US008956371B2

(12) **United States Patent**
Hawkins et al.

(10) **Patent No.: US 8,956,371 B2**
(45) **Date of Patent: *Feb. 17, 2015**

(54) **SHOCKWAVE BALLOON CATHETER SYSTEM**

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(73) Assignee: **Shockwave Medical, Inc.**, Fremont, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 294 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/482,995**

(22) Filed: **Jun. 11, 2009**

(65) **Prior Publication Data**

US 2009/0312768 A1 Dec. 17, 2009

Related U.S. Application Data

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(51) **Int. Cl.**
A61B 17/22 (2006.01)
A61B 17/225 (2006.01)
A61B 17/3207 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/2202*** (2013.01); *A61B 17/22022* (2013.01); *A61B 17/2251* (2013.01); *A61B 17/320725* (2013.01); *A61B 2017/22024* (2013.01); *A61B 2017/22025* (2013.01); ***A61B 17/22029*** (2013.01); *A61B 2017/22058* (2013.01); *A61B 2017/22061* (2013.01); *A61B 2017/22062* (2013.01)
USPC **606/128**; 601/4; 606/194

(58) **Field of Classification Search**
USPC 606/48, 50, 127, 128, 159, 167, 169, 606/170, 1–4; 601/2, 4; 604/22; 600/439
See application file for complete search history.

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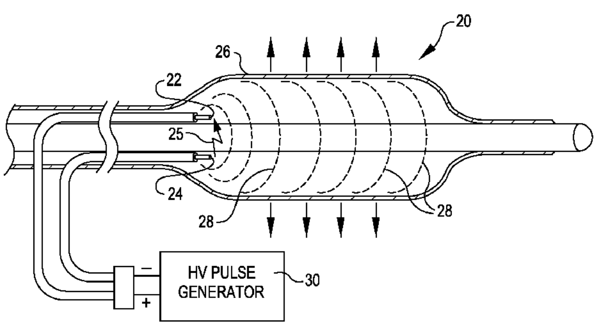
Primary Examiner — Kathleen Holwerda
(74) *Attorney, Agent, or Firm* — Morrison & Foerster LLP

(57) **ABSTRACT**

A system for breaking obstructions in body lumens includes a catheter including an elongated carrier, a balloon about the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least one electrode within the balloon that forms a mechanical shock wave within the balloon. The system further includes a power source that provides electrical energy to the arc generator.

17 Claims, 8 Drawing Sheets



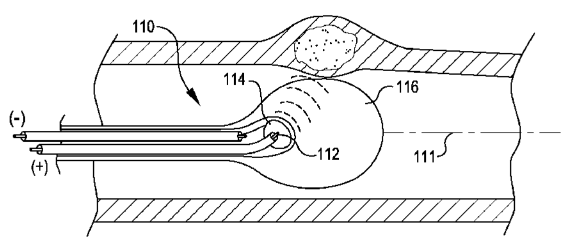


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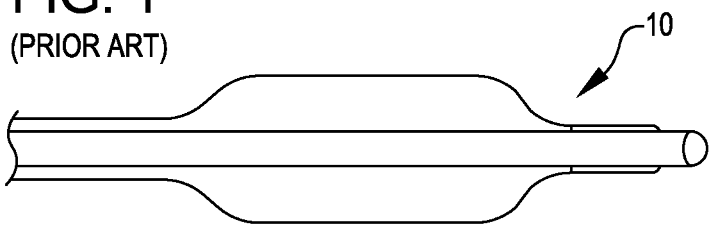
FIG. 1
(PRIOR ART)



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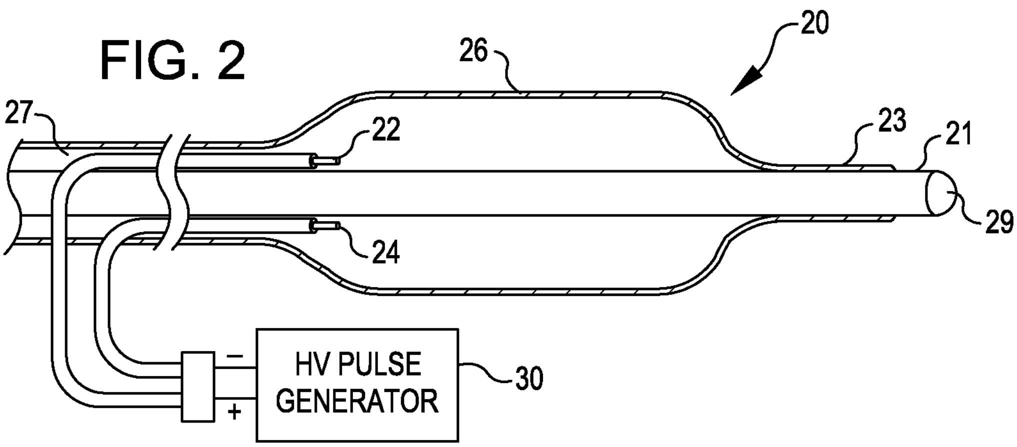

