(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2018 (27.12.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/236551 A1

(51) International Patent Classification:
A61B 17/22 (2006.01)

(21) International Application Number:
PCT/US2018/034855

(22) International Filing Date:
29 May 2018 (29.05.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/521,994 19 June 2017 (19.06.2017) US

(71) Applicant: **SHOCKWAVE MEDICAL, INC.** [US/US]; 48501 Warm Springs Boulevard, Suite 108, Fremont, CA 94539 (US).

(72) Inventor: **NGUYEN, Hoa, D.**; c/o Shockwave Medical, Inc., 48501 Warm Springs Boulevard, Suite 108, Fremont, CA 94539 (US).

(74) Agent: **STALLMAN, Michael, A.**; Morrison & Foerster LLP, 425 Market Street, San Francisco, CA 94105 (US).

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

WO 2018/236551 A1

(54) Title: DEVICE AND METHOD FOR GENERATING FORWARD DIRECTED SHOCK WAVES

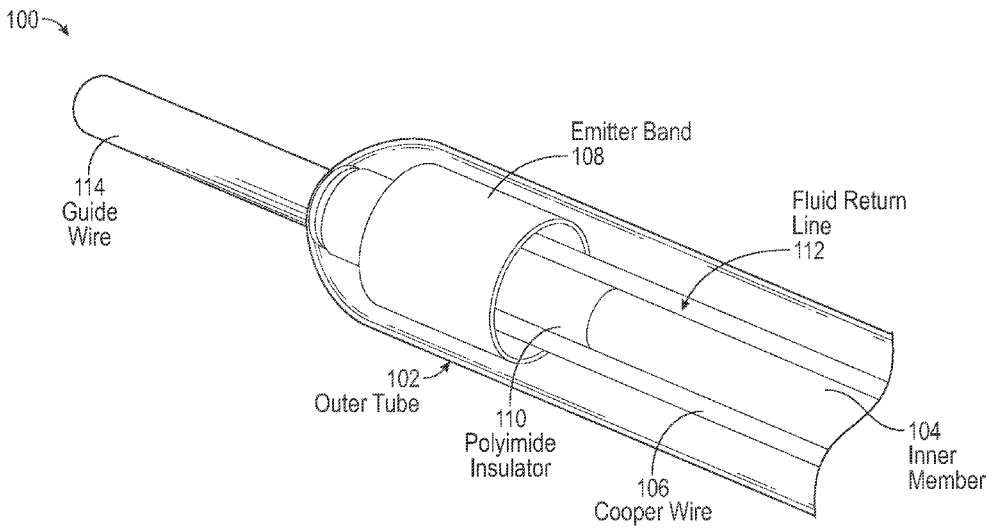

FIG. 1

(57) Abstract: Described herein is a shock wave device (100) for the treatment of vascular occlusions. The shock wave device includes an outer covering (102) and an inner member connected at a distal end of the device. First and second conductive wires (106) extend along the length of the device within the volume between the outer covering and the inner member. A conductive emitter band (108) circumscribes the ends of the first and second wires to form a first spark gap between the end of the first wire and the emitter band and a second spark gap between the end of the second wire and the emitter band. When the volume is filled with conductive fluid and a high voltage pulse is applied across the first and second wires, first and second shock waves can be initiated from the first and second spark gaps.

[Continued on next page]

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

Published:

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

DEVICE AND METHOD FOR GENERATING FORWARD DIRECTED SHOCK WAVES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to provisional application Serial No. 62/521,994, filed June 19, 2017, the entire disclosure of which is incorporated by reference.

FIELD

[0002] The present disclosure relates generally to the generation of shock waves, and, more specifically, to the generation of shock waves within vascular or urinary structures.

BACKGROUND

[0003] The subject invention relates to treating calcified lesions in blood vessels, or obstructions in other vessels, such as kidney stones in ureters. One common approach to addressing this issue is balloon angioplasty. In this type of procedure, a catheter, carrying a balloon, is advanced into the vasculature along a guide wire until the balloon is aligned with the occlusion. The balloon is then pressurized in a manner to reduce or break the occlusion. When inflated to high pressures, angioplasty balloons can have a specific maximum diameter to which they will expand. Generally, the opening in the vessel under a concentric lesion will typically be much smaller. As the pressure is increased to open the passage way for blood flow, the balloon will be confined to the size of the opening in the calcified lesion (before it is broken open). As the pressure builds, a tremendous amount of energy is stored in the balloon until the calcified lesion breaks or cracks. That energy is then released and results in the rapid expansion of the balloon to its maximum dimension and may stress and injure the vessel walls.

[0004] Recently, the assignee herein has developed a system and method for breaking up calcium deposits in, for example, arteries and veins. Such a system is described, for example in U.S. Patent Nos. 8,956,371 and 8,888,788, both of which are incorporated herein by reference. Embodiments described therein include a catheter having balloon, such as an angioplasty balloon, at the distal end thereof arranged to be inflated with a fluid. Disposed within the balloon is a shock wave generator that may take the form of, for example, a pair of electrodes, which are coupled to a high voltage source at the proximal end of the catheter through a connector. When

the balloon is placed adjacent a calcified region of a vein or artery and a high voltage pulse is applied across the electrodes, a shock wave is formed that propagates through the fluid and impinges upon the wall of the balloon and the calcified region. Repeated pulses break up the calcium without damaging surrounding soft tissue. A similar technique can be used to treat kidney stones in the ureter. The shock waves generated by such systems typically propagate in all directions from the electrodes.

[0005] Arteries are sometimes totally occluded with a thrombus, plaque, fibrous plaque, and/or calcium deposits. When this condition is present, the physician typically first passes a soft narrow guide wire down the artery and through the occluded area. The guide wire may be as small as 0.014 inches in diameter and usually has a soft flexible tip to help avoid penetrating the artery wall in artery corners. The angioplasty balloon is then fed down the artery on the guide wire to the desired location of the blockage. Unfortunately, many times the physician is faced with a chronic occlusion which is not passable with a guide wire. This occurs when the occlusion is so tight and solid that the soft guide wire cannot penetrate through it. Stiffer guide wires may be used in these cases, but they must be used very carefully because they can easily penetrate the artery wall when forced against the chronic total occlusion.

[0006] Guide wires have been proposed that utilize radio frequency energy to open the occlusion. Unfortunately, the heat generated by the radio frequency energy to open the occlusion is intense and can damage the walls of the artery or vessel. The radio frequency energy produces a plasma which burns anything in its path. Hence, such systems must be used carefully and must be continuously moved without pause to avoid artery or vessel damage. Moreover, such an approach requires a centering mechanism that keeps the plasma centered in the artery or vessel. Such centering is difficult to achieve, especially in the corners and bends of the arteries or veins.

