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(54) **SHOCKWAVE GENERATING DEVICE**

(57) The present disclosure relates to a shockwave generating device. The device for treating calcified lesions in blood vessels by way of shockwaves, the device comprising:
- a balloon, which balloon is fillable with conductive fluid;
- an electrode assembly arranged within the balloon, which electrode assembly comprises:
- a first conductive layer extending through the balloon; and
- a second conductive layer extending through the balloon; and
- means for propagating shock waves generated by a shockwave generator, in the conductive fluid in the balloon.

SHOCKWAVE GENERATING DEVICE

Angioplasty balloons are commonly used to open calcified lesions in the walls of blood vessels. However, as an angioplasty balloon is inflated to expand the lesion in the vascular wall, the inflation pressure stores a tremendous amount of energy in the balloon until the calcified lesion breaks or cracks. That stored energy is then released and may stress and injure the wall of the blood vessel.

Electrohydraulic lithotripsy has been used for breaking calcified lesions in the vasculature. Shockwaves generated by lithotripsy electrodes may be used to fracture a calcified lesion to help prevent sudden stress and injury to a blood vessel or valve wall when it is dilated using a balloon. Methods, devices, system for treating stenotic or calcified vessels or calcified aortic valves are described, for example in U.S. Patent Pub. No. 2009/0312768, U.S. Patent Pub. No. 2014/0005576, and U.S. Patent No. 8,888,788. As described in those applications, a balloon is placed adjacent a treatment site and is inflated with a liquid. Within the balloon is a shockwave generator that produces shockwaves that propagate through the liquid and impinge upon the target tissue prior to balloon expansion.

There is a continuing need in the art for improved shockwave generating device designs and for shockwave generating devices that can improve deliverability to treatment sites and be readily manufactured at low cost.

Described herein are low-profile electrode assemblies which may be used, for example, in conjunction with shockwave angioplasty balloon catheters. Such devices may, for instance, be used to break up calcified lesions in the vasculature. The present disclosure pertains to a device according to the claims 1-14.

The present disclosure also pertains to devices for generating shockwaves comprising:

a) an inner electrode assembly comprising an inner elongate member, an inner conductive layer disposed over the inner elongate member, an insulating layer disposed over the inner conductive layer, an outer conductive layer disposed over the insulating layer, and a multilayer aperture that comprises a first aperture extending through the insulating layer and a second aperture extending through the outer conductive layer, wherein the first aperture and the second aperture are coaxial with one another, and wherein the multi-layer aperture:
    i) exposes a portion of an upper surface of the inner conductive layer at a bottom of the multi-layer aperture, which corresponds to a first electrode; and
    ii) exposes at least a lateral surface of the outer conductive layer surrounding the multi-layer aperture, which corresponds to a second electrode;

b) a balloon, wherein the multi-layer aperture of the inner electrode assembly is positioned inside the balloon; and

c) an elongate shaft comprising a lumen that is configured to introduce conductive fluid into the balloon.

In some embodiments, which can be used in conjunction with the above aspects, a width of the first aperture is the same as a width of the second aperture.

In some embodiments, which can be used in conjunction with the above aspects, a width of the first aperture is different from a width of the second aperture, in which case a width of the first aperture may be smaller than a width of the second aperture, or a width of the first aperture may be greater than a width of the second aperture.

In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, the device may comprise a plurality of the multi-layer apertures. In certain of these embodiments, at least some of the plurality of the multi-layer apertures are circumferentially offset from each other. For example, the plurality of the multi-layer apertures may comprise:

a) two multi-layer apertures that are circumferentially offset from one another by an angle of 180°;

b) three multi-layer apertures that are circumferentially offset from one another by an angle of 120°;

c) four multi-layer apertures that are circumferentially offset from one another by an angle of 90°;

d) five multi-layer apertures that are circumferentially offset from one another by an angle of 72°;

e) six multi-layer apertures that are circumferentially offset from one another by an angle of 60°; or

f) eight multi-layer apertures that are circumferentially offset from one another by an angle of 45°, among other possibilities.

It will be understood that a skilled person could also envisage other possible offsets.

In certain of these embodiments, at least some of the plurality of the multi-layer apertures are longitudinally offset from each other. In certain of these embodiments, at least some of the plurality of the multi-layer apertures are both circumferentially and longitudinally offset from each other.

In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, the device may further comprise an additional insulating layer disposed over at least a portion of the outer conductive layer. In these embodiments, the multi-layer aperture may comprise a third aperture formed in the additional insulating layer, which third aperture may or may not be coaxial with the first aperture and the second aperture.

In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, a proximal end of the balloon may be attached to a distal end of the elongate shaft, and a distal end of the balloon may be attached to a distal end of the inner electrode assembly. In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, the inner elongate member may comprise a lumen. In certain of these embodiments, a guidewire may be disposed within the lumen of the inner elongate member.

The disclosure also relates to a system according to claim 15.

In other aspects of the present disclosure, systems are provided that comprise:

a) a device for generating shockwaves in accordance with any of the above aspects and embodiments; and
b) a voltage generator in electrical connection with the inner and outer conductive layers and configured to apply a voltage pulse across the inner and outer conductive layers that is of sufficient magnitude and duration to generate a shock wave.

The present disclosure also relates to a method for providing a device according to the claaims 16-24.

In other aspects of the present disclosure, methods of making medical devices for generating shockwaves are provided, the methods comprising forming an inner electrode assembly comprising an inner elongate member, an inner conductive layer disposed over the inner elongate member, an insulating layer disposed over the inner conductive layer, an outer conductive layer disposed over the insulating layer, and a multilayer aperture that comprises a first aperture extending through the insulating layer and a second aperture extending through the outer conductive layer, wherein the first aperture and the second aperture are coaxial with one another, and wherein the multi-layer aperture exposes:

i) a portion of an upper surface of the inner conductive layer at a bottom of the multi-layer aperture, which corresponds to a first electrode; and
ii) at least a lateral surface of the outer conductive layer surrounding the multi-layer aperture, which corresponds to a second electrode.

In some embodiments, which can be used in conjunction with any of the above aspects, the method further comprises incorporating the inner electrode assembly into a balloon catheter that comprises a balloon and an elongate shaft comprising a lumen that is configured to introduce conductive fluid into the balloon, such that the multi-layer aperture of the inner electrode assembly is positioned inside the balloon.

In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, forming the inner electrode assembly may comprise:

a) inserting a first subassembly into a second subassembly, the first subassembly comprising the inner elongate member and the inner conductive layer disposed over the inner elongate member, and the second subassembly comprising the insulating layer, the outer conductive layer disposed over the insulating layer, the first aperture extending through the insulating layer, and the second aperture extending through the outer conductive layer; and

b) affixing the first subassembly to the second subassembly.

In certain of these embodiments, the first subassembly may be affixed to the second subassembly by shrinking the second subassembly onto a surface of the first subassembly.

In some embodiments, which can be used in conjunction with any of the above aspects and embodiments, forming the inner electrode assembly comprises forming the multi-layer aperture in an assembly that comprises the inner elongate member, the inner conductive layer disposed over the inner elongate member, the insulating layer disposed over the inner conductive layer, and the outer conductive layer disposed over the insulating layer. In certain of these embodiments, the forming the multi-layer aperture comprises:

i) forming the second aperture in the outer conductive layer by a first process that removes a material of the outer conductive layer, thereby exposing the lateral surface of the outer conductive layer; and

ii) forming the first aperture in the insulating layer using a second process that removes a material of the insulating layer, thereby exposing an upper surface of the inner conductive layer.

For instance, the first process may be one that selectively removes the material of the outer conductive layer relative to the material of the insulating layer, and the second process may be one that selectively removes the material of the insulating layer relative to a material of the inner conductive layer.

These and other aspects, embodiments and advantages of the present disclosure will become immediately apparent to those of ordinary skill in the art upon review of the detailed description and claims to follow.

- FIG. 1 depicts a schematic cross-sectional view of a shockwave angioplasty device, in accordance with the present disclosure.
- FIGS. 2A-2B are schematic cross-sectional views illustrating a process for forming a first subassembly, in accordance with the present disclosure.
- FIGS. 3A-3B are schematic cross-sectional views illustrating a process for forming a second subassembly, in accordance with the present disclosure.
- FIGS. 4A-4B are schematic cross-sectional views illustrating a process for forming an inner electrode assembly, in accordance with the present disclosure.
- FIGS. 5 and 6 are schematic side views illustrating inner electrode assemblies, in accordance with the present disclosure.