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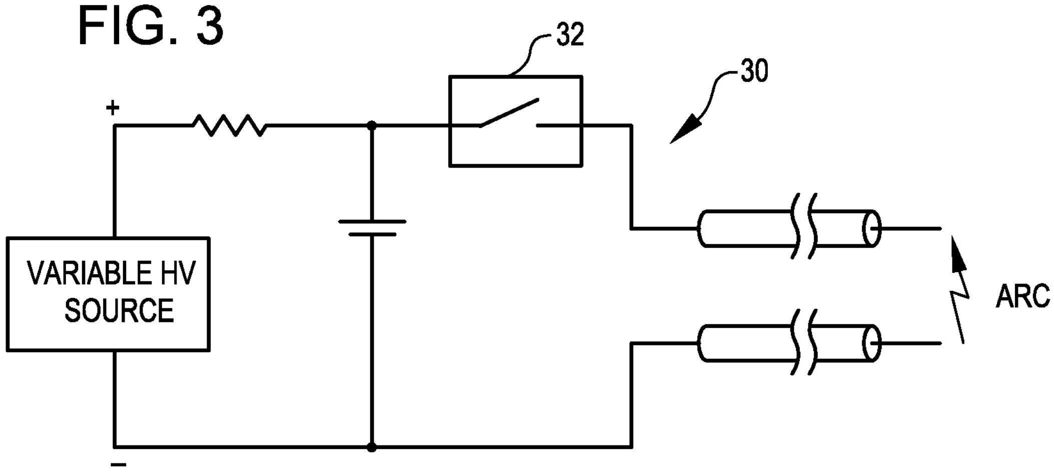
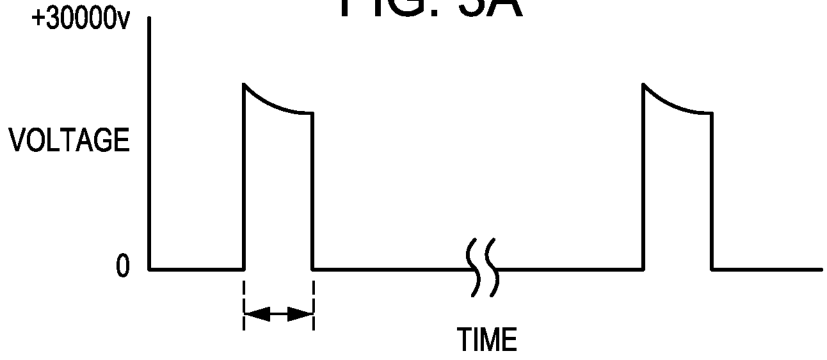


FIG. 3A



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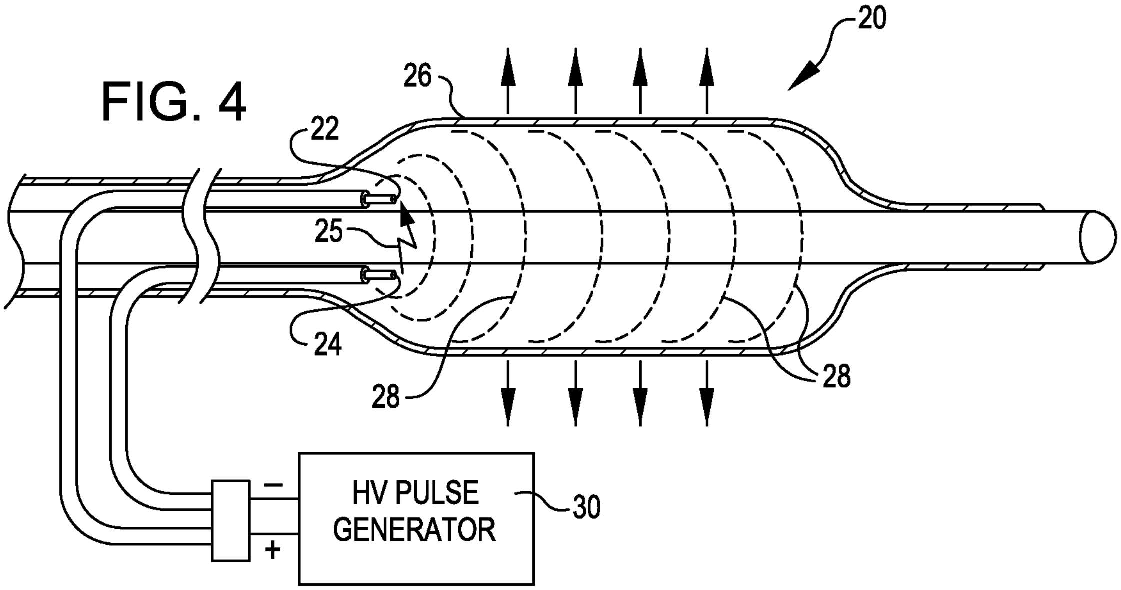