[0007] More recently, the assignee herein has proposed providing an electrode on the tip of a guide wire for generating forward directed shock waves to open a total occlusion enough to permit a guide wire and angioplasty balloon to be fed there through. In addition, such system avoids damage to the artery or vessel. This approach is disclosed in U.S. Patent Publication No. 2015/0320432, also incorporated herein by reference.

[0008] The subject invention relates to yet another alternative approach for generating forward directed shock waves that can be integrated with an angioplasty balloon. This approach can also be used in conjunction with other types of shock wave electrodes.

BRIEF SUMMARY

[0009] Described herein are shock wave devices and methods for the treatment of plaques or obstructions in vessels. The vessels may include blood vessels in a patient's vascular system or ureters in the patient's urinary system. One example of a shock wave device includes an outer covering and an inner member forming a guide wire lumen. The outer covering and inner member are connected at a distal end of the device, and a volume between the outer covering and the inner member is fillable with a conductive fluid. A first conductive wire and a second conductive wire extend along the length of the device within the volume between the outer covering and the inner member and end proximate to the distal end of the device. The lengths of the first and second wires are insulated and the ends of the first and second wires are uninsulated. A conductive emitter band circumscribes the ends of the first and second wires and forms a first spark gap between the end of the first wire and the emitter band and a second spark gap between the end of the second wire and the emitter band. When the volume is filled with the conductive fluid and a high voltage pulse is applied across the first and second wires, first and second shock waves will be initiated from the first and second spark gaps.

[0010] In some examples, the device further includes an insulting sheath circumscribing the inner member in a region proximate to the ends of the first and second wires. In some variations, the outer covering comprises an angioplasty balloon. In some examples, the emitter band is a cylindrical tube that extends closer to the distal end of the device than the first and second wires. In some examples, the device further includes a fluid pump connected to a proximal end of the device configured to provide conductive fluid to the volume between the outer covering and the inner member, and a fluid return line having an inlet proximate to the distal end of the device and configured to remove the conductive fluid from the volume between the outer covering and the inner member. The fluid pump and fluid return line may be configured to circulate the conductive fluid under pressure within the volume between the outer covering and the inner member. In some examples, the device further includes a pressure relief valve at an outlet of the fluid return line.

[0011] In some examples, the device further includes a third conductive wire and a fourth conductive wire extending along the length of the device within the volume between the outer covering and the inner member and ending proximate to the distal end of the device. The lengths of the third and fourth wires may be insulated and the ends of the third and fourth wires may be uninsulated. The conductive emitter band may circumscribe the ends of the third and fourth wires and form a third spark gap between the end of the third wire and the emitter band and a fourth spark gap between the end of the fourth wire and the emitter band. When the volume is filled with the conductive fluid and a second high voltage pulse is applied across the third and fourth wires, third and fourth shock waves may be initiated from the third and fourth spark gaps. In some examples, the conductive fluid comprises saline or a combination of saline and a contrasting agent. In some examples, the device further includes one or more secondary emitter bands disposed at a medial location of the device and configured to initiate at least a third shock wave from the medial location.

[0012] One example of a method includes introducing a shock wave device into a vessel, advancing the shock wave device within the vessel such that a distal end of the shock wave device faces a first treatment region, and applying a high voltage pulse across first and second wires to initiate first and second shock waves from first and second spark gaps formed between the first and second wires and an emitter band. The positioning of the first and second wires and the emitter band results in the first and second shock waves propagating in a substantially forward direction.

[0013] In some examples, the method further includes, after the applying step, advancing the shock wave device further within the vessel such that an angioplasty balloon is aligned with the first treatment region or second treatment region, and inflating the angioplasty balloon. In some examples, the method further includes, after the applying step, advancing the shock wave device further within the vessel such that one or more secondary emitter bands at a medial location of the device are aligned with the first treatment region or a second treatment region, and initiating third shock waves from the secondary emitter bands. In some examples, the vessel is a blood vessel of a patient's vascular system or a ureter of the patient's urinary system. In some examples, first treatment region includes a chronic total occlusion (CTO), circumferential calcium, or a kidney stone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 depicts a cutaway perspective view of an example shock wave device for generating forward directed shock waves, in accordance with some embodiments.

[0015] FIG. 2 depicts a side sectional view of an example shock wave device for generating forward directed shock waves, in accordance with some embodiments.

[0016] FIG. 3 depicts a front sectional view of an example shock wave device for generating forward directed shock waves, in accordance with some embodiments.

[0017] FIG. 4 depicts an extended side sectional view of an example shock wave device for generating forward directed shock waves, in accordance with some embodiments.

[0018] FIG. 5 depicts a side view of an extended length of an example shock wave device, in accordance with some embodiments.

[0019] FIG. 6 is a flowchart representation of an exemplary method for generating forward directed shock waves.

DETAILED DESCRIPTION

[0020] Described herein are devices, systems, and methods for generating shock waves that propagate in a substantially forward direction to treat vascular diseases, such as chronic total occlusion (CTO) or circumferential calcium, or to treat urinary diseases, such as concretions or kidney stones in the ureter. In accordance with the present disclosure, a shock wave device includes an outer covering and an inner member forming a guide wire lumen. The outer covering and inner member are connected at a distal end of the device. A first conductive wire and a second conductive wire extend along the length of the device within the volume between the outer covering and the inner member, and end proximate to the distal end of the device. A conductive emitter band circumscribes the ends of the first and second wires to form a first spark gap between the end of the first wire and the emitter band and a second spark gap between the end of the second wire and the emitter band.

[0021] When the volume is filled with conductive fluid (e.g., saline and/or imaging contrast agent) and a high voltage pulse is applied across the first and second wires, first and second

shock waves can be initiated from the first and second spark gaps. The voltage may range from 100 to 10,000 volts for various pulse durations. This high voltage may generate a gas bubble at the end surface of a wire and cause a plasma arc of electric current to traverse the bubble to the emitter band and create a rapidly expanding and collapsing bubble, which in turn creates a mechanical shock wave at the distal end of the device. The positioning of the emitter band in relation to the end of the wire may result in the shock wave propagating out in a substantially forward direction toward the distal end of the device. The shock waves may be mechanically conducted through the conductive fluid and through the outer covering in the substantially forward direction to apply mechanical force or pressure to impinge on an occlusion or calcium facing the distal end of the device. The size, rate of expansion and collapse of the bubble (and therefore, the magnitude, duration, and distribution of the mechanical force) may vary based on the magnitude and duration of the voltage pulse, as well as the distance between the end of the wire and the emitter band. The emitter band may be made of materials that can withstand high voltage levels and intense mechanical forces (e.g., about 1000-2000 psi or 68-136 ATM in a few microseconds) that are generated during use. For example, the emitter band may be made of stainless steel, tungsten, nickel, iron, steel, and the like.

