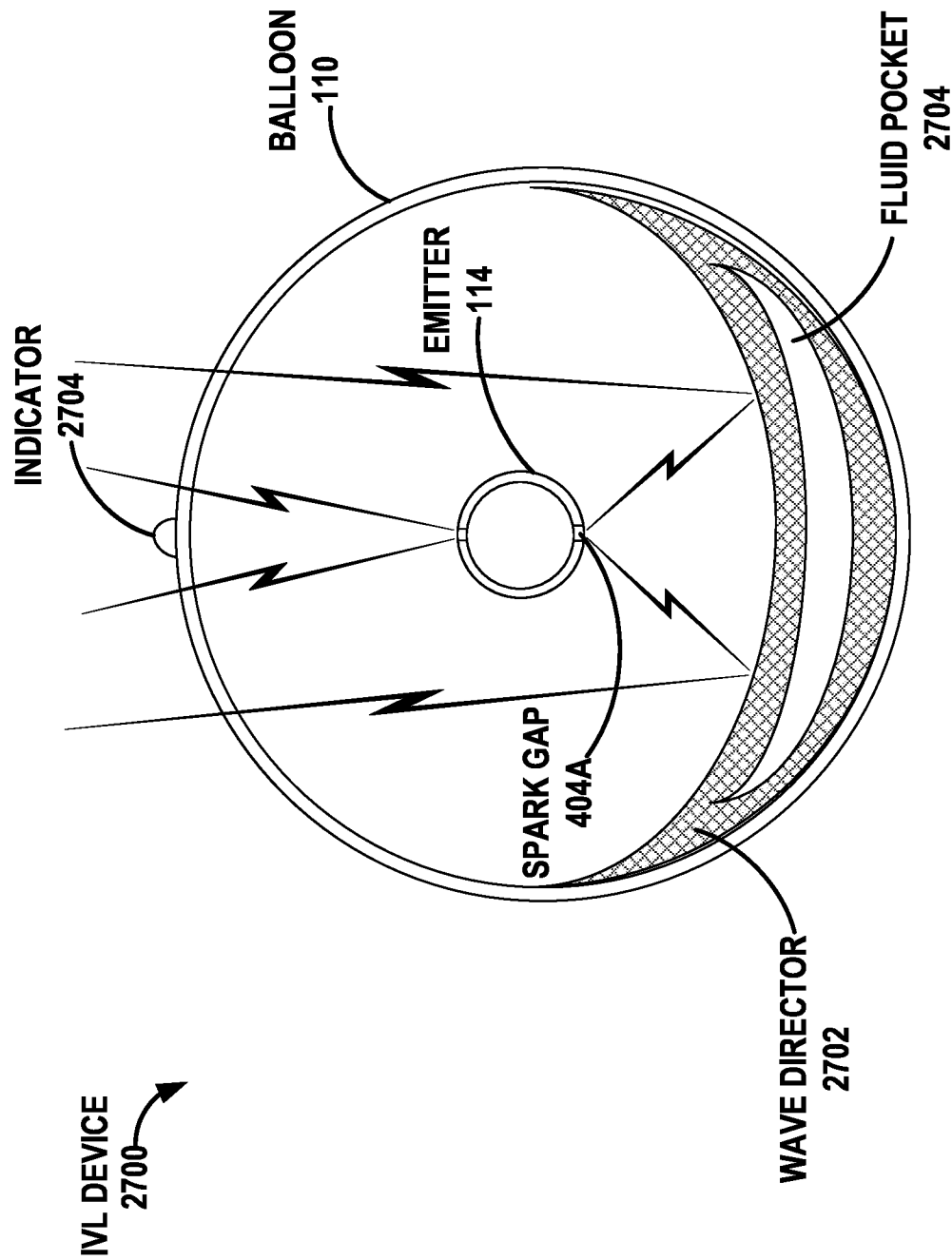