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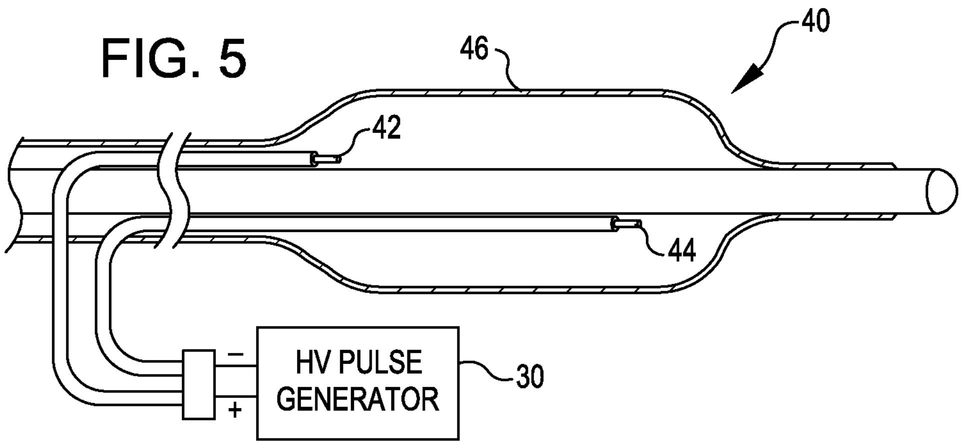

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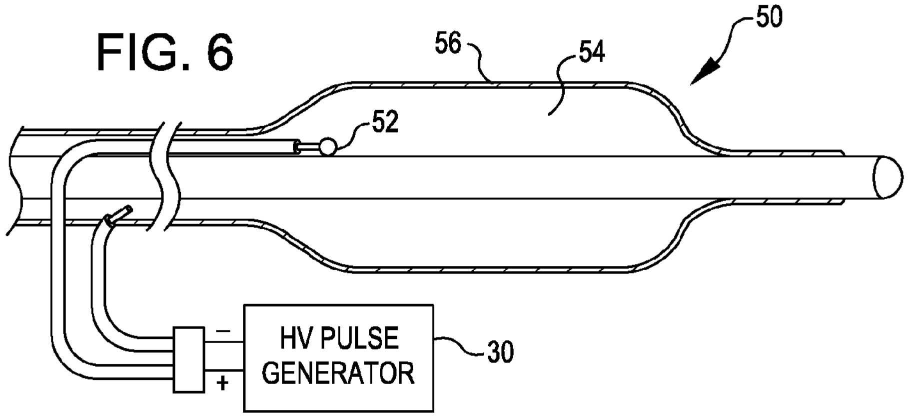

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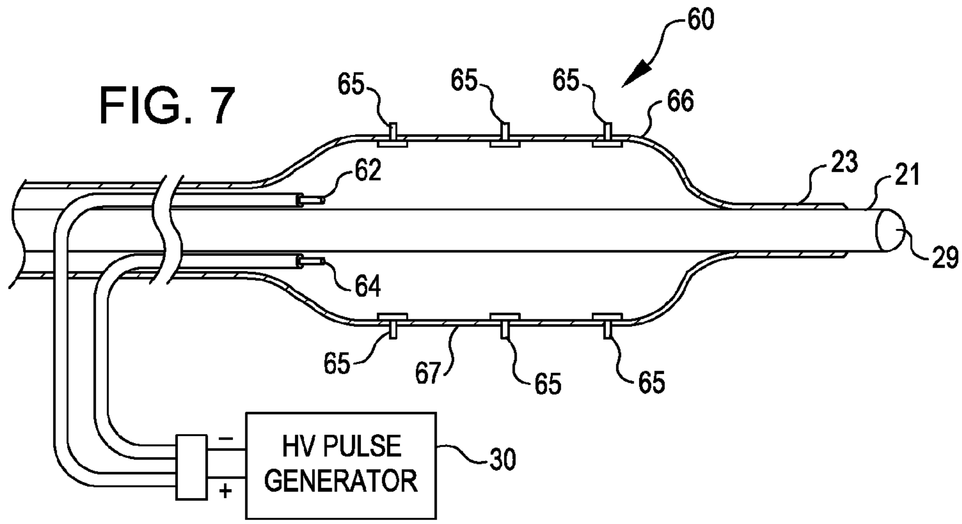