- FIGS. 7A-7B are schematic cross-sectional views illustrating a process for forming an inner electrode assembly, in accordance with the present disclosure.
- FIGS. 8A and 8B are schematic cross-sectional and side views, respectively, illustrating an inner electrode assembly, in accordance with the present disclosure.
- FIG. 9 is schematic side view illustrating an inner electrode assembly, in accordance with the present disclosure.

Described herein are devices and systems that comprise one or more shockwave generators comprising shockwave-generating electrodes. The shockwave generators are integral to an inner electrode assembly, which may be sealed within a balloon that is inflated with a conductive fluid (e.g., saline, imaging contrast agent, etc.). The inner electrode assembly may be attached to a source of high voltage pulses, for example, ranging from 100 to 10,000 volts, more typically 100 to 3,000 volts, for various pulse durations, which, without wishing to be bound by theory, may generate rapidly expanding and collapsing bubbles, which in turn create mechanical shockwaves within the balloon. Shockwaves may be mechanically conducted through the fluid and through a wall of the balloon to apply mechanical stress to break apart calcified lesions that may be present on or in the vasculature walls.

FIG. 1 is a schematic illustration of a shockwave angioplasty device 100 in accordance with the present disclosure. The device 100 of FIG. 1 includes an inner electrode assembly 102, an outer tubular member 120, and a balloon 130. The inner electrode assembly 102 includes an inner elongate member 110, an inner conductive layer 112 disposed over the inner elongate member 110, an insulating layer 114 disposed over the inner conductive layer 112, an outer conductive layer 116 disposed over the insulating layer 114, and an optional additional insulating layer 118 disposed over the outer conductive layer 116.

The inner elongate member 110 may be formed from any suitable material, beneficially a low-friction polymeric material such as, for example, polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), a copolymer of hexafluoropropylene and tetrafluoroethylene, or high-density polyethylene (HDPE), among other possibilities. The inner elongate member 110 may range, for example, from 0.46 mm to 1.1 mm in outer diameter, among other possibilities. The inner elongate member 110 may include a guide wire lumen 110l extending along a length of its longitudinal axis. The guide wire lumen 110l may range, for example, from 0.36 mm to 0.97 mm in diameter, among other possibilities.

The inner conductive layer 112 and the outer conductive layer 116 may be formed from any material that is able to support the voltages that are required for shockwave generation and to withstand the forces generated by the same. For example, the inner conductive layer 112 and the outer conductive layer 116 may be made of tungsten, nickel, iron, steel, including stainless steel, copper, gold, and the like. The inner conductive layer 112 may range, for example, from 0.00013 mm to 0.0013 mm in thickness, among other possibilities. The outer conductive layer 116 may range, for example, from 0.00013 mm to 0.0013 mm in thickness, among other possibilities.

The insulating layer 114 may be made of any material having a breakdown voltage that is sufficiently great to withstand voltages that are generated during shockwave generation, for example, fluoropolymers (e.g., PTFE, FEP, etc.), polyethylene terephthalate (PET), polyimide (e.g., Kapton), polyamides, polyamide block polyether copolymers, polyester block copolymers, and the like. As discussed further below, in some embodiments, the insulating layer 114 may be formed from a shrinkable material, for example, a heat-shrinkable material. The insulating layer 114 may range, for example, form 0.01 mm to 0.08 mm in thickness, among other possibilities.

The optional additional insulating layer 118 may be formed by the same materials as the insulating layer 114, although the electrical demands upon the additional insulating layer 118 may not be as great as those associated with insulating layer 114. The additional insulating layer 118 may range, for example, from 0.01 mm to 0.08 mmin thickness, among other possibilities.

The inner electrode assembly 102 further includes a plurality of multi-layer apertures 102a (six shown, three of which are labeled), each including a first aperture 114a extending through the insulating layer 114, a second aperture 116a extending through the outer conductive layer 116, and a third aperture 118a extending through the optional additional insulating layer 118. The first aperture 114a, second aperture 116a, and third aperture 118a are preferably coaxial with one another. Within each multi-layer aperture 102a lies an exposed portion of the inner conductive layer 112, which corresponds to an inner electrode 112e. In the embodiment shown, an exposed portion of the outer conductive layer 116 is also contained within each multi-layer aperture 102a, corresponding to an outer electrode 116e. By applying a voltage pulse of suitable magnitude and duration across the inner electrode 112e and outer electrode 116e in the presence of a conductive liquid, microbubble creation and collapse may be initiated in the vicinity of each multi-layer aperture 102a, leading to the creation of a shockwave, which propagates radially outward from the side of the inner electrode assembly 102. Thus, each aperture in FIG. 1 corresponds to a shockwave generator. The inner electrode 112e may be a positive electrode and the outer electrode 116e may be a negative electrode or ground electrode, conversely, the outer electrode 116e may be a positive electrode and the inner electrode 112e may be a negative electrode or ground electrode, and so forth. More broadly, a potential difference is established between the inner electrode 112e and the outer electrode 116e that has a magnitude and duration sufficient for shockwave creation.

The multi-layer apertures 102a (and thus the shockwave generators) may be distributed along a longitudinal length of the elongate member. For example, the multi-layer apertures 102a may be longitudinally spaced by a distance ranging from about 4mm to 25mm, among other possible values.

As an alternative or in addition to being distributed along a longitudinal length of the elongate member, the multi-layer apertures 102a may be distributed around a circumference of the elongate member 110. For example, the multi-layer apertures 102a may comprise any of the following:

- two multi-layer apertures 102a that are circumferentially offset from one another by an angle of 180°;
- three multi-layer apertures 102a that are circumferentially offset from one another by an angle of 120°;
- four multi-layer apertures 102a that are circumferentially offset from one another by an angle of 90°;
- five multi-layer apertures 102a that are circumferentially offset from one another by an angle of 72°;
- six multi-layer apertures 102a that are circumferentially offset from one another by an angle of 60°; or
- eight multi-layer apertures 102a that are circumferentially offset from one another by an angle of 45°.

It will be understood that a skilled person could also envisage other possible offsets.

The first aperture 114a, a second aperture 116a and (optional) third aperture 118a may be in the shape of a circle, oval, ellipse, polygon, or any other desired shape. In addition to the thickness of the insulating layer 114, the nature of the path that the current travels during shockwave formation is influenced by the size and location of the first aperture 114a in the insulating layer 114 and the size and location of the second aperture 116a in the outer conductive layer 116. The first aperture 114a in the insulating layer 114 may be the same size as the second aperture 116a in the outer conductive layer 116, or may be smaller than the second aperture 116a in the outer conductive layer 116. The third aperture 118a in the optional additional insulating layer 118 may be may be the same size as the second aperture 116a in the outer conductive layer 116 or may be larger than the second aperture 116a in the outer conductive layer 116.

In certain beneficial embodiments, the first aperture 114a in the insulating layer 114 may have a diameter ranging from 0.48 mm to 1.09 mm, among other possible values, the second aperture 116a in the outer conductive layer 116 may have a diameter ranging from 0.51 mm to 1.12 mm, among other possible values, and the third aperture 118a in the optional additional insulating layer 118 may have a diameter ranging from 0.53 mm to 1.14 mm, among other possible values. The ratio of the diameters between the first aperture 114a, the second aperture 116a, and the third aperture 118a may be varied to change the nature of the generated shockwave.

In some embodiments, the widths of one or more of the first apertures 114a, second apertures 116a and optional third apertures 118a may vary along a longitudinal length of the inner electrode assembly 102. For example, aperture widths may be varied along the longitudinal length of the inner electrode assembly 102 such that shockwave generators at the proximal and distal ends of the array deliver higher power shockwaves than those delivered at the center of the array.

The inner electrode assembly 102 may be used in conjunction with an axially extending catheter that further includes a balloon 130 and an outer tubular member 120. The multi-layer apertures 102a (and thus the shockwave generators) of the inner electrode assembly 102 are positioned within the balloon 130. A proximal end 130p of the balloon 130 is attached to a distal end 120d of the outer tubular member 120, and a distal end 130d of the balloon 130 is attached to the distal end 102d of the inner electrode assembly 102. Although the layers 112, 114, 116, 118 are shown extending proximally beyond the proximal end 130p of the balloon 130, this is not required. For example, electrical leads can be provided, which extend the length of the catheter and connect the inner and outer conductive layers 112, 116 to a suitable voltage source.

