

## **ELECTRODE AND CATHETER DESIGN FOR DIRECTIONAL LITHOTRIPSY CATHETERS**

### **CROSS-REFERENCE TO RELATED APPLICATIONS**

**[0001]** This application claims priority to U.S. Patent Application Serial No. 18/523,630 entitled “ELECTRODE AND CATHETER DESIGN FOR DIRECTIONAL LITHOTRIPSY CATHETERS” filed on November 29, 2023, which is hereby incorporated by reference in its entirety. This application is related to U.S. Patent Application Serial No. 18/071,240 entitled “ELECTRODE DESIGN FOR DIRECTIONAL LITHOTRIPSY CATHETERS” filed on November 29, 2022, which claims priority to U.S. Provisional Patent Application Serial No. 63/284,582 entitled “DUAL-LAYER ELECTRODE DESIGN FOR LITHOTRIPSY CATHETERS” filed on November 30, 2021, and to U.S. Provisional Patent Application Serial No. 63/349,994 entitled “HELICAL ELECTRODE DESIGN FOR LITHOTRIPSY CATHETERS” filed on June 7, 2022, which are hereby incorporated by reference in their entireties.

### **FIELD OF THE DISCLOSURE**

**[0002]** The present disclosure relates generally to the field of medical devices and methods, and more specifically to electrode assemblies for inclusion in catheter devices used for treating lesions in a body lumen, such as calcified lesions and occlusions in vasculature and kidney stones in the urinary system.

### **BACKGROUND**

**[0003]** Calcified lesions in body lumens can negatively impact patient health. For example, when calcium builds up in the walls of the coronary arteries, the calcification of the arteries can restrict blood flow to the heart muscle, which can eventually lead to a heart attack. Catheter devices are one type of device that can be used to treat calcified lesions in a body lumen, such as an artery. When treating lesions with a catheter device, it is important to minimize the damage to the surrounding soft tissues, while still breaking up the lesion as much as possible.

**[0004]** A wide variety of catheters have been developed for treating lesions, such as calcified lesions and plaques in vasculature associated with arterial disease. For example, treatment systems for percutaneous coronary angioplasty or peripheral angioplasty use

angioplasty balloons to dilate a calcified lesion and restore normal blood flow in a vessel. In these types of procedures, a catheter carrying a balloon is advanced into the vasculature along a guidewire until the balloon is aligned with calcified plaques. The balloon is then pressurized (normally to greater than 10 atmospheres (“atm”)), causing the balloon to expand in a vessel to push calcified plaques back into the vessel wall and dilate occluded regions of vasculature. Balloons having different diameters and lengths can be used to access different anatomy, appropriate to coronary vasculature or different types of peripheral vasculature (e.g., above-the-knee, below-the-knee, arm artery disease, etc.).

**[0005]** More recently, the technique and treatment of intravascular lithotripsy (“IVL”) has been developed, which is an interventional procedure to modify calcified plaque in diseased arteries. The mechanism of plaque modification is through use of a catheter having one or more acoustic shock wave-generating sources located within a liquid that can generate acoustic shock waves that modify the calcified plaque. IVL devices vary in design with respect to the energy source used to generate the acoustic shock waves, with two exemplary energy sources being electrohydraulic generation and laser generation.

**[0006]** For electrohydraulic generation of acoustic shock waves, a conductive solution (e.g., saline) may be contained within an enclosure that surrounds electrodes or can be flushed through a tube that surrounds the electrodes. The calcified plaque modification is achieved by creating acoustic shock waves within the catheter by an electrical discharge across the electrodes. This discharge creates one or more rapidly expanding vapor bubbles that generate the acoustic shock waves. These shock waves propagate radially outward and modify calcified plaque within the blood vessels. For laser generation of acoustic shock waves, a laser pulse is transmitted into and absorbed by a fluid within the catheter. This absorption process rapidly heats and vaporizes the fluid, thereby generating the rapidly expanding vapor bubble, as well as the acoustic shock waves that propagate outward and modify the calcified plaque. The acoustic shock wave intensity is higher if a fluid is chosen that exhibits strong absorption at the laser wavelength that is employed. These examples of IVL devices are not intended to be a comprehensive list of potential energy sources to create IVL shock waves.

**[0007]** The IVL process may be considered different from standard atherectomy procedures in that it cracks calcium but does not liberate the cracked calcium from the tissue.

Hence, generally speaking, IVL should not require aspiration nor embolic protection. Further, due to the compliance of a normal blood vessel and non-calcified plaque, the shock waves produced by IVL do not modify the normal vessel or non-calcified plaque.

[0008] More specifically, catheters to deliver IVL therapy have been developed that include pairs of electrodes for electrohydraulically generating shock waves inside an angioplasty balloon. Shock wave devices can be particularly effective for treating calcified plaque lesions because the acoustic pressure from the shock waves can crack and disrupt lesions near the angioplasty balloon without harming the surrounding tissue. In these devices, a catheter is advanced over a guidewire through a patient's vasculature until it is positioned proximal to and/or aligned with a calcified lesion in a body lumen. The balloon is then inflated with a fluid (e.g., for electrohydraulically generated acoustic shock waves, a conductive fluid such as a saline solution) so that the balloon expands (e.g., to a relatively low pressure of 2-4 atm) to contact the lesion, but is not inflated to a pressure that substantively displaces the lesion. Voltage pulses can then be supplied to the emitters (e.g., by applying a voltage across one or more electrode pairs of an emitter) to produce acoustic shock waves that propagate through the walls of the angioplasty balloon and into the lesions. Once the lesions have been cracked by the acoustic shock waves, the balloon can be expanded further to increase the cross-sectional area of the lumen and improve blood flow through the lumen. Alternative devices to deliver IVL therapy can be within a closed volume other than an angioplasty balloon, such as a cap, balloons of variable compliancy, or other enclosures.

[0009] Catheters have also been developed that include electrode pairs for generating directed cavitation bubbles (i.e., the generated vapor bubbles collapsing) for the treatment of calcified lesions in vasculature. In these devices, an open-ended catheter is advanced into a patient's vasculature using a guidewire until it is proximal to a lesion. A relatively lower voltage is applied across the electrode pairs at a relatively higher repetition rate, causing gas cavitation bubbles to form on the surface of the electrodes. The cavitation bubbles begin to accumulate on the electrodes, until fluid flow through the open distal tip of the catheter flows the cavitation bubbles into a target lesion in the body lumen. Once the lesion has been sufficiently reduced by the cavitation bubbles, debris can be aspirated from the treatment site and the catheter can be removed from the vessel. Implementations of such open-ended

catheters allow for a degree of directional control, guiding where the cavitation bubbles are formed and how they progress and develop outward from the catheter.

**[0010]** Despite these advances in electrode assembly design, the duration of a treatment with a shock wave or cavitation catheter is limited by the lifespan of electrode pairs included in the catheter, which slowly erode and degrade as shock waves and/or cavitation bubbles are generated across the electrodes. Many currently available catheter designs include electrodes formed from conductive wires or other narrow conductive materials, which have a relatively small conductive surface area and degrade quickly during a procedure. Other electrode assemblies degrade in random or unfavorable patterns that reduce the lifespan of the electrodes. Accordingly, many catheters cannot be used for more than one hour before the electrodes have eroded too far to continue treatment. As a result, many currently available designs lack the longevity necessary for longer shock wave procedures, such as procedures to remove resistant lesions and treat more chronically occluded regions of vasculature. Thus, provided herein are variations of electrode structures and designs to address the unmet need for shock wave and cavitation catheter designs that incorporate electrode assemblies with an increased lifespan and more favorable degradation patterns. In particular, the electrode structures and designs herein also provide for a significant degree of directional control for the formation of a shock waves and cavitation bubbles emitted from the electrode assembly.

### SUMMARY

**[0011]** A catheter having an electrode pair that is configured to generate shock waves and/or cavitation bubbles can be useful to treat calcified lesions in a body lumen (such as the vasculature) without damaging the surrounding soft tissues. When used to treat lesions, voltage can be applied across the electrodes which causes shock waves and/or cavitation bubbles to form. Thereafter, the shock waves and/or cavitation bubbles can be flowed outwardly, such as from the distal end of an open-ended catheter, to the treatment location. Once the lesion has been sufficiently reduced, debris can be aspirated from the treatment site.

**[0012]** When using such catheter devices to treat and remove calcified lesions, the electrodes of the electrode pair can erode. Erosion of the electrodes (also referred to as degradation) can then limit the duration of the treatment because once the erosion proceeds too far, the electrodes will no longer generate shock waves and/or cavitation bubbles that are capable of treating lesions. Thus, prolonging the life of the electrodes is a paramount concern

for electrode assemblies used in catheters to calcified occlusions (e.g., lesions). Moreover, ensuring that the erosion proceeds in a relatively controlled manner is also a paramount concern, because largely asymmetrical erosion can severely shorten the usable duration of the electrodes.

**[0013]** In some embodiments, the above goals are realized in a catheter that includes an electrode assembly formed from concentric conductive metal sheaths separated by an insulating layer. Shock waves and/or cavitation bubbles are formed across the distal side edges of the conductive sheaths, which act as electrodes of an electrode pair, causing the distal side edges to slowly degrade over time. The distal side edges of the conductive sheaths are shaped such that the degradation proceeds in a semi-controlled manner and is more evenly distributed around the circumference of the conductive sheaths. This increases the longevity of the electrode assembly, allowing for longer duration treatments with a catheter.

**[0014]** Exemplary embodiments provide a catheter for treating an occlusion in a body lumen. The catheter includes an elongated tube and a cylindrical inner conductive sheath mounted within the elongated tube. The inner conductive sheath has a distal side edge. A cylindrical outer conductive sheath is mounted circumferentially around the inner conductive sheath within the elongated tube. The outer conductive sheath has a distal side edge proximal to the distal side edge of the inner conductive sheath. An insulation sheath is mounted within the elongated tube between the outer conductive sheath and the inner conductive sheath. When a voltage pulse is applied across the inner conductive sheath and the outer conductive sheath, current flows across an arcing region between the inner conductive sheath and the outer conductive sheath to generate cavitation bubbles and/or shock waves, which can be used to treat an occlusion in a body lumen.

**[0015]** According to an aspect, provided herein is a catheter system comprising an electrode assembly that includes a conductive sheath mounted within the catheter, an insulation sheath circumferentially mounted within the conductive sheath, and a flat coil disposed on an inner surface of the insulation sheath. In one or more examples, the conductive sheath and the flat coil can form the electrodes of an electrode pair such that when a voltage is applied to the electrode assembly, current travels between the flat coil and the conductive sheath. As the current travels, an arcing region can appear at the shortest distance between the flat coil and the conductive sheath. At the arcing region, shock wave and/or

cavitation bubbles can be created. Thus, in one or more examples, when a voltage pulse is applied across the flat coil and the conductive sheath of the electrode assembly, cavitation bubbles and/or shock waves can be generated, which can be used to treat an occlusion in a body lumen.

[0016] Various embodiments of the present disclosure can have a catheter for treating an occlusion in a body lumen, where that catheter includes: an elongated tube; a cylindrical inner conductive sheath mounted within the elongated tube, the inner conductive sheath having a distal side edge; a cylindrical outer conductive sheath mounted circumferentially around the inner conductive sheath within the elongated tube, the outer conductive sheath having a distal side edge proximal to the distal side edge of the inner conductive sheath; and an insulation sheath mounted within the elongated tube between the outer conductive sheath and the inner conductive sheath; where when a voltage pulse is applied across the inner conductive sheath and the outer conductive sheath, current flows across an arcing region between the inner conductive sheath and the outer conductive sheath to generate cavitation bubbles and/or shock waves. In some aspects, the elongated tube includes a fluid lumen for flowing conductive fluid along the catheter and through a fluid outflow port at a distal end of the catheter. In such aspects, the outer conductive sheath, the insulation sheath, and the inner conductive sheath are mounted within the fluid lumen such that fluid flowing through the fluid lumen flows through the inner conductive sheath. In other aspects, the elongated tube includes an aspiration lumen for removing debris from the body lumen and in optional aspects also includes a guidewire lumen sized to receive a guidewire. In further aspects, the arcing region is located where the distal side edge of the outer conductive sheath is closest to the distal side edge of the inner conductive sheath. In such aspects, generating cavitation bubbles and/or shock waves causes the distal side edge of the inner conductive sheath to erode proximate to the arcing region, and the erosion of the inner conductive sheath causes current to flow across a secondary arcing region between the distal side edge of the inner conductive sheath and the distal side edge of the outer conductive sheath. In similar aspects, generating cavitation bubbles and/or shock waves causes the distal side edge of the outer conductive sheath to erode proximate to the arcing region, and the erosion of the outer conductive sheath causes current to flow across a secondary arcing region between the distal side edge of the outer conductive sheath and the distal side edge of the inner conductive sheath. In some aspects, when a voltage pulse is applied, a positive pressure spike is generated, and thereafter, a negative pressure spike is generated.

[0017] Various embodiments of the present disclosure can have a catheter for treating an occlusion in a body lumen, the catheter including: an elongated tube; a cylindrical conductive sheath mounted within the elongated tube, the conductive sheath having a distal side edge; an insulation sheath mounted circumferentially within the conductive sheath, the insulation sheath having a distal side edge proximal to the distal side edge of the conductive sheath; a flat coil disposed on an inner surface of the insulation sheath, the flat coil having a distal end proximal to the distal side edge of the conductive sheath and the distal side edge of the insulation sheath; and where when a voltage pulse is applied across the flat coil and the conductive sheath, current flows across an arcing region between the flat coil and the conductive sheath to generate cavitation bubbles and/or shock waves. In some aspects, the flat coil has a rectangular cross-section with a planar inner surface on a side opposite the inner surface of the insulation sheath. In other aspects, the elongated tube comprises a fluid lumen for flowing conductive fluid along the catheter and through a fluid outflow port at a distal end of the catheter, and the conductive sheath, the insulation sheath, and the flat coil can all be mounted within the fluid lumen such that fluid flowing through the fluid lumen flows through the flat coil. In further aspects, the arcing region is located where the distal side edge of the conductive sheath is closest to the distal end of the flat coil. In such aspects, generating cavitation bubbles and/or shock waves causes the insulation sheath to erode proximate to the arcing region, and the erosion of the insulation sheath exposes an outer surface of the flat coil causing current to flow across a secondary arcing region between the outer surface of the flat coil and the distal side edge of the conductive sheath. Similarly, generating cavitation bubbles and/or shock waves causes the distal side edge of the conductive sheath to erode proximate to the arcing region, and the erosion of the conductive sheath begins before the erosion of the insulation sheath begins. In some aspects, the elongated tube includes an aspiration lumen for removing debris from the body lumen, and in optional aspects, the elongated tube includes a guidewire lumen sized to receive a guidewire. In alternative aspects, the flat coil is constructed with one or more cross ties extending along a length of the flat coil between each coil of the flat coil. In other aspects, an adhesive is disposed in an area between coils of the flat coil on an inner surface of the insulation sheath, where the adhesive fills the area between the coils and secures the flat coil to the insulation sheath. In further aspects, when the voltage pulse is applied, a positive pressure spike is generated, and thereafter, a negative pressure spike is generated.

[0018] Various embodiments of the present disclosure can have a catheter system for treating an occlusion in a body lumen, the catheter system comprising a catheter including: an elongated tube and an electrode assembly; the elongated tube comprising a first lumen and a second lumen; the first lumen being configured to receive a guidewire; the second lumen having the electrode assembly disposed therein; and the electrode assembly comprising a first cylindrical electrode, an insulating layer arranged around the first cylindrical electrode, and a second cylindrical electrode arranged around the insulating layer, the first cylindrical electrode and the second cylindrical electrode being electrically connected to a power source, where when a voltage pulse is applied across the first cylindrical electrode and the second cylindrical electrode, current flows across an arcing region between the first cylindrical electrode and the second cylindrical electrode to generate one or more shock waves and one or more cavitation bubbles. In one aspect, the elongated tube further includes a third lumen, where the third lumen is configured to be an aspiration lumen. In another aspect, the third lumen is D-shaped. In a further aspect, the elongated tube further comprises a fourth lumen, where the fourth lumen is configured to be similar in size and located within the elongated tube in a position symmetrical to the first lumen. In yet another aspect, the insulating layer is formed of a ceramic or a polymeric layer covered with a ceramic material. In a further aspect, the arcing region is located between a distal edge of the first cylindrical electrode and a distal edge of the second cylindrical electrode. In other aspects, the catheter system further includes an atraumatic tip arranged around the distal end of the catheter, where the atraumatic tip has a circumferential configuration, a ribbed configuration, or a flanged configuration. In other aspects, the catheter system further includes a dual-pump module comprising an infusion pump and an aspiration pump, wherein the second lumen is in fluid communication with the infusion pump, wherein an aspiration lumen is in fluid communication with the aspiration pump, and wherein the dual-pump module is in operational communication with the power source, such that before a cycle of voltage pulses is applied across the first cylindrical electrode and the second cylindrical electrode, the infusion pump will begin operation, and such that after the cycle of voltage pulses are concluded, the aspiration pump will continue to operate for a period of time.

[0019] Various embodiments of the present disclosure include a catheter system for treating an occlusion in a body lumen, the catheter system with a catheter having: an elongated tube; a peripheral electrode disposed within the elongated tube; an electrode assembly disposed within the peripheral electrode, the electrode assembly comprising an

electrode layer and an insulating layer; and a guidewire lumen configured to receive a guidewire and disposed within the electrode assembly; where the peripheral electrode and the electrode layer of the electrode assembly are each electrically connected to a power source, where when a voltage pulse is applied across the electrode layer and the peripheral electrode, current flows across an arcing region between the electrode layer and the peripheral electrode to generate one or more shock waves and one or more cavitation bubbles. In some aspects, the peripheral electrode is a cylindrical electrode sheath. In other aspects, the insulating layer is formed of a ceramic or a portion of the insulating layer is covered with a ceramic material. In further aspects, a portion of the guidewire lumen is formed of a ceramic or a portion of the guidewire lumen is covered with a ceramic material. In some aspects, the catheter further includes an atraumatic tip arranged around the distal end of the catheter, where the atraumatic tip has a circumferential configuration, a ribbed configuration, or a flanged configuration. In some aspects, the catheter system further includes a dual-pump module comprising an infusion pump and an aspiration pump, wherein the second lumen is in fluid communication with the infusion pump, wherein an aspiration lumen is in fluid communication with the aspiration pump, and wherein the dual-pump module is in operational communication with the power source, such that before a cycle of voltage pulses is applied across the first cylindrical electrode and the second cylindrical electrode, the infusion pump will begin operation, and such that after the cycle of voltage pulses are concluded, the aspiration pump will continue to operate for a period of time.

**[0020]** Various embodiments of the present disclosure are directed to an electrode assembly for treating an occlusion in a body lumen, the electrode assembly having: an outer sheath that is electrically conductive; an insulating layer disposed within the outer sheath; an inner sheath disposed within the insulating layer; a first flat wire disposed between the inner sheath and the insulating layer; and a second flat wire disposed between the inner sheath and the insulating layer at a position 180° relative to the first flat wire, where the first flat wire, the second flat wire, and the outer sheath are each electrically connected to a power source, where when a voltage pulse is applied across either or both of the first flat wire and the second flat wire to the outer sheath, current flows across an arcing region between the flat wires and the outer sheath to generate shock waves and cavitation bubbles.

**[0021]** Various embodiments of the present disclosure are directed to a catheter-centering structure having: a distal cap configured to fit onto a distal end of a catheter device, the distal

cap having a ring shape; and a radially expanding structure coupled to the distal cap, extending in a proximal direction along the length of the catheter. In some implementations, the radially expanding structure has a plurality of longitudinal struts connected to a mechanism that can linearly translate the longitudinal struts along the length of the catheter such that the plurality of longitudinal struts are configured to expand and retract in a radial direction relative to the longitudinal axis of the catheter. In other implementations, the radially expanding structure is a balloon in fluid communication with a fluid source, wherein the balloon is configured to inflate and deflate in a radial direction relative to the longitudinal axis of the catheter.

### BRIEF DESCRIPTION OF THE FIGURES

[0022] Illustrative aspects of the present disclosure are described in detail below with reference to the following drawing figures. It is intended that that embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

[0023] FIGS. 1A-1G illustrate a mode of action for generating forward-firing cavitation bubbles using electrode assemblies, according to aspects of the present disclosure.

[0024] FIG. 2 illustrates an exemplary erosion pattern for the degradation of a cylindrical electrode.

[0025] FIG. 3 illustrates a perspective view of an exemplary electrode assembly of a catheter, according to aspects of the present disclosure.