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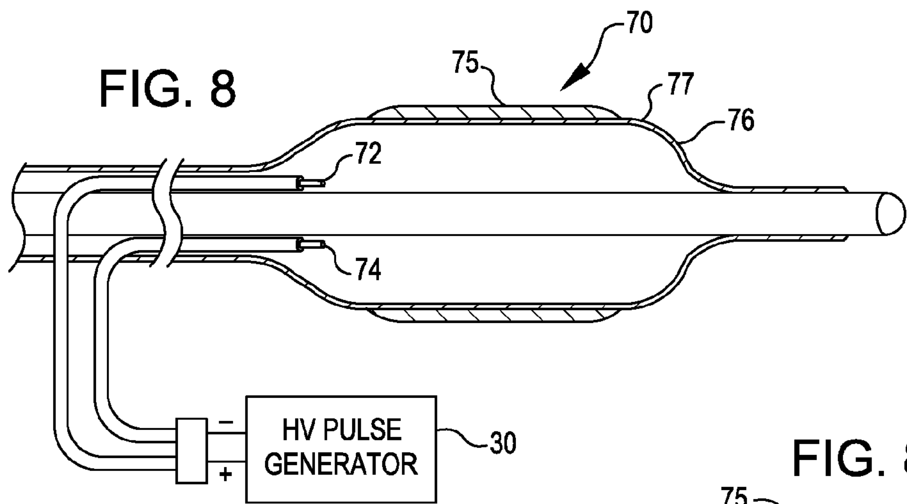
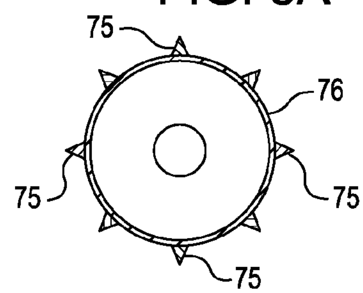


FIG. 8A



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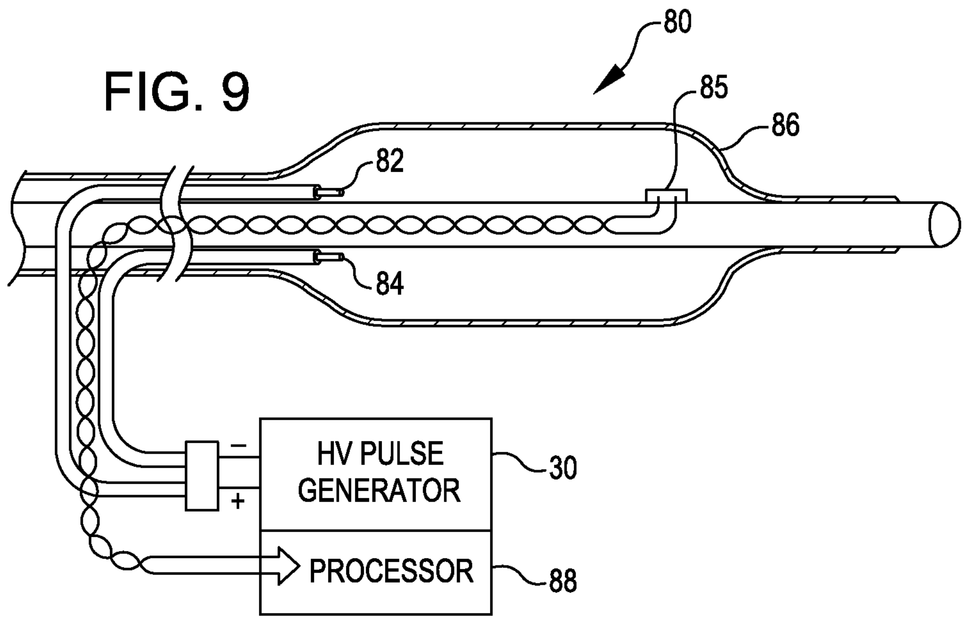

80
85
86
82
84
HV PULSE GENERATOR
30
PROCESSOR
88
−
+

FIG. 10

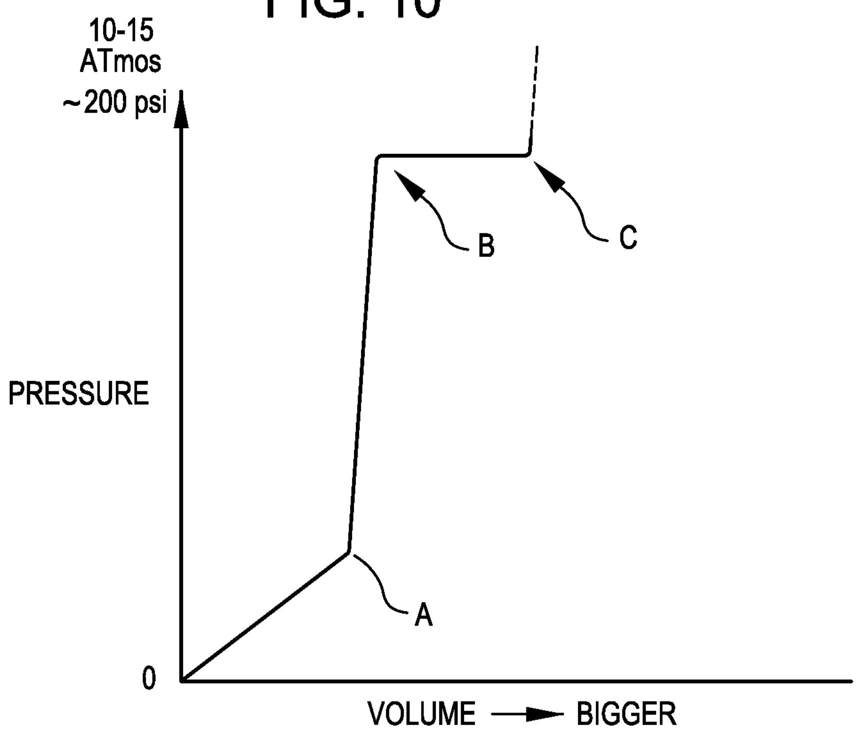

10-15
ATmos
~200 psi
PRESSURE
0
VOLUME ⟶ BIGGER
A
B
C

FIG. 10A
(PRIOR ART)