The balloon 130 may be a single layer or multi-layer balloon formed of any suitable material, including polyethylene terephthalate (PET), polyether block amide (e.g., PEBAX), polyamide (e.g., nylon), polyethylene, polyurethane, silicone, and other materials known in the medical balloon art. The balloon 130 may be attached to the outer tubular member 120 and the inner electrode assembly 102 using any method known in the balloon art, including, for example, a suitable adhesive 122. In the embodiment shown, conductive fluid may be introduced into and removed from the balloon 130 through a lumen 120l that lies between the inner electrode assembly 102 and the outer tubular member 120.

In this regard, it is noted that devices in accordance with the present disclosure can be used in conjunction with standard balloon manufacturing methods, except that the inner is in the form of an inner electrode assembly 102, which is constructed so that there are multiple locations in which multi-layer apertures 102a are provided, which correspond to shockwave generators. In this regard, when filled with a conductive fluid, the multi-layer apertures 102a provide electrical pathways between the inner and outer conductive layers 112, 116, such that a voltage generator can be used to apply a voltage across the inner and outer conductive layers 112, 116 that is of suitable magnitude and duration for shockwave generation. The shockwave generators are integral to the inner electrode assembly 102. The voltage generator is connected to the inner and outer conductive layers 112, 116 of the inner electrode assembly 102, and applies a suitable voltage across the inner and outer conductive layers 112, 116. In some embodiments, leads can be extended along the inner member 110, which are attached to the inner and outer conductive layers 112, 116 proximate the proximal end of the balloon 130. The leads may also be connected to a voltage generator.

Without wishing to be bound by theory, applying a voltage across the inner and outer conductive layers 112, 116, can create high temperature zones in the vicinity of the apertures 102a, which in turn creates micro bubbles of steam. The creation and collapse of the bubbles creates shockwaves which radiate outward from the inner electrode assembly 102. These shockwaves may be used, for example, to disrupt hard calcified lesions in a vessel surrounding the balloon 130, making is easier for the balloon 130 to expand the vessel. The lower pressure required for expansion typically creates a better clinical outcome than POBA (plain old balloon angioplasty). In addition, the breakup of calcified lesions may provide channels for improved uptake of drug from a drug coated balloon.

Shockwave intensity may be controlled in various ways including, for example, by controlling the width of the first apertures 114a, second apertures 116a and third apertures 118a within the multi-layer apertures 102a, by controlling the thickness of the insulating layer 114, by controlling the number of multi-layer apertures 102a (and thus the number of shockwave generators), and by controlling the magnitude and duration of the voltage that is applied by the voltage generator to the inner and outer conductive layers 112, 116.

Other aspects of the present disclosure pertain to methods of making medical devices for generating shockwaves. The methods include forming inner electrode assemblies 102 like those described above, in particular, inner electrode assemblies 102 that comprise an inner elongate member 110, an inner conductive layer 112 disposed over the inner elongate member 110, an insulating layer 114 disposed over the inner conductive layer 112, an outer conductive layer 116 disposed over the insulating layer 114, an optional additional insulating layer 118 disposed over the outer conductive layer 116, and one or more multi-layer apertures 102a extending from an outer surface of the inner electrode assembly 102 down to the inner conductive layer 112 of the inner electrode assembly 102, each multi-layer aperture 102a corresponding to a shockwave generator.

In some embodiments, for example, a first subassembly is inserted into a second subassembly, and the first and second subassemblies are then affixed to one another. For example, and with reference to Figs. 2A-2B, a first subassembly 102s1 may be formed by taking an elongate member 110 as shown in Fig. 2A and forming a conductive layer 112 on the elongate member 110 using any suitable method, for example, by depositing a conductive layer 112 on an elongate member 110 using a suitable process, such as physical vapor deposition process, a chemical vapor deposition process, or an electroplating process, or by wrapping a conductive layer 112 around an elongate member 110. In one specific embodiment, a metal conductive layer 112 may be sputter deposited on an elongate member 110 in the form of a PTFE tube.

Referring now to Figs. 3A-3B, a second subassembly 102s2 may be formed by first creating a tubular member that comprises an insulating layer 114 and a conductive layer 116 like that shown in Fig. 3A (as well as an optional additional insulating layer, not shown). For example, using any suitable layer formation method, a conductive layer 116 may be formed on an outer surface of an insulating layer 114 in the form of a tube of insulating material. For instance, a conductive layer 116 may be deposited on an insulating layer 114 in form of a tube of insulating material using a suitable deposition process, such as a physical vapor deposition process, a chemical vapor deposition process, or an electroplating process. In one particular embodiment, a layer of conductive material may be applied to a heat-shrinkable tube of insulating material, for example, a heat-shrinkable FEP tube, a heat-shrinkable PET tube, or nylon, polyolefins, among other possibilities.

Subsequently, apertures 114a, 116a may be formed in the tubular member 114, 116 using a suitable physical, chemical, or physicochemical process, such as, for example, mechanical drilling, laser drilling, or masking and etching, among other processes, thereby completing the second subassembly 102s2.

In a subsequent step, the first subassembly 102s1 of Fig. 2B is positioned inside the second subassembly 102s2 of Fig. 3B to form an assembly like that shown in Fig. 4A. Subsequently, the second subassembly 102s2 is shrunk onto the first subassembly 102s1, for example, via heat shrinking or another suitable process, thereby forming an inner subassembly 102 as shown in Fig. 4B. A side view of the inner assembly 102 of Fig. 4B is shown in Fig. 5. To enhance the shrinkage process, in some embodiments, the outer conductive layer 116 in the second subassembly 102s2 may be provided over only a portion of the surface of the second subassembly 102s2. For example, the outer conductive layer 116 may be present as a series of conductive lines as shown in Fig 6, or more complex patterns may be employed such as barber-pole and zig-zag patterns (see also, for example, Fig. 8, discussed further below).

In some embodiments, an inner electrode assembly 102 like that shown in Fig. 7B is created by forming apertures 102a in an assembly 103 like that shown in Fig. 7A, which includes an inner elongate member 110, an inner conductive layer 112 disposed over the inner elongate member 110, an insulating layer 114 disposed over the inner conductive layer 112, an outer conductive layer 116 disposed over the insulating layer 114, and optionally an additional insulating layer (not shown). The apertures may be formed, for example, using any suitable physical, chemical, or physicochemical process, such as mechanical drilling, laser drilling, or masking and etching processes, among others.

In some instances, a process may be selected in which apertures are formed using a process that selectively removes material making up a given layer, relative to another material making up an underlying layer. For example, a process may be selected in which conductive material in the outer conductive layer 116 is selectively removed relative to insulating material in the insulating layer 114 underlying the outer conductive layer 116, such that the insulating layer 114 acts as a stop layer when apertures 116a are formed in the outer conductive layer 116. For instance, a process may be selected which removes conductive material from the outer conductive layer 116 at a rate that is at least two times, more beneficially at least four times, even more beneficially at least ten times, the rate at which the process removes insulating material from insulating layer 114.

After forming apertures 116a, another process may be selected in which insulating material in the insulating layer 114 is selectively removed relative to conductive material in the inner conductive layer 112 underlying the insulating layer 114, such that the inner conductive layer 112 acts as a stop layer when apertures 114a are formed in the insulating layer 114. For instance, a process may be selected which removes insulating material from the insulating layer 114 at a rate that is at least two times, more beneficially at least four times, even more beneficially at least ten times the rate at which that process removes conductive material from the inner conductive layer 112.

As a specific example, metallic material may be selectively removed from the outer conductive layer 116 (relative to material in the insulating layer 114) using an eximer laser or using a suitable plasma etching chemistry, whereas insulating material may be selectively removed from the insulating layer 114 (relative to the inner conductive layer 112) using a CO_2 laser or an eximer laser or using a suitable plasma etching chemistry. Plasma etching chemistries in which insulating materials (e.g., fluoropolymers) are selectively etched relative to conductive materials (e.g., metals), and in which conductive materials are selectively etched relative to insulating materials, are known in the semiconductor processing industry.

Using these and other processes, a wide range of aperture sizes and layer layouts may be created, one example of which is an inner assembly 102 like that shown in schematic cross-sectional and side views in Figs. 8A and 8B, another of which is an inner assembly 102 like that shown in schematic side view in Fig. 9.

Although various embodiments are specifically illustrated and described herein, it will be appreciated that modifications and variations of the present disclosure are covered by the above teachings and are within the purview of the appended claims without departing from the spirit and intended scope of the disclosure.

CLAUSES

1. A device for treating calcified lesions in blood vessels by way of shockwaves, the device comprising:
    - a balloon, which balloon is fillable with conductive fluid;
    - an electrode assembly arranged within the balloon, which electrode assembly comprises:
        - a first conductive layer extending through the balloon; and
        - a second conductive layer extending through the balloon; and
    - means for propagating shock waves generated by a shockwave generator, in the conductive fluid in the balloon.