[0026] FIG. 4A illustrates a side view of an exemplary inner conductive sheath of an electrode assembly, such as the electrode assembly of FIG. 3, according to aspects of the present disclosure.

[0027] FIG. 4B illustrates a perspective view of an exemplary inner conductive sheath of an electrode assembly, such as the electrode assembly of FIG. 3, according to aspects of the present disclosure.

[0028] FIG. 5A illustrates a left side cross-sectional view of an exemplary electrode assembly of a catheter, according to aspects of the present disclosure.

[0029] FIG. 5B illustrates a front view of the exemplary electrode assembly of FIG. 4A, according to aspects of the present disclosure.

[0030] FIG. 6 illustrates a perspective view of the exemplary electrode assembly of FIG. 3 after the inner conductive sheath has been degraded by the generation of a series of shock waves or cavitation bubbles, according to aspects of the present disclosure.

[0031] FIG. 7A illustrates a front side view of an exemplary inner conductive sheath of an electrode assembly, such as the electrode assembly of FIG. 6, according to aspects of the present disclosure.

[0032] FIG. 7B illustrates a perspective view of an exemplary inner conductive sheath of an electrode assembly, such as the electrode assembly of FIG. 6, according to aspects of the present disclosure.

[0033] FIG. 8A illustrates a left side cross-sectional view of an exemplary electrode assembly of a catheter, such as the electrode assembly of FIG. 6, according to aspects of the present disclosure.

[0034] FIG. 8B illustrates a front view of an exemplary electrode assembly of a catheter, such as the electrode assembly of FIG. 6, according to aspects of the present disclosure.

[0035] FIG. 8C illustrates an enlarged and more detailed cross-sectional view of the degraded distal side edge of the exemplary electrode assembly of FIG. 8A, according to aspects of the present disclosure.

[0036] FIG. 9A illustrates a perspective view of an exemplary electrode assembly of a catheter, according to aspects of the present disclosure.

[0037] FIG. 9B illustrates a left side cross-sectional view of the exemplary electrode assembly of a catheter shown in FIG. 9A, according to aspects of the present disclosure.

[0038] FIG. 10 illustrates a perspective view of the exemplary electrode assembly of FIG. 9A after the outer conductive sheath has been degraded by the generation of a series of shock waves or cavitation bubbles, according to aspects of the present disclosure.

[0039] FIG. 11A illustrates a left side cross-sectional view of the exemplary electrode assembly of a catheter shown in FIG. 10, according to aspects of the present disclosure.

[0040] FIG. 11B illustrates a front view of the exemplary electrode assembly of a catheter shown in FIG. 10, according to aspects of the present disclosure.

[0041] FIG. 11C illustrates an enlarged and more detailed cross-sectional view of the degraded distal side edge of the exemplary electrode assembly of FIG. 11A, according to aspects of the present disclosure.

[0042] FIG. 12 illustrates a perspective view of the distal end of an exemplary catheter, according to aspects of the present disclosure.

[0043] FIG. 13A illustrates a top side cross-sectional view of the distal end of the exemplary catheter shown in FIG 12, according to aspects of the present disclosure.

[0044] FIG. 13B illustrates a left side view of the distal end of the exemplary catheter shown in FIG. 12, according to aspects of the present disclosure.

[0045] FIG. 13C illustrates a front view of the distal end of the exemplary catheter shown in FIG. 12, according to aspects of the present disclosure.

[0046] FIG. 14A illustrates a perspective view of the distal end of an exemplary catheter having a guidewire lumen, according to aspects of the present disclosure.

[0047] FIG. 14B illustrates a perspective view of the distal end of an exemplary catheter having a guidewire lumen, according to aspects of the present disclosure.

[0048] FIG. 15A illustrates a top side cross-sectional view of the distal end of the exemplary catheter shown in FIG. 14B, according to aspects of the present disclosure.

[0049] FIG. 15B illustrates a left side view of the distal end the exemplary catheter shown in FIG. 14B, according to aspects of the present disclosure.

[0050] FIG. 15C illustrates a front view the distal end of the exemplary catheter shown in FIG. 14B, according to aspects of the present disclosure.

[0051] FIG. 16 is a graph showing measurements of pressure generated by a device fabricated in accordance with FIGS. 3 to 5.

[0052] FIG. 17 illustrates a perspective view of an exemplary electrode assembly of a catheter, according to aspects of the present disclosure.

[0053] FIG. 18 illustrates a perspective view of an exemplary flat coil of an electrode assembly, according to aspects of the present disclosure.

[0054] FIG. 19 illustrates a perspective view of an exemplary flat coil with cross ties of an electrode assembly, according to aspects of the present disclosure.

[0055] FIG. 20 illustrates a perspective cross-sectional view of an exemplary electrode assembly of a cathode, according to aspects of the present disclosure.

[0056] FIG. 21A illustrates a left side cross-sectional view of an exemplary electrode assembly of a catheter, according to aspects of the present disclosure.

[0057] FIG. 21B illustrates a front view of the exemplary electrode assembly of FIG. 21A, according to aspects of the present disclosure.

[0058] FIG. 22 is a graph showing measurements of pressure generated by a device fabricated in accordance with FIG. 17.

[0059] FIG. 23 illustrates a perspective view of the exemplary electrode assembly of FIG. 17 before any erosion, according to aspects of the present disclosure.

[0060] FIG. 24A illustrates an enlarged detail view of the eroded distal side edge of the exemplary electrode assembly of FIG. 17, according to aspects of the present disclosure.

[0061] FIG. 24B illustrates an enlarged detail view of the eroded distal side edge of the exemplary electrode assembly of FIG. 17 as the erosion expands, according to aspects of the present disclosure.

[0062] FIG. 25A illustrates a perspective view of the exemplary electrode assembly of FIG. 17 after initial erosion caused by the generation of a series of shock waves and/or cavitation bubbles, according to aspects of the present disclosure.

[0063] FIG. 25B illustrates a perspective view of the exemplary electrode assembly of FIG. 17 after extensive erosion caused by the generation of a series of shock waves and/or cavitation bubbles, according to aspects of the present disclosure.

[0064] FIG. 26 illustrates a perspective view of the distal end of an exemplary catheter according to aspects of the present disclosure.

[0065] FIG. 27A illustrates a left side cross-sectional view of the distal end of an exemplary catheter, according to aspects of the present disclosure.

[0066] FIG. 27B illustrates a front view of the distal end of an exemplary catheter, according to aspects of the present disclosure.

[0067] FIGS. 28A and 28B illustrate perspective views of exemplary electrode assemblies having an interior coiled electrode with a curved distal tip, according to aspects of the present disclosure.

[0068] FIG. 28C illustrates a perspective view of an exemplary electrode assembly having dual interior coiled electrodes with curved distal tips, according to aspects of the present disclosure.

[0069] FIG. 28D illustrates a perspective view of an exemplary electrode assembly having an interior coiled electrode an inner insulation layer, according to aspects of the present disclosure.

[0070] FIG. 29 illustrates a perspective view of an exemplary electrode assembly having an exterior coiled electrode and a solid tube interior electrode, according to aspects of the present disclosure.

[0071] FIG. 30 illustrates a perspective view of an exemplary electrode assembly having an exterior clockwise coiled electrode and an interior counterclockwise coiled electrode, according to aspects of the present disclosure.

[0072] FIG. 31A illustrates a perspective view of an exemplary electrode assembly having an exterior electrode having cut-out patterning, according to aspects of the present disclosure.

[0073] FIGS. 31B through 31E illustrate an exemplary progression of electrode degradation for an electrode having cut-out patterning as shown in FIG. 31A, according to aspects of the present disclosure.

[0074] FIGS. 32A through 32H, are captured images from a high-speed video showing an exemplary electrode assembly generating a forward-directional vapor bubble, according to aspects of the present disclosure.

[0075] FIG. 33 illustrates a perspective view of an exemplary electrode assembly of a catheter having a ceramic insulating layer, according to aspects of the present disclosure.

[0076] FIG. 34 illustrates a perspective view of an exemplary electrode assembly of a catheter having flat wires positioned between cylindrical layers, according to aspects of the present disclosure.

[0077] FIG. 35A illustrates a perspective view of the distal end of a catheter having four lumens, according to aspects of the present disclosure. FIGS. 35A-1 and 35A-2 illustrate exemplary emitter assemblies that can be used in catheters as disclosed herein. FIGS. 35B-35D illustrate the catheter distal end of FIG. 35A further including variations of a distal tip, according to aspects of the present disclosure.

[0078] FIG. 36A illustrates a perspective view of the distal end of a catheter having three lumens, according to aspects of the present disclosure. FIGS. 36B-36D illustrate the catheter distal end of FIG. 36A further including variations of a distal tip, according to aspects of the present disclosure.

[0079] FIG. 37A illustrates a perspective view the distal end of a catheter having two lumens, according to aspects of the present disclosure. FIGS. 37B-37D illustrate the catheter distal end of FIG. 37A further including variations of a distal tip, according to aspects of the present disclosure.

[0080] FIG. 38A illustrates a perspective view the distal end of a catheter having concentric components, according to aspects of the present disclosure. FIGS. 38B-38D illustrate the catheter distal end of FIG. 38A further including variations of a distal tip, according to aspects of the present disclosure.

[0081] FIG. 39 is an exemplary schematic of a dual-pump injection and aspiration system for use with catheter and generator systems, according to aspects of the present disclosure.

[0082] FIGS. 40A and 40B illustrate a catheter-centering structure having radially expanding longitudinal struts, according to aspects of the present disclosure.

[0083] FIGS. 41A and 41B illustrate a catheter-centering structure having an expandable member, according to aspects of the present disclosure.

### DETAILED DESCRIPTION

[0084] The following description is presented to enable a person of ordinary skill in the art to make and use the various embodiments disclosed herein. Descriptions of specific devices, assemblies, techniques, and applications are provided only as examples. Various modifications to the examples described herein will be readily apparent to those of ordinary skill in the art, and the general principles described herein may be applied to other examples and applications without departing from the spirit and scope of the various embodiments. Thus, the various embodiments are not intended to be limited to the examples described herein and shown, but rather are to be accorded the scope consistent with the claims.

[0085] Efforts have been made to improve the design of electrode assemblies included in shock wave and directed cavitation catheters. For instance, low-profile electrode assemblies have been developed that reduce the crossing profile of a catheter and allow the catheter to more easily navigate calcified vessels to deliver shock waves in more severely occluded regions of vasculature. Examples of low-profile electrode designs can be found in U.S. Patent Nos. 8,888,788, 9,433,428, and 10,709,462, and in U.S. Publication No. 2021/0085383, all of which are incorporated herein by reference. Other catheter designs have improved the delivery of shock waves, for instance, by specific electrode construction and configuration thereby directing shock waves in a forward direction to break up tighter and harder-to-cross occlusions in vasculature. Examples of forward-firing catheter designs can be found in U.S. Patent Nos. 10,966,737, 11,478,261, and 11,596,423, and in U.S. Publication Nos. 2023/0107690 and 2023/0165598, all of which are incorporated herein by reference.

[0086] In contrast with the IVL method of action described above for closed-system catheters, the open-system forward-firing cavitation (“FFC”) method of action leverages the

cavitation jetting effect of the bubble collapse to erode target lesion or tissue. In the context of the present disclosure, a closed-system device refers to catheters that function (e.g., generating shock waves) within a balloon, cap, or physically constrained by the structure of the catheter. In contrast, an open-system device refers to catheters that function (e.g., generating shock waves and cavitation bubbles) within a lumen of a body, generally unconstrained by the structure of the catheter. For closed-system devices, the formation of the initial shock wave can be maximized while the generation of vapor bubbles (and their resulting cavitation) can be minimized by various means, including controlling parameters such as the pulse width and frequency of the voltage pulses delivered to the shock wave generators. The physical and structural constraints of a closed-system device also limit the effect of cavitation bubbles in such devices. On the other hand, open-system FFC devices can be optimized to control and direct the cavitation effect in combination with the shock waves generated by IVL. As a cavitation bubble collapses, having a degree of directionality based upon its point of origin, the collapse can produce a jetting effect pushing the surrounding fluid forward in the same direction as the progression of the bubble collapse (see, e.g., FIGS. 32A-32G herein).

[0087] The force generated by the cavitation jetting effect can be up to or greater than 120 atm at the site of treatment. Moreover, the area of action for the cavitation jetting effect can be about or less than one square millimeter ( $\sim 1 \text{ mm}^2$ ). Of course, the area of action is dependent on the size of the cavitation bubble and thus dependent on the size of the catheter and shock wave-generating assembly, which for purposes of treating vascular tissue is designed to be small enough to be deliverable and functionally safe within a patient. While the pressure generated by FFC can be the primary mode of treating tissue, this mode of treatment does not have to be divorced or operated in isolation from IVL shock waves. Indeed, whereas in closed-system devices, the formation of vapor bubbles may be minimized, for an open-system device, the controlled parameters can be optimized for vapor bubble formation following IVL shock wave generation. Moreover, the shock waves formed by IVL, which can have an effective pressure of from 25 atm to 50 atm or greater at the site of treatment.

[0088] Described herein are catheters incorporating design elements that improve the lifespan of an electrode assembly, allowing for longer-duration shock wave and cavitation treatments. As shock waves and/or cavitation bubbles are generated across an electrode pair,

the electrode surface slowly erodes at the location where current flows between the electrodes (i.e., at an “arcing region” between the electrodes of a pair). Once an initial arcing region has been eroded and the distance between the electrodes at the initial arcing region increases, current may begin to flow from an undesirable secondary arcing region or may cease to flow entirely, such that shock waves and/or cavitation bubbles are no longer generated. Over the course of a treatment, the electrodes may erode and degrade in a non-uniform manner that limits the usable lifespan of the electrode assembly. For instance, when the electrodes are formed from insulated wires or other narrow conductive materials with a relatively small conductive surface area, erosion of the electrodes advances quickly and can result in the early termination of shock wave procedures. Other catheter designs may include electrodes that are a uniform distance apart across their surfaces, causing degradation to proceed in a stochastic manner that results in uncontrolled and uneven degradation across the electrode surface. Another electrode design can be formed from two cylindrical conductive metal sheaths mounted concentrically within a catheter, which can demonstrate a longer lifespan than insulated wire electrode designs. However, as the lifespan of the electrode design directly impacts treatment duration, increasing the lifespan of the electrodes is desirable.

**[0089]** To increase the lifespan of an electrode assembly, in some of the implementations described herein, the electrode assemblies have been shaped such that degradation proceeds in a predictable or semi-controlled manner across the surface area of an electrode. In particular, the electrode pairs of the assemblies are shaped such that certain portions of the electrode surfaces are closer in distance, while other portions are farther apart. Accordingly, when a voltage is applied across the electrode pairs, current initially flows across an initial arcing region where the electrodes are closest in distance. Once the electrode surface erodes at the initial arcing region, current begins to flow across a secondary arcing region that provides a new least-resistance (i.e., closest distance) path between the electrodes. As the treatment continues, successively farther-distance portions will begin to degrade as the arcing region moves across the remaining surface area of the electrode.

**[0090]** To increase the lifespan of an electrode assembly, in other implementations described herein, the assemblies can incorporate a flat uninsulated helical electrode. The flat helical electrode can have a larger cross-sectional area relative to round wires, which can ensure that the flat helical electrode has a lower resistance and thus supplies a higher current flow to the arcing region. Relative to an electrode pair with two concentric conductive

sheaths, the flat helical electrode can generate usable cavitation for a longer duration, thereby enabling longer shock wave and cavitation treatments. Further, the use of a flat helical electrode can improve manufacturability of the electrode assemblies.

[0091] Depending on the shape of the electrodes, the location of the initial and further arcing regions can be configured to be relatively predictable or predetermined. For instance, by providing a gradual slope along the surface of the electrode, or a series of notches, waves, or other shapes along the electrode surface, certain portions of an electrode surface can be placed a predetermined distance from a corresponding electrode of a pair. Through the course of a procedure, the surface of the electrodes degrades in a semi-controlled manner according to the relative distance between the electrodes of the pair, beginning with the closest-distance portion of the electrode surface (i.e., the initial arcing region), and continuing to successively farther portions of the electrode surface. This results in more even erosion across the electrode surface and increased longevity of an electrode assembly, allowing for longer-duration shock wave and/or cavitation treatments.

[0092] The catheter designs described herein may be similar to current shock wave catheters in that they include at least one electrode pair within the working length of a catheter that delivers acoustic shock waves and/or cavitation bubbles to a treatment site proximate to the catheter's distal tip. For instance, as described in U.S. Patent No. 10,709,462, incorporated herein by reference, a first electrode of a catheter can be formed from a side edge of a conductive metal sheath mounted within the catheter. An electrode pair can be formed by positioning a second conductive material a controlled distance (i.e., a gap) apart from the conductive sheath to allow for a reproducible arc across the electrodes for a given current and voltage. In some examples, as described in the above reference, a second electrode of an electrode pair can be formed from an electrically conductive portion (e.g., an insulation-removed portion) of a wire extending along the length of the catheter. Additionally or alternatively, as described herein, an exemplary electrode pair can be formed from two cylindrical conductive metal sheaths mounted concentrically within a catheter. Such an electrode assembly may have a relatively smaller crossing profile compared to existing electrode assembly designs, for instance, with a crossing profile between 0.8 mm and 1.2 mm in diameter. Such an electrode assembly design may also facilitate manufacturing of a catheter by simplifying the process for constructing the electrode assembly.

[0093] As provided herein, it should be appreciated that any disclosure of a numerical range describing dimensions or measurements, such as thicknesses, length, weight, time, frequency, temperature, voltage, current, angle, etc., is inclusive of any numerical increment or gradient within the ranges set forth relative to the given dimension or measurement. Furthermore, numerical designators such as “first,” “second,” “third,” “fourth,” etc. are merely descriptive and do not indicate a relative order, location, or identity of elements or features described by the designators. For instance, a “first” shock wave may be immediately succeeded by a “third” shock wave, which is then succeeded by a “second” shock wave. As another example, a “third” emitter may be used to generate a “first” shock wave, and vice versa. Accordingly, numerical designators of various elements and features are not intended to limit the disclosure and may be modified and interchanged.

[0094] In some embodiments, a catheter as disclosed herein is a so-called “rapid exchange-type” (“Rx”) catheter provided with an opening portion through which a guidewire is guided (e.g., through a middle portion of a central tube in a longitudinal direction). In other embodiments, a catheter may be an “over-the-wire-type” (“OTW”) catheter in which a guidewire lumen is formed throughout the overall length of the catheter, and a guidewire is guided through the proximal end of a hub.

[0095] FIGS. 1A-1G illustrate a mode of action for generating forward-firing cavitation bubbles using electrode assemblies. An exemplary electrode assembly 10 is illustrated in perspective view in FIG. 1A, having an outer electrode 12 and an inner electrode 14, and is understood to be submerged within a conductive fluid. It should be appreciated that in other implementations and variations, the electrodes of an electrode assembly may be configured in different orientations and different shapes or present different profiles relative to each other. FIG. 1B illustrates the electrode assembly 10 in a front view, and FIG. 1C illustrates the electrode assembly in a cross-sectional side profile view. Both FIG. 1B and FIG. 1C further illustrate the location of an electrical spark 16, which can be generated in the gap between outer electrode 12 and inner electrode 14 when energy is applied across the paired electrodes of the electrode assembly 10. Depending on the polarity of the power source, the current driven to the electrode assembly 10 can travel from the inner electrode 14 across to the outer electrode 12, or vice versa. The electrical spark 16 formed by the electrode assembly causes a vapor bubble 18 to form within the conductive fluid.

[0096] FIGS. 1D-1G illustrate the expansion and collapse of the vapor bubble 18 generated by the electrical spark 16. In FIG. 1D, approximately 250-280 microseconds (“ $\mu$ s”) after the occurrence of the electrical spark 16, the vapor bubble 18 forms and expands originating from the location of the electrical spark 16. At least in part due to the arrangement of the inner electrode 14 and the outer electrode 12 relative to each other, the expansion of vapor bubble 18 is directed distally from the open end of the electrode assembly 10. In particular, as shown in this example, the cylindrical walls of the electrode assembly 10 and the outer electrode 12 constrain the initial expansion space of the vapor bubble 18, directing the vapor bubble 18 outward and in a distal direction (relatively forward) away from the electrode assembly 10. Further, the position of the inner electrode 14 within the structure of the electrode assembly 10 centralizes the origin point for expansion of the vapor bubble 18, reducing any bias away from a longitudinal centerline of the electrode assembly 10. In other words, the vapor bubble 18 starts expanding in the middle of the electrode assembly cylinder and, accordingly, continues to expand in a direction relatively outward and distal (forward) from the end of the electrode assembly.