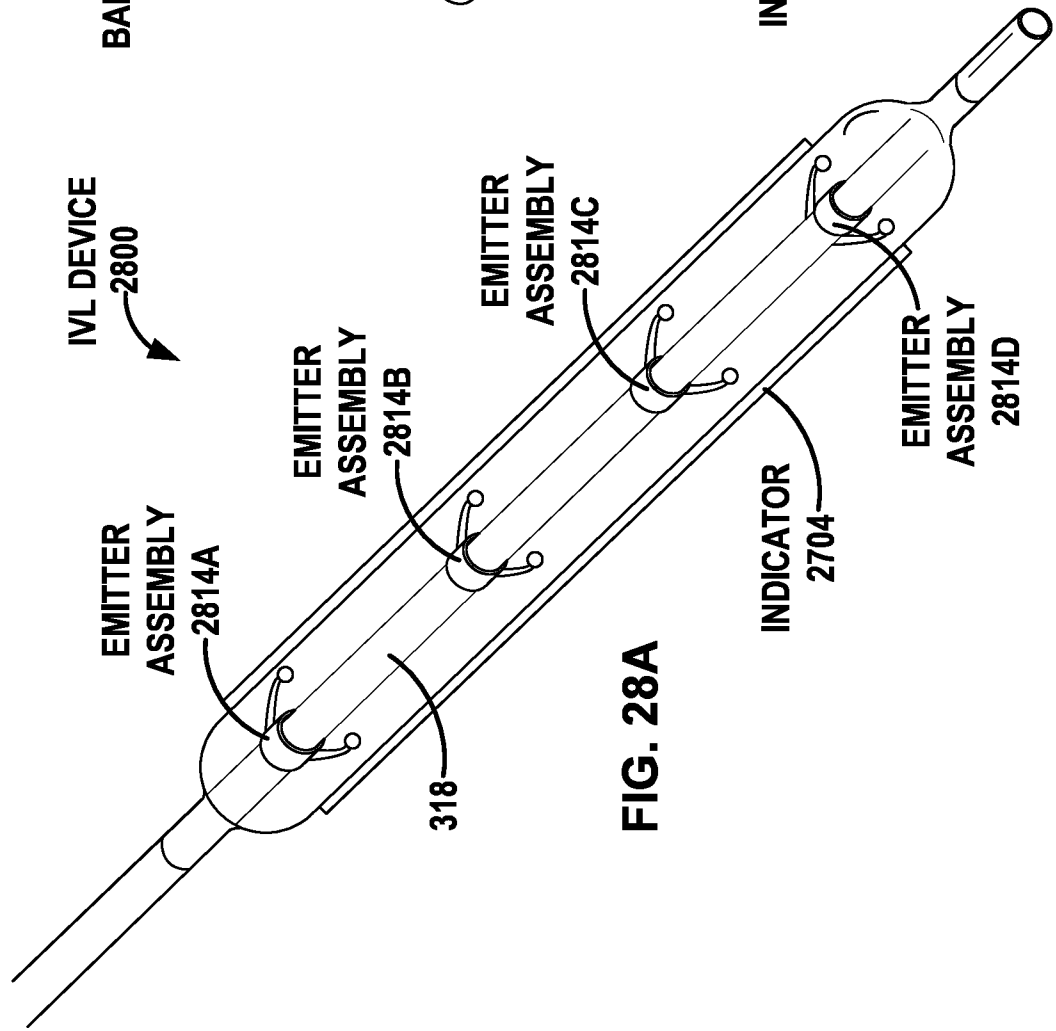