2. The device according to clause 1, wherein the shockwave propagating means comprise an aperture arranged between the first and second conductive layers, whereby the first conductive layer forms a floor of the aperture and whereby an opening in the second conductive layer is arranged opposite the aperture floor, whereby the second conductive layer forms a side of the aperture.

3. The device according to clause 2, wherein an insulating layer is arranged between the first and second conductive layers, which insulating layer has an opening coaxial with the opening in the second conductive layer, whereby the side of the aperture is also formed by the insulating layer.

4. The device according to any of the clauses 1-3, further comprising an elongate shaft comprising a lumen configured to introduce the conductive fluid into the balloon.

5. The device according to any of the preceding clauses, wherein the electrode assembly further comprises an elongate member, whereby the first, or inner, conductive layer is disposed over the inner elongate member, whereby the insulating layer is disposed over the inner conductive layer, whereby the second, or outer, conductive layer is disposed over the insulating layer, and whereby the aperture is formed by a multilayer aperture, which multilayer aperture comprises a first aperture formed by the opening in the insulating layer and a second aperture, formed by the opening in the outer conductive layer, wherein the first aperture and the second aperture are coaxial with one another, and wherein the multi-layer aperture exposes:
    i) a portion of an upper surface of the inner conductive layer at a bottom of the multi-layer aperture, the floor of the aperture, which corresponds to a first electrode; and

ii) at least a lateral surface of the outer conductive layer surrounding the multi-layer aperture, the side of the aperture, which corresponds to a second electrode.

6. The device of clause 5, wherein a width of the first aperture is the same as a width of the second aperture, or wherein a width of the first aperture is different from a width of the second aperture.

7. The device of any one of clauses 5-6, comprising a plurality of said multi-layer apertures.

8. The device of any of the clauses 5-7, wherein at least some of the plurality of said multi-layer apertures are circumferentially offset from each other, wherein at least some of the plurality of said multi-layer apertures are longitudinally offset from each other, or wherein at least some of the plurality of said multi-layer apertures are both circumferentially and longitudinally offset from each other.

9. The device of any of the clauses 5-8, wherein the plurality of said multi-layer apertures comprises:
    a) two multi-layer apertures that are circumferentially offset from one another by an angle of 180°;
    b) three multi-layer apertures that are circumferentially offset from one another by an angle of 120°;
    c) four multi-layer apertures that are circumferentially offset from one another by an angle of 90°;
    d) five multi-layer apertures that are circumferentially offset from one another by an angle of 72°;
    e) six multi-layer apertures that are circumferentially offset from one another by an angle of 60°; or
    f) eight multi-layer apertures that are circumferentially offset from one another by an angle of 45°.

10. The device of any one of the preceding clauses, further comprising an additional insulating layer disposed over at least a portion of the outer conductive layer.

11. The device of clause 10, wherein the multi-layer aperture comprises a third aperture formed in the additional insulating layer and wherein the third aperture is coaxial with the first aperture and the second aperture.

12. The device of any one of the preceding clauses 4-11, wherein a proximal end of the balloon is attached to a distal end of the elongate shaft, and wherein a distal end of the balloon is attached to a distal end of the inner electrode assembly.

13. The device of any one of clauses 4-12, wherein the inner elongate member comprises a lumen, preferably wherein a guidewire is disposed in the lumen.

14. The device according to any of the preceding clauses 1-13, further comprising a shock wave generator, preferably a voltage generator in electrical connection with the inner and outer conductive layers and configured to apply a voltage pulse across the inner and outer conductive layers.

15. A system comprising:
    - a device in accordance with any one of clauses 1-14; and
    - a shockwave generator, which shockwave generator is preferably a voltage generator in electrical connection with the inner and outer conductive layers and configured to apply a voltage pulse across the inner and outer conductive layers that is of sufficient magnitude and duration to generate a shock wave.

16. A method of making a medical device suitable for generating shockwaves, said method comprising:
    - creating an electrode assembly comprising a first conductive layer; and
    - a second conductive layer; and
    - arranging means for propagating shockwaves with the first and second conductive layers.

17. The method according to clause 16, wherein the step of arranging the shockwave propagating means comprises arranging an aperture between the first and second conductive layers, which aperture is formed by the first conductive layer forming a floor of the aperture and an opening in the second conductive layer opposite the aperture floor, whereby the second conductive layer forms a side of the aperture.

18. The method according to clauses 16 or 17, further comprising the step of arranging an insulating layer between the first and second conductive layers, in which insulating layer is

arranged an opening coaxial with the opening in the second conductive layer so that the side of the aperture is also formed by the insulating layer.

19. The method of any of the clauses 16-18, whereby the first, or inner, conductive layer is disposed over an inner elongate member, whereby the insulating layer is disposed over the inner conductive layer, whereby the second, or outer, conductive layer is disposed over the insulating layer, and whereby the aperture is formed by a multilayer aperture, which multilayer aperture comprises a first aperture formed by the opening in the insulating layer and a second aperture, formed by the opening in the outer conductive layer, wherein the first aperture and the second aperture are coaxial with one another, and wherein the multi-layer aperture exposes:
    i) a portion of an upper surface of the inner conductive layer at a bottom of the multi-layer aperture, the floor of the aperture, which corresponds to a first electrode; and
    ii) at least a lateral surface of the outer conductive layer surrounding the multi-layer aperture, the side of the aperture, which corresponds to a second electrode.

20. The method of clause 19, further comprising incorporating the inner electrode assembly into a balloon catheter that comprises a balloon and an elongate shaft comprising a lumen that is configured to introduce conductive fluid into the balloon, such that the multi-layer aperture of the inner electrode assembly is positioned inside the balloon.

21. The method of any one of clauses 19-20, wherein forming the electrode assembly comprises:
    - inserting a first subassembly into a second subassembly, the first subassembly comprising the inner elongate member and the inner conductive layer disposed over the inner elongate member, and the second subassembly comprising the insulating layer, the outer conductive layer disposed over the insulating layer, the first aperture extending through the insulating layer, and the second aperture extending through the outer conductive layer; and
    - affixing the first subassembly to the second subassembly, preferably wherein the first subassembly is affixed to the second subassembly by shrinking the second subassembly onto a surface of the first subassembly.

22. The method of any one of clauses 19-21, wherein forming the inner electrode assembly comprises forming the multi-layer aperture in an assembly that comprises the inner elongate member, the inner conductive layer disposed over the inner elongate member, the insulating layer disposed over the inner conductive layer, and the outer conductive layer disposed over the insulating layer.

23. The method of clause 22, wherein forming the multi-layer aperture comprises:
    i) forming the second aperture in the outer conductive layer by a first process that removes a material of the outer conductive layer, thereby exposing the lateral surface of the outer conductive layer; and
    ii) (ii) forming the first aperture in the insulating layer using a second process that removes a material of the insulating layer, thereby exposing an upper surface of the inner conductive layer.

24. The method of clause 23, wherein the first process is one that selectively removes the material of the outer conductive layer relative to the material of the insulating layer, and wherein the second process is one that selectively removes the material of the insulating layer relative to a material of the inner conductive layer.

CONCLUSIES

1. Inrichting voor behandeling van verkalkte laesie in bloedvaten door middel van schokgolven, de inrichting omvattende:
   - een ballon, waarbij de ballon vulbaar is met geleidende vloeistof;
   - een elektrode samenstel ingericht binnen in de ballon, waarbij het elektrode samenstel omvat:
     - een eerste geleidende laag die zich uitrekt door de ballon; en
     - een tweede geleidende laag die zich uitrekt door de ballon; en
   - middelen om schokgolven gegenereerd door een schokgolfgenerator voort te planten in de geleidende vloeistof in de ballon.

2. Inrichting volgens conclusie 1, waarbij de middelen voor schokgolf voortplanting een opening ingericht tussen de eerste en tweede geleidende lagen omvat, waarbij de eerste geleidende laag een vloer van de opening vormt, en waarbij een opening in de tweede geleidende laag is ingericht tegenover de openingsvloer, waarbij de tweede geleidende laag een zijde van de opening vormt.

3. Inrichting volgens conclusie 2, waarbij een isolerende laag is ingericht tussen de eerste en tweede geleidende laag, voorbij de isolerende laag een opening heeft die coaxiaal is met de opening in de tweede geleidende laag, waarbij de zijde van de opening is gevormd door de isolerende laag.

4. Inrichting volgens één der conclusies 1-3, verder omvattende een verlengde schacht omvattende een kanaal ingericht om de geleidende vloeistof in de ballon in te brengen.