[0097] The progression in the change of the shape of the vapor bubble 18, the expansion and collapse of the vapor bubble 18, further shows the mode of action for implementations of the present disclosure. In FIG. 1D, the vapor bubble 18 is expanding outward from the origin point of the vapor bubble 18 (i.e., where the electrical spark 16 occurred). In FIG. 1E, the vapor bubble 18 has a relatively more spherical shape and has moved forward away from its origin point. In FIG. 1F, the vapor bubble 18 has moved further forward and has begun collapsing, having a shape that is relatively elliptical, with the vapor bubble 18 impinging inward at its trailing edge and extending to a focal point at its leading edge. In FIG. 1G, the vapor bubble 18 has moved yet further forward away from its origin point and has collapsed with further impingement at its trailing edge to have a wishbone shape. At this point, the leading edge of the vapor bubble 18 is approximately 1 mm in front of the distal end of the electrode assembly. The leading edge of the vapor bubble 18, as shown in FIG. 1G, has a focal point that has extended prominently forward, and without being bound to this theory, it is at this extended focal point that a maximum force (approximately 0.5-1.0 N) is exerted by the vapor bubble 18. Accordingly, a surface positioned at the distance where maximum force is exerted by the vapor bubble 18 can be ablated by that force of the vapor bubble 18. For clinical applications considered by the present disclosure, such surfaces can be fibrous tissue, calcified tissue, lesions, or other tissues within a patient body.

[0098] The cycle of running energy across the electrodes to generate an electrical spark and a subsequent vapor bubble can be on the order of 30 seconds (“sec”). Accordingly, in some embodiments, twenty cycles for a total run time of 10 minutes can be run to repeatedly and quickly ablate a target tissue, where the ablation can be characterized as a “chipping away” mode of action. In other embodiments, the frequency of electrical spark generation can be relatively greater, in the range from about 100 Hz to 200 Hz (e.g., 125 Hz, 150 Hz, 175 Hz, and other increments of frequency within this range), where the ablation can be characterized as a “woodpecker” mode of action. It should be appreciated that other exemplary numbers of cycles and total run times can be used to achieve similar ablative effects.

[0099] FIG. 2 illustrates an exemplary erosion pattern for the degradation of a cylindrical electrode 20. As illustrated, the cylindrical electrode 20 is formed of a conductive sheet 22 (e.g., a metal or an alloy) that has been rolled into a cylindrical shape. In such constructions, there will often be a seam 24 (shown with a dashed line in FIG. 2) where the edges of the conductive sheet 22 meet to form a cylindrical tube. It is generally observed that electrical current will tend to arc at locations on an electrode where there is a sharp edge or corner; in the context of cylindrical electrode 20, the seam 24 will accordingly present a relatively sharp edge where current will preferentially arc toward and thus primarily erode the conductive sheet 22. Erosion region 26 illustrates an exemplary erosion pattern that tracks along the seam 24 in a longitudinal direction down the length of cylindrical electrode 20, gradually widening and degrading the distal end of cylindrical electrode 20, but ultimately creating an uneven and irregularly shaped electrode edge. Without mitigation, such an irregularly shaped electrode can lead to misfiring of an electrode, and in the context of a shock wave-generating device, to the failure to generate shock waves and cavitation bubbles.

[0100] There are several differences with the mode of action of both previously implemented IVL applications and the present disclosure in comparison with traditional lithotripsy. In contrast with traditional lithotripsy, IVL is not an extracorporeal treatment, leading to substantially different decisions to deliver shock waves in an intravascular environment. Further, lithotripsy uses a focused ultrasound that can deliver high-intensity short pulses, with energy in the range of 30-50 megapascals (“MPa”) at a frequency of 500-800 kHz. Moreover, lithotripsy typically targets soft tissue, which is not the typical target tissue for IVL applications.

[0101] In contrast with previously implemented IVL applications, the present disclosure does not generate shock waves within a balloon or other sealed volume. Accordingly, there is a greater flexibility to the pressures used and types of tissues that can be treated. In further contrast with previously implemented IVL applications, the structures of the present disclosure have different acoustic properties. Embodiments of the present disclosure generate a lower peak positive pressure, a similar peak negative pressure, at higher frequency (100-200 Hz in the present disclosure versus 1-2 Hz for traditional IVL). In addition, the present disclosure aims at pulverizing lesions and aspirating debris, compared to IVL, which breaks lesions that remain *in situ*. Moreover, traditional IVL relies on the initial shock wave with a high peak positive to break calcified lesions and has a lower peak negative, which helps to prevent soft tissue damage. As is understood from the present disclosure, directional lithotripsy can take advantage of the initial and subsequent shock waves generated to break calcified lesions while still avoiding soft tissue damage.

[0102] FIG. 3 illustrates an exemplary electrode assembly 100 of a catheter. The assembly 100 includes a first cylindrical conductive sheath configured as an inner conductive sheath 120 and a second cylindrical conductive sheath configured as an outer conductive sheath 122. The outer conductive sheath 122 is mounted circumferentially around and concentric with the inner conductive sheath 120, such that the inner and outer conductive sheaths form respective inner and outer electrodes of an electrode pair. The conductive sheaths 120, 122 are formed from a conductive material, such as a conductive metal or alloy, that has been shaped into an extended tubular or cylindrical shape. In some examples, the inner conductive sheath 120 and/or outer conductive sheath 122 are formed from an erosion-resistant metal tubing, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper tubing. The inner conductive sheath 120 may be any desired thickness, for example, between 0.002 and 0.003 inches thick. The outer conductive sheath 122 may be relatively thicker than the inner conductive sheath. For instance, the outer conductive sheath 122 could be approximately 0.004 to 0.006 inches thick. However, in other examples, the inner conductive sheath 120 is thicker than the outer conductive sheath 122. For instance, the inner conductive sheath 120 could be between 0.004 and 0.006 inches thick, and the outer conductive sheath 122 could be relatively thinner, e.g., between 0.002 and 0.003 inches thick.

[0103] The inner conductive sheath 120 and the outer conductive sheath 122 each includes a respective distal side edge 121, 123. The distal side edge 121 of the inner

conductive sheath 120 is positioned proximate to the distal side edge 123 of the outer conductive sheath 122 to provide an arcing region between the sheaths across which current can flow to generate a shock wave inside the catheter. Together, the distal side edge 121 of the inner conductive sheath 120 and the distal side edge 123 of the outer conductive sheath 122 form an electrode pair of the electrode assembly 100. As will be described in more detail below, the distal side edge 121 of the inner conductive sheath 120 may be shaped such that a particular portion of the distal side edge 121 (e.g., portion 125) is closer to the outer conductive sheath 122 than the remainder of the distal side edge (i.e., to provide a predetermined initial arcing region between the conductive sheaths).

**[0104]** As seen in FIG. 3, the inner conductive sheath 120 and the outer conductive sheath 122 are separated by a cylindrical insulating layer 140, e.g., an insulation sheath, mounted between and concentric with the conductive sheaths 120, 122. The insulating layer 140 is formed from a non-conductive insulating material that prevents unintended current flow between the inner surface of the outer conductive sheath 122 and the outer surface of the inner conductive sheath 120. In some examples, the insulating layer 140 is formed from a polymeric material, e.g., a polyimide, shaped into an extended tubular or cylindrical shape. In some examples, the insulating layer 140 is approximately 0.002 to 0.004 inches thick. As seen in FIG. 3, the insulating layer 140 has a distal side edge 141 that is proximate to (e.g., flush with) the distal side edges 121, 123 of the respective inner and outer conductive sheaths 120, 122. The proximal side edge of the insulating layer 140 extends beyond the proximal side edge of at least one of the inner conductive sheath 120 and/or the outer conductive sheath 122 to prevent unintended current flow between the proximal side edges of the conductive sheaths 120, 122. The shape and position of the insulation layer 140 ensure that the initial arcing region between the inner conductive sheath 120 and outer conductive sheath 122 (i.e., the path of least resistance for current flow, normally the closest-distance location between the sheaths) is between the respective distal side edges 121, 123, and more particularly at the flush portion 125 of the inner conductive sheath 120.

**[0105]** FIGS. 4A-4B illustrate an exemplary cylindrical inner conductive sheath 120 of an electrode assembly, such as the electrode assembly 100 of FIG. 3. FIG. 4A shows a side view of the exemplary inner conductive sheath 120, and FIG. 4B shows a perspective view of the exemplary inner conductive sheath 120. In some examples, the distal side edge 121 of the inner conductive sheath 120 is shaped to have various regions that are closer or farther away

from the paired distal side edge 123 of the outer conductive sheath 122, which can thereby promote degradation in a predefined or semi-controlled manner. For instance, the distal side edge 121 of the inner conductive sheath 120 could be shaped such that a portion 125 of the distal side edge 121 is closest to the distal side edge 123 of the outer conductive sheath 122 in order to provide a predetermined initial arcing region for current flow between the conductive sheaths 120, 122. Second and further arcing regions could be provided by shaping additional portions of the distal side edge 121 to be the second closest to the distal side edge 123, and so on.

**[0106]** FIGS. 5A-5B provide more detailed views of the electrode assembly 100 shown in FIG. 3. FIG. 5A illustrates a left-side cross-sectional view of the electrode assembly 100. FIG. 5B illustrates a front view of the exemplary electrode assembly 100, showing the cutting plane used to generate the cross-sectional view in FIG. 5A. As seen in FIG. 5A, at least a portion of the distal side edge 121 of the inner conductive sheath 120 is angled relative to the distal side edge 123 of the outer conductive sheath 122. At least a further portion (i.e., portion 125) of the distal side edge 121 is substantially flush with the distal side edge 123 of the outer conductive sheath 122 and the distal side edge 141 of the insulating layer 140 to provide an initial arcing region that is a relatively short distance away from the distal side edge 123 of the outer conductive sheath 122. The angled portion of the distal side edge 121 is angled in a proximal direction relative to the distal side edge 123 of the outer conductive sheath 122, such that the angled portion is farther away from the distal side edge 123 of the outer conductive sheath 122 than the flush portion 125. In some examples, the angled portion is angled a relatively small amount, e.g., between 2 and 4 degrees or less than 2 degrees. However, in other examples, the angled portion of the distal side edge 121 is angled a relatively larger amount, e.g., between 4 and 10 degrees, between 10 and 20 degrees, between 20 and 45 degrees, or greater than 45 degrees relative to the distal side edge 123 of the outer conductive sheath 122. It is understood that the angled portion of the distal edge 121 can be at any increment or gradient of degree within the above-stated ranges.

**[0107]** Returning to FIG. 3, the electrode assembly 100 also includes two insulated wires 130, 132 extending along the length of the catheter. More particularly, a first insulated wire 130 is electrically connected with the inner conductive sheath 120, and a second insulated wire 132 is electrically connected with the outer conductive sheath 122. The insulated wires 130, 132 provide an electrical connection between the conductive sheaths 120, 122 and an

external voltage source, e.g., a high-voltage pulse generator (not pictured). In some examples, the inner conductive sheath 120 is connected to a positive terminal of the voltage source, and the outer conductive sheath 122 is connected to a negative terminal of the voltage source or to ground. However, the reverse connection is also envisioned (i.e., with the outer conductive sheath 122 connected to a positive terminal, and the inner conductive sheath connected to a negative terminal or to ground). In some examples, the conductive portions of the wires 130, 132 are heat-sealed or otherwise fixed to the conductive sheaths 120, 122 to provide a direct electrical connection. The insulated wires 130, 132 may extend within a fluid lumen of the catheter, e.g., fixed to a side wall of the lumen or disposed within grooves extending along the lumen. In other examples, the wires 130, 132 extend through a separate lumen of the catheter, e.g., a wire lumen.

**[0108]** A series of high-voltage pulses can be delivered across the wires 130, 132 by an external voltage source, e.g., a pulsed high-voltage source, to generate a series of shock waves and/or cavitation bubbles at the electrode assembly 100. Negative and positive terminals of the external voltage source are connected to the proximal ends of the first insulated wire 132 and the second insulated wire 132, creating a potential difference across the inner conductive sheath 120 and the outer conductive sheath 122 (i.e., an electrode pair of the electrode assembly) when high-voltage pulses are delivered across the wires 130, 132. The potential difference causes current to flow through the electrode pair to generate shock waves and/or cavitation bubbles. The direction of current flow is dependent on the polarity of the electrodes, with current flowing from the more positively charged electrode (i.e., the electrode that is connected to the positive terminal of the voltage source) to the more negatively charged electrode (i.e., the electrode that is connected to the negative terminal of the voltage source). The duration and magnitude of the voltage pulse is sufficient to generate a gas bubble on the surface of the electrodes (i.e., on the distal side edges 121, 123 of the conductive sheaths 120, 122) and/or a shock wave.

**[0109]** The magnitude and other characteristics of the cavitation bubbles and/or shock waves can be controlled by adjusting the magnitude and duration of the applied voltage pulses. For instance, delivering relatively lower voltages at higher repetition rates (e.g., voltages between about 800 V and 2000 V, and repetition rates between about 20 Hz and 200 Hz) generally produces cavitation bubbles on the electrodes. When a series of relatively lower-voltage and higher-repetition-rate voltage pulses are applied across the wires 130, 132,

a plurality of gas cavitation bubbles accumulate on the surface of the electrodes. The cavitation bubbles can be flowed through the open tip of a catheter and into a treatment site to break up a calcified lesion. Applying higher-voltage pulses at lower repetition rates (e.g., voltages between about 2500 V and 6000 V, and repetition rates between about 1 Hz and 4 Hz) produces higher magnitude acoustic shock waves in the catheter. When a series of relatively higher-voltage pulses are applied across the wires 130, 132, a plasma arc of electric current eventually forms across a bubble at the arcing region (e.g., flush portion 125) between the inner conductive sheath 120 and the outer conductive sheath 122. The current traverses the bubble and creates a rapidly expanding and collapsing bubble that produces an acoustic shock wave that propagates toward a target lesion. The characteristics of the cavitation bubbles and/or shock waves can also be controlled by adjusting aspects of the electrode assembly, e.g., the distance between electrodes of an electrode pair, the surface area of the electrodes, and the shape of the electrodes.

**[0110]** FIG. 16 is a graph showing measurements of pressure generated by a device fabricated in accordance with FIGS. 3-5. The measurements were made by a hydrophone located about 10 mm from the emitter location, where, in the context of the present disclosure, an emitter broadly refers to the region of the electrode assembly where the current travels across the electrode pair, generates a shock wave, and propagates a resulting bubble. The measurements in FIG. 16 are in megapascals, and as a general estimate, the pressure close to the emitter at 1 mm in front of the emitter (i.e., the distance of cavitation bubble and subsequent shock wave formation), is about an order of magnitude greater than the pressure measured at the hydrophone 10 mm distant. As can be seen in FIG. 16, there is a large positive spike at the beginning of the shock wave pulse of about 1.32 MPa. Based on the measurement at the hydrophone, the estimated pressure close to the emitter (1 mm) would be about 13.2 MPa. A smaller but still significant negative spike is recorded near the end of the pulse, about 9  $\mu$ s after the initial positive spike. The negative pressure spike is caused by the collapse of the vapor bubble. At a distance of 10 mm from the emitter, the hydrophone measured 0.19 MPa, corresponding to an estimated negative pressure close to the emitter of about 1.9 MPa. Accordingly, the peak-to-peak difference in pressure at 1 mm from the emitter would be about 15 MPa. As noted herein, this type of pressure swing can enhance clearing of the lesions from the treatment site.

[0111] The magnitude and frequency of the voltage pulses can also be controlled to improve the characteristics of acoustic pressure waves resulting from the generation of shock waves or cavitation bubbles at an electrode pair. For instance, delivering voltage pulses with relatively short pulse widths, e.g., below 50  $\mu$ s, can produce acoustic pressure waves having relatively high-amplitude negative pressures. Increased negative pressures can improve the mechanism of action of a shock wave or cavitation catheter by providing a negative suction-like force that facilitates the clearing of lesions and debris from a treatment site. In some examples, voltage pulses can be delivered across an electrode pair at relatively low frequencies, e.g., frequencies between 30 and 40 Hz, between 40 and 50 Hz, or greater than 50 Hz, and relatively short pulse widths, e.g., pulse widths of approximately or less than 10  $\mu$ s, to produce acoustic pressure waves having high negative pressure. In certain examples, an electrode pair of a catheter can produce acoustic pressure waves having peak negative pressures of approximately 3 MPa, with peak-to-peak pressures of approximately 10 MPa. However, in other examples, an electrode pair may produce acoustic pressure waves having even greater peak pressure, for instance, peak pressures between 10 and 20 MPa, between 20 and 40 MPa, or up to 50 MPa.

[0112] When voltage pulses are applied during a shock wave and/or cavitation treatment, current flows across the lowest-resistance path between the electrodes of an electrode pair, which is generally the location where the electrodes are closest in distance. Thus, an initial arcing region is located where the distal side edge 121 of the inner conductive sheath 120 is closest to the distal side edge 123 of the outer conductive sheath 122. Repeated generation of cavitation bubbles and/or shock waves will cause the electrodes to erode proximate the initial arcing region. For instance, in the example shown in FIG. 3, generating cavitation bubbles and/or shock waves will cause the distal side edge 121 of the inner conductive sheath 120 to erode proximate to the portion 125 of the distal side edge 121 that is flush with and closest to the distal side edge 123 of the outer conductive sheath 122. Throughout the course of a treatment, the distal side edge 121 of the inner conductive sheath 120 will continue to erode proximate to the initial arcing region. Once the initial arcing region erodes far enough that it is no longer the shortest distance between the inner conductive sheath 120 and the outer conductive sheath 122, current will begin to flow across a secondary arcing region that provides the shortest distance path between the distal side edge 123 of the outer conductive sheath 122 and the partially degraded distal side edge 121 of the inner conductive sheath 120. As the shock wave treatment continues, the angled shape of the inner conductive sheath 120

promotes degradation in a semi-controlled pattern around the distal side edge 121 of the inner conductive sheath, beginning at the flush portion 125 and proceeding along the portions of the distal side edge 121 that are successively farther from the outer conductive sheath 122. In other words, the structure of the constituent electrodes guides the location of the electrical arcs and thereby partially controls the pattern of electrode erosion throughout use of the electrode assembly.

**[0113]** FIG. 6 illustrates a partially eroded exemplary electrode assembly 100, such as the assembly 100 shown in FIGS. 3 and 5A-5B, after the inner conductive sheath 120 has been at least partially eroded by the generation of a series of shock waves and/or cavitation bubbles. FIG. 7A shows a side view of the exemplary eroded inner conductive sheath 120, and FIG. 7B shows a perspective view of the exemplary eroded inner conductive sheath 120. FIGS. 8A-8B provide more detailed views of the partially eroded electrode assembly 100 shown in FIG. 6. FIG. 8A illustrates a left-side cross-sectional view of the exemplary eroded electrode assembly 100. FIG. 8B illustrates a front view of the exemplary electrode assembly 100 showing the cutting plane used to generate the sectional view in FIG. 8A. FIG. 8C shows an enlarged left-side cross-sectional view of the exemplary electrode assembly 100 shown in FIG. 8A to provide a more detailed view of the degraded distal side edge of the inner conductive sheath 120.

**[0114]** As seen in FIGS. 6, 7A-7B, and 8A-8C, the repeated generation of shock waves and cavitation bubbles has caused the distal side edge 121 of the inner conductive sheath 120 to erode proximate to the initial arcing region, creating one or more divots in the distal side edge 121. The degradation of the electrode surface at the initial arcing region has increased the distance between the portion 125 and the distal side edge 123 of the outer conductive sheath 122, causing a different portion 126 of the electrode surface to become closer in distance to the distal side edge 123 (accordingly, portion 125 is no longer flush as shown in FIGS. 4B, 5A, and 5B). As additional voltage pulses are applied across the sheaths 120, 122, erosion of the inner conductive sheath 120 at the initial arcing region will cause current to flow across a secondary arcing region between the distal side edge 121 of the inner conductive sheath 120 and the distal side edge 123 of the outer conductive sheath 122 (e.g., a region proximate to the new closest-in-distance portion 126).

[0115] In the particular embodiment shown in FIGS. 6 and 8A-8C, the secondary arcing region is proximate to the initial arcing region around the circumference of the distal side edge 121. The gradually sloping angle of the distal side edge 121 causes degradation to proceed outward from the initial arcing region (e.g., a region proximate to portion 125) to portions of the distal side edge 121 that are farther and farther from the distal side edge 123 of the outer conductive sheath 122 (e.g., to portion 126 and then subsequent farther-in-distance portions of the distal side edge 121). Eventually, when the entire circumference of the distal side edge 121 has eroded to an approximately equal distance from the distal side edge 123 of the outer conductive sheath 122, degradation may proceed in a stochastic manner as current flows across the relatively least-resistance (i.e., closest-distance) path between the sheaths 120, 122.