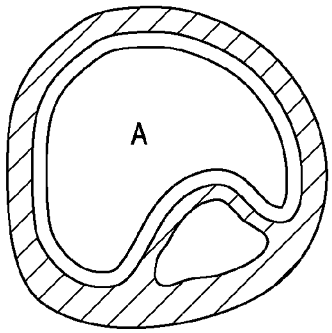


FIG. 10B
(PRIOR ART)

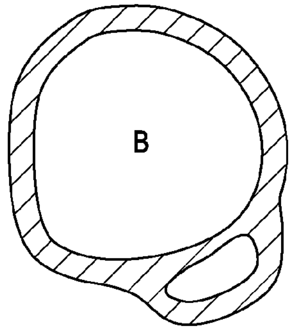


FIG. 10C
(PRIOR ART)

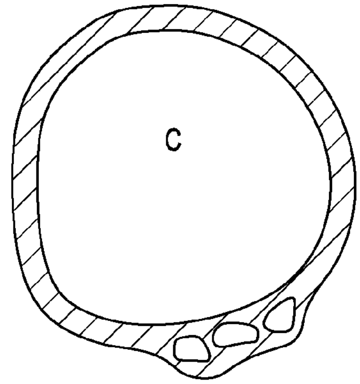


FIG. 11

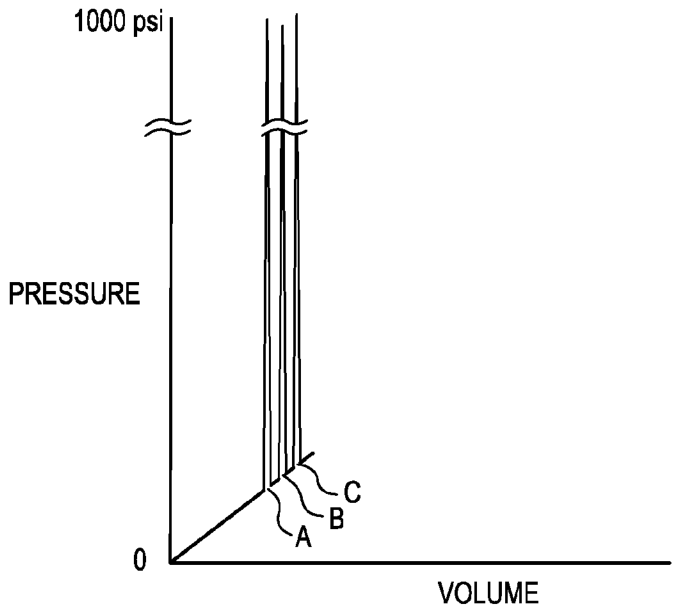


FIG. 11A

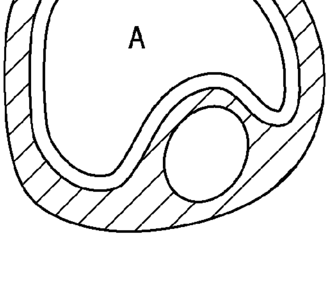