5. Inrichting volgens één der voorgaande conclusies, waarbij het elektrode samenstel verder een langwerpig element omvat, waarbij de eerste, of binnenste, geleidende laag is over het binnenste langwerpig element is geplaatst, waarbij de isolerende laag over de binnenste geleidende laag is geplaatst, waarbij de tweede, of buitenste, geleidende laag over de isolerende laag is geplaatst, en waarbij de opening door een opening met meerdere lagen is gevormd, waarbij de opening met meerdere lagen een eerste opening omvat gevormd door de opening in de isolerende laag en een tweede opening, gevormd door de opening in de buitenste geleidende laag, waarbij de eerste opening en de tweede opening coaxiaal zijn aan elkaar, en waarbij de opening met meerdere lagen toont:

i) een deel van een boven oppervlak van de binnenste geleidende laag bij een onderkant van de opening met meerdere lagen, de vloer van de opening, die overéén komt met een eerste elektrode; en

ii) ten minste een lateraal oppervlak van de buitenste geleidende laag die de opening met meerdere lagen omgeeft, de zijde van de opening, die overéén komt met een tweede electrode.

6. Inrichting volgens conclusie 5, waarbij een breedte van de eerste opening gelijk is aan een breedte van de tweede opening, of waarbij een breedte van de eerste opening verschillend is van de breedte van de tweede opening.

7. Inrichting volgens één der conclusies 5-6, omvattende een veelvoud van openingen met meerdere lagen.

8. Inrichting volgens één der conclusies 5-7, waarbij ten minste sommige van de veelvoud van openingen met meerdere lagen rondomvoerend met offset van elkaar zijn voorzien, waarbij ten minste sommige van de veelvoud van de openingen met meerdere lagen longitudinaal offset van elkaar zijn voorzien, of waarbij ten minste sommige van de veelvoud van de openingen met meerdere lagen zowel rondomvoerend en longitudinaal offset van elkaar zijn.

9. Inrichting volgens één der conclusies 5-8, waarbij de veelvoud van de openingen met meerdere lagen omvat:

a) twee meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek hoek van 180°;

b) drie meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek van 120°;

c) vier meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek van 90°;

d) vijf meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek van 72°;

e) zes meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek van 60°; of

f) acht meerlaagse openingen die rondomvoerend offset van elkaar zijn door een hoek van 45°.

10. Inrichting volgens één der voorgaande conclusies, verder omvattende een extra isolerende laag geplaatst over ten minste een deel van de buitenste geleidende laag.

11. Inrichting volgens conclusie 10, waarbij de openingen met meerdere lagen een derde opening gevormd in de extra isolerende laag omvat en waarbij de derde opening coaxiaal is met de eerste opening en de tweede opening.

12. Inrichting volgens één der conclusies 4-11, waarbij een proximaal eind van de ballon is verbonden aan een distaal eind van de verlengde schacht, en waarbij een distaal eind van de ballon is verbonden aan een distaal eind van het binnenste elektrode samenstel.

13. Inrichting volgens één der conclusies 4-12, waarbij het binnenste verlengde element een kanaal omvat, bij voorkeur waarbij een gidsdraad is geplaatst in het kanaal.

14. Inrichting volgens één der conclusies 1-13, verder omvattende een schokgolfgenerator, bij voorkeur een spanningsgenerator die in elektrische verbinding staat met de binnenste en buitenste geleidende laag en die is ingericht om een spanningspuls door de binnenste en buitenste geleidende laag toe te passen.

15. Systeem omvattende:
   - een inrichting volgens één der conclusies 1-14; en
   - een schokgolfgenerator, waarbij de schokgolfgenerator bij voorkeur een spanningsgenerator is die in elektrische verbinding staat met de binnenste en buitenste geleidende laag en die is ingericht om een spanningspuls door de binnenste en buitenste geleidende laag toe te passen die voldoende grootte en voortduring heeft om een schokgolf te genereren.

16. Werkwijze voor het vervaardigen van het geschikt maken van een medische inrichting voor het genereren van schokgolven, de werkwijze omvattende:
   - het maken van een elektrode samenstel omvattende:
     - een eerste geleidende laag; en
     - een tweede geleidende laag; en
   - het ordenen van middelen voor het voortplanten van schokgolven met de eerste en tweede geleidende laag.

17. Werkwijze volgens conclusies 16, waarbij de stap van het ordenen van de schokgolf voortplantingsmiddelen het ordenen van een opening tussen de eerste en tweede geleidende lagen omvat, waarbij de opening is gevormd door de eerste geleidende laag die een vloer vormt van de opening en een opening in de tweede geleidende laag tegenover de openingsvloer, waarbij de tweede geleidende laag een zijde van de opening vormt.

18. Werkwijze volgens conclusie 16 of 17, verder omvattende de stap van het ordenen van een isolerende laag tussen de eerste en tweede geleidende laag, waarin de isolerende laag is geordend met een opening die coaxiaal is ten opzichte van de opening in de tweede geleidende laag zodat de zijde van de opening ook door de isolerende laag is gevormd.

19. Werkwijze volgens één der conclusies 16-18, waarbij de eerste, of binnenste, geleidende laag is geplaatst over een verlengd element, waarbij de isolerende laag is geplaatst over de binnenste geleidende laag, waarbij de tweede, of buitenste, geleidende laag is geplaatst over de isolerende laag, en waarbij de opening is gevormd door een opening met meerdere lagen, de opening met meerdere lagen omvat een eerste opening gevormd door de opening in de isolerende laag en een tweede opening, gevormd door de opening in de buitenste geleidende laag, waarbij de eerste opening en de tweede opening coaxiaal zijn aan elkaar, en waarbij de opening met meerdere lagen toont;

i) een deel van een boven oppervlak van de binnenste geleidende laag bij een onderkant van de opening met meerdere lagen, de vloer van de opening, die overéénkomt met een eerste elektrode; en

ii) ten minste een lateraal oppervlak van de buitenste geleidende laag die de opening met meerdere lagen omgeeft, de zijde van de opening, die overéén komt met een tweede electrode.

20. Werkwijze volgens conclusie 19, verder omvattende het opnemen van het binnenste elektrode samenstel in een ballon katheder dat een ballon en een verlengde schacht omvat, omvattende een kanaal dat is ingericht om geleidende vloeistof in de ballon in te brengen, zodat de opening met meerdere lagen van het binnenste elektrode samenstel binnenin de ballon is geplaatst.

21. Werkwijze volgens één der conclusies 19-20, waarbij het vormen van het elektrode samenstel omvat:

- het invoegen van een eerste sub-samenstel in een tweede sub-samenstel, waarbij het eerste sub-samenstel omvattende het binnenste langwerpige element en de binnenste geleidende laag is geplaatst over het binnenste langwerpige element, en de het tweede sub-samenstel omvattende de isolerende laag, de buitenste geleidende laag geplaatst over de isolerende laag, de eerste opening uitgestrekt door de isolerende laag, en de tweede opening uitgestrekt door de buitenste geleidende laag; en

- het aanbrengen van het eerste sub-samenstel aan het tweede sub-samenstel, bij voorkeur waarbij het eerste sub-samenstel is aangebracht aan het tweede sub-samenstel door krimp van het tweede sub-samenstel op een oppervlak van het eerste sub-samenstel.

22. Werkwijze volgens één der conclusies 19-21, waarbij het vormen van het binnenste elektrode samenstel omvat het vormen van de opening met meerdere lagen in een samenstel dat binnenste verlengd element, de binnenste geleidende laag geplaatst over het binnenste verlengde element, de isolerende laag geplaatst over de binnenste geleidende laag, en de buitenste geleidende laag geplaatst over de isolerende laag omvat.

23. Werkwijze van conclusie 22, waarbij het vormen van de opening met meerdere lagen omvat:
    i) het vormen van de tweede opening in de buitenste geleidende laag door een eerste proces dat materiaal van de buitenste geleidende laag verwijdert, daarbij het lateraal oppervlak van de buitenste geleidende laag blootleggend; en
    ii) het vormen van de eerste opening in de isolerende laag gebruik makend van een tweede proces dat materiaal van de isolerende laag verwijdert, daarbij een bovenste oppervlak van de binnenste geleidende laag blootleggend.

24. Werkwijze van conclusie 23, waarbij het eerste proces er één is dat selectief het materiaal van de buitenste geleidende laag verwijderd relatief ten opzichte van het materiaal van de isolerende laag, en waarbij het tweede proces er één is dat selectief het materiaal van de isolerende laag verwijderd relatief ten opzichte van een materiaal van de binnenste geleidende laag.