[0116] In the embodiments shown in FIGS. 6, 7A-7B, and 8A-8C, the erosion is shown as affecting primarily the distal side edge 121 of the inner conductive sheath 120. This is the observed pattern, particularly when the inner conductive sheath 120 is connected to the positive terminal of a voltage source. It should be noted that the distal side edge 123 of the outer conductive sheath 122 may also erode in a similar fashion, particularly if the polarity of the power supply with respect to the sheaths is reversed such that the outer conductive sheath 122 is connected to the positive terminal of the voltage source. When the polarity of the electrode assembly is reversed, current flows in the opposite direction across the arcing region between the sheaths 120, 122, causing erosion that affects primarily the distal side edge 123 of the outer conductive sheath 122. Electrode assembly designs where the erosion occurs primarily on the outer conductive sheath 122 may provide an increased electrode lifespan compared to assemblies where erosion occurs primarily on the inner conductive sheath 120, due to the relatively larger circumference and greater electrode surface area of the outer conductive sheath's distal side edge 123.

[0117] In these example embodiments, the distal side edge 123 of the outer conductive sheath 122 may be shaped to promote degradation in a predetermined or semi-controlled manner, e.g., shaped similarly to the distal side edge 121 of the inner conductive sheath 120 shown in FIGS. 6, 7A-7B, and 8A-8C. As described previously in relation to the inner conductive sheath 120, the outer conductive sheath 122 can be shaped such that various regions of the distal side edge 123 are closer or farther away from the paired distal side edge 121 of the inner conductive sheath 120. For instance, the distal side edge 123 of the outer

conductive sheath 122 could be shaped such that a portion 125 of the distal side edge 121 is closest to the distal side edge 121 of the inner conductive sheath 120 to provide a predetermined initial arcing region. Second and further arcing regions could be provided by shaping additional portions of the distal side edge 123 to be the second closest to the distal side edge 121, and so on.

**[0118]** FIGS. 9A and 9B illustrate one exemplary electrode assembly, where the distal side edge 123 of the outer conductive sheath 122 is angled relative to the distal side edge 121 of the inner conductive sheath 120. At least a portion, here portion 127, of the distal side edge 123 is substantially flush with the distal side edge 121 of the inner conductive sheath 120 and the distal side edge of the insulating layer 140 to provide an initial arcing region that is a relatively short distance away from the distal side edge 121 of the inner conductive sheath 120. As seen in FIGS. 9A-9B, the surface of the distal side edge 123 gradually slopes away from the distal side edge 121 of the inner conductive sheath 120 in a proximal direction relative to the distal side edge 121. In some examples, the distal side edge 123 is angled a relatively small amount, e.g., between 2 and 4 degrees or less than 2 degrees. However, in other examples, distal side edge 123 is angled a relatively larger amount, e.g., between 4 and 10 degrees, between 10 and 20 degrees, between 20 and 45 degrees, or greater than 45 degrees relative to the distal side edge 121 of the inner conductive sheath 120. It is understood that the angled portion of the distal edge 123 can be at any increment or gradient of degree within the above-stated ranges.

**[0119]** FIG. 10 illustrates the electrode assembly of FIGS. 9A-9B after the outer conductive sheath 122 has been at least partially eroded by the generation of a series of shock waves and/or cavitation bubbles. FIGS. 11A-11C provide more detailed views of the partially eroded electrode assembly 100 shown in FIG. 10. FIG. 11A illustrates a left-side cross-sectional view of the partially eroded electrode assembly 100. FIG. 11B illustrates a front view of the partially electrode assembly 100 showing the cutting plane used to generate the sectional view in FIG. 11A. FIG. 11C shows an enlarged left-side cross-sectional view of the exemplary electrode assembly 100 shown in FIG. 11A to provide a more detailed view of the degraded distal side edge of the inner conductive sheath 120. As seen in FIGS. 10 and 11A-11C, the repeated generation of shock waves and/or cavitation bubbles has caused the distal side edge 123 of the outer conductive sheath 122 to erode proximate to the initial arcing region, increasing the distance between the portion 127 and the distal side edge 121 of the

inner conductive sheath 120. Eventually, erosion of the outer conductive sheath 122 at the initial arcing region causes a different portion 128 of the distal side edge 123 to become closer in distance to the distal side edge 121 of the inner conductive sheath 120. As additional voltage pulses are applied across the sheaths 120, 122, current will begin to flow across a secondary arcing region between the distal side edge 123 of the outer conductive sheath 122 and the distal side edge 121 of the inner conductive sheath 120 that provides the new closest-in-distance path between the sheaths. In the particular embodiment shown in FIGS. 10 and 11A-11C, the gradually sloping angle of the distal side edge 123 causes degradation to proceed outward from the initial arcing region (e.g., a region proximate to portion 127) to portions of the distal side edge 123 that are farther and farther from the distal side edge 121 of the inner conductive sheath 120 (e.g., to portion 128 and then subsequent farther-in-distance portions of the distal side edge 123).

**[0120]** While FIGS. 3, 5A-5B, 6, 8A-8C, 9A-9B, 10, and 11A-11C illustrate exemplary electrode assemblies formed from concentric conductive sheaths 120, 122 shaped with angled distal side edges 121, 123, other electrode configurations may also result in favorable degradation patterns. For instance, in some examples, one or more of the distal side edges 121, 123 are shaped with a different pattern that places various portions of the edge at different predetermined distances from the other conductive sheath, e.g., shaped with undulating waves, notches, differently angled portions, or some other surface configuration. Further, while the preceding example electrode assemblies include only one shaped conductive sheath, in some examples, both the inner conductive sheath 120 and the outer conductive sheath 122 include shaped distal side edges 121, 123. Additionally or alternatively, the insulating layer 140 could be shaped to promote erosion in a desired pattern across the conductive sheaths 120, 122. For instance, the insulating layer 140 could have a shaped (e.g., angled) distal side edge, or one or more apertures through the insulating layer defining various arcing regions between the inner conductive sheath 120 and the outer conductive sheath 122.

**[0121]** To even further increase the usable lifespan of an electrode assembly included in a catheter, the polarity of the electrode assembly can be switched one or more times during a shock wave or cavitation procedure. For instance, U.S. Patent No. 10,226,265, incorporated herein by reference, describes switching the polarity of voltage pulses applied across an electrode pair to cause the direction of current flow to change during a procedure. As

described previously, an electrode connected to a positive terminal of a voltage source generally experiences increased erosion compared to an electrode connected to a negative terminal or to ground. Accordingly, switching the polarity of an electrode assembly during a procedure can allow a user to control the relative degradation at the surface of each electrode of an electrode pair. Over the course of a shock wave or cavitation procedure, polarity switching can be used to more evenly distribute degradation across both electrodes of an electrode pair, increasing the usable lifespan of an electrode assembly. It should be noted that electrode polarity switching can be implemented in any electrode assembly design, including, but not limited to, the assemblies shown throughout the present disclosure.

**[0122]** Polarity switching can be implemented using a controller, e.g., a polarity switching circuit and/or a multiplexer, in electrical connection with the external voltage source and the electrode assembly. As described previously, the external voltage source is configured to selectively deliver a series of high-voltage pulses across the wires 130, 132 of the electrode assembly to generate shock waves and/or cavitation bubbles at an electrode pair of the assembly. The direction of current flow across the electrode pair is determined by the polarity of the electrodes, i.e., the relative negative and positive charges of the electrodes. The polarity can be modified by selectively connecting the positive and negative terminals of the voltage source across the first and second insulated wires 130, 132 to cause current to flow in a particular direction across the electrodes of electrode pair (i.e., from the positive electrode to the negative electrode). Accordingly, the controller is configured to control the direction of current flow through an electrode pair by selectively delivering high-voltage pulses with a desired polarity across an electrode assembly.

**[0123]** When a series of voltage pulses is delivered across an electrode assembly, the polarity can be controlled by the controller such that a certain number of pulses in the series cause current to flow in a first direction, and the remaining number of pulses in the series cause current to flow in a second direction opposite the first direction. In a particular example, the polarity of the assembly can be switched at periodic intervals during a procedure, e.g., with the controller causing polarity switches after every voltage pulse or after a certain number of voltage pulses (e.g., switching polarity every two, three, four, or more pulses of a series). In another example, the controller can be configured to control the polarity such that a certain proportion of voltage pulses cause current to flow in a first direction, and a remaining proportion of voltage pulses cause current to flow in a second

direction opposite the first direction. For instance, the polarity of the assembly may be controlled such that current flows in a first direction for one-half ( $\frac{1}{2}$ ), one-third ( $\frac{1}{3}$ ), or one-fourth ( $\frac{1}{4}$ ) of the voltage pulses in a series, and flows in the opposite direction for the remaining pulses in the series.

[0124] To selectively promote erosion of the outer conductive sheath 122, the controller may cause a relatively greater number of voltage pulses of a series to be delivered with the outer conductive sheath connected to the positive terminal of the voltage source. For instance, the controller may cause current to flow from the inner conductive sheath 120 to the outer conductive sheath 122 for one-fifth ( $\frac{1}{5}$ ), one-fourth ( $\frac{1}{4}$ ), one-third ( $\frac{1}{3}$ ), two-fifths ( $\frac{2}{5}$ ), one-half ( $\frac{1}{2}$ ), three-fifths ( $\frac{3}{5}$ ), two-thirds ( $\frac{2}{3}$ ), three-fourths ( $\frac{3}{4}$ ), four-fifths ( $\frac{4}{5}$ ), or some other proportion or ratio of the voltage pulses of a series. However, a controller can be configured to switch the polarity of an electrode assembly such that current flows in a particular direction across the assembly for any desired proportion of voltage pulses of a series.

[0125] Moreover, a controller can be configured with a progressing sequence of voltage pulsing, such that the number of pulses in a given direction (e.g., from inner conductive sheath 120 to outer conductive sheath) can increase or decrease over the course of use. For a decreasing example, in a given treatment procedure with 300 pulses the first half (150 pulses) of a voltage pulsing sequence may have a ratio of four-fifths ( $\frac{4}{5}$ ) with 120 pulses with current going in the inner-to-outer direction and 30 pulses with current going in the outer-to-inner direction, and the second half (the remaining 150 pulses) of the voltage pulsing sequence may have a ratio of one-half ( $\frac{1}{2}$ ) with 75 pulses for current in each direction. It can be understood that further variations of pulse sequencing can be extrapolated from this example.

[0126] In some examples, the controller automatically initiates polarity switches based on readings at a sensor in electrical connection with the controller. For instance, the sensor may be configured to measure operating parameters of the electrode assembly, such as current flow through the assembly, voltage pulse width, time from the delivery of a voltage pulse to the initiation of a shock wave across an electrode pair, temperature of one or more of the electrodes, or some other parameter. If the parameter is greater than or lower than a predefined polarity switching threshold, the controller changes the direction of current flow across the electrode pair by modifying the polarity of the voltage pulses. In some examples, the sensor is configured to measure a parameter that correlates with the relative erosion of the

electrodes of an electrode pair, so that the controller can initiate polarity switches automatically to balance the erosion between the electrodes of the pair. In a particular example, the sensor measures the flow of current across an electrode pair, and the controller automatically initiates a polarity switch when current falls below a predefined polarity switching threshold value (e.g., a threshold that indicates that current flow has been negatively impacted by electrode degradation). In another example, the sensor measures a voltage pulse width or a duration of time between the delivery of a voltage pulse and the initiation of a shock wave or cavitation bubble at an electrode pair. If the voltage pulse width or duration of time measured by the sensor exceeds a predefined polarity switching threshold value (e.g., a threshold indicating that the formation of a shock waves/cavitation bubbles has been negatively impacted by electrode degradation), the controller automatically initiates a polarity switch to change the direction of current flow through the electrode pair.

**[0127]** In some examples, the controller is configured to terminate the delivery of voltage pulses when a parameter measured by the sensor is greater than or lower than a termination threshold value (e.g., to end the shock wave or cavitation procedure responsive to an error mode or undesirable operating conditions detected by the sensor). In such examples, the threshold value for polarity switching may be a function of the termination threshold value. For instance, polarity switching may be implemented when the measured parameter is greater than or lower than approximately 70% of the termination threshold. In a particular example, the termination threshold is 100 milliseconds (“ms”) between the delivery of a voltage pulse and the initiation of a shock wave or cavitation bubble at an electrode pair, and the polarity switching threshold is approximately 70 ms between the delivery of the pulse and the generation of a shock wave or cavitation bubble. In other examples, polarity switches may be initiated when the measured parameter is between 50% and 70%, between 70% and 90%, or between 90% and 100% of the termination threshold value.

**[0128]** FIG. 12 illustrates a perspective view of the distal end of an exemplary catheter 101 that includes a dual-layer electrode assembly, such as any of the exemplary electrode assemblies 100 shown throughout and described in this disclosure. FIGS. 13A-13C provide additional views of the distal end of the exemplary catheter 101 shown in FIG. 12, particularly illustrating fluid lumen 152 and aspiration lumen 154. FIG. 13A provides a top-side cross-sectional view of the exemplary catheter 101 depicting the flow of fluid through the catheter body. FIG. 13B provides a left-side view of the exemplary catheter 101 showing

the cutting plane used to generate the sectional view in FIG. 13A. FIG. 13C provides a front view of the exemplary catheter 101 depicting the fluid lumen 152 and the aspiration lumen 154.

**[0129]** FIGS. 14A-14B illustrate perspective views of alternative embodiments of a catheter 101 further featuring a guidewire lumen 156. FIG. 14A provides an example including an electrode assembly having a shaped inner conductive sheath 120 (e.g., one of the exemplary electrode assemblies throughout this disclosure). FIG. 14B provides an example of a similar catheter design including an electrode assembly having a shaped outer conductive sheath 122. FIGS. 15A-15C provide additional views of the distal end of the exemplary catheter 101 shown in FIG. 14B, including a top-side cross-sectional view in FIG. 15A; a left-side view in FIG. 15B showing the cutting plane used to generate the sectional view in FIG. 15A; and a front view in FIG. 15C depicting the fluid lumen 152, the aspiration lumen 154, and the guidewire lumen 156.

**[0130]** As seen in FIGS. 12 and 14A-14B, an exemplary catheter 101 includes an annular catheter body, i.e., an elongated tube 160, that terminates at a distal end (i.e., the end of the catheter 101 shown in FIGS. 12 and 14A-14B that is introduced into a body lumen). The elongated tube 160 is formed from a rigid or semi-rigid material, such as a shaped polymeric material. The elongated tube 160 includes a number of lumens, for instance, a fluid lumen 152, an aspiration lumen 154, and optionally a guidewire lumen 156. The fluid lumen 152 is configured for flowing a fluid, e.g., a conductive fluid such as saline, along the length of the catheter body and through a fluid outflow port 162 at a distal end of the elongated tube 160. The aspiration lumen 154 is configured to receive debris from the treatment site through a fluid inflow port 164 and flow the debris through the lumen 154 to a proximal portion of the catheter 101. In some examples, the catheter 101 further includes one or more aspiration ports 166 extending through side walls of the elongated tube 160, such that debris can be suctioned through the side walls and into the aspiration lumen 154. In some examples, and as seen in FIGS. 14A-14B, the catheter 101 includes a guidewire lumen 156 sized to receive a guidewire. To facilitate positioning of the catheter 101 with a body lumen, a guidewire can be inserted through the guidewire lumen, and the catheter can be maneuvered over the guidewire through the lumen to a treatment site proximate to a lesion.

[0131] As seen in FIGS. 12, 13A, 14A-14B, and 15A, an electrode assembly is mounted within the elongated tube 160 proximate to the distal tip of the catheter 101 such that shock waves can be generated within the catheter body. In some examples, the electrode assembly is mounted within the fluid lumen 152 such that fluid flowing through the lumen flows across the electrode assembly. The outer conductive sheath 122 is mounted inside the fluid lumen 152 adjacent to the walls of the fluid lumen 152, such that the outer surface of the outer conductive sheath 122 contacts the inner surface of the fluid lumen 152. The insulation layer 140 is mounted in the fluid lumen 152 inside and concentric with the outer conductive sheath 122 such that the outer surface of the insulation layer 140 contacts the inner surface of the outer conductive sheath 122. The inner conductive sheath 120 is also mounted in the fluid lumen 152 inside and concentric with the outer conductive sheath 122 and the insulation layer 140, with the outer surface of the inner conductive sheath 120 contacting the inner surface of the insulation layer 140. In other words, the outer conductive sheath 122 is mounted within the fluid lumen 152 circumferentially around the inner conductive sheath 120, with the insulation layer 140 positioned therebetween.

[0132] FIGS. 13A and 15A both depict the flow of fluid, e.g., conductive fluid, through the distal end of the exemplary catheter 101. As seen in FIGS. 13A-13C and 15A-15C, the electrode assembly is mounted within the fluid lumen 152 of the catheter 101 such that fluid flowing through the fluid lumen 152 flows through the inner conductive sheath 120 before exiting the fluid outflow port 162 (see, e.g., the upper horizontal arrow *F1* in FIGS. 13A and 15A, representing the flow of fluid through the fluid lumen 152). The conductive fluid in the catheter 101 provides a path for current to flow between the inner conductive sheath 120 and the outer conductive sheath 122, i.e., to allow for the generation of cavitation bubbles and/or shock waves during a treatment. Fluid flow through the inner conductive sheath 120 can also cause cavitation bubbles produced by the electrode assembly to flow out of the distal end of the catheter 101 and into a lesion to aid in cracking and disrupting the lesion. Additionally, the flow of fluid through the inner conductive sheath 120 can be used to clear debris from the surface of the electrodes (e.g., debris produced from erosion of the surfaces of the inner conductive sheath 120 and/or outer conductive sheath 122) and to regulate the temperature of the electrode assembly (e.g., by cooling the electrode assembly). Fluid can be received into the catheter 101 through a fluid inflow port 164 located at the distal end of the aspiration lumen 154. In some examples, fluid may also be received via aspiration ports 166 extending through the outer surface of the elongated tube 160. Inward suction through the aspiration

lumen 154 allows the catheter 101 to circulate fluid through the treatment site to aspirate the site and remove any bubbles and debris produced during treatment (see, e.g., the lower horizontal arrow *F2* and three vertical arrows *F3* in FIGS. 13A and 15A, representing the flow of fluid into the aspiration lumen 154).

[0133] FIG. 17 illustrates a perspective view of an exemplary electrode assembly 200 of a catheter. In one or more examples, the electrode assembly 200 can be used to generate shock waves and/or cavitation bubbles to treat calcified lesions in the vasculature of a patient using acoustic pressure without harming the surrounding tissue. As shown in FIG. 17, the electrode assembly 200 includes a flat helical wire configured as a flat coil 220 and a cylindrical conductive sheath configured as a conductive sheath 222, separated by an insulation sheath 240. The insulation sheath 240 is mounted circumferentially within the conductive sheath 222, with the flat coil 220 disposed on an inner surface of the insulation sheath 222 such that the flat coil 220 and the conductive sheath 222 form respective electrodes of an electrode pair.

[0134] The conductive sheath 222 and the flat coil 220 can be formed from a conductive material, such as a conductive metal or alloy. In one or more examples, the conductive sheath 222 can be formed from an erosion-resistant metal tubing, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper tubing that has been shaped into an extended tubular or cylindrical shape. The flat coil 220 can similarly be formed from an erosion-resistant metal material, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper that has been shaped into a flat helical coil. The flat coil 220 can be any desired thickness, for example, between 0.002 and 0.003 inches thick. In one or more examples, the conductive sheath 222 can be relatively thicker than the flat coil 220. For instance, the conductive sheath 222 could be approximately 0.004 to 0.006 inches thick. Alternatively, the flat coil 220 can be thicker than the conductive sheath 222. For example, the flat coil 220 could be between 0.004 and 0.006 inches, while the conductive sheath 222 can be relatively thinner, e.g., between 0.002 and 0.003 inches thick.

[0135] In one or more examples, the flat coil 220 and the conductive sheath 222 form an electrode pair of an electrode assembly for a catheter. As shown in FIG. 17, the flat coil 220 has a distal end 221, and the conductive sheath has a distal side edge 223. The distal end 221 of the flat coil 220 is positioned proximate to the distal side edge 223 of the (relatively outer)

conductive sheath 222, to create an arcing region across which current can flow between the flat coil 220 and the conductive sheath 222. In one or more examples, current flowing across this arcing region can generate shock waves and/or cavitation bubbles inside the catheter.