[0022] FIG. 1 depicts a cutaway perspective view of an example shock wave device 100 for generating forward directed shock waves, in accordance with some embodiments. The device 100 includes an outer covering 102 (e.g., a flexible outer tube) and an inner member 104 that forms a lumen for a guide wire 114. The outer covering 102 and inner member 104 are connected at a distal end of the device 100, where the guide wire 114 may exit the device 100. The interior volume of the device 100 between the outer covering 102 and inner member 104 may be filled with a conductive fluid (e.g., saline and/or imaging contrast agent). Two insulated conductive wires 106 (e.g., insulated copper wires) extend along the length of the device 100 within the interior volume. While only one wire 106 is visible in FIG. 1, the second wire 106 extends along an opposing side of the inner member 104, as shown in FIGS. 2-3. The two wires 106 end near the distal end of the device 100 where the guide wire exits the lumen formed by the inner member 104. The ends of the two wires 106 include uninsulated portions (not shown). For example, the flat circular surfaces at the ends of the two wires may be uninsulated. An emitter band 108 is positioned within the interior volume around the ends of the two wires 106. The emitter band 108 may be a conductive cylinder with a diameter larger than the total diameter of the inner member 104 and the two wires 106 combined, such that the emitter band circumscribes

the ends of the two wires 106 without contacting the wires, as shown in FIG. 2. An insulating sheath 110 (e.g., a polyimide insulator) may be positioned around the inner member 104 to separate the two wires 106 from the inner member 104 and to further insulate the two wires 106 from one another. In this way, the preferred conductive path between the two wires 106 is through the emitter band 108. When a high voltage pulse is applied across the two wires 106, an electrical current will arc from the uninsulated end of one wire to the emitter band 108, and then arc again from the emitter band 108 to the uninsulated end of the other wire. As a result, shock waves are initiated at the distal end of the shock wave device 100, which then propagate through the conductive fluid and the wall of the outer covering 102 to impinge on an occlusion or calcification.

[0023] In some embodiments, the device 100 may include a second pair of wires (not shown) offset from wires 106 by 90 degrees. For example, if wires 106 are positioned at 0 and 180 degrees, the second pair of wires may be positioned at 90 and 270 degrees. The second pair of wires also end near the distal end of the device 100 and include uninsulated portions at their ends. The emitter band 108 circumscribes the ends of the second pair of wires as well. A separate high voltage pulse may be applied across the second pair of wires to generate a second pair of arcs with the emitter band 108. As a result, a second set of shock waves are initiated from the distal end of the device 100. The first pair of wires 106 and the second pair of wires may be activated alternately, which may improve the effectiveness of the device 100 by further spreading the shock waves.

[0024] A fluid return line 112 with an inlet near the distal end of the device 100 draws in the conductive fluid from the interior volume, while a fluid pump (not shown) pumps in additional conductive fluid via a fluid inlet (shown in FIG. 5) at a proximal end of the device 100. In this way, the fluid return line 112 and fluid pump circulate the conductive fluid under pressure within the interior volume. Circulation of the conductive fluid may prevent bubbles created by the device 100 from becoming trapped within the distal tip of the device 100 due to the limited space within the tip. Furthermore, circulation of the conductive fluid may aid in cooling the device 100 and treatment site.

[0025] FIG. 2 depicts a side sectional view of an example shock wave device 100 for generating forward directed shock waves, in accordance with some embodiments. As shown in

FIG. 2, the two conductive wires 106 (e.g., polyimide-insulated copper wires) are positioned along opposing sides of the inner member 104. Each of the wires 106 include uninsulated wire ends 202. The insulating sheath 110 (e.g., polyimide tubing) is positioned in a region proximate to the uninsulated wire ends 202 to decrease the likelihood of electrical current arcing from one wire end to the other. The emitter band 108 is positioned with a forward edge closer to the distal end of the device 100 than the wire ends 202, such that two spark gaps are formed between each of the wire ends 202 and the emitter band 108. The positioning of the wire ends 202, insulating sheath 110, and emitter band 108 makes it so that when a high voltage pulse is applied across the two wires 106, an electrical current will arc from the uninsulated end of one wire to the emitter band 108, and then arc again from the emitter band 108 to the uninsulated end of the other wire. As a result, shock waves are initiated at the distal end of the shock wave device 100, which then propagate through the conductive fluid and the wall of the outer covering 102 to impinge on an occlusion or calcification. The positioning of the emitter band 108 closer to the distal end of the device than the wire ends 202 helps to encourage the shock waves to propagate in a substantially forward direction (e.g., longitudinally out of the distal end of the device 100). Shock waves may be generated repeatedly, as may be desirable by the practitioner to treat a region of vasculature.

[0026] FIG. 3 depicts a front sectional view of an example shock wave device 100 for generating forward directed shock waves, in accordance with some embodiments. As shown in FIG. 3, the emitter band 108 circumscribes the two conductive wires 106 (e.g., insulated copper wires) and the fluid return line 112. The fluid return line 112 includes an inlet that draws in conductive fluid from the interior volume of the device to allow the conductive fluid to be circulated within the distal end of the device 100.

[0027] FIG. 4 depicts an extended side sectional view of an example shock wave device 100 for generating forward directed shock waves, in accordance with some embodiments. As shown in FIG. 4, in some embodiments, the outer covering of the device 100 includes an angioplasty balloon 402. The balloon 402 may be inflated by pumping additional fluid into the interior volume of the device. The balloon 402 may be inflated before or after applying shock waves to a treatment region. For example, in some embodiments, after forward directed shock waves are initiated using the emitter band 108 at the distal end of the device 100 to break apart an occlusion, the device 100 is advanced further into a patient's vascular, and the balloon 402 is inflated in the region of the occlusion to further treat the region.

[0028] In some embodiments, the shock wave device 100 may include secondary emitter bands 404 located in a medial location of the device 100. The device 100 shown in FIG. 4 includes two secondary emitter bands 404, but various numbers of secondary bands 404 may be used. For example, in some embodiments, the device 100 may include a single secondary emitter band 404. In other embodiments, the device 100 may include five or more secondary emitter bands 404. The secondary emitter bands 404 may generate shock waves using a variety of techniques. For example, the secondary emitter bands 404 may generate shock waves using low-profile or coplanar electrodes, such as those described in U.S. Patent Number 8,888,788 and U.S. Application Number 15/346,132, which are hereby incorporated by reference in their entireties. The shock waves may radiate in a substantially radial direction from the medial location of the secondary emitter bands 404. In some embodiments, the secondary emitter bands 404 may initiate shock waves independently of the emitter band 108 at the distal end of the device 100. For example, in some embodiments, after forward directed shock waves are initiated using the emitter band 108 at the distal end of the device 100 to break apart an occlusion, the device 100 is advanced further into a patient's vascular until the medial location of a secondary emitter band 404 is aligned with the region of the occlusion. Then additional shock waves may be initiated from the secondary emitter band 404 to further treat the region. In order to permit independent operation, additional conductive wires may be provided between the high voltage source and the second emitter bands 404.