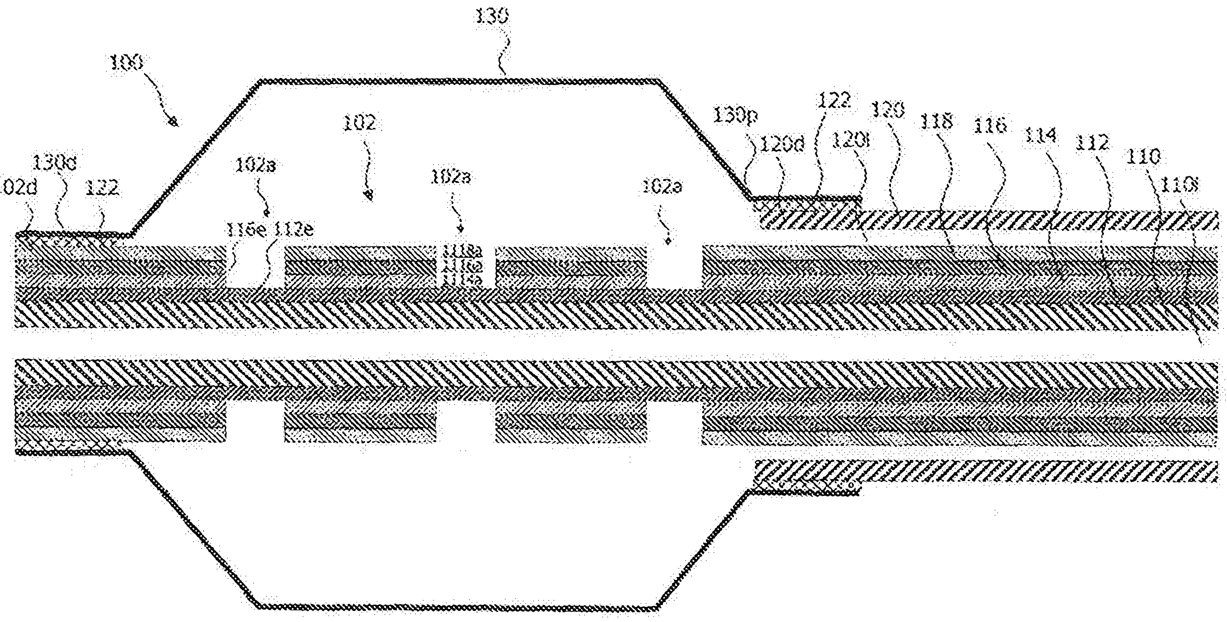
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FIG. 1