**[0136]** As seen in FIG. 17, the flat coil 220 and the conductive sheath 222 are separated by the insulation sheath 240. The insulation sheath 240 can be formed from a non-conductive insulating material that prevents unintended current flow between certain regions of the flat coil 220 and the conductive sheath 222. In one or more examples, the insulation sheath 240 can block any flow of current between the flat coil 220 and the conductive sheath 222 along the length of the insulation sheath 240. Because current is prevented from flowing between the flat coil 220 and the conductive sheath 222 along the length of the insulation sheath 240, the current can only flow across the arcing region between the distal end 223 of the conductive sheath 222 and the distal end 221 of the flat coil 220. In one or more examples, the insulation sheath 240 can be formed from a polymeric material, e.g., a polyimide, that is shaped into an extended tubular or cylindrical shape. In one or more examples, the insulation sheath 240 can be approximately 0.002 to 0.004 inches thick.

**[0137]** As shown in FIG. 17, the insulation sheath 240 has a distal side edge 241. In one or more examples, the distal side edge 241 of the insulation sheath 240 can be proximate to (e.g., flush with) the distal side edges of the conductive sheath 222 and/or the flat coil 220. The proximal side edge of the insulation sheath 240 can extend beyond the proximal side edge of at least one of the conductive sheath 222 and the flat coil 220 to prevent unintended current flow between the proximal side edges of the conductive sheath 222 and the flat coil 220. The shape and position of the insulation sheath 240 can ensure that the arcing region between the flat coil 220 and the conductive sheath 222 (e.g., the path of least resistance for current flow, normally the closest distance between the flat coil and the sheath) is between the distal end 221 and the distal side edge 223 of the flat coil 220 and the conductive sheath 222, respectively. In one or more examples, the arcing region will initially begin more particularly at the distal end 221 of the flat coil 220 that is located at the very end of the coil.

**[0138]** FIG. 18 illustrates a perspective view of an exemplary flat coil 220 of an electrode assembly, such as the electrode assembly 200 of FIG. 17. As shown in FIG. 18, the flat coil 220 is shaped as a flat wire with a rectangular cross-section that loops around a central axis in a series of coils. In one or more examples, and as will be discussed below, the flat coil 220

can be disposed on an inner surface of the insulation sheath 240 of the electrode assembly 200. In such configuration, the flat coil 220 can include a flat planar inner surface near the distal end 221 of the flat coil 220 that is on a side opposite to the inner surface of the insulation sheath 240. In one or more examples, the flat coil 220 can be manufactured via laser-cutting the shape of the flat coil 220 from an erosion-resistant metal tubing, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper tubing.

**[0139]** FIG. 19 illustrates a perspective view of an exemplary flat coil 320 with cross ties of an electrode assembly, which can also be used in devices such as the electrode assembly 200 of FIG. 17. As shown, the flat coil 320 is shaped similarly to the flat coil 220 of FIG. 18, with a rectangular cross-section that loops around a central axis in a series of coils. Distinct from the flat coil 220 of FIG. 18, however, the flat coil 320 has a number of cross ties 323 that extend between the successive turns of the flat coil 320. That is, the cross ties 323 bridge the gap between each turn of the coil. Similar to the flat coil 220 of FIG. 18, the flat coil 320 can be disposed on an inner surface of an insulation sheath such as the insulation sheath 240 such that the flat coil 320 includes a flat planar inner surface near the distal end 321 of the flat coil 320 that is on a side opposite to the inner surface of the insulation sheath 240. In one or more examples, the cross ties 323 can provide improved structural stability for the flat coil 320. In one or more examples, the flat coil 320 can be manufactured via laser-cutting the shape of the flat coil 320 from an erosion-resistant metal tubing, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper tubing.

**[0140]** FIG. 20 illustrates a perspective cross-sectional view of an exemplary electrode assembly 200 of a cathode. As shown in FIG. 20, the flat coil 220 has a number of individual coils 225 (i.e., “turns” of the flat coil 220) that are each disposed on an inner surface 243 of the insulation sheath 240. In one or more examples, the flat coil 220 can be bonded to the insulation sheath 240 by an adhesive. The adhesive (not shown) can be applied between the coils 225 of the flat coil 220 and be permitted to wick around the inner surface 243 of the insulation sheath 240 such that the adhesive fills the area between each adjacent coils 225 and secures the flat coil 220 to the insulation sheath 240.

**[0141]** FIG. 21A illustrates a left-side cross-sectional view of an exemplary electrode assembly 200 of a catheter, and FIG. 21B illustrates a front view of the exemplary electrode assembly 200 of FIG. 21A, showing the cutting plane used to generate the cross-sectional

view of FIG. 21A. As discussed above, the flat coil 220 of the electrode assembly 200 can have a rectangular cross-section and include a flat planar inner surface that is on a side opposite to the inner surface of the insulation sheath 240. This is shown more clearly in FIG. 21A, which illustrates that the flat coil 220 has a rectangular cross-section that is disposed on the inner surface of the insulation sheath 240. As visible near the distal end 221 of the flat coil 220, the flat coil has a planar inner surface that is on a side opposite the inner surface of the insulation sheath 240.

**[0142]** Returning now to FIG. 17, the electrode assembly 200 can also include two insulated wires 230, 232, extending along the length of the catheter. In particular, a first insulated wire 230 can be electrically connected to the flat coil 220 and a second insulated wire 232 can be electrically connected to the conductive sheath 222. In one or more examples, the insulated wires 230, 232 can provide an electrical connection between the flat coil 220, the conductive sheath 222, and an external voltage source, e.g., a high-voltage pulse generator (not pictured). In one or more examples, the flat coil 220 can be connected to a positive terminal of the voltage source, with the conductive sheath 222 connected to a negative terminal of the voltage source or to ground. Alternatively, the flat coil 220 can be connected to a negative terminal of the voltage source or to ground, while the conductive sheath is connected to a positive terminal of the voltage source. The conductive portions of the wires 230, 232 can be heat-sealed or otherwise fixed to the conductive sheath 222 and the flat coil 220 to provide a direct electrical connection. In one or more examples, the insulated wires 230, 232 can extend within a fluid lumen of the catheter, e.g., fixed to a side wall of the lumen or disposed within grooves extending along the lumen. The wires 230, 232 can also extend through a separate lumen of the catheter, e.g., a wire lumen. In one or more examples, the wires 230, 232 can be insulated copper wires.

**[0143]** In one or more examples, a series of high-voltage pulses can be transmitted across the wires 230, 232 by an external voltage source, e.g., a pulsed high-voltage source, to generate a series of shock waves and/or cavitation bubbles at the electrode assembly 200. Negative and positive terminals of the external voltage source can be connected to the proximal ends of the first insulated wire 230 and the second insulated wire 232, thereby creating a potential difference across the flat coil 220 and the conductive sheath 222 (i.e., an electrode pair of the electrode assembly) when high-voltage pulses are delivered across the wires 230, 232. The potential difference can cause current to flow between the electrode pair

to generate shock waves and/or cavitation bubbles. In one or more examples, the direction of the current flow can be dependent on the polarity of the electrodes, with current flowing from the more positively charged electrode (i.e., the electrode connected to the positive terminal of the voltage source via one of the wires 230, 232) to the more negatively charged electrode (i.e., the electrode connected to the negative terminal of the voltage source via one of the wires 230, 232). The duration and magnitude of each of the voltage pulses can be sufficient to generate a gas bubble (e.g., a cavitation bubble) on the surface of the electrodes (i.e., on the distal end 221 of the flat coil 220 and the distal side edge 223 of the conductive sheath 222).

**[0144]** In one or more examples, the magnitude and other characteristics of the shock waves and/or cavitation bubbles generated can be controlled by adjusting the magnitude and duration of the applied voltage pulses. For instance, delivering relatively lower voltages at high repetition rates (e.g., voltages between about 800 V and 2000 V and repetition rates between about 20 Hz and 200 Hz) can generally produce cavitation bubbles on the electrodes. Delivering relatively higher voltage pulses at lower repetition rates (e.g., voltages between about 2500 V and 6000 V and repetition rates between about 1 Hz and 4 Hz) can generally produce acoustic shock waves with a higher magnitude relative to cavitation bubbles. For directional lithotripsy electrode assemblies and emitters as considered herein, implementations using lower voltages at high repetition rates have been found to be advantageous to achieve the desired ablative mode of action. Accordingly, embodiments of the present disclosure can be implemented using voltages from about 200 V to about 10,000 V, and more particularly using voltages from about 1500 V to 2000 V, and increments and gradients of voltage within these ranges (e.g., 1.60 kV, 1.70 kV, 1.80 kV, 1.90 kV). Similarly, electrode assemblies and emitters as considered herein can be implemented using frequencies such as from about 50 Hz to 500 Hz, from about 100 Hz to 200 Hz, from about 125 Hz to 175 Hz, and at increments and gradients of frequency within that range. In one or more examples, the characteristics of the shock waves and/or cavitation bubbles can also be controlled by adjusting structural aspects of the electrode assembly, e.g., the distance between electrodes of an electrode pair, the surface area of the electrodes, the shape of the electrodes, etc.

**[0145]** When a series of relatively lower voltages at high repetition rates are transmitted across the wires 230, 232, a plurality of gas cavitation bubbles can accumulate on the surface

of the electrodes (e.g., at the distal end 221 of the flat coil 220 and the distal side edge 223 of the conductive sheath 222) of the electrode assembly 200. In one or more examples, cavitation bubbles formed on the surface of the electrodes can flow out through an open tip of the catheter and into a treatment site to break up a calcified lesion. When a series of relatively higher voltages at low repetition rates are transmitted across the wires 230, 232, a plasma arc of electric current can form across a bubble generated at the arcing region between the electrodes (i.e., at the closest distance between the distal end 221 of the flat coil 220 and the distal side edge 223 of the conductive sheath 222). The electric current can traverse the bubble, thereby creating a rapidly expanding and collapsing bubble that produces an acoustic shock wave that propagates outward from the catheter toward a treatment site to break up a calcified lesion.

**[0146]** In contrast with solid cylindrical conductive elements used as an electrode, the flat coil 220 provides a guide for controlled erosion. Whereas a simple cylinder (as part of an electrode pair) will degrade in a somewhat random pattern as current travels across the electrode pair, the flat coil 220 takes advantage of the inclination of electrical current to traverse the shortest path from one electrode across to the other electrode of an electrode pair. Accordingly, the distal end 221 of the flat coil will generally be along the path of least resistance, or in other words, at the shortest distance between the flat coil 220 and the conductive sheath 222. The erosion of flat coil 220 will tend to occur at the distal end 221, consistently moving the distal end 221 back as the flat coil 220 shortens (which, in the example of FIG. 17, would be in a clockwise direction). While the location of the distal end 221 will move as erosion processes, the consistency of the location of the spark gap at the distal end 221 is relatively not as random as would be observed along the edge of a solid cylinder. Thus, the flat coil 220 can provide for a sequence of shock waves and cavitation bubbles with a more consistent origin point and less potential for interference over the course of a treatment regimen.

**[0147]** FIG. 22 is a graph showing estimated measurements of pressure generated by a device fabricated in accordance with FIG. 17, focusing on the initial period of the spark generation, before cavitation bubbles are formed. The estimated measurements depicted in FIG. 22 are depicted in megapascals and were based off measurements by a hydrophone located about 10 mm from the emitter location. As shown, there exists a large positive spike of about 4.2 MPa, followed by a negative spike to a magnitude of -2.03 MPa, resulting with

a peak-to-peak magnitude of 6.23 MPa. The peak-to-peak magnitude of 6.23 MPa can enhance the breaking up of lesions at a treatment site.

**[0148]** In one or more examples, the rise time can be correlated with the efficacy of a catheter that incorporates an electrode design such as the electrode assembly 200 of FIG. 17. That is, a fast rise time can enhance the performance of the catheter when attempting to bore through a calcified lesion. As shown in FIG. 22, the positive peak has a relatively fast rise time with a narrow apex before falling, thus a device fabricated according to FIG. 17 can perform better than other devices with slower rise times and/or wider peaks (which can be indicative of a slower pressure differential). As shown here, the positive and negative spikes in pressure are caused by the spark generation itself. Subsequently in a cycle of firing the electrode assembly, a positive spike can be caused by the initial bursting of a vapor bubble with the negative spike caused by the collapse of that bubble.

**[0149]** In one or more examples, the pressure magnitude and frequency resulting from the voltage pulses can be controlled to improve the characteristics of the acoustic pressure waves. For instance, delivering voltage pulses with relatively short pulse widths, e.g., below 50  $\mu$ s, can produce acoustic pressure waves with relatively high-amplitude negative pressures. Increased negative pressures can provide a negative suction-like force that may facilitate the clearing of lesions and debris from a treatment site. In one or more examples, the voltage pulses can be delivered across an electrode pair at relatively low frequencies, e.g., frequencies between 30 and 40 Hz, between 40 and 50 Hz, or greater than 50 Hz. Similarly, in one or more examples, the voltage pulses can have relatively short pulse widths, e.g., pulse widths between 2 and 20  $\mu$ s, pulse widths of about 5  $\mu$ s, pulse widths of about 10  $\mu$ s, or pulse widths less than 2  $\mu$ s, to produce acoustic pressure waves having high negative pressure.

**[0150]** As discussed above, as shock waves and/or cavitation bubbles are generated by voltage pulses transmitted across an electrode pair, the electrode surface can slowly erode at the arcing region between the electrodes. FIG. 23 illustrates a perspective view of the exemplary electrode assembly 200 of FIG. 17 before any erosion. As mentioned above, the initial arcing region can generally be located at the path of least resistance between the electrodes of the electrode pair. Referring to FIG. 23, the path of least resistance between the flat coil 220 and the conductive sheath 222 (i.e., the electrodes) will be the location where the gap between the flat coil 220 and the conductive sheath 222 is the shortest and not obstructed

by the insulation sheath 240. As shown in FIG. 23, the initial arcing region can thus be located between the distal end 221 of the flat coil 220 and the distal side edge 223 of the conductive sheath 222.

**[0151]** Repeated generation of shock waves and/or cavitation bubbles by applying voltage to the electrode assembly 200 can then cause the electrodes to erode proximate to the initial arcing region. This is shown more clearly in FIGS. 24A and 24B, which illustrate an enlarged detail view of the erosion process of the electrodes of the electrode assembly 200 of FIG. 17. As shown in FIG. 24A, the distal side edge 223 of the conductive sheath 222 has begun to erode at the arcing region where the distal side edge 223 of the conductive sheath 222 is closest to the distal end 221 of the flat coil 220. In one or more examples, erosion will begin on the conductive sheath 222 before beginning on the flat coil 220. For instance, as shown in FIG. 24A, the distal edge 223 of the conductive sheath 222 has begun to erode, but the distal end 221 of the flat coil 220 has not. As shown in FIG. 24A, however, the distal end 221 of the flat coil 220 has begun to erode. Thus, the erosion of the distal side edge 223 of the conductive sheath 222 can be more extensive relative to the erosion of the distal end 221 of the flat coil 220 (as visible in FIG. 24B), because the erosion began on the conductive sheath 222 before beginning on the flat coil 220.

**[0152]** In one or more examples, the insulation sheath 240 will also erode based on the application of voltage to the electrode assembly 200. As shown in FIG. 24A, the distal edge 241 of the insulation sheath 240 began after the erosion of the distal side edge 223 of the conductive sheath 222. It is contemplated, however, that the insulation sheath 240 may begin to erode before the conductive sheath 222 begins to erode. As the conductive sheath 222 and the insulation sheath 240 erode, the erosion can expose an outer surface 227 of the flat coil 220, as shown in FIG. 24A as part of distal end 221. In one or more examples, the erosion of the insulation sheath 240 can permit the erosion of the flat coil 220 to begin. The exposure of the outer surface 227 of the flat coil 220 can permit the arcing region to shift; wherein rather than proceeding between the distal end 221 of the flat coil, the arcing region may proceed between the outer surface 227 of the flat coil 220 and the distal side edge 223 of the conductive sheath 222. In one or more examples, rather than shifting, however, the arcing region may expand. That is, the arcing region may proceed between the entire exposed region of the flat coil, including both the distal end 221 and the exposed outer surface 227, and the distal side edge 223 of the conductive sheath 222.

[0153] As the erosion begins to wear away the distal end 221 of the flat coil 220, the arcing region can proceed to follow the coils of the flat coil 220. That is, in one or more examples, the arcing region can follow the end of the flat coil 220 as the coil erodes. As seen in FIG. 24B, the progressive erosion of flat coil 220 can lead to the region of exposed outer surface 227 being completely eroded and therefore no longer present; of course, as degradation continues further, regions of exposed outer surface 227 may be cyclically exposed and then eroded. Therefore, the inclusion of the flat coil 220 as one of the electrodes of the electrode assembly 200 can permit the erosion of the electrodes to proceed in a semi-controlled predictable manner that follows the flat coil 220. This erosion progression is shown in FIGS. 25A and 25B, with FIG. 25A illustrating the electrode assembly 200 after the initial erosion begins and FIG. 25B illustrating the electrode assembly after extensive erosion has occurred. Further, erosion that is controlled by the presence of the material of the flat coil 220 can provide for a relatively more even or uniform erosion pattern that progresses around the circumference of the conductive sheath 222.

[0154] As shown in FIG. 25A, the erosion of the conductive sheath 222 and the insulation sheath 240 has begun at the initial arcing region near the end of the flat coil 220, but the erosion of the flat coil 220 has not yet begun. In contrast, FIG. 25B depicts extensive erosion, illustrated by the deformed shape of both the conductive sheath 222 and the insulation sheath 240 at the distal side edges 223 and 241, respectively. Relative to FIG. 25A, the flat coil 220 shown in FIG. 25B has eroded to remove entire turns of the flat coil 220 (the end of which is no longer visible because it has eroded along the turns of the coils).

[0155] As discussed above, in a circuit, current can generally flow from a positively charged source to a negatively charged source. Moreover, the positive and negative terminals of a voltage source can be connected via the wires 230 and 232 to the flat coil 220 and the conductive sheath 222. In one or more examples, if the flat coil 220 is connected to the negative terminal and the conductive sheath 222 is connected to the positive terminal, the erosion can begin on the conductive sheath 222 first. Alternatively, in examples where the flat coil 220 is connected to the positive terminal and the conductive sheath 222 is connected to the negative terminal, the erosion may begin on the flat coil 220 first. Accordingly, reversing the polarity of the electrode assembly (e.g., by swapping which electrode is connected to the positive or negative terminal, also referred to as “polarity switching”) can cause the current to flow in the opposite direction across the arcing region. Altering the

direction of the current flow can impact which electrode of the electrode assembly 200 experiences the most erosion.

**[0156]** In one or more examples, the surface area difference between the electrodes can impact the longevity of the device. A first electrode with a larger surface area relative to a second electrode may be able to withstand more erosion than the smaller second electrode. As evident in FIG. 17, the conductive sheath 222 has a greater surface area than the flat coil 220. Thus, in one or more examples, designing the electrode assembly 200 such that erosion occurs primarily on the conductive sheath 222 may enable the electrode assembly 200 capable of performing a longer treatment than if the erosion occurred primarily on the flat coil 220.

**[0157]** In one or more examples, the usable lifespan of an electrode assembly such as the electrode assembly 200 can be extended by switching the polarity of the electrodes one or more times during the treatment procedure. For instance, U.S. Patent No. 10,226,265 describes switching the polarity of voltage pulses applied across an electrode pair to switch the direction of current flow during a procedure. As described previously, an electrode connected to a positive terminal of a voltage source may generally experience increased erosion compared to an electrode connected to a negative terminal or to ground. Accordingly, switching the polarity of an electrode assembly during a procedure can allow a user to control the relative erosion at the surface of each electrode of an electrode pair. Over the course of a treatment procedure, polarity switching can be used to more evenly distribute erosion across both electrodes of an electrode pair, increasing the usable lifespan of an electrode assembly.

**[0158]** In one or more examples, the electrode assembly 200 can be used in a catheter that implements the above polarity-switching technique. Polarity switching can be implemented using a controller, e.g., a polarity-switching circuit and/or a multiplexer, in electrical connection with the external voltage source and the electrode assembly. As discussed above, an external voltage source connected to the electrode assembly 200 can be configured to selectively deliver a series of high-voltage pulses across the wires 230, 232 to cause current to flow in a particular direction across the electrodes (i.e., from the positive electrode to the negative electrode). Thus, in one or more examples, a controller can be configured to control the direction of current flow across the electrodes (e.g., the conductive sheath 222 and the flat

coil 220) of the electrode assembly 200 by altering the polarity of the electrodes. In one or more examples, the controller can be configured to switch the polarity after a specified duration or after a certain number of pulses. For example, the polarity of the electrode assembly can be switched after a specified number of minutes, after a specified number of seconds, after every voltage pulse, after a specified number of pulses, etc.