FIG. 11B

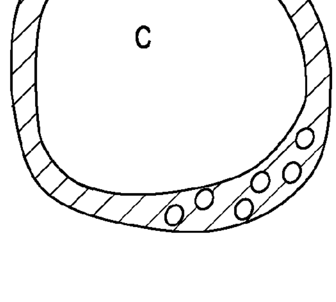


FIG. 12

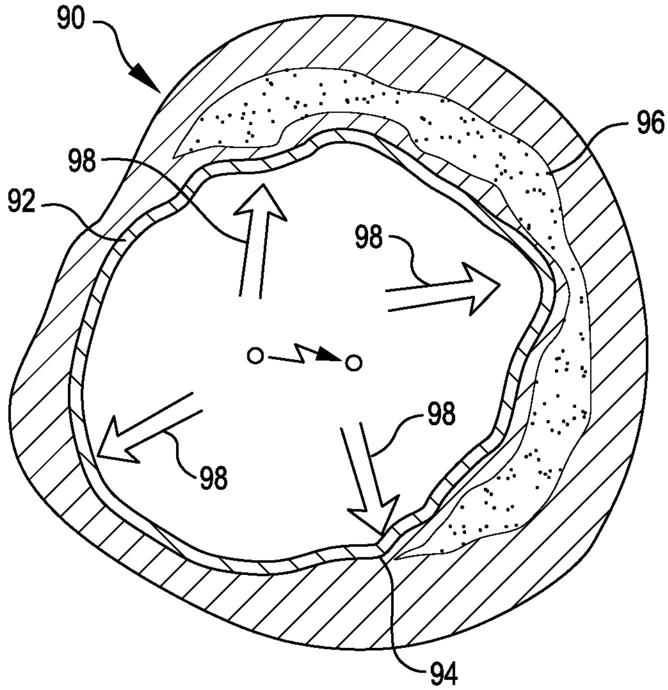


FIG. 13

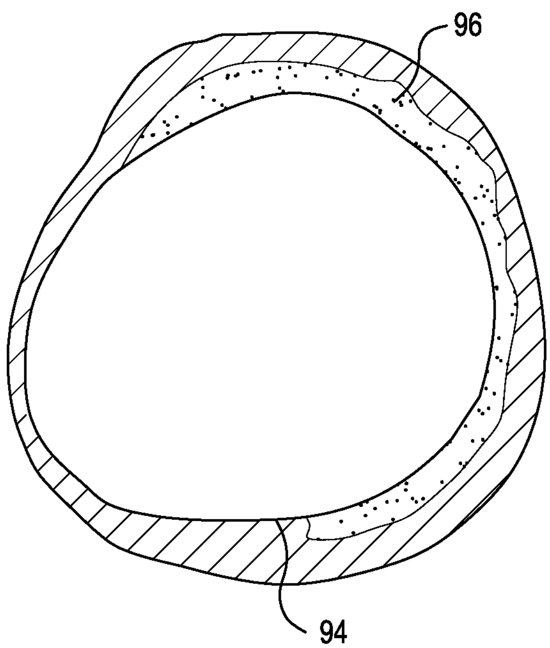
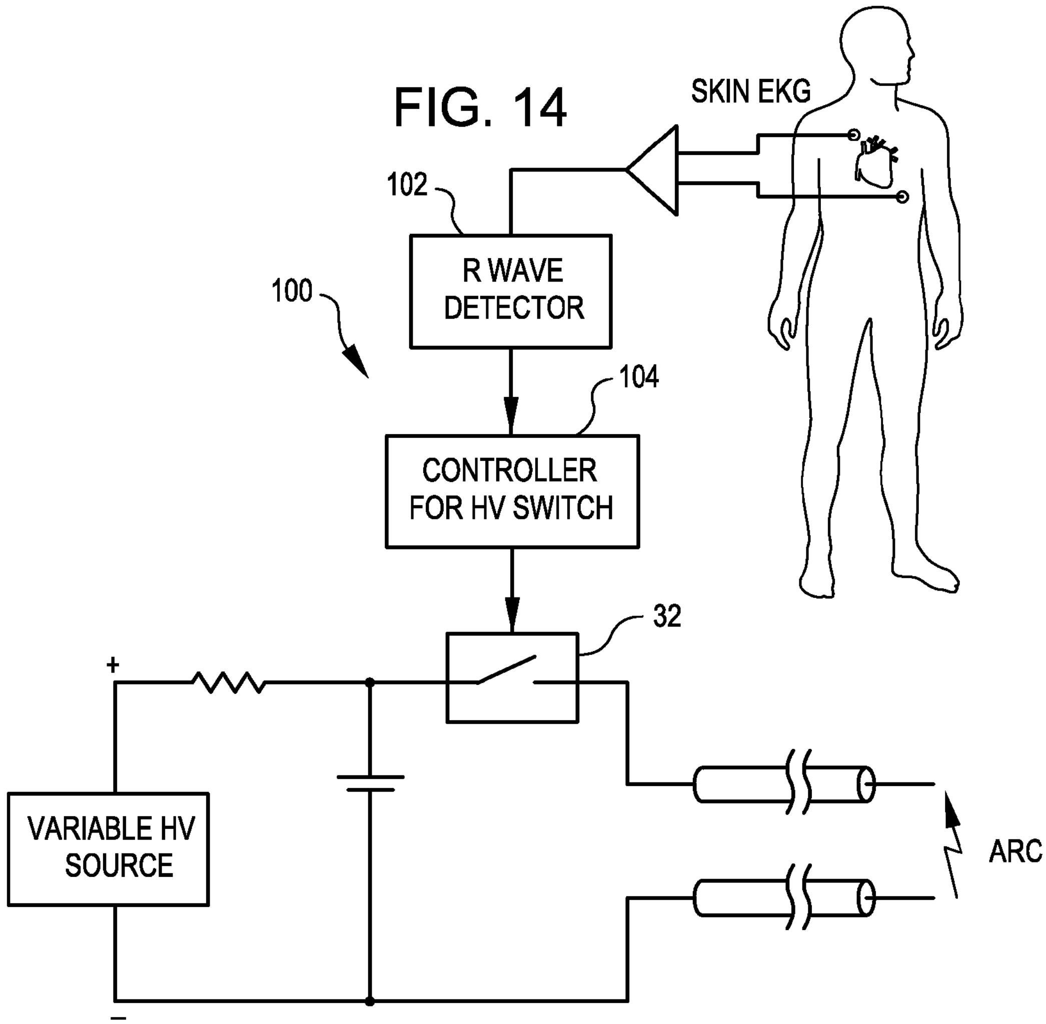
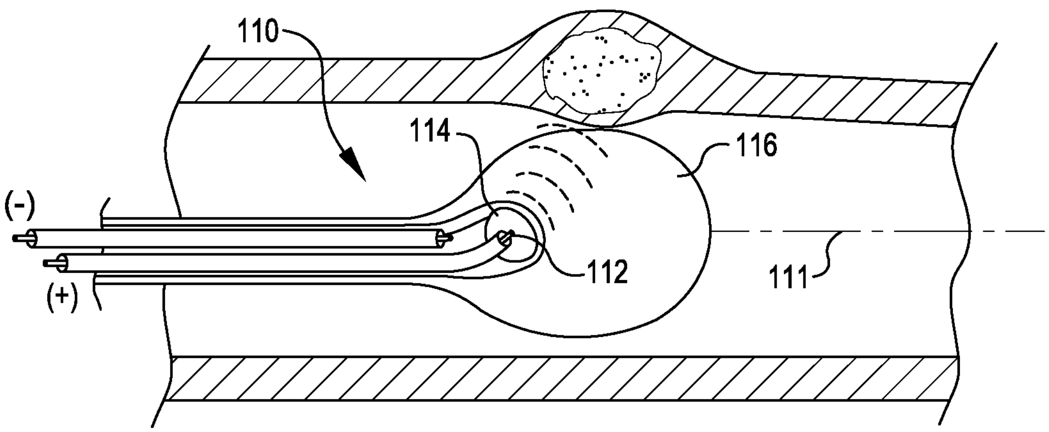