[0029] In some embodiments, forward directed shock waves from the emitter band 108, radial directed shock waves from the secondary emitter bands 404, and inflation of the angioplasty balloon 402 may be utilized in various sequences and combinations to treat plaques or obstructions in vessels. The vessels may include blood vessels in a patient's vascular system or ureters in the patient's urinary system.

[0030] FIG. 5 depicts a side view of an extended length of an example shock wave device 100, in accordance with some embodiments. The shock wave device 100 may be in communication with a fluid source and fluid pump (not shown) that introduces conductive fluid into an interior volume of the device 100 via a fluid inlet 502. The fluid pump may fill the interior volume with fluid to a certain pressure. The conductive fluid may be circulated within the interior volume of the device 100 by drawing fluid into the fluid return line shown in FIGS. 1 and 3, and then dispelling it through a waste outlet 504. The waste outlet 504 may include a pressure relief valve

to maintain the fluid pressure within the interior volume of the device while the conductive fluid is circulated. Circulation of the conductive fluid may prevent bubbles created by the device 100 from becoming trapped within the distal tip of the device 100 due to the limited space within the tip. Trapped bubbles may block subsequent shock waves from propagating from the device 100, thus it is beneficial to prevent their build-up. In some embodiments, the waste outlet 504 may be connected to the fluid source so that the fluid pump recirculates the waste fluid.

[0031] FIG. 6 is a flowchart representation of an exemplary method for generating forward directed shock waves. As depicted in FIG. 6, a shock wave device is introduced into a vessel (602). The vessel may include blood vessels in a patient's vascular system or ureters in the patient's urinary system. The shock wave device may be the device 100 described in reference to FIGS. 1-5. The shock wave device is advanced within the vessel such that a distal end of the device faces a first treatment region (604). The first treatment region may include a chronic total occlusion (CTO), circumferential calcium, a kidney stone, or other obstructions or concretions. Once the distal end of the shock wave device is facing the first treatment region, a high voltage pulse is applied across first and second wires to initiate first and second shock waves from first and second spark gaps formed between the first and second wires and an emitter band (606). Due to the positioning of the first and second wires and the emitter band, the first and second shock waves propagate in a substantially forward direction out of the shock wave device to impinge on the occlusion or calcium in the first treatment area. In some embodiments, the shock wave device may then be advanced further within the vessel such that an angioplasty balloon is aligned with the first treatment region or with a second treatment region (608). The angioplasty balloon may then be inflated in the first or second treatment regions (610). In this way, conventional angioplasty balloon treatments may be applied to treat one or more treatment regions after the shock wave treatments are applied. Alternatively or in addition, in some embodiments, the shock wave device may be advanced further within the vessel such that a secondary emitter band at a medial location of the device is aligned with the first treatment region or with a second treatment region (612). Third shock waves may then be initiated from the secondary emitter band to apply additional shock wave treatment to the first or second treatment areas (614). Steps 604-614 may be carried out in various sequences or combinations, and repeated as necessary, when appropriate to treat the patient.

[0032] While this invention has been particularly shown and described with references to embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention. For all of the embodiments described above, the steps of the methods need not be performed sequentially.

CLAIMS

What is claimed is:

1. A shock wave device, comprising:

an outer covering;

an inner member, wherein the outer covering and inner member are connected at a distal end of the device, and wherein a volume between the outer covering and the inner member is fillable with a conductive fluid;

a first conductive wire and a second conductive wire extending along the length of the device within the volume between the outer covering and the inner member and ending proximate to the distal end of the device, wherein the lengths of the first and second wires are insulated and wherein there is an uninsulated portion on each of the first and second wires near the distal end thereof; and

a conductive emitter band circumscribing the ends of the first and second wires and forming a first spark gap between the end of the first wire and the emitter band and a second spark gap between the end of the second wire and the emitter band, wherein when the volume is filled with the conductive fluid and a high voltage pulse is applied across the first and second wires, first and second shock waves will be initiated from the first and second spark gaps.

2. The device of claim 1, further comprising:

an insulting sheath circumscribing the inner member in a region proximate to the ends of the first and second wires.

3. The device of claim 1, wherein the outer covering comprises an angioplasty balloon.

4. The device of claim 1, wherein the emitter band is a cylindrical tube that extends closer to the distal end of the device than the ends of first and second wires.

5. The device of claim 1, further comprising:

a fluid pump connected to a proximal end of the device configured to provide conductive fluid to the volume between the outer covering and the inner member; and

a fluid return line having an inlet proximate to the distal end of the device and configured to remove the conductive fluid from the volume between the outer covering and the inner member,

wherein the fluid pump and fluid return line are configured to circulate the conductive fluid under pressure within the volume between the outer covering and the inner member.

6. The device of claim 5, further comprising:

a pressure relief valve at an outlet of the fluid return line.

7. The device of claim 1, further comprising:

a third conductive wire and a fourth conductive wire extending along the length of the device within the volume between the outer covering and the inner member and ending proximate to the distal end of the device, wherein the lengths of the third and fourth wires are insulated and wherein there is an uninsulated portion on each of the third and fourth wires near the distal end thereof; and

wherein the conductive emitter band circumscribes the ends of the third and fourth wires and forms a third spark gap between the end of the third wire and the emitter band and a fourth spark gap between the end of the fourth wire and the emitter band, wherein when the volume is filled with the conductive fluid and a second high voltage pulse is applied across the third and fourth wires, third and fourth shock waves will be initiated from the third and fourth spark gaps.

8. The device of claim 1, wherein the conductive fluid comprises saline or a combination of saline and a contrasting agent.

9. The device of claim 1, further comprising:

one or more secondary emitter bands disposed at a medial location of the device and configured to initiate third shock waves from the medial location.

10. The device claim 1, wherein the inner member includes a guide wire lumen.

11. A method for treating vascular plaques, comprising:

introducing a shock wave device into a patient's vasculature, the shock wave device comprising:

an outer covering;

an inner member, wherein the outer covering and inner member are connected at a distal end of the device, and wherein a volume between the outer covering and the inner member is filled with a conductive fluid;

a first conductive wire and a second conductive wire extending along the length of the device within the volume between the outer covering and the inner member and ending proximate to the distal end of the device, wherein the lengths of the first and second wires are insulated and wherein there is an uninsulated portion on each of the first and second wires near the distal end thereof;

a conductive emitter band circumscribing the ends of the first and second wires and forming a first spark gap between the end of the first wire and the emitter band and a second spark gap between the end of the second wire and the emitter band;

advancing the shock wave device within the vasculature such that the distal end of the shock wave device faces a first treatment region; and

applying a high voltage pulse across the first and second wires to initiate first and second shock waves from the first and second spark gaps.

12. The method of claim 11, wherein the outer covering comprises an angioplasty balloon and the method further comprises:

after the applying step, advancing the shock wave device further within the vascular such that the angioplasty balloon is aligned with the first treatment region; and

inflating the angioplasty balloon.