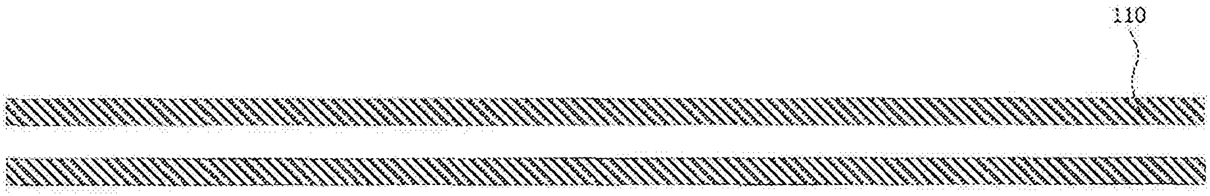

FIG. 2A

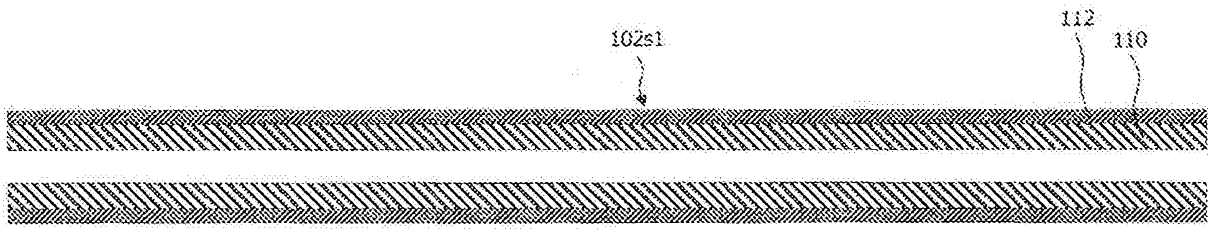

FIG. 2B

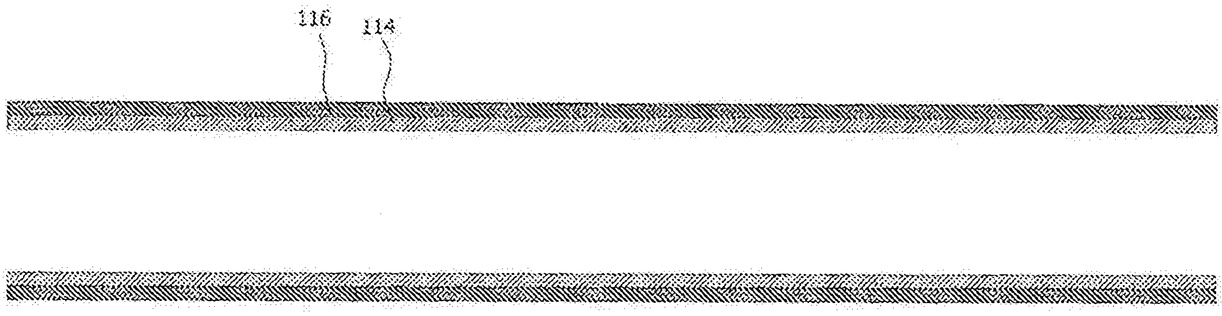

FIG. 3A

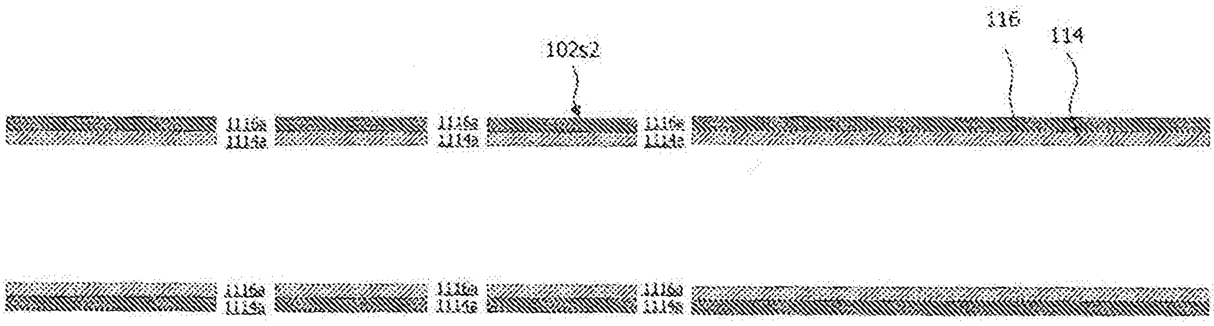

FIG. 3B

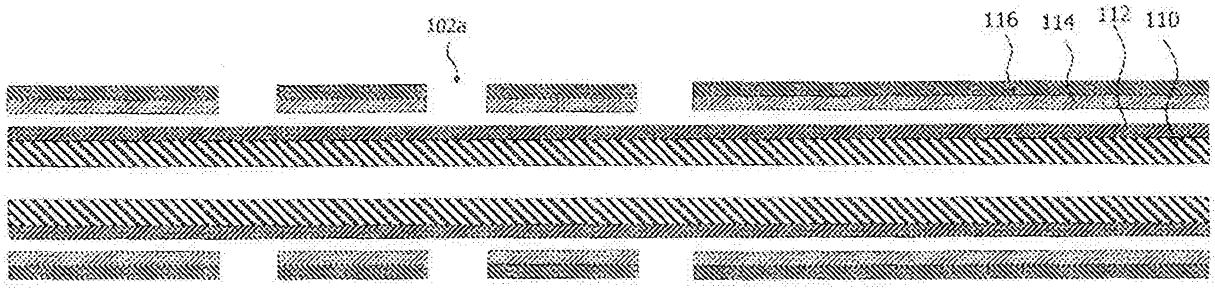

FIG. 4A

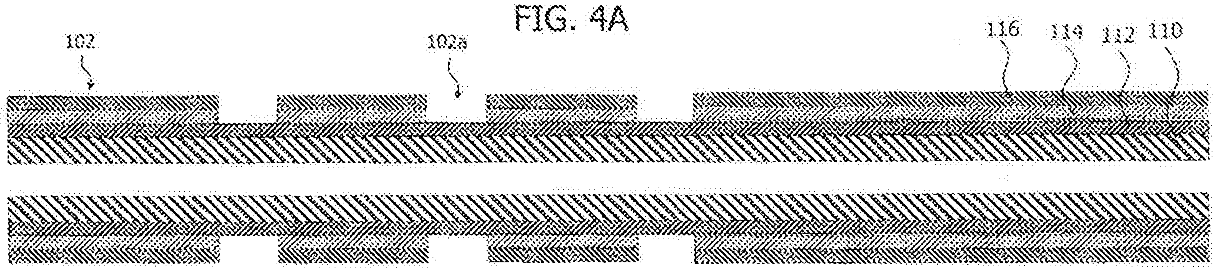

FIG. 4B

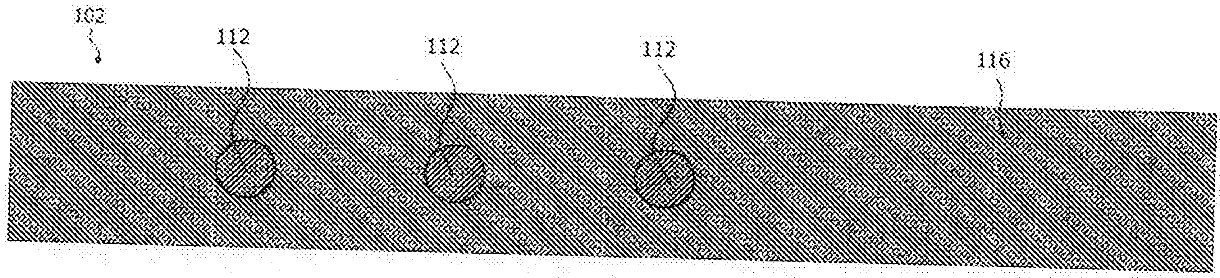

FIG. 5

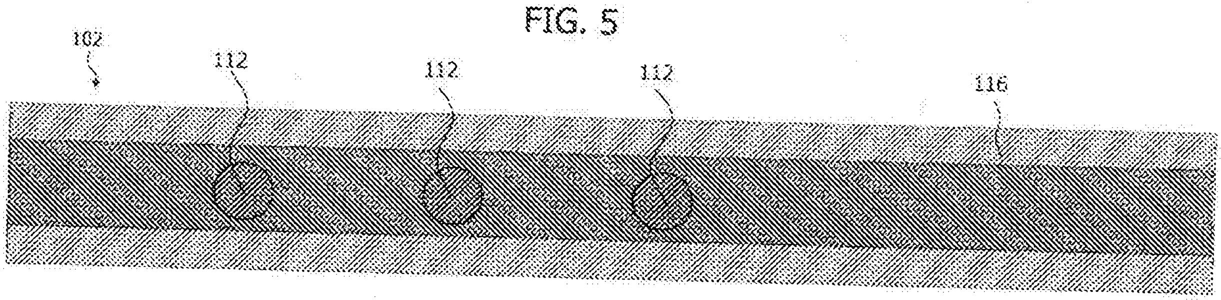

FIG. 6

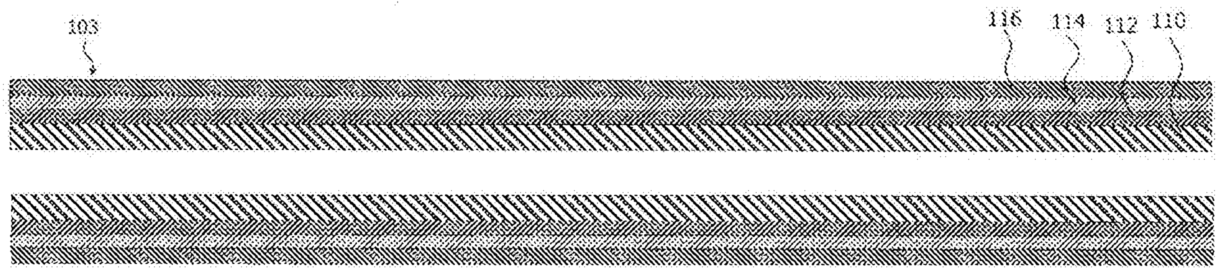

FIG. 7A

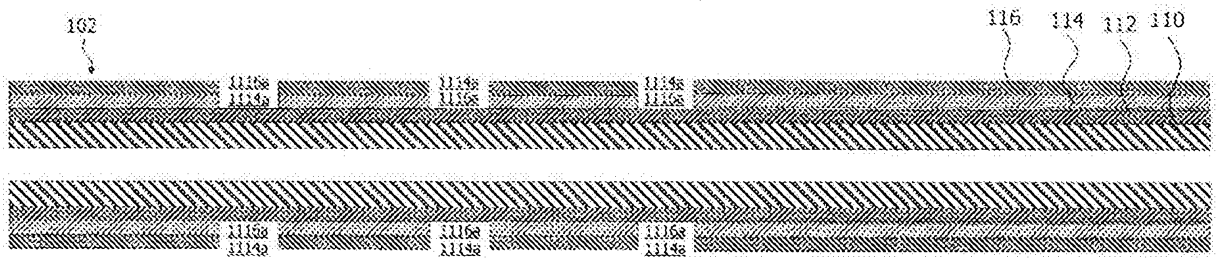

FIG. 7B

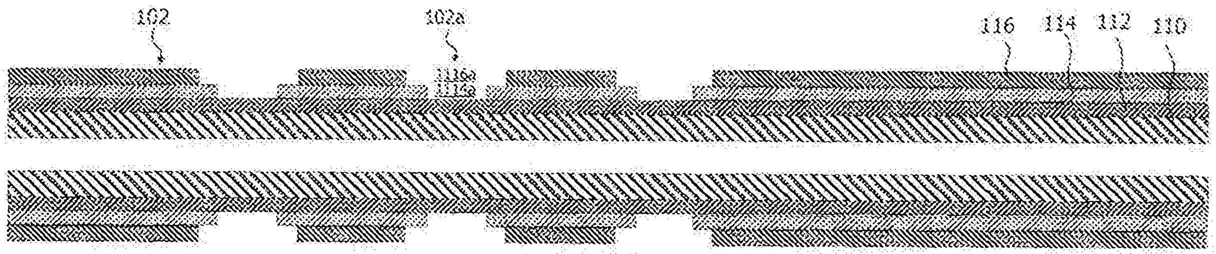

FIG. 8A

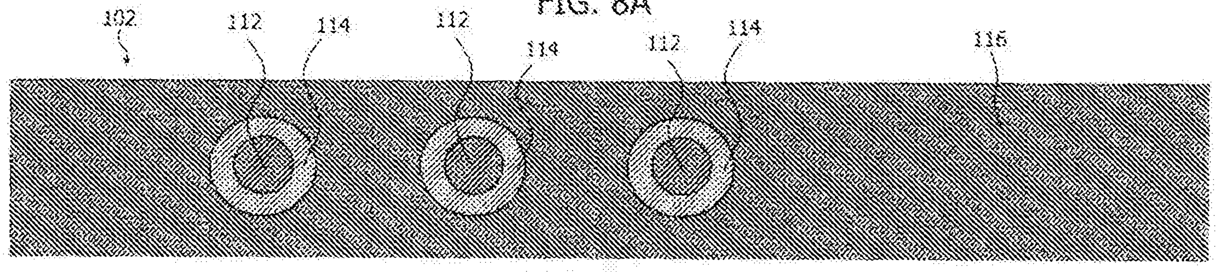

FIG. 8B

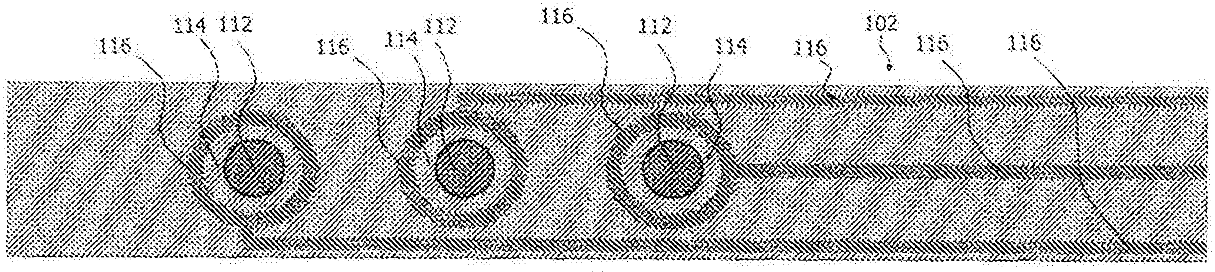

FIG. 9

ABSTRACT

The present disclosure relates to a shockwave generating device. The device for treating calcified lesions in blood vessels by way of shockwaves, the device comprising:

- a balloon, which balloon is fillable with conductive fluid;
- an electrode assembly arranged within the balloon, which electrode assembly comprises:
    - a first conductive layer extending through the balloon; and
    - a second conductive layer extending through the balloon; and
- means for propagating shock waves generated by a shockwave generator, in the conductive fluid in the balloon.