FIG. 14



SKIN EKG
102
R WAVE DETECTOR
100
104
CONTROLLER FOR HV SWITCH
32
+
VARIABLE HV SOURCE
−
ARC

FIG. 15



SHOCKWAVE BALLOON CATHETER SYSTEM

PRIORITY CLAIM

The present application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/061,170, filed Jun. 13, 2008, which application is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

The present invention relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery. It is particularly useful when the lesion is a calcified lesion in the wall of the artery. Calcified lesions require high pressures (sometimes as high as 10-15 or even 30 atmospheres) to break the calcified plaque and push it back into the vessel wall. With such pressures comes trauma to the vessel wall which can contribute to vessel rebound, dissection, thrombus formation, and a high level of restenosis. Non-concentric calcified lesions can result in undue stress to the free wall of the vessel when exposed to high pressures. An angioplasty balloon when inflated to high pressures can have a specific maximum diameter to which it will expand but 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 the balloon will be confined to the size of the open 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.

SUMMARY OF THE INVENTION

The invention provides a catheter that comprises an elongated carrier, a dilating balloon about the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least one electrode within the balloon that forms a mechanical shock wave within the balloon.

The at least one electrode may include a single metallic electrode of a pair of metallic electrodes. The electrodes may be radially displaced from each other or longitudinally displaced from each other. The at least one electrode may be formed of stainless steel.

The balloon may be formed of non-compliant material or of compliant material. The dilating balloon may have at least one stress riser carried on its surface.

The catheter may further comprise a sensor that senses reflected energy. The sensor may be distal to the at least one electrode. The sensor may be disposed on the carrier.

The catheter may further comprise a reflector within the dilating balloon that focuses the shock waves. The reflector may form one of the at least one electrodes. The catheter has a center line and the reflector may be arranged to focus the shock waves off of the catheter center line.

The fluid may be saline. The fluid may include an x-ray contrast.

The catheter may further include a lumen for receiving a guide wire. The lumen may be defined by the carrier.

The invention further provides a system comprising a catheter including an elongated carrier, a dilating balloon about

the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least one electrode within the balloon that forms a mechanical shock wave within the balloon. The system further comprises a power source that provides electrical energy to the arc generator.

The power source is preferably arranged to provide pulsed high voltage. The power source may be arranged to provide high voltage pulses having selectable pulse durations, selectable voltage amplitudes, and/or selectable pulse repetition rates.

The system may further comprise an R wave detector that synchronizes the mechanical shock waves with cardiac R waves.

The at least one electrode may include a single metallic electrode of a pair of metallic electrodes. The electrodes may be radially displaced from each other or longitudinally displaced from each other. The at least one electrode may be formed of stainless steel.

The balloon may be formed of non-compliant material or of compliant material. The dilating balloon may have at least one stress riser carried on its surface.

The catheter may further comprise a sensor that senses reflected energy. The sensor may be distal to the at least one electrode. The sensor may be disposed on the carrier.

The catheter may further comprise a reflector within the dilating balloon that focuses the shock waves. The reflector may form one of the at least one electrodes. The catheter has a center line and the reflector may be arranged to focus the shock waves off of the catheter center line.

The fluid may be saline. The fluid may include an x-ray contrast.

The catheter may further include a lumen for receiving a guide wire. The lumen may be defined by the carrier.

The invention further provides a method comprising the step of providing a catheter including an elongated carrier, a dilating balloon about the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least one electrode within the balloon that forms a mechanical shock wave within the balloon. The method further comprises the steps of inserting the catheter into a body lumen of a patient adjacent an obstruction of the body lumen, admitting fluid into the balloon, and applying high voltage pulses to the arc generator to form a series of mechanical shocks within the balloon.