13. The method of claim 11, wherein the outer covering comprises an angioplasty balloon, the method further comprising:

after the applying step, advancing the shock wave device further within the vascular such that the angioplasty balloon is aligned with a second treatment region; and

inflating the angioplasty balloon.

14. The method of claim 11, wherein the shock wave device further comprises one or more secondary emitter bands disposed at a medial location of the device, the method further comprising:

after the applying step, advancing the shock wave device further within the vascular such that the medial location of the one or more secondary emitter bands is aligned with the first treatment region; and

initiating third shock waves from the one or more secondary emitter bands.

15. The method of claim 11, wherein the shock wave device further comprises one or more secondary emitter bands disposed at a medial location of the device, the method further comprising:

after the applying step, advancing the shock wave device further within the vascular such that the medial location of the one or more secondary emitter bands is aligned with a second treatment region; and

initiating third shock waves from the one or more secondary emitter bands.

16. The method of claim 11, wherein the vessel is a blood vessel of a patient's vascular system or a ureter of the patient's urinary system.

17. The method of claim 11, wherein first treatment region includes a chronic total occlusion (CTO), circumferential calcium, or a kidney stone.

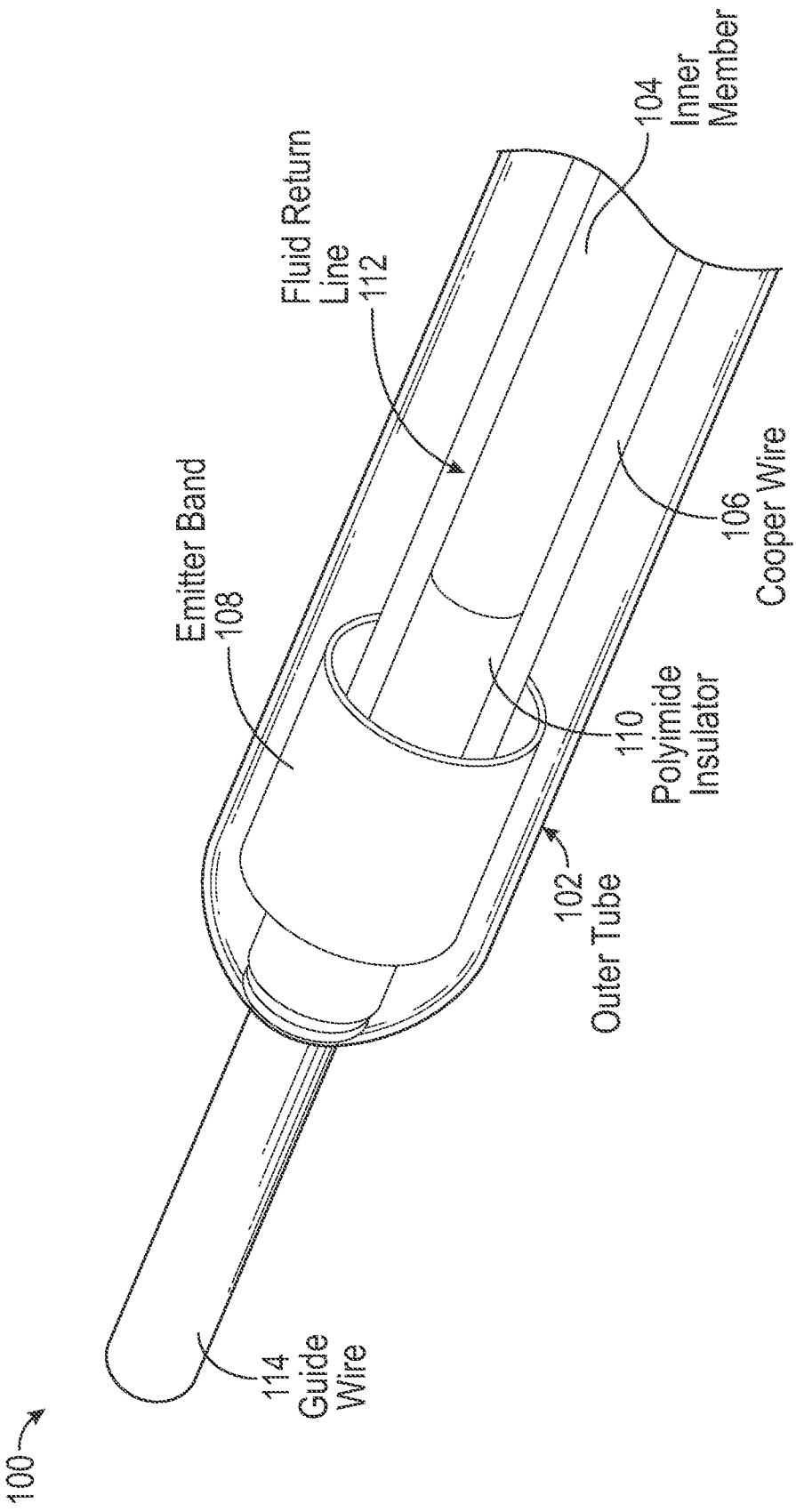
100
114
Guide
Wire
102
Outer Tube
110
Polyimide
Insulator
106
Cooper Wire
104
Inner
Member
Fluid Return
Line
112
Emitter Band
108