**[0159]** In one or more examples, the controller may be configured to alter polarity based on readings from a sensor in electrical connection with the controller. For example, the sensor may be configured to measure operating parameters such as the current flow, voltage pulse width, time between voltage pulse and the initiation of a shock wave or cavitation bubble, temperature of one or more of the electrodes, and other such measurable parameters and characteristics of a functional catheter. The controller may be configured to alter the polarity based on a given parameter exceeding a predetermined threshold. In one or more examples, the sensor can measure the current flow across the electrodes, and the controller can automatically switch the polarity of the electrode assembly when the current falls below a predefined threshold (e.g., a threshold that indicates the current flow has decreased because of electrode erosion). In one or more examples, the sensor can measure the temperature proximate to the electrodes, and the controller can automatically pause or terminate current flow to the electrode assembly when the current falls exceeds a predefined threshold (e.g., a threshold that indicates the temperature of the electrodes is above a target operating status). The controller can also be configured to terminate the delivery of voltage pulses when a measured parameter is greater or lower than a termination threshold value. In one or more examples, the termination threshold values can signify an error mode or undesirable operating conditions.

**[0160]** In one or more examples, the electrode assembly 200 can be used with a catheter to treat an occlusion (e.g., lesions) in a body lumen, such as calcified lesions in vasculature associated with arterial disease. As described above, the electrode assembly 200 can be configured to generate one or more shock waves and/or cavitation bubbles in response to the application of voltage across the electrodes (e.g., the conductive sheath 222 and the flat coil 220) of the electrode assembly 200. When placed within a catheter, the shock waves and/or cavitation bubbles created by the electrode assembly 200 can be directed toward occlusions in a treatment area and can begin to break apart the occlusions as described above.

[0161] FIG. 26 illustrates a perspective view of the distal end of an exemplary catheter 201, according to one or more embodiments. The catheter 201 can include an annular catheter body, such as the elongated tube 260. The elongated tube 260 can be formed from a rigid or semi-rigid material, such as a shaped polymeric material. As shown in FIG. 26, the catheter 201 includes an electrode assembly 200 mounted at the distal end of the catheter 201 within the elongated tube 260. In one or more examples, the electrode assembly 200 can be as described above and can include a conductive sheath mounted within the elongated tube 260, an insulation sheath mounted circumferentially within the conductive sheath, and a flat coil disposed on an inner surface of the insulation sheath. (Alternative implementations of the electrode assembly can have other structures as described herein, for example, using a cylindrical inner electrode instead of a flat coil electrode as illustrated.) Thus, in one or more examples, the catheter 201 can be configured to deliver one or more shock waves and/or cavitation bubbles to a treatment site when a voltage pulse is applied across the flat coil and the conductive sheath of the electrode assembly 100 to create an arcing region as described above.

[0162] As shown in FIG. 26, the catheter 201 also includes a number of aspiration ports 266, as well as a fluid lumen 252, an aspiration lumen 254, and optionally a guidewire lumen 256. The guidewire lumen 256 can be sized to receive a guidewire that can be used to position the catheter 201 within a body cavity or lumen. To position the catheter 201, a guidewire can be inserted through the guidewire lumen 256 and used to locate the elongated tube 260 of the catheter 201 proximate to a treatment site. In one or more examples, the catheter 201 can be configured without the guidewire lumen 256 (e.g., for a rapid exchange implementation of the catheter assembly).

[0163] The lumens of the catheter 201 are shown more clearly in FIG. 27A, which illustrates a left-side cross-sectional view of the distal end of an exemplary catheter such as the catheter 201 cut across the cutting plane shown in FIG. 27B, which illustrates a front view of the distal end of the catheter.

[0164] In one or more examples, the fluid lumen 252 can be configured for flowing a fluid along the length of the catheter body and through a fluid outflow port 262 at the distal end of the catheter 201. The aspiration lumen 254 can be configured to receive debris from the treatment site through a fluid inflow port 264 at the distal end of the catheter 201 and/or

through the aspiration ports 266 shown in FIG. 26. In one or more examples, the catheter 201 can provide inward suction that causes fluid to be drawn into the aspiration lumen 254 and further enables the catheter 201 to circulate fluid through the treatment site by supplying fluid via the fluid lumen 252 and removing fluid via the aspiration lumen 254. For example, as shown in FIG. 27A, the arrows illustrate the fluid flow, which exits the catheter 201 (arrow *F1*) through the fluid outflow port 262, and subsequently enters the catheter at one or more of the fluid inflow port 264 (arrow *F2*) and the aspiration ports 266 (arrows *F3*), ultimately returning down to the proximal end of the catheter 201.

[0165] As shown in FIG. 27A, the electrode assembly 200 is mounted within the fluid lumen 252 of the catheter 201. In one or more examples, the fluid conveyed through the fluid lumen 252 can be a conductive fluid. Thus, in one or more examples, the conductive fluid flowing through the fluid lumen 252 flows through the electrode assembly before exiting the catheter 201. The conductive fluid can provide a path for current to flow between the flat coil 220 and the conductive sheath 222, thereby enabling the generation of shock wave and/or cavitation bubbles during a treatment. In one or more examples, the shock wave and/or cavitation bubbles created can flow out of the fluid outflow port 262 of the catheter 201 toward the treatment location.

[0166] In embodiments of the present disclosure, electrodes formed of a coiled wire structure can provide an advantage in controlling the location of a spark gap and arcing between electrodes during the course of activating an FFC catheter. In embodiments of electrode assemblies where both electrodes are formed of cylindrical structures (i.e., hypotubes), the location of arcing and spark generation may be irregular and variable along the edges of the hypotubes. The corresponding erosion of the hypotubes is similarly irregular and variable in location, potentially leading to a changing and increasingly long distance for the location of where the spark gap occurs. One approach to maintaining control of electrode erosion and corresponding maintenance of the spark gap distance is by using coiled wires. Such coiled wires can be standard round wires or flat wires. During activation of the FFC catheter, the coiled wire as one electrode will erode, as will the complementary electrode (often a hypotube), but the location of arcing and erosion is controlled to be relative to the distal tip of the eroding coiled wire, thereby controlling the location and distance of the spark gap. Control of the location and distance of the spark gap can lead to increased longevity and consistency of the FFC device.

[0167] FIGS. 28A and 28B illustrate perspective views of exemplary electrode assemblies 400 and 450, respectively, having an interior coiled electrode 420 with a curved distal tip 421. Similar to the embodiments shown in FIGS. 25A and 25B, the interior coil electrode 420 (shown here as a flat coil) is positioned within a cylindrical outer electrode 422 (alternatively referred to as a conductive sheath) with an insulation layer 440 therebetween. A first insulated wire 430 is electrically connected with the interior coil electrode 420, and a second insulated wire 432 is electrically connected with the cylindrical outer electrode 422. In contrast with the embodiments shown in FIGS. 25A and 25B, the curved distal tip 421 is bent so as to be initially centered within the circumference of the concentric cylindrical outer electrode 422 and insulation layer 440. Because bubble erosion occurs where spark travels across the electrodes, in the embodiments of FIGS. 25A and 25B, that erosion will start at the edge of the outer electrode where the distal end and edge of the flat coil is located. Accordingly, with the distal end of a coil located at the edge of the cylinder, the erosion will initiate at an off-center position. In FIGS. 28A and 28B, the curved distal tip 421 of the interior coiled electrode 420 moves the initial spark gap location to the center of the cylindrical electrode assembly, which can further aid in directing a relatively even erosion of the cylindrical outer electrode 422. Moreover, initiating the sparks and generated shock waves to the center of the electrode assembly 400 can align and center the cavitation bubbles formed by the electrode assembly. The centered location of bubble formation, being aligned with the centerline or longitudinal axis of the overall catheter, can provide for greater precision in delivering shock wave treatment.

[0168] The difference between the electrode assembly 400 in FIG. 28A and the electrode assembly 450 in FIG. 28B is a difference in how the interior coil electrode 420 is positioned. In FIG. 28A with electrode assembly 400, the interior coil electrode 420 is flush (or near flush) with the distal edge of the cylindrical outer electrode 422. In FIG. 28B with electrode assembly 450, the interior coil electrode 420 is recessed a distance within insulation layer 440 away from the distal edge of the cylindrical outer electrode 422. The depth by which interior coil electrode 420 is recessed can be equal to the width of one, two, three, or three or more turns of the interior coil electrode 420. In the embodiment of FIG. 28B, the recessed location of the spark gap and subsequent shock wave can lead to bubble formation that is at least partially within the barrel of the electrode assembly 450 lumen as defined by the insulation layer 440 and cylindrical outer electrode 422. Accordingly, the expansion of a cavitation bubble formed within that lumen is primarily directed out the distal end of the electrode

assembly 450, imparting corresponding directionality to the bubble and shock wave treatment.

**[0169]** While erosion of the interior coil electrode 420 will eventually progress toward the cylinder walls, the centered location of the initial sparks and bubble formation may have a continuing effect throughout a cycle of shock wave generation and treatment. In other words, due to physical factors such as residual electrical potential, the fluid dynamics trailing a prior bubble formation, and the like, subsequent bubbles may also be formed in a centered location aligned with the centerline of the overall catheter even though the curved distal tip 421 will be fully eroded and the eroding distal end of the interior coil electrode 420 will be alongside the interior wall of the insulation layer 440.

**[0170]** FIG. 28C illustrates a perspective view of an exemplary electrode assembly 460 having dual interior coiled electrodes with curved distal tips, more specifically a first interior coiled electrode 470 with a first curved distal tip 471 and a second interior curved coiled electrode 472 with a second curved distal tip 473. Both first interior coiled electrode 470 and second interior curved coiled electrode 472 are illustrated as flat wires each in a helix shape, aligned with each other such that the thickness of one flat wire lies within the gap or pitch of the other flat wire, thereby forming a double helix structure. As viewed straight-on from the distal end of assembly 460 in FIG. 28C, both the first interior coiled electrode 470 and second interior curved coiled electrode 472 turn in a counterclockwise direction. It should be appreciated that in alternative embodiments both the first interior coiled electrode 470 and second interior curved coiled electrode 472 can turn in a clockwise direction. It should be further appreciated that in alternative embodiments the first interior coiled electrode 470 can turn in a counterclockwise and the second interior curved coiled electrode 472 can turn in a clockwise direction, or vice versa. The first interior coiled electrode 470 and second interior curved coiled electrode 472 are both positioned within a cylindrical outer electrode 422 (alternatively referred to as a conductive sheath) with an insulation layer 440 therebetween. A first insulated wire 430 is electrically connected with the cylindrical outer electrode 422. A second insulated wire 432 branches into two legs, a first wire leg 432a electrically connected with the first interior coiled electrode 470 and a second wire leg 432b electrically connected with second interior curved coiled electrode 472.

[0171] In some implementations of electrode assembly 460, second insulated wire 432 can provide electricity from a power source to both first interior coiled electrode 470 and second interior curved coiled electrode 472. Accordingly, the electrical current can arrive at both first curved distal tip 471 and second curved distal tip 473 near simultaneously and form separate and/or combined spark gaps between the distal tips and cylindrical outer electrode 422. Current can then return back to the power source along first insulated wire 430 (acting as a ground for the circuit).

[0172] FIG. 28D illustrates a perspective view of an exemplary electrode assembly 480 having an interior coiled electrode 420 an inner insulation layer 482. Interior coil electrode 420 is positioned within cylindrical outer electrode 422 with insulation layer 440 therebetween. First insulated wire 430 is electrically connected with the interior coil electrode 420, and second insulated wire 432 is electrically connected with the cylindrical outer electrode 422. In this implementation, an additional inner insulation layer 482 is positioned within the space on the inside of the interior coiled electrode 420. The inner insulation layer 482 can further aid in control of the location of arcing and spark gaps, focusing the transmission of current at the distal tip of the interior coiled electrode 420 as erosion of the coiled electrode progresses.

[0173] FIG. 29 illustrates a perspective view of an exemplary electrode assembly 500 having an exterior coiled electrode 522 and a solid tube interior electrode 520, with an insulation layer 540 therebetween. In this embodiment, first insulated wire 530 is electrically connected to exterior coiled electrode 522 and second insulated wire 532 is electrically connected to solid tube interior electrode 520. As noted herein, when implementing polarity switching, it can be advantageous for longevity of the overall device for a solid cylindrical element to be the electrode that is primarily connected to the positive terminal of the voltage source. As shown here, when the cylindrical conductive element of solid tube interior electrode 520 is paired with the flat coil of exterior coiled electrode 522 as the complementary electrode, the ratio of how frequently the solid tube interior electrode 520 receives current acting as the positive terminal can lead to that solid cylindrical element getting hotter than the exterior coiled electrode 522. Accordingly, the wire connecting to the positive terminal of the voltage source (in this implementation being the second insulated wire 532) is moved to be in electrical communication with the solid tube interior electrode 520 to thereby localize and control the heat of the device. The erosion of the exterior coiled

electrode 522 and solid tube interior electrode 520 and corresponding shock wave and bubble formation can mirror the embodiments described herein, such as in FIG. 17.

**[0174]** FIG. 30 illustrates a perspective view of an exemplary electrode assembly 600 having an exterior clockwise coiled electrode 622 and an interior counterclockwise coiled electrode 620. In this embodiment, insulation layer 640 is positioned between the two coiled electrodes, with first insulated wire 630 connected to interior counterclockwise coiled electrode 620, and with second insulated wire 632 connected to exterior clockwise coiled electrode 622. The use of two coils twisted in opposing directions further works to maintain a consistency in the spark position and location of shock wave formation. In this implementation, current will travel across between the distance between interior coil distal tip 621 and the exterior coil distal tip 623 and erosion will primarily occur at these locations. As each of the exterior clockwise coiled electrode 622 and the interior counterclockwise coiled electrode 620 are degraded, the respective the exterior coil distal tip 623 and interior coil distal tip 621 will erode and move around the circumference of the insulation layer 640 therebetween. The distance between the exterior coil distal tip 623 and interior coil distal tip 621 will vary as erosion of each element progresses, but that distance will be no greater than the diameter of the insulation layer 640. Accordingly, on average, the spark gap distance between the interior coil distal tip 621 and the exterior coil distal tip 623 as erosion progresses will be maintained within a desired range. Moreover, because each electrode is a coil having their respective distal tips degraded, this implementation can avoid the risk of a permanent erosion bias developing on one side or area of an electrode. It should be readily understood that in an alternative implementation, an exterior coil electrode can be wound in a counterclockwise direction and an interior coil electrode can be wound in a clockwise direction.

**[0175]** FIG. 31A illustrates a perspective view of an exemplary electrode assembly 700 having an outer electrode 722 with erosion-control gaps 729 arranged in a pattern around the surface of the outer electrode 722. In this implementation, the inner electrode is a flat coil 720 having a curved distal tip 721 that is bent so as to be initially centered, with an insulation layer 740 layered in between the flat coil 720 and the outer electrode 722. A first insulated wire 730 is electrically connected to outer electrode 722, and a second insulated wire is electrically connected to the flat coil 720. As noted in FIG. 2, a cylindrical electrode manufactured as a rolled hypotube will often have electrical current tend to arc at locations

where there is a sharp edge or corner, and thus erosion will tend to track down a seam of the rolled hypotube material. Taking advantage of the tendency of electrical current to arc toward sharp edges, the electrode assembly 700 implementation as shown in FIG. 31A uses the erosion-control gaps 729 to draw the arc of current around the full circumference of the outer electrode distal edge 723 as the outer electrode 722 erodes. Specifically, as erosion of the outer electrode 722 progresses from the distal to the proximal end of the electrode assembly 700, corresponding with the outer electrode distal edge 723 eroding back in the proximal direction along the length of electrode assembly 700, the forwardmost erosion-control gaps 729 in the outer electrode 722 will become exposed as points for electrical current to arc toward and generate sparks. Accordingly, the location of outer electrode 722 erosion can be localized at the distal-most exposed sharp edges of the erosion-control gaps 729.

**[0176]** As erosion of the outer electrode distal edge 723 continues, and as the forwardmost erosion-control gaps 729 are degraded, different (relatively proximate) erosion-control gaps 729 will become exposed and present a shorter distance for spark gaps and current arcing. Thus, the location of sparking and erosion will tend toward the sharp edges of the erosion-control gaps 729 that are subsequently exposed. As the material around the subsequently erosion-control gaps 729 are degraded, the shortest distance for current arcing can return to previous erosion-control gaps 729 or to different further subsequent erosion-control gaps 729 in the outer electrode. By guiding the location of spark gaps to different areas of the outer electrode distal edge 723 by use of the structure of the erosion-control gaps 729, the overall degradation pattern of the outer electrode 722 can be maintained as relatively even, and thereby avoid directional bias or other physical failure risks resulting from uneven erosion of outer electrode 722.

**[0177]** The erosion-control gaps 729 are illustrated as each having an oblong shape, but in other aspects the erosion-control gaps 729 can have circular shapes, rectangular shapes, triangular shapes, diamond shapes, curved arcs, other geometrical shapes, or combinations thereof. In some aspects, the erosion-control gaps 729 pass through the complete thickness of outer electrode 722. In other aspects, erosion-control gaps 729 pass only partway through the thickness of outer electrode 722. The pattern of the erosion-control gaps 729 can be angled relative to each other in an alternating columns as shown in FIG. 31A. In alternative embodiments, the erosion-control gaps 729 can be patterned at angles parallel to each other,

arranged in a gruyère pattern, patterned as rotationally offset rings when viewed along the length of the outer electrode 722, or otherwise arranged in a regular pattern. The erosion-control gaps 729 can be formed in outer electrode 722 by a laser-cutting process or the like as known in the field. It should be readily understood that any of the inner-located electrodes described herein can be used in combination with outer electrode 722.

**[0178]** FIGS. 31B-31E illustrate an exemplary progression of electrode degradation for outer electrode 722 having erosion-control gaps 729 in a cut-out patterning as shown in FIG. 31A. The progression of erosion region 713 is shown in FIG. 31B as having degraded outer electrode 722 and consuming most of the forwardmost erosion-control gap 729 and having reached a subsequent erosion-control gap 729' along the length of outer electrode 722. In FIG. 31C, erosion region 713 has spread in a relatively lateral direction (rightward in the figure) around the circumference of the outer electrode close to the next subsequent erosion-control gap 729'. In FIG. 31D, erosion region 713 has continued to spread in a relatively lateral direction (leftward in the figure) around the circumference of the outer electrode close to the next subsequent erosion-control gap 729'', while also continuing to erode around the erosion-control gap 729'. Finally in FIG. 31E, the erosion control region 713 continues to degrade outer electrode 722 in a generally even manner, eroding electrode material relatively equally around erosion-control gaps 729' and 729''. Accordingly, the erosion-control gap 729 in outer electrode 722 prevent the development of an uneven and irregularly shaped electrode edge over the normal course of degradation due to sparking and cavitation bubble formation.

**[0179]** In alternative embodiments of the various outer-located electrodes described above, a seamless hypotube can be used to minimize current arcing that may result in uneven erosion of the respective electrode. Further, in the embodiments set forth above, it can be understood that the metals or alloys used for the various cylindrical or coiled electrodes, positioned in an interior or exterior location, can be made from erosion-resistant materials such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, copper, or combinations thereof.

**[0180]** FIGS. 32A-32H, are paired sets of images and graphs capturing the action of an electrode assembly as described herein, particularly in reference to FIG. 17. Specifically, each of FIGS. 32A-32H shows captured images from a high-speed video showing an exemplary electrode assembly generating a forward-directional vapor bubble. Paired with

each image is a graph displaying the average pressure measurement (in MPa) over time ( $\mu$ s) for the electrode assembly generating such forward-directional vapor bubbles. The pressure measurements were taken by a hydrophone located about 10 mm from the emitter location. As noted above, the pressure close to the emitter ( $\sim 1$  mm) is about an order of magnitude greater than the pressure measured at the hydrophone 10 mm distant from the end of the emitter. The solid circle shown in each graph corresponds to the time of measurement and image capture in the associated image.

[0181] FIG. 32A shows the initial spark at the distal end of the electrode assembly; the pressure measured at this start point (close to 0  $\mu$ s) is about 0.25 MPa. FIG. 32B shows the moment immediately subsequent to the spark generation in FIG. 32A, with pressure dropped to just below about 0.0 Mpa. FIG. 32C shows the formation of an initial bubble at beyond 100  $\mu$ s after the spark generation; the pressure measured at this point remains close to about 0.0 Mpa. FIG. 32D shows the beginning of the bubble breaking and collapse at about 300  $\mu$ s; the pressure measured at this point peaks at just above about 0.8 MPa. FIG. 32E shows the continuation of the bubble collapse at about 325  $\mu$ s; the pressure measured at this point drops down to about  $-0.1$  MPa. FIG. 32F shows the dissipation of the initial bubble at about 440  $\mu$ s; the pressure measured at this point is again about 0.0 MPa. FIG. 32G shows the formation of a secondary bubble driven by the fluid dynamic forces of the expansion and collapse of the initial bubble, occurring at about 480  $\mu$ s; the pressure measured at this point is at a secondary peak of about 0.3 MPa. FIG. 32H shows the dissipation of the secondary bubble at about 550  $\mu$ s after the spark generation; the pressure measured at this point is again about 0.0 MPa.