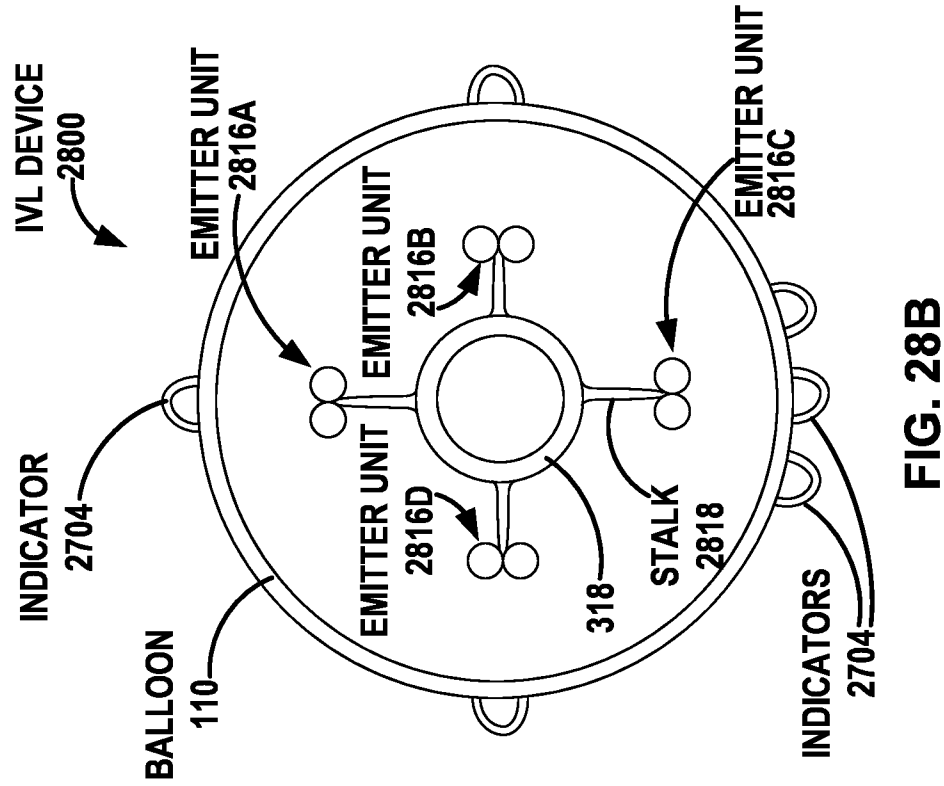