FIG. 1

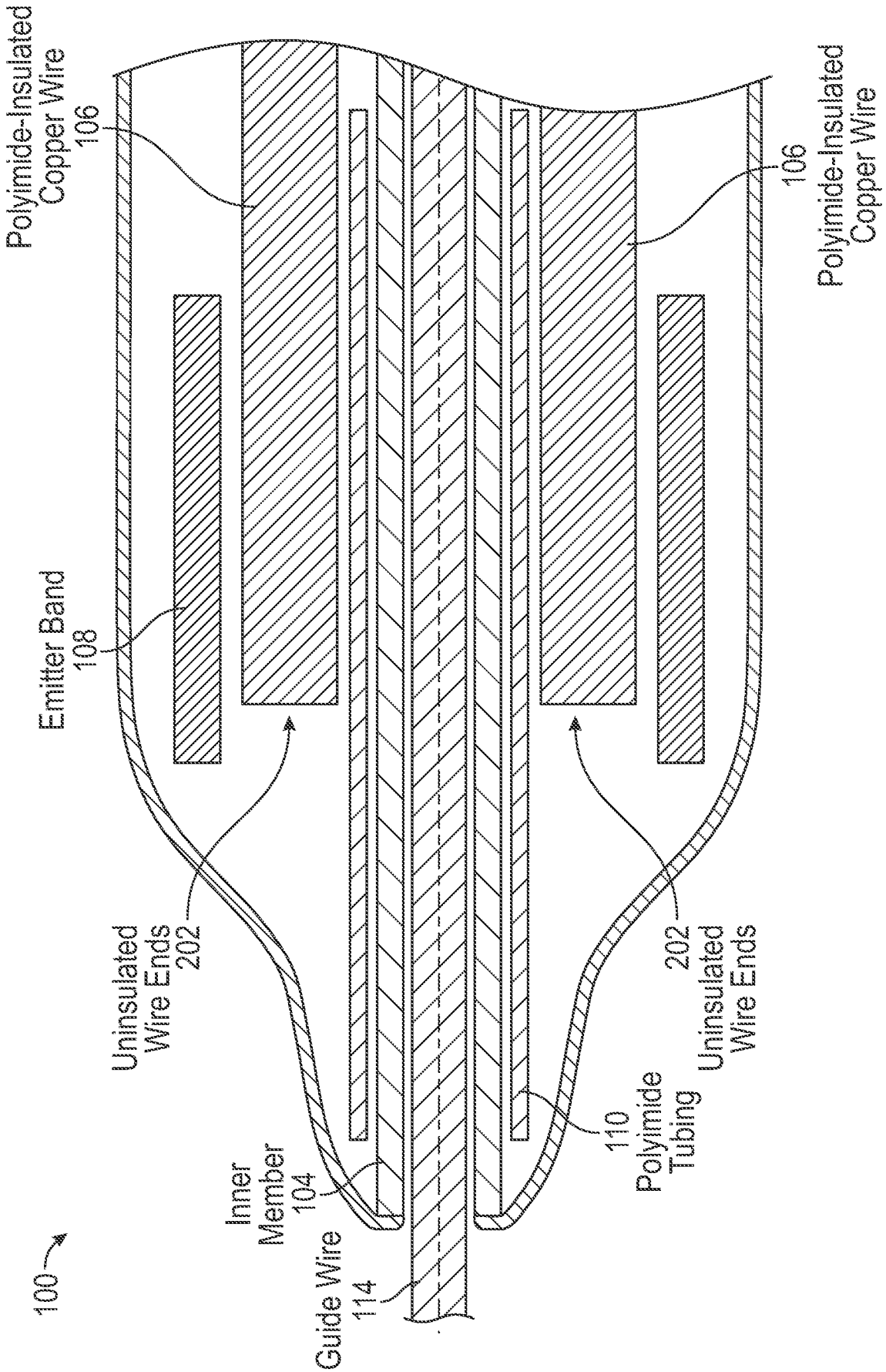
Polyimide-Insulated Copper Wire
106
Emitter Band
108
Uninsulated Wire Ends
202
Inner Member
104
Guide Wire
114
100
110
Polyimide Tubing
202
Uninsulated Wire Ends
106
Polyimide-Insulated Copper Wire

FIG. 2

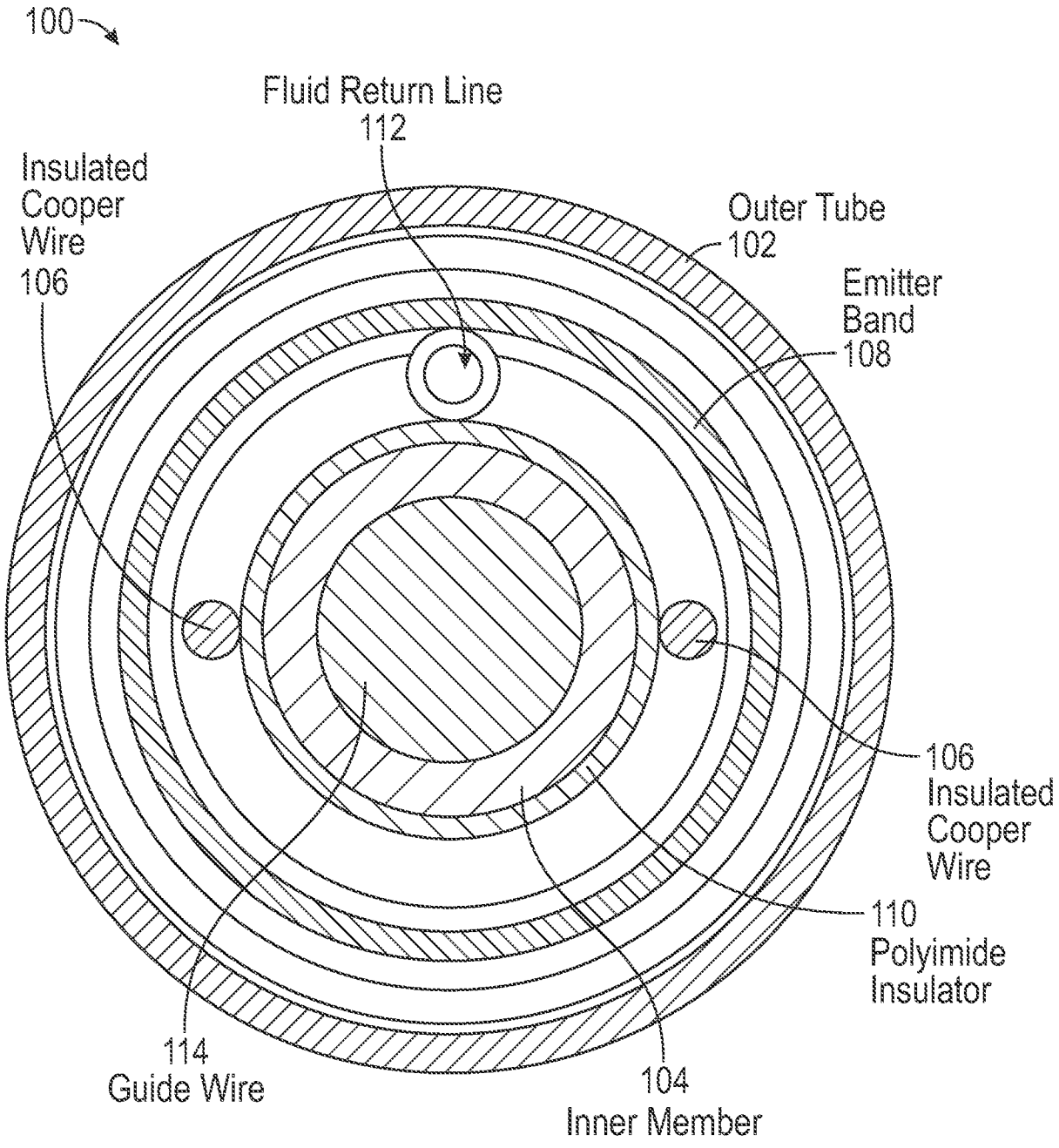
100
Fluid Return Line
112
Insulated
Cooper
Wire
106
Outer Tube
102
Emitter
Band
108
106
Insulated
Cooper
Wire
110
Polyimide
Insulator
114
Guide Wire
104
Inner Member