[0182] As understood from FIGS. 32A-32H, the exemplary electrode assembly as described herein is fully capable of generating shock waves and cavitation bubbles that have a forward directionality. After a voltage pulse is applied, a positive pressure spike is generated (e.g., as in FIG. 32D), and thereafter a negative pressure spike is generated (e.g., as in FIG. 32E). Moreover, the strength and pressure generated by these shock wave and bubbles are sufficient to implement IVL therapy and may have further application in ablative *in vivo* processes. The observed results of the exemplary electrode assembly track earlier understandings of IVL, where both an initial and a secondary bubble are generated with their respective pressures. In forward-firing directional applications, both the initial and the

secondary bubbles can be optimized to produce peak pressures that are both functional for delivering therapy to a tissue or other *in vivo* structure.

[0183] FIG. 33 illustrates a perspective view of an exemplary electrode assembly of a catheter having a ceramic insulating layer 840. The electrode assembly 800 includes a first cylindrical electrode 820 and a second cylindrical electrode 822 (optionally referred to as an outer sheath). A ceramic insulating layer 840 is disposed concentrically within the second cylindrical electrode 822, and the first cylindrical electrode 820 is disposed concentrically within the ceramic insulating layer 840. Second cylindrical electrode 822 is electrically connected to a first insulated wire 830, and first cylindrical electrode 820 is electrically connected to a second insulated wire 832. As noted elsewhere herein, and as applicable to other implementations of the insulated wires, a first insulated wire can carry a positive charge making the electrode it is connected to a cathode, while a second insulated wire can carry a negative charge making the electrode it is connected to an anode. The polarity of these wires can be switched as desired at a power source coupled to both wires.

[0184] The ceramic insulating layer 840 is an electrical insulator, which can be fully formed of a ceramic or can be a ceramic covering (coated or glazed) on top of a polymeric material. In this and other disclosed implementations, the ceramic material used as the electrical insulator can be zirconia-based, alumina-based, steatite-based, silicon carbide-based, cordierite-based, or mullite-based. The ceramic material used for a ceramic insulating layer can have a thermal conductivity of from 20 to 40 W/mK, where the limiting or permitting of thermal transfer can be selected to control for erosion rate of the coupled electrodes. The ceramic material used for a ceramic insulating layer can be a nonporous ceramic (< 20% porosity) or a porous ceramic (20-95% porosity).

[0185] Advantages of a ceramic insulator as compared to a polymeric insulator in these applications include increased durability and reduced erosion of the insulating layer. In embodiments of the present disclosure, a ceramic insulating layer 840 can withstand the shock and force of arcing and shock wave generation without experiencing substantive degradation. In some examples, the ceramic insulating layer 840 can retain structural integrity for up to and greater than fifty cycles of device activation, at a voltage of up to 4000 V, where each cycle can be up to or greater than 30 sec, and where the frequency of arc firing is from 50 to 250 Hz (or greater). Due to the reduced erosion, the amount of particulates

generated is minimized and discoloration (e.g., browning) of the polymeric material is minimized. The wall thickness of the ceramic insulating layer 840 can be from 0.002 to 0.020 inches, whether formed of polymeric material, ceramic material, or a material having a ceramic coating or glaze.

[0186] From other perspectives, the use of a ceramic insulating layer is counterintuitive for vascular catheters, because the ceramic is a relatively more rigid component that may negatively affect the flexibility and deliverability of the catheter. However, the resilience and durability of ceramic insulators can reduce the amount of ceramic coverage needed, as compared to polymeric insulators. For example, within the distal end 800, a ceramic insulating layer 840 formed of or covered with ceramic may only need extend from 2% to 15% of the length distal end 800, as measured from the arcing region of the first cylindrical electrode 820 and a second cylindrical electrode 822. In embodiments where the insulating layer is covered with a ceramic, the ceramic material may be coated, glazed, adhered, or friction fit onto the insulating layer.

[0187] FIG. 34 illustrates a perspective view of an exemplary electrode assembly 900 of a catheter having flat wires positioned between cylindrical layers. The electrode assembly 900 includes a first cylindrical sheath referred to as an inner sheath 920 that is formed of or covered with a non-conductive material and a second cylindrical sheath referred to as an outer sheath 922 that is formed of a conductive metal (e.g., stainless steel). The second cylindrical sheath outer sheath 922 is mounted circumferentially around and concentric with the inner sheath 920. The hollow space within the inner sheath 920 can be used for a guidewire or other catheter tools, passing through the electrode assembly 900 to the distal end of the catheter. Positioned within the inner circumference of the outer sheath 922 is an insulating sheath 940, formed of or covered with an electrically insulating material such as a polymer or a ceramic as disclosed herein. Positioned between the inner sheath 920 and the insulating sheath 940 are a first flat wire 910 and a second flat wire 912. Each of first flat wire 910 and second flat wire 912 can be formed of an electrically conductive metal or alloy as disclosed herein. In some examples, the first flat wire 910, the second flat wire 912, and the outer sheath 922 are formed from an erosion-resistant metal such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper.

[0188] Outer sheath 922 is electrically connected to a first insulated wire 930, and both first flat wire 910 and second flat wire 912 are electrically connected to a second insulated wire 932. When voltage is provided to first flat wire 910 and second flat wire 912 (either simultaneously or sequentially), the current will lead to an arc from the distal ends of each flat wire to the distal edge 921 of outer sheath 922. As understood throughout this disclosure, the electrical sparking from that arc will generate a shock wave and a cavitation bubble, directed generally forward from the distal end of the electrode assembly 900. It can be appreciated that the current and polarity of the system can be alternated during operation of the FFC device.

[0189] The use of flat wires in electrode assembly 900 allows for a reduction in profile and cross-section of the distal end of the electrode assembly 900, thereby making the overall catheter more deliverable at a site of treatment. As arranged on opposite sides of the inner sheath 920 (at locations 180 degrees opposite each other), the flat wires 910, 912 further provide for a greater degree of flexibility in the spatial plane in which they are aligned. Any reduction of flexibility in the plane transverse to the alignment of the flat wires 910, 912 can be mitigated by using relatively short-length flat wires 910, 912 that extend a length generally equivalent to the length of the outer sheath 922. Further, the use of two flat wires in this embodiment can distribute the effects of erosion across the two flat wires 910, 912 and also across the circumference of distal edge 921 of outer sheath 922. The distribution of erosion effects can lead to a longer duration of effective shock wave and cavitation bubble generation.

[0190] FIG. 35A illustrates a perspective view of the distal end 1000 of a catheter having four lumens, more specifically using four-lumen tubing 1002 to form the distal end 1000 of the catheter. The four-lumen tubing 1002 is shown as having a braided structure to reinforce the strength of the distal end 1000, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the four-lumen tubing 1002 can be a uniform or homogeneous material, without a braided component. Within four-lumen tubing 1002, a first lumen 804 (optionally referred to as a “guidewire lumen”) can be formed to receive a guidewire 1006 therein. The guidewire 1006 can function to guide the distal end 1000 of a catheter to a treatment location, where the catheter is moved to pass over the guidewire 1006. Further within four-lumen tubing 1002 is a second lumen 1008 (optionally referred to as an “emitter lumen”), which can be formed to receive an emitter assembly 1010.

While emitter assembly 1010 resides within second lumen 1008, there can remain space between the outer surface of emitter assembly 1010 and the inner surface of second lumen 1008 where a fluid can be flowed between the two surfaces. Such fluid can be an electrically conductive fluid like saline or other fluid as disclosed herein. Injection of an electrically conductive fluid can facilitate the generation of plasma arcs at the distal end of the emitter assembly 1010 when voltage is applied to the electrodes of the emitter assembly.

**[0191]** Emitter assembly 1010 is represented in a generalized fashion, as various embodiments of emitter assemblies disclosed throughout this disclosure can be utilized in this location. FIGS. 35A-1 and 35A-2 illustrate exemplary embodiments of emitter assembly 1010 that can be used with the distal end 1000 of emitter assemblies. However, it should be appreciated that any emitter assembly disclosed herein (see, e.g., FIGS. 3, 6, 9A, 17, 23, 28A-28D, 33, 34, etc.) can be used in the illustrated location.

**[0192]** FIG. 35A-1 has an outer electrode 1012, an electrically insulating layer 1014, and an inner electrode 1016, each shown as having a generally cylindrical shape and concentric arrangement. Inner electrode 1016 can be a hypotube or a wire (either round or flat) and thus form a hollow region 1011. Emitter assembly 1010 utilizes inner electrode 1016 as a first conductor and outer electrode 1012 as a second conductor. The outer electrode 1012 is mounted circumferentially around and concentric with inner electrode 1016 to form an electrode pair. In some examples, the inner electrode 1016 and/or outer electrode 1012 are formed from an erosion-resistant metal tubing, such as stainless steel, platinum, palladium, iridium, molybdenum, tungsten, or copper tubing. The thicknesses of the inner electrode 1016 and the outer electrode 1012 may be any desired thickness, for example, between 0.002 and 0.006 inches thick. In some implementations, the thickness of the outer electrode 1012 walls may be relatively thicker than the inner electrode 1016, and in other implementations, the thickness of the inner electrode 1016 walls may be relatively thicker than the outer electrode 1012. The distal edges of the inner electrode 1016 and the outer electrode 1012 provide an arcing region between the sheaths across which current can flow to generate a shock wave.

**[0193]** Inner electrode 1016 and outer electrode 1012 are separated by electrically insulating layer 1014. The electrically insulating layer 1014 is formed from a non-conductive insulating material that prevents unintended current flow between the inner electrode 1016

and outer electrode 1012; in other words, the insulator prevents arcing between the two electrodes except as desired at the distal edges of the emitter assembly 1010. In some examples, the electrically insulating layer 1014 is formed from a non-conductive polymeric material, e.g., a polyimide, shaped into an extended tubular or cylindrical shape. In other implementations, the electrically insulating layer 1014 is formed of a ceramic or a ceramic coating or glaze on top of a polymeric material as discussed above.

**[0194]** FIG. 35A-2 has an outer electrode 1012, an electrically insulating layer 1014, and an inner wire electrode 1017, where in contrast with FIG. 35A-1 there is no void space in the center of the emitter assembly 1010. In this implementation, emitter assembly 1010 utilizes inner wire electrode 1017 as a first conductor and outer electrode 1012 as a second conductor. Inner wire electrode 1017 and outer electrode 1012 are separated by electrically insulating layer 1014. The electrically insulating layer 1014 is formed from a non-conductive insulating material that prevents unintended current flow between the inner wire electrode 1017 and outer electrode 1012; in other words, the insulator prevents arcing between the two electrodes except as desired at the distal edges of the emitter assembly 1010.

**[0195]** Four-lumen tubing 1002 further includes a third lumen 1013 (optionally referred to as an “aspiration lumen”), which can be formed to provide egress for fluid from the area surrounding the distal end 1000 of the catheter. Paired with the second lumen 1008 that can be in fluid communication with a fluid source to inject fluid into the area surrounding the distal end 1000 of the catheter (e.g., to provide an electrically conductive solution for forming plasma arcs and allowing for sparks to occur), the third lumen can be used to aspirate away or provide egress for fluids and any materials in that same area. In other words, the fluid injected into an area through second lumen 1008 can escape that area through third lumen 1013. Moreover, any tissue or lesion material dislodged from the vasculature in the area surrounding the distal end 1000 of the catheter can also be removed via third lumen 1013. Thus, the pressure within the vasculature can be maintained at a safe level by balancing the fluid(s) injected and removed from the treatment area.

**[0196]** Finally, four-lumen tubing 1002 includes a fourth lumen 1015 (optionally referred to as an “ancillary lumen” or a “flexibility lumen”) that can be provided as structurally mirroring the first lumen 1004 to allow for symmetrical flexibility of the catheter. It should be appreciated that, while in FIG. 35A, second lumen 1008 and third lumen 1013 are

illustrated as having a generally equal diameter, both of which are larger than the diameter of first lumen 1004 and fourth lumen 1015 (which respectively have generally equal diameters to each other), the diameters of any of these lumens can vary according to the needed function and implements that may be passed through those lumens. In various implementations, each of first lumen 1004, second lumen 1008, third lumen 1013, and fourth lumen 1015 can individually and separately have a diameter that ranges from 0.010 to 0.040 inches.

**[0197]** FIGS. 35B-35D illustrate the catheter distal end 1000 of FIG. 35A further including variations of a distal tip, more specifically, an atraumatic tip on the end of four-lumen tubing 1002. Atraumatic tips can be used to ensure that the functional elements of an FFC device do not inadvertently contact tissue and also to provide a set-back distance for the emitter assembly 1010 from any target tissue or lesion material. The set-back distance can provide sufficient space such that following the spark and generation of a shock wave, a vapor bubble can form in front of the emitter assembly 1010 and subsequently collapse and provide a forward-directed cavitation jetting effect. In various implementations, the set-back distance provided by an atraumatic tip can be from between 1.0 and 5.0 mm.

**[0198]** FIG. 35B illustrates the catheter distal end 1000 having a circular atraumatic tip 1018, which simply covers the circumference of the catheter distal end 1000, leaving the space directly in front of the emitter assembly 1010 unobstructed. FIG. 35C illustrates the catheter distal end 1000 having a ribbed atraumatic tip 1019, generally framing around the open ends of the lumens within the four-lumen tubing 1002, while leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The thickness of the rib structures of ribbed atraumatic tip 1019 can be optimized for allowing bubble formation while still providing for structural support of the ribbed atraumatic tip 1019 itself. FIG. 35D illustrates the catheter distal end 1000 having a flanged atraumatic tip 1020, which generally covers the circumference of the catheter distal end 1000, with flanges directed toward the longitudinal axis of the catheter, leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The flanges of flanged atraumatic tip 1020 can optionally have a triangular shape and have cutout regions (as illustrated), which may provide for easier bubble formation, but in other embodiments may have other shapes (e.g., semi-circular) and/or be solid pieces without cut-out regions.

[0199] FIG. 36A illustrates a perspective view of the distal end of a catheter having three lumens, more specifically using three-lumen tubing 1022 to form the distal end 1000 of the catheter. The three-lumen tubing 1022 is shown as having a braided structure to reinforce the strength of the distal end 1000, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the three-lumen tubing 1022 can be a uniform or homogeneous material, without a braided component. Within three-lumen tubing 1022, first lumen 1004 can be formed to receive a guidewire 1006 therein. The guidewire 1006 can function to guide the distal end 1000 of a catheter to a treatment location, where the catheter is moved to pass over the guidewire 1006. Further within three-lumen tubing 1022 is second lumen 1008, which can be formed to receive the emitter assembly 1010. As in other embodiments, while emitter assembly 1010 resides within second lumen 1008, there can remain space between the outer surface of emitter assembly 1010 and the inner surface of second lumen 1008 where a fluid can be flowed between the two structures. Such fluid can be an electrically conductive fluid like saline or other fluid as disclosed herein. Injection of an electrically conductive fluid can facilitate the generation of plasma arcs at the distal end of the emitter assembly 1010 when voltage is applied to the electrodes of the emitter assembly.

[0200] Three-lumen tubing 1022 further includes a third lumen 1013, which can be formed to provide egress for fluid from the area surrounding the distal end 1000 of the catheter. In contrast with other embodiments of a third lumen 1013, as shown in FIG. 36A, third lumen 1013 has a D-shaped profile which can provide for greater ease of aspiration. Paired with the second lumen 1008 that can be in fluid communication with a fluid source to inject fluid into the area surrounding the distal end 1000 of the catheter, the third lumen can be used to aspirate away or provide egress for fluids and any materials in that same area. In other words, the fluid injected into an area through second lumen 1008 can escape that area through third lumen 1013. Moreover, any tissue or lesion material dislodged from the vasculature in the area surrounding the distal end 1000 of the catheter can also be removed via third lumen 1013. Thus, the pressure within the vasculature can be maintained at a safe level by balancing the fluid(s) injected and removed from the treatment area. In various implementations, each of first lumen 1004, second lumen 1008, and third lumen 1013 can individually and separately have a diameter or width that ranges from 0.010 to 0.080 inches.

[0201] FIGS. 36B-36D illustrate the catheter distal end of FIG. 36A further including variations of a distal tip, particularly having an atraumatic tip. FIG. 36B illustrates the

catheter distal end 1000 having a circular atraumatic tip 1018, which simply covers the circumference of the catheter distal end 1000, leaving the space directly in front of the emitter assembly 1010 unobstructed. FIG. 36C illustrates the catheter distal end 1000 having a ribbed atraumatic tip 1019, generally framing around the open ends of the lumens within the three-lumen tubing 1022, while leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The thickness of the rib structures of ribbed atraumatic tip 1019 can be optimized for allowing bubble formation while still providing for structural support of the ribbed atraumatic tip 1019 itself. FIG. 36D illustrates the catheter distal end 1000 having a flanged atraumatic tip 1020, which generally covers the circumference of the catheter distal end 1000, with flanges directed towards the longitudinal axis of the catheter, leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The flanges of flanged atraumatic tip 1020 can optionally have a triangular shape and have cutout regions (as illustrated), which may provide for easier bubble formation, but in other embodiments may have other shapes (e.g., semi-circular, trapezoidal, etc.) and/or be solid pieces without cut-out regions.

**[0202]** FIG. 37A illustrates a perspective view the distal end of a catheter having two lumens, more specifically using two-lumen tubing 1032 to form the distal end 1000 of the catheter. The two-lumen tubing 1032 is shown as having a braided structure to reinforce the strength of the distal end 1000, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the two-lumen tubing 1032 can be a uniform or homogeneous material, without a braided component. Within two-lumen tubing 1032, first lumen 1004 can be formed to receive a guidewire 1006 therein. The guidewire 1006 can function to guide the distal end 1000 of a catheter to a treatment location, where the catheter is moved to pass over the guidewire 1006. Further within two-lumen tubing 1032 is second lumen 1008, which can be formed to receive the emitter assembly 1010. As in other embodiments, while emitter assembly 1010 resides within second lumen 1008, there can remain space between the outer surface of emitter assembly 1010 and the inner surface of second lumen 1008 where a fluid can be flowed between the two structures. Such fluid can be an electrically conductive fluid like saline or other fluid as disclosed herein. Injection of an electrically conductive fluid can facilitate the generation of plasma arcs at the distal end of the emitter assembly 1010 when voltage is applied to the electrodes of the emitter assembly. In implementations of an FFC device using a two-lumen tubing 1032, a separate aspiration channel can be used to draw off excess fluid and tissue material from within the vasculature.

[0203] FIGS. 37B-37D illustrate the catheter distal end of FIG. 37A further including variations of a distal tip, particularly having an atraumatic tip. FIG. 37B illustrates the catheter distal end 1000 having a circular atraumatic tip 1018, which simply covers the circumference of the catheter distal end 1000, leaving the space directly in front of the emitter assembly 1010 unobstructed. FIG. 37C illustrates the catheter distal end 1000 having a ribbed atraumatic tip 1019, generally framing around the open ends of the lumens within the two-lumen tubing 1032, while leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The thickness of the rib structures of ribbed atraumatic tip 1019 can be optimized for allowing bubble formation while still providing for structural support of the ribbed atraumatic tip 1019 itself. FIG. 37D illustrates the catheter distal end 1000 having a flanged atraumatic tip 1020, which generally covers the circumference of the catheter distal end 1000, with flanges directed towards the longitudinal axis of the catheter, leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The flanges of flanged atraumatic tip 1020 can optionally have a triangular shape and have cutout regions (as illustrated), which may provide for easier bubble formation, but in other embodiments may have other shapes (e.g., semi-circular, trapezoidal, etc.) and/or be solid pieces without cut-out regions.

[0204] FIG. 38A illustrates a perspective view of the distal end of a catheter having concentric components, more specifically using single-lumen tubing 1042 to form the distal end 800 of the catheter. The single-lumen tubing 1042 is shown as having a braided structure to reinforce the strength of the distal end 1000, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the single-lumen tubing 1042 can be a uniform or homogeneous material, without a braided component. Within single-lumen tubing 1042, main lumen 1004 can be formed to receive a guidewire 1006, a dedicated guidewire lumen 1007, and an electrode assembly 1010 (see, e.g., FIG. 35A-1). The guidewire 1006 can function to guide the distal end 1000 of a catheter to a treatment location, where the catheter is moved to pass over the guidewire 1006 housed within the dedicated and electrically isolated guidewire lumen 1007.