FIG. 27



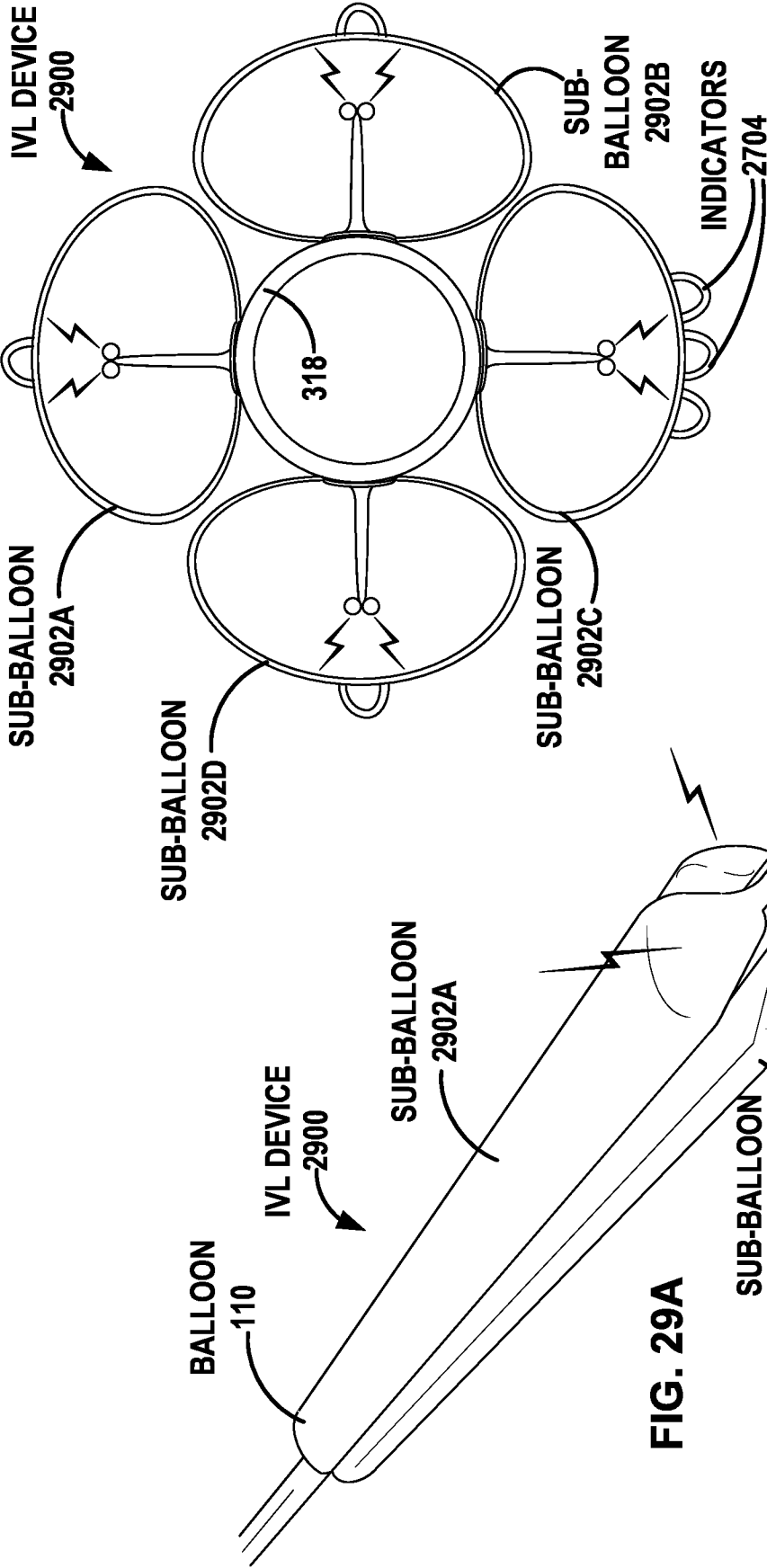


FIG. 29B

FIG. 29A

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2022/018030

A. CLASSIFICATION OF SUBJECT MATTER A61B 17/22(2006.01)i; A61B 18/26(2006.01)i; A61B 18/24(2006.01)i; A61B 18/00(2006.01)i According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B 17/22(2006.01); A61B 18/14(2006.01); A61L 29/14(2006.01); A61M 25/10(2006.01) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Korean utility models and applications for utility models Japanese utility models and applications for utility models Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) eKOMPASS(KIPO internal) & Keywords: intravascular, lithotripsy, system, energy, generator, catheter, elongated, body, balloon, pressure-wave, emitter, sensor, electrode, spark gap, optical, fiber, laser-cutting, hypotube, conductive, wire, fracturing, member, wave, director		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020-0085458 A1 (SHOCKWAVE MEDICAL, INC.) 19 March 2020 (2020-03-19) paragraphs [0007], [0020]-[0037]; figures 1A-6	1-13,20-22,26,27, 33-38,49,53,58-60
Y		23-25,28-32,39-48, 50-52,54-57,61-72
A		14-19,73-82
Y	US 2020-0383724 A1 (SHOCKWAVE MEDICAL, INC.) 10 December 2020 (2020-12-10) paragraphs [0052]-[0082]; figures 1-16	23-25
Y	US 2016-0287323 A1 (TORAY INDUSTRIES INC.) 06 October 2016 (2016-10-06) paragraphs [0031]-[0062]; figures 1-6	28-32
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 07 June 2022		Date of mailing of the international search report 07 June 2022
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon 35208, Republic of Korea Facsimile No. +82-42-481-8578		Authorized officer KIM, Yeon Kyung Telephone No. +82-42-481-3325