FIG. 3

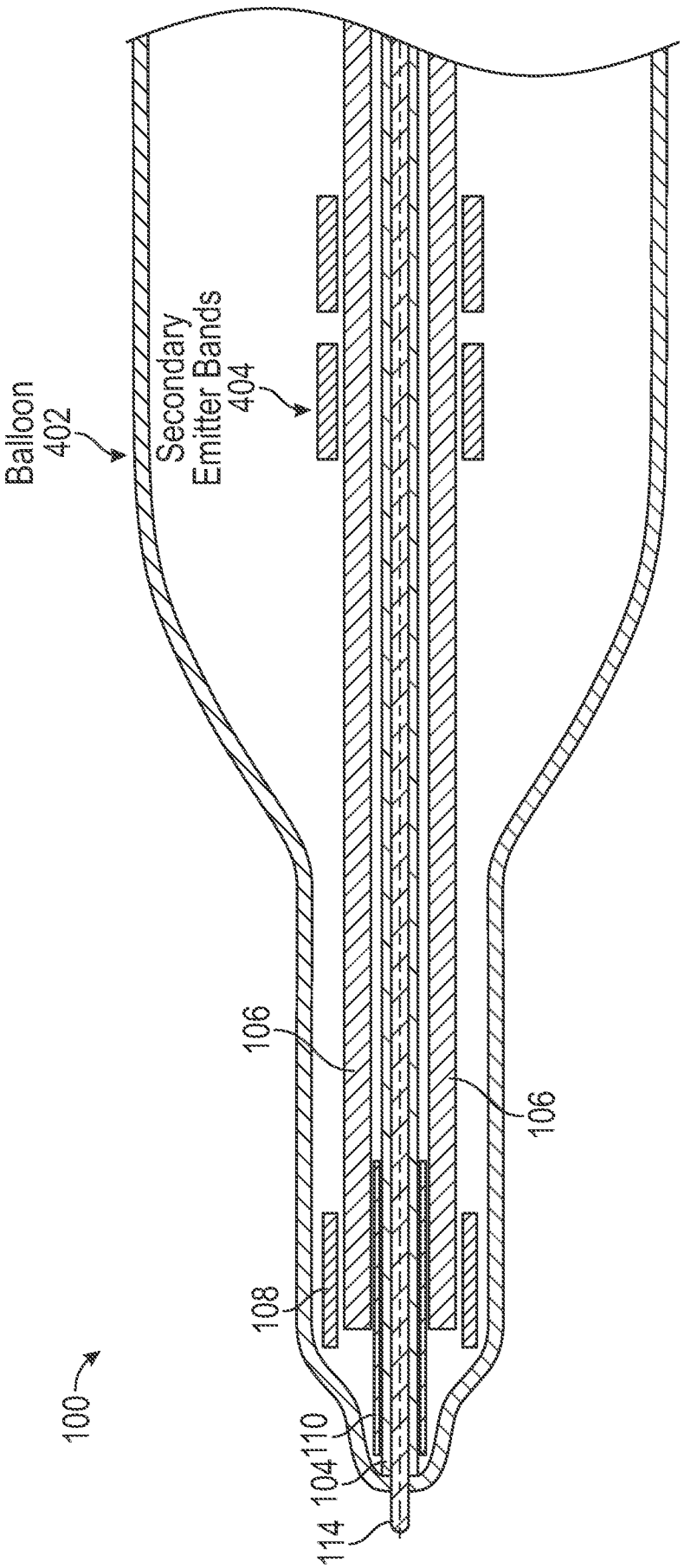
Balloon
402
Secondary
Emitter Bands
404
106
106
108
100
110
104
114