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE **2L/2VW05/5**
Nederlands aanvraag nr. **2019807**	Indieningsdatum **26-10-2017**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Boston Scientific Scimed, Inc.**	
Datum van het verzoek voor een onderzoek van internationaal type **25-11-2017**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN70088**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)
Volgens de internationale classificatie (IPC) **A61B17/22**

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK	
Onderzochte minimumdocumentatie	
Classificatiesysteem	Classificatiesymbolen
IPC	**A61B:A61M**
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen	

III. ☐	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV. ☐	**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2019807

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61B17/22
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte mimimum documentatie (classificatie gevolgd door classificatiesymbolen)
A61B A61M

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)

EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
Y,D	US 2014/005576 A1 (ADAMS JOHN [US] ET AL) 2 januari 2014 (2014-01-02) in de aanvraag genoemd * alinea [0050] - alinea [0065]; figuren 1-8 * -----	1-24
Y	GB 1 082 397 A (OLEG GAVRILOVICH BALAEV; NICKOLAI AKIMOVICH KOROL) 6 september 1967 (1967-09-06) * bladzijde 1, regel 79 - bladzijde 2, regel 118; figuren 1-4 * -----	1-24
A	US 2015/039002 A1 (HAWKINS DANIEL [US]) 5 februari 2015 (2015-02-05) * alinea [0019] - alinea [0046]; figuren 1-6 * ----- -/--	1-24

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid

22 juni 2018

Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type

Naam en adres van de instantie

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De bevoegde ambtenaar

Neef, Tatjana

2

Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2019807

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie *	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	WO 2014/025397 A1 (SHOCKWAVE MEDICAL INC [US]) 13 februari 2014 (2014-02-13) * figuren 1-7 * -----	1-24

2

Formulier PCT/ISA/201 (vervolg tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek

NL 2019807

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 2014005576 A1	02-01-2014	AU 2013284490 A1	15-01-2015
		BR 112014032669 A2	27-06-2017
		CA 2877160 A1	03-01-2014
		CN 104582597 A	29-04-2015
		EP 2866689 A1	06-05-2015
		JP 6104375 B2	29-03-2017
		JP 2015522344 A	06-08-2015
		US 2014005576 A1	02-01-2014
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WRITTEN OPINION

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SN70088	26.10.2017		NL2019807

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Applicant
Boston Scientific Scimed, Inc.

This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☒ Box No. VII — Certain defects in the application
- ☒ Box No. VIII — Certain observations on the application

Examiner
Neef, Tatjana

WRITTEN OPINION

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material:

☐ on paper

☐ in electronic form

c. time of filing/furnishing:

☐ contained in the application as filed.

☐ filed together with the application in electronic form.

☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	1-24
	No:	Claims	
Inventive step	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Box No. VIII Certain observations on the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 US 2014/005576 A1 (ADAMS JOHN [US] ET AL) 2 januari 2014 (2014-01-02)in de aanvraag genoemd

D2 GB 1 082 397 A (OLEG GAVRILOVICH BALAEV; NICKOLAI AKIMOVICH KOROL) 6 september 1967 (1967-09-06)

D3 US 2015/039002 A1 (HAWKINS DANIEL [US]) 5 februari 2015 (2015-02-05)

D4 WO 2014/025397 A1 (SHOCKWAVE MEDICAL INC [US]) 13 februari 2014 (2014-02-13)

2 The present application does not meet the criteria of patentability, because the subject-matter of claim 1 does not involve an inventive step.

2.1 D1 may be regarded as being the prior art closest to the subject-matter of claim 1 and claim 16, and discloses: Inrichting voor behandeling van verkalkte laesie in bloedvaten door middel van schokgolven (para. 50- 54), de inrichting omvattende:
- een ballon (26, 326,), waarbij de ballon vulbaar is met geleidende vloeistof (para. 13, 53, 54);
- een elektrode samenstel (322, 342; 242, 250) ingericht binnen in de ballon (fig. 3- 6), het samenstel omvat een eerste (344) en een tweede geleidende element (346) die zich uitrekt door de ballon en middelen (322, 342) om schokgolven gegenereerd door een schokgolfgenerator voort te planten in de geleidende vloeistof in de ballon (para. 60- 64).
The subject-matter of claim 1 therefore differs from this known device in that het elektrode samenstel omvat:
- een eerste geleidende *laag* die zich uitrekt door de ballon; en
- een tweede geleidende *laag* die zich uitrekt door de ballon.
Similar applies for the corresponding method of making the device according to claim 16.

The problem to be solved by the present invention may therefore be regarded as how to provide an alternative electrode arrangement providing means for propagating shockwaves generated by a shockwave generator.

The solution proposed in claim 1 and 16 of the present application cannot be considered a s involving an inventive step for the following reasons: D1 discloses that electric conductors 344, 346 are arranged in the elongate base member of the device, that extend through the balloon and that provide means (322, 324, 348, 350) for generation of shockwaves which are created by apertures (348, 350) created in the material of the insulating base member to expose the different conductors to provide the means for generation of shockwaves. Therefore D1 differs more precisely from claims 1, 16 in that D1 uses co-extruded wires in the elongated base member. D1 already shows already the use of one conductive layer in figure 4 and the use of making apertures to expose the surface of the conductive layer. Further is already known to use conductive layers in catheters for shockwave generation to treat calcified lesions, see D2 (figure 1-4, p. 1, l. 81- p. 2, l. 27) and to expose part of the inner layer by removing part of the outer layer (fig. 3). Therefore the use of conductive layers instead of conductors would have been obvious for the person skilled in the art.
Consequently, the subject-matter of claims 1 and 16 does not involve an inventive step.

2.2 Dependent claims 2-15, 17-24 do not appear contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of inventive step.
The dependent apparatus claims 2-15, 17-24 relate to minor constructional features and or changes which are revealed in the prior art quoted in the search report (e.g. D1- D4, passages as cited in the search report) and/or which form part of the normal consideration of the person skilled in the art, i.e. they are the result of routine engineering and do not constitute an inspired design.
- claims 2- 11, 17- 19, 21- 24: apertures, insulating layers, layers with apertures, layered elongate base member, location, orientation of apertures on the elongate member (routine engineering/obvious design alternatives; see e.g. D1, D3, D4: multiple apertures, different locations, different sizes, layered elongate member: D2)
- claims 12, 13, 20: balloon catheter, balloon attached to distal end, lumen for

guidewire (well-known/ routine engineering, see e,g, D1- D4)
- claims 15, 14: device or system with the device further with a shock wave generator (known to the person skilled in the art; see any of D1- D4)

Re Item VII

Certain defects in the application

1 Independent apparatus claim 1 and method claim 16 are not in the two-part form, with those features known in combination from the prior art being placed in the preamble and the remaining features being included in the characterising part.

2 The features of the claims are not provided with reference signs placed in parentheses.

3 The relevant background art disclosed in D2, D3, D4 is not mentioned in the description, nor is this document identified therein.

Re Item VIII

Certain observations on the application

1 Claims are not clear.

1.1 Claims 14 and 15 are not concise, both claims result essentially in the same apparatus once called a system and once a device with a device according to the previous device claims and a shockwave generator. Dependency of claim 15 on claim 14 would lead to a system with two shock wave generators, which casts additional doubt on the dependency of claims 15.

1.2 The terms "preferably" used in claims 14, 15 provides an unclarity, the term do not have a limiting effect on the scope of the claim, therefore features following such expressions are regarded as entirely optional.

1.3 Claims 1 and 16 seem not supported by the description, as its scope appears broader than justified by the description and drawings, some features that are essential to the definition of the invention seem to be missing. The features seem to be at least the elongated member on which the layers are arranged, first insulating layer, possibly second insulating layer and the apertures through the layers which create the 'means for propagating shockwaves', in the description no other alternative means then the apertures were disclosed as 'means for propagating shockwaves' inside the balloon.