[0205] Electrode assembly 1010 can be the embodiment as shown in FIG. 35A-1, having a hollow region 1011 to accommodate guidewire lumen 1007. Guidewire lumen 1007 can be an electrical insulator formed of a polymeric material, a ceramic material, or a material coated or glazed with a ceramic covering. In some embodiments, the amount of ceramic

along the length of the guidewire lumen 1007 may only extend along a portion of the component from the distal end of the catheter in a proximal direction. In some embodiments, the portion of the guidewire lumen 807 having a ceramic component can be from 1.0 to 5.0 mm in length measured from the distal end of the catheter. In implementations of an FFC device using a single-lumen tubing 1042 embodiments, a separate aspiration channel can be used to draw off excess fluid and tissue material from within the vasculature.

**[0206]** FIGS. 38B-38D illustrate the catheter distal end of FIG. 38A further including variations of a distal tip, particularly having an atraumatic tip. FIG. 38B illustrates the catheter distal end 1000 having a circular atraumatic tip 1018, which simply covers the circumference of the catheter distal end 1000, leaving the space directly in front of the emitter assembly 1010 unobstructed. FIG. 38C illustrates the catheter distal end 1000 having a ribbed atraumatic tip 1019, generally framing around the open ends of the lumens within the tubing 1042, while leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The thickness of the rib structures of ribbed atraumatic tip 1019 can be optimized for allowing bubble formation while still providing for structural support of the ribbed atraumatic tip 1019 itself. FIG. 38D illustrates the catheter distal end 1000 having a flanged atraumatic tip 1020, which generally covers the circumference of the catheter distal end 1000, with flanges directed toward the longitudinal axis of the catheter, leaving the space directly in front of the emitter assembly 1010 generally unobstructed. The flanges of flanged atraumatic tip 1020 can optionally have a trapezoidal shape and have cutout regions (as illustrated), which may provide for easier bubble formation, but in other embodiments may have other shapes (e.g., semi-circular, triangular, etc.) and/or be solid pieces without cut-out regions.

**[0207]** FIG. 39 is an exemplary schematic of a dual-pump injection and aspiration system 1100 for use with catheter and generator systems as disclosed herein. Pump assembly 1102 includes a first pump referred to as an infusion pump 1104, which is in fluid communication with fluid source 1106 and is arranged to pump fluid to a catheter device. Fluid source 1106 can be a reservoir that provides an electrically conductive solution to the catheter device. Pump assembly 1102 further includes a second pump referred to as an aspiration pump 1108, which is in fluid communication with a waste cartridge 1110 and is arranged to pump fluid away from the catheter device. Waste cartridge 1110 can be a removable and replaceable module that collects fluid and other organic materials drawn away from the catheter.

Optionally, waste cartridge can be connected to a waste port such that the cartridge does not require frequent removal, replacement, or cleanings. In various embodiments, either or both of infusion pump 1104 and aspiration pump 1108 can be syringe pumps, reciprocating pumps, rotary pumps, peristaltic pumps, lobe pumps, radial pumps, and the like.

[0208] The dual-pump injection and aspiration system 1100 is in electrical and operational communication with the control device 1120 for the catheter, with a first motor 1121 that controls the function of the infusion pump 1104, and with a second motor 1122 that controls the function of the aspiration pump 1108. In order to generate the electrical spark at the distal end of an FFC device catheter, the electrically conductive fluid must be present at the electrodes. Accordingly, when the control device 1120 is operated to activate the FFC component of the catheter, the control device 1120 can operate the first motor 1121 to drive the infusion pump 1104 and begin delivery of electrically conductive fluid before providing voltage across the electrodes. This synchronization between the infusion pump 1104 and the operation of the FFC device results in a lead time of from 0.5 to 1.5 sec during which the first motor 1121 drives the infusion pump 1104 before voltage is delivered to the FFC device. Similarly, once activation of the FFC component of the catheter has ceased, there may remain a volume of injected fluid and also loose or debulked organic material at the site of treatment. Accordingly, when the control device 1120 ceases to deliver voltage to the FFC device, the control device 1120 can still operate the second motor 1122 to drive aspiration pump 1108 to remove such remaining excess materials. This synchronization between the aspiration pump 1108 and the operation of the FFC device results in a lag time of from 0.5 to 1.5 sec during which the second motor 1122 drives the aspiration pump 1108 after delivery of voltage to the FFC device has ceased.

[0209] During treatment with the FFC device, the flow of fluid injected into the vasculature at the treatment site must be balanced with the draw of fluid and other organic material out of the vasculature at the treatment site. In various embodiments of the present disclosure, the flow infused and subsequently removed from the region around the FFC device can be from 1.0 to 30.0 mL/min. Given the organic material that may be debulked by the FFC device at the site of treatment, it is possible that the aspiration pump 1108 will have to apply more work to maintain an exit flow equal to the injection flow provided by the infusion pump 1104; due to the presence of organic matter, the fluid being aspirated may be more viscous than the fluid injected.

[0210] In some implementations, the ratio of work done by the aspiration pump 1108 relative to the infusion pump 1104 (in other words, how much harder the second motor 1122 drives the aspiration pump 1108 relative to how hard the first motor 1121 drives the infusion pump 1104) can be a preset ratio of 1.2:1, 1.5:1, 2:1, 3:1, and the like. The infusion pump 1104 and the aspiration pump 1108 can be operated in either a coupled or a decoupled state, and their respective first motor 1121 and second motor 1122 can accordingly be controlled in a linked or an independent manner.

[0211] In other implementations, the internal diameter (“ID”) of the tubing leading out from the infusion pump 1104 and the tubing leading into the aspiration pump 1108 can be optimized to maintain a target balance of fluid pressure – for example, the tubing leading into the aspiration pump 1108 can have a greater ID than the tubing leading out from the infusion pump 1104 in order to accommodate the volume of fluid and organic matter being aspirated from a treatment site. Further, the tubing leading into the aspiration pump 1108 having a greater ID than the tubing leading out from the infusion pump 1104 can also provide for a degree of safety, reducing the risk of a vessel bursting due to the larger ID for aspiration.

[0212] In further implementations, the first motor 1121 and second motor 1122 can be adjusted in real-time to drive their respective pumps at rates appropriate to maintain a balance of injected fluid and withdrawn fluid or slurry from the vasculature. In such cases, monitoring the fluid pressure of both flows is needed, which can be accomplished by use of a first pressure sensor 1112 coupled to monitor the flow of the infusion pump 1104 and by use of a second pressure sensor 1114 coupled to monitor the flow of the aspiration pump 1108. Both the first pressure sensor 1112 and the second pressure sensor 1114 are in electronic communication with the control device 1120, providing pressure signals to allow for optimization of the function and adjustment of the controlled motors.

[0213] It can be further appreciated that the stable and consistent positioning of an FFC device and catheter within the vasculature is important to ensure therapy is applied to the correct and intended target lesion, leading to developments in anchoring and positioning structures of the catheter. Such positioning can be centering, offsetting, or angling the operative region of an FFC device.

[0214] FIGS. 40A and 40B illustrate a catheter-centering structure 1206 having radially expanding longitudinal struts 1210. The catheter-centering structure 1206 can be fit onto the

distal end 1200 of a catheter, where the distal end 1200 includes a lumen structure 1202 and an emitter end assembly 1204. As illustrated, the lumen structure 1202 can have a braided component to reinforce the strength of the distal end 1200, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the lumen structure 1202 can be a uniform or homogeneous material, without a braided component. The emitter end assembly 1204 can be any one of the lumen structures having emitter electrodes, guidewires, infusion lumens, aspiration lumens, and the like as disclosed herein (the exemplary illustration here being with the structure as shown in FIG. 36A).

**[0215]** The catheter-centering structure 1206 can include a distal cap 1208 and longitudinal struts 1210. Distal cap 1208 can be formed of a plastic, polymeric, metal, or alloy material, and can further be shaped to have an atraumatic tip. Distal cap 1208 is secured to the open end of distal end 1200, providing an anchoring point for the distal section of the longitudinal struts 1210. Distal cap 1208 can have a ring shape to allow for unobstructed operation of devices at the end of the catheter and can be secured to the distal end 1200 with an adhesive, via frictional fit, by mechanical clamping or swaging, or the like. Longitudinal struts 1210 can be formed of a plastic, polymeric, metal, or alloy material, having relatively greater flexibility than the material of distal cap 1208. In some embodiments, the longitudinal struts 1210 can be a material that has a spring force or shape memory to drive the shape of the longitudinal struts to either a straight shape or to a curved shape. The proximal sections of longitudinal struts 1210 can be connected to a translating member (not shown) at the proximal end of the catheter (i.e., located outside of a patient where an operator can articulate the translation movement) such that the longitudinal struts 1210 can be pushed or pulled relative to the position of the distal cap 1208.

**[0216]** In FIG. 40A, the longitudinal struts 1210 have a straight shape, running parallel and flat alongside the outer surface of the lumen structure 1202, and it is in this configuration that the emitter end assembly 1204 can be delivered through vasculature to a target treatment site. In FIG. 40B, the longitudinal struts 1210 have a curved shape, expanding radially away from the outer surface of the lumen structure 1202. In the expanded configuration shown in FIG. 40B, longitudinal struts 1210 can contact surrounding vessel walls of vasculature, thereby anchoring the forward-firing electrode structure of the device within a vessel. The longitudinal struts 1210 can exert force within vessel walls such that the tissue of the vessel walls is not damaged but still sufficient to prevent excessive vibration or motion of the

catheter distal end 1200 when the electrodes of the FFC device are activated and cavitation bubbles are generated. The catheter-centering structure 1206 utilizing longitudinal struts 1210 has a further potential advantage in allowing for blood flow passing between the struts during anchoring and operation of the FFC device, which may be necessary for systemic blood flow and pressure control. Following treatment or operation of the FFC device, the longitudinal struts 1210 can be returned to the flat configuration as shown in FIG. 40A for further movement within or removal from vasculature.

**[0217]** In some embodiments, a catheter-centering structure includes spaced apart longitudinal struts, as shown in FIG. 40A. In other embodiments, a catheter-centering structure includes a sleeve with a plurality of longitudinal slits that allow the structure to expand radially when contracted longitudinally.

**[0218]** FIGS. 41A and 41B illustrate a catheter-centering structure 1216 having an expandable member 1214. The catheter-centering structure 1216 can be fit onto the distal end 1200 of a catheter, where the distal end 1200 includes a lumen structure 1202 and an emitter end assembly 1204. As illustrated, the lumen structure 1202 can have a braided component to reinforce the strength of the distal end 1200, allowing for improved resilience and deliverability of the catheter within a subject. In other embodiments, the lumen structure 1202 can be a uniform or homogeneous material, without a braided component. The emitter end assembly 1204 can be any one of the lumen structures having emitter electrodes, guidewires, infusion lumens, aspiration lumens, and the like as disclosed herein (the exemplary illustration here being with the structure as shown in FIG. 37A).

**[0219]** The catheter-centering structure 1216 can include a distal cap 108, a collar 1212, and expandable member 1214 (here illustrated as an intravascular balloon). Distal cap 1208 can be formed of a plastic, polymeric, metal, or alloy material, and can further be shaped to have an atraumatic tip. Collar 1212 can be formed of similar materials as distal cap 1208, and further connects the distal end of expandable member 1214 to the distal cap 1208. Distal cap 1208 is secured to the open end of distal end 1200, providing an anchoring point for the distal section of the expandable member 1214. Distal cap 1208 can have a ring shape to allow for unobstructed operation of devices at the end of the catheter and can be secured to the distal end 1200 with an adhesive, via frictional fit, by mechanical clamping or swaging, or the like. Expandable member 1214 can be formed of a polymeric material, such as materials

used for compliant, semi-compliant, or non-compliant vasculature balloons. The proximal sections of expandable member 1214 can be connected to a fluid or gas source (not shown) at the proximal end of the catheter (i.e., located outside of a patient where an operator can control inflation and deflation) such that the expandable member 1214 can be inflated or deflated radially from the outer surface of lumen structure 1202.

**[0220]** In FIG. 41A, the expandable member 1214 is not inflated, lying flat alongside the outer surface of the lumen structure 1202, and it is in this configuration that the emitter end assembly 1204 can be delivered through vasculature to a target treatment site. In FIG. 41B, the expandable member is inflated, extending radially away from the outer surface of the lumen structure 1202. In the expanded configuration shown in FIG. 41B, the outer surface of expandable member 1214 can contact surrounding vessel walls of vasculature, thereby anchoring the forward-firing electrode structure of the device within a vessel. The expandable member 1214 can exert force within vessel walls such that the tissue of the vessel walls is not damaged but still sufficient to prevent excessive vibration or motion of the catheter distal end 1200 when the electrodes of the FFC device are activated and cavitation bubbles are generated. The catheter-centering structure 1206 utilizing an expandable member 1214 has a further potential advantage in controlling blood flow from passing between the struts, where sealing the treatment area within a vessel is necessary during treatment, during anchoring and operation of the FFC device. Following treatment or operation of the FFC device, the expandable member 1214 can be returned to the flat configuration as shown in FIG. 40A for further movement within or removal from vasculature.

**[0221]** Although the electrode assemblies and catheter devices described herein have been discussed primarily in the context of treating coronary indications, such as lesions in vasculature, the electrode assemblies and catheters herein can be used for a variety of indications. For instance, similar designs could be used for treating soft tissues, such as cancer and tumors (i.e., non-thermal ablation methods), blood clots, fibroids, cysts, organs, scar and fibrotic tissue removal, or other tissue destruction and removal. Electrode assembly and catheter designs could also be used for neurostimulation treatments, targeted drug delivery, treatments of tumors in body lumens (e.g., tumors in blood vessels, the esophagus, intestines, stomach, or vagina), wound treatment, non-surgical removal and destruction of tissue, or used in place of thermal treatments or cauterization for venous insufficiency and

fallopian ligation (i.e., for permanent female contraception). Further, the electrode assemblies and catheters described herein could also be used for tissue engineering methods, for instance, for mechanical tissue decellularization to create a bioactive scaffold in which new cells (e.g., exogenous or endogenous cells) can replace the old cells; introducing porosity to a site to improve cellular retention, cellular infiltration/migration, and diffusion of nutrients and signaling molecules to promote angiogenesis, cellular proliferation, and tissue regeneration similar to cell replacement therapy. Such tissue engineering methods may be useful for treating ischemic heart disease, fibrotic liver, fibrotic bowel, and traumatic spinal cord injury (“SCI”). For instance, for the treatment of SCI, the devices and assemblies described herein could facilitate the removal of scarred spinal cord tissue, which acts like a barrier for neuronal reconnection, before the injection of an anti-inflammatory hydrogel loaded with lentivirus to genetically engineer the spinal cord neurons to regenerate.

**[0222]** It should be noted that the elements and features of the example catheters illustrated throughout this specification and drawings may be rearranged, recombined, and modified without departing from the present invention. For instance, while this specification and drawings describe and illustrate several example electrode assemblies, the present disclosure is intended to include catheters having a variety of electrode configurations. Further, the number, placement, and spacing of the electrode pairs and assemblies can be modified without departing from the subject invention.

**[0223]** It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications, alterations, and combinations can be made by those skilled in the art without departing from the scope and spirit of the invention. Any of the variations of the various catheters disclosed herein can include features described by any other catheters or combination of catheters herein. Furthermore, any of the methods can be used with any of the catheters disclosed. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

**CLAIMS**

1. A catheter system for treating an occlusion in a body lumen, the catheter system comprising a catheter including:
  - an elongated tube and an electrode assembly;
  - the elongated tube comprising a first lumen and a second lumen;
  - the first lumen being configured to receive a guidewire;
  - the second lumen having the electrode assembly disposed therein; and
  - the electrode assembly comprising a first cylindrical electrode, an insulating layer arranged around the first cylindrical electrode, and a second cylindrical electrode arranged around the insulating layer, the first cylindrical electrode and the second cylindrical electrode being electrically connected to a power source, where when a voltage pulse is applied across the first cylindrical electrode and the second cylindrical electrode, current flows across an arcing region between the first cylindrical electrode and the second cylindrical electrode to generate one or more shock waves and one or more cavitation bubbles.
2. The catheter system of claim 1, wherein the elongated tube further comprises a third lumen, where the third lumen is configured to be an aspiration lumen.
3. The catheter system of claim 2, wherein the third lumen is D-shaped.
4. The catheter system of claim 2, wherein the elongated tube further comprises a fourth lumen, where the fourth lumen is configured to be similar in size and located within the elongated tube in a position symmetrical to the first lumen.
5. The catheter system of claim 1, wherein the insulating layer is formed of a ceramic or of a polymeric layer covered with a ceramic material.
6. The catheter system of claim 1, wherein the arcing region is located between a distal edge of the first cylindrical electrode and a distal edge of the second cylindrical electrode.
7. The catheter system of claim 1, further comprising an atraumatic tip arranged around the distal end of the catheter.

8. The catheter system of claim 7, wherein the atraumatic tip has a circumferential configuration, a ribbed configuration, or a flanged configuration.
9. The catheter system of claim 1, further comprising a dual-pump module comprising an infusion pump and an aspiration pump, wherein the second lumen is in fluid communication with the infusion pump, wherein an aspiration lumen is in fluid communication with the aspiration pump, and wherein the dual-pump module is in operational communication with the power source, such that before a cycle of voltage pulses is applied across the first cylindrical electrode and the second cylindrical electrode the infusion pump will begin operation, and such that after the cycle of voltage pulses are concluded the aspiration pump will continue to operate for a period of time.
10. A catheter system for treating an occlusion in a body lumen, the catheter system comprising a catheter comprising:
- an elongated tube;
  - a peripheral electrode disposed within the elongated tube;
  - an electrode assembly disposed within the peripheral electrode, the electrode assembly comprising an electrode layer and an insulating layer; and
  - a guidewire lumen configured to receive a guidewire and disposed within the electrode assembly;
- where the peripheral electrode and the electrode layer of the electrode assembly are each electrically connected to a power source, where when a voltage pulse is applied across the electrode layer and the peripheral electrode, current flows across an arcing region between the electrode layer and the peripheral electrode to generate one or more shock waves and one or more cavitation bubbles.
11. The catheter of claim 10, wherein the peripheral electrode is a cylindrical electrode sheath.
12. The catheter of claim 10, wherein the insulating layer is formed of a ceramic or a portion of the insulating layer is covered with a ceramic material.

13. The catheter of claim 10, wherein a portion of the guidewire lumen is formed of a ceramic or a portion of the guidewire lumen is covered with a ceramic material.
14. The catheter of claim 10, further comprising an atraumatic tip arranged around the distal end of the catheter.
15. The catheter of claim 14, wherein the atraumatic tip has a circumferential configuration, a ribbed configuration, or a flanged configuration.
16. The catheter system of claim 10, further comprising a dual-pump module comprising an infusion pump and an aspiration pump, wherein a first lumen is in fluid communication with the infusion pump, wherein a second lumen is in fluid communication with the aspiration pump, and wherein the dual-pump module is in operational communication with the power source, such that before a cycle of voltage pulses is applied across the electrode layer and the peripheral electrode the infusion pump will begin operation, and such that after the cycle of voltage pulses are concluded the aspiration pump will continue to operate for a period of time.
17. An electrode assembly for treating an occlusion in a body lumen, the electrode assembly comprising:
- an outer sheath that is electrically conductive;
  - an insulating layer disposed within the outer sheath;
  - an inner sheath disposed within the insulating layer;
  - a first flat wire disposed between the inner sheath and the insulating layer; and
  - a second flat wire disposed between the inner sheath and the insulating layer at a position 180° relative to the first flat wire, where the first flat wire, the second flat wire, and the outer sheath are each electrically connected to a power source, where when a voltage pulse is applied across either or both of the first flat wire and the second flat wire to the outer sheath, current flows across an arcing region between the flat wires and the outer sheath to generate shock waves and cavitation bubbles.
18. A catheter-centering structure comprising:

a distal cap configured to fit onto a distal end of a catheter device, the distal cap having a ring shape; and

a radially-expanding structure coupled to the distal cap, extending in a proximal direction along the length of the catheter device.

19. The catheter-centering structure of claim 18, wherein the radially-expanding structure comprises a plurality of longitudinal struts connected to a mechanism that can linearly translate the longitudinal struts along the length of the catheter such that the plurality of longitudinal struts are configured to expand and retract in a radial direction relative to the longitudinal axis of the catheter.

20. The catheter-centering structure of claim 18, wherein the radially-expanding structure is a balloon in fluid communication with a fluid source, wherein the balloon is configured to inflate and deflate in a radial direction relative to the longitudinal axis of the catheter.