FIG. 4

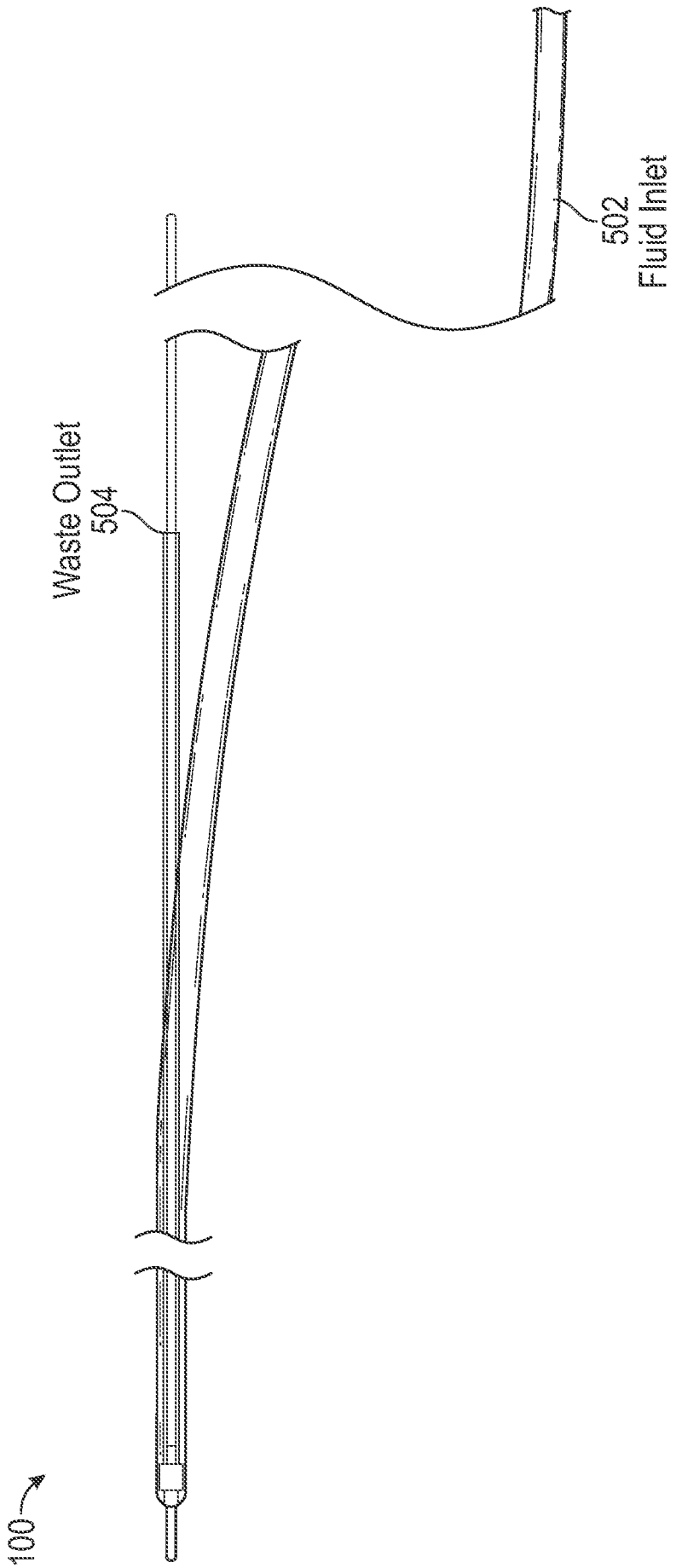

FIG. 5

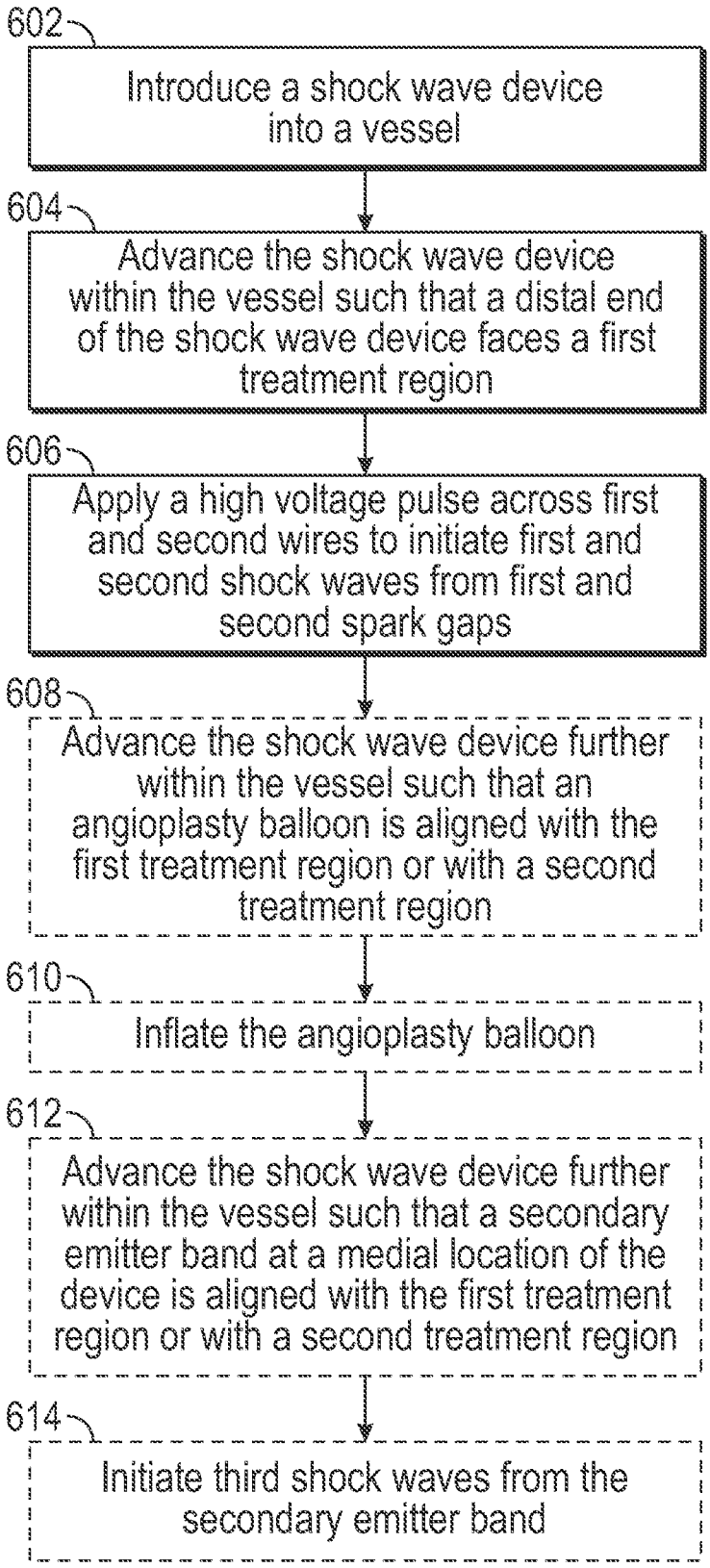
602
Introduce a shock wave device into a vessel
604
Advance the shock wave device within the vessel such that a distal end of the shock wave device faces a first treatment region
606
Apply a high voltage pulse across first and second wires to initiate first and second shock waves from first and second spark gaps
608
Advance the shock wave device further within the vessel such that an angioplasty balloon is aligned with the first treatment region or with a second treatment region
610
Inflate the angioplasty balloon
612
Advance the shock wave device further within the vessel such that a secondary emitter band at a medial location of the device is aligned with the first treatment region or with a second treatment region
614
Initiate third shock waves from the secondary emitter band

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/034855

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 8 956 371 B2 (HAWKINS ET AL.) 17 February 2015 (2015-02-17) cited in the application abstract; figure 1	1
A	US 5 254 121 A (MANEVITZ BERNARD [US] ET AL) 19 October 1993 (1993-10-19) abstract; figures 5-7	1
A	WO 92/03975 A1 (CANNON ROBERT L III [FR]) 19 March 1992 (1992-03-19) page 4, line 36 - page 5, line 4; figures 9a,b	1
A	US 8 888 788 B2 (SHOCKWAVE MEDICAL INC [US]) 18 November 2014 (2014-11-18) cited in the application abstract; figures 1-6a	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 August 2018	23/08/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers, Roelof

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/034855

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/034855

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8956371 B2	17-02-2015	AU 2009257368 A1	17-12-2009
		CA 2727429 A1	17-12-2009
		EP 2300091 A2	30-03-2011
		ES 2671898 T3	11-06-2018
		JP 5636363 B2	03-12-2014
		JP 2011524203 A	01-09-2011
		JP 2014208305 A	06-11-2014
		JP 2016137333 A	04-08-2016
		JP 2018015649 A	01-02-2018
		JP 2018015650 A	01-02-2018
		US 2009312768 A1	17-12-2009
		US 2011166570 A1	07-07-2011
		US 2013030447 A1	31-01-2013
		US 2015238208 A1	27-08-2015
		WO 2009152352 A2	17-12-2009
US 5254121 A	19-10-1993	NONE	
WO 9203975 A1	19-03-1992	AU 8611291 A	30-03-1992
		DE 69111457 D1	24-08-1995
		DE 69111457 T2	11-01-1996
		EP 0547146 A1	23-06-1993
		FR 2666231 A1	06-03-1992
		WO 9203975 A1	19-03-1992
US 8888788 B2	18-11-2014	AU 2013300176 A1	12-02-2015
		CA 2881208 A1	13-02-2014
		CN 104582621 A	29-04-2015
		EP 2879607 A1	10-06-2015
		JP 6257625 B2	10-01-2018
		JP 2015528327 A	28-09-2015
		JP 2017176883 A	05-10-2017
		US 2014039513 A1	06-02-2014
		US 2014052147 A1	20-02-2014
		US 2015073430 A1	12-03-2015
		US 2016331389 A1	17-11-2016
		WO 2014025397 A1	13-02-2014