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2022/018030

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2020-0155818 A1 (COVIDIEN LP) 21 May 2020 (2020-05-21) paragraphs [0015]-[0037]; figures 1-6	39-48
Y	US 2016-0324571 A1 (BIOSENSE WEBSTER (ISRAEL) LTD.) 10 November 2016 (2016-11-10) paragraphs [0034]-[0061]; figures 1-7	50-52
X	US 2020-0000484 A1 (SHOCKWAVE MEDICAL, INC.) 02 January 2020 (2020-01-02) paragraphs [0002], [0036]-[0059]; figures 1-17	73-79
Y		54,55,61-72
Y	US 2004-0015184 A1 (BOYLE, W. J. et al.) 22 January 2004 (2004-01-22) paragraphs [0024]-[0036]; figures 1-6	56,57
X	US 2002-0052621 A1 (FRIED, N. M. et al.) 02 May 2002 (2002-05-02) paragraphs [0002], [0024]-[0045]; figures 1-6	80-82
Y		64-66
Y	US 2016-0135828 A1 (SHOCKWAVE MEDICAL, INC.) 19 May 2016 (2016-05-19) paragraphs [0022]-[0062]; figures 1A-12	67-72

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US2022/018030

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)		Publication date (day/month/year)
US	2020-0085458	A1	19 March 2020	US	10555744 B2	11 February 2020
				US	2017-0135709 A1	18 May 2017
				WO	2017-087195 A1	26 May 2017
US	2020-0383724	A1	10 December 2020	AU	2013-284490 A1	15 January 2015
				AU	2013-284490 B2	17 May 2018
				AU	2018-204691 A1	19 July 2018
				AU	2018-204691 B2	27 June 2019
				CA	2877160 A1	03 January 2014
				CA	3079283 A1	03 January 2014
				CN	104582597 A	29 April 2015
				CN	104582597 B	01 February 2017
				EP	2866689 A1	06 May 2015
				EP	2866689 B1	21 July 2021
				EP	3909529 A1	17 November 2021
				EP	3909529 A4	17 November 2021
				JP	2015-522344 A	06 August 2015
				JP	6104375 B2	29 March 2017
				US	10682178 B2	16 June 2020
				US	2014-0005576 A1	02 January 2014
				US	2014-0243820 A1	28 August 2014
				US	2017-0258523 A1	14 September 2017
				US	2018-0256250 A1	13 September 2018
				US	9011463 B2	21 April 2015
				US	9642673 B2	09 May 2017
				US	9993292 B2	12 June 2018
				WO	2014-004887 A1	03 January 2014
US	2016-0287323	A1	06 October 2016	CA	2901243 A1	02 October 2014
				CN	105050520 A	11 November 2015
				CN	105050520 B	27 June 2017
				EP	2979655 A1	03 February 2016
				EP	2979655 B1	07 November 2018
				JP	6287833 B2	07 March 2018
				KR	10-2015-0135264 A	02 December 2015
				KR	10-2178429 B1	13 November 2020
				US	11172983 B2	16 November 2021
				US	2017-0112813 A1	27 April 2017
				WO	2014-157633 A1	02 October 2014
US	2020-0155818	A1	21 May 2020	US	10576254 B2	03 March 2020
				US	2018-0036518 A1	08 February 2018
US	2016-0324571	A1	10 November 2016	AU	2016-202412 A1	24 November 2016
				CA	2928076 A1	07 November 2016
				CN	106109005 A	16 November 2016
				EP	3090696 A1	09 November 2016
				EP	3090696 B1	10 April 2019
				EP	3572021 A1	27 November 2019
				JP	2016-209585 A	15 December 2016
				JP	6749785 B2	02 September 2020
				US	10828099 B2	10 November 2020
				US	2018-0168726 A1	21 June 2018

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US2022/018030

Patent document cited in search report				Publication date (day/month/year)			Patent family member(s)			Publication date (day/month/year)		
							US	9907610	B2	06 March 2018		
US	2020-0000484	A1	02 January 2020				US	10441300	B2	15 October 2019		
							US	2018-0303501	A1	25 October 2018		
							WO	2018-194752	A1	25 October 2018		
US	2004-0015184	A1	22 January 2004				US	6582448	B1	24 June 2003		
							US	7048758	B2	23 May 2006		
US	2002-0052621	A1	02 May 2002				US	7137395	B2	21 November 2006		
							WO	01-64123	A2	07 September 2001		
							WO	01-64123	A3	21 March 2002		
US	2016-0135828	A1	19 May 2016				WO	2016-077627	A1	19 May 2016		