The method may include the further step of detecting cardiac R waves of the patient's heart, and synchronizing the mechanical shocks with the detected R waves.

The method may further include the step of varying one of the repetition rate, amplitude and duration of the high voltage pulses to vary the intensity of the mechanical shock waves.

The method may include the further step of sensing reflected energy within the catheter.

The method may include the further step of placing a guide wire into the body lumen and guiding the catheter into the body lumen along the guide wire.

The method may include the further step of focusing the mechanical shockwaves. The mechanical shockwaves may be focused away from the catheter center axis.

The method may include the further steps of adding an x-ray contrast to the fluid and visualizing the catheter under fluoroscopy.

BRIEF DESCRIPTION OF THE DRAWINGS

For illustration and not limitation, some of the features of the present invention are set forth in the appended claims. The various embodiments of the invention, together with representative features and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

FIG. **1** is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter.

FIG. **2** is a side view of a dilating angioplasty balloon catheter with two electrodes within the balloon attached to a source of high voltage pulses according to one embodiment of the invention.

FIG. **3** is a schematic of a high voltage pulse generator.

FIG. **3**A shows voltage pulses that may be obtained with the generator of FIG. **3**.

FIG. **4** is a side view of the catheter of FIG. **2** showing an arc between the electrodes and simulations of the shock wave flow.

FIG. **5** is a side view of a dilating catheter with insulated electrodes within the balloon and displaced along the length of the balloon according to another embodiment of the invention.

FIG. **6** is a side view of a dilating catheter with insulated electrodes within the balloon displaced with a single pole in the balloon and a second being the ionic fluid inside the balloon according to a further embodiment of the invention.

FIG. **7** is a side view of a dilating catheter with insulated electrodes within the balloon and studs to reach the calcification according to a still further embodiment of the invention.

FIG. **8** is a side view of a dilating catheter with insulated electrodes within the balloon with raised ribs on the balloon according to still another embodiment of the invention.

FIG. **8**A is a front view of the catheter of FIG. **8**.

FIG. **9** is a side view of a dilating catheter with insulated electrodes within the balloon and a sensor to detect reflected signals according to a further embodiment of the invention.

FIG. **10** is a pressure volume curve of a prior art balloon breaking a calcified lesion.

FIG. **10**A is a sectional view of a balloon expanding freely within a vessel.

FIG. **10**B is a sectional view of a balloon constrained to the point of breaking in a vessel.

FIG. **10**C is a sectional view of a balloon after breaking within the vessel.

FIG. **11** is a pressure volume curve showing the various stages in the breaking of a calcified lesion with shock waves according to an embodiment of the invention.

FIG. **11**A is a sectional view showing a compliant balloon within a vessel.

FIG. **11**B is a sectional view showing pulverized calcification on a vessel wall.

FIG. **12** illustrates shock waves delivered through the balloon wall and endothelium to a calcified lesion.

FIG. **13** shows calcified plaque pulverized and smooth a endothelium restored by the expanded balloon after pulverization.

FIG. **14** is a schematic of a circuit that uses a surface EKG to synchronize the shock wave to the "R" wave for treating vessels near the heart.

FIG. **15** is a side view, partly cut away, of a dilating catheter with a parabolic reflector acting as one electrode and provides a focused shock wave inside a fluid filled compliant balloon.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter **10**. Such catheters are usually non-complaint with a fixed maximum dimension when expanded with a fluid such as saline.

FIG. **2** is a view of a dilating angioplasty balloon catheter **20** according to an embodiment of the invention. The catheter **20** includes an elongated carrier, such as a hollow sheath **21**, and a dilating balloon **26** formed about the sheath **21** in sealed relation thereto at a seal **23**. The balloon **26** forms an annular channel **27** about the sheath **21** through which fluid, such as saline, may be admitted into the balloon to inflate the balloon. The channel **27** further permits the balloon **26** to be provided with two electrodes **22** and **24** within the fluid filled balloon **26**. The electrodes **22** and **24** are attached to a source of high voltage pulses **30**. The electrodes **22** and **24** are formed of metal, such as stainless steel, and are placed a controlled distance apart to allow a reproducible arc for a given voltage and current. The electrical arcs between electrodes **22** and **24** in the fluid are used to generate shock waves in the fluid. The variable high voltage pulse generator **30** is used to deliver a stream of pulses to the electrodes **22** and **24** to create a stream of shock waves within the balloon **26** and within the artery being treated (not shown). The magnitude of the shock waves can be controlled by controlling the magnitude of the pulsed voltage, the current, the duration and repetition rate. The insulating nature of the balloon **26** protects the patient from electrical shocks.

The balloon **26** may be filled with water or saline in order to gently fix the balloon in the walls of the artery in the direct proximity with the calcified lesion. The fluid may also contain an x-ray contrast to permit fluoroscopic viewing of the catheter during use. The carrier **21** includes a lumen **29** through which a guidewire (not shown) may be inserted to guide the catheter into position. Once positioned the physician or operator can start with low energy shock waves and increase the energy as needed to crack the calcified plaque. Such shockwaves will be conducted through the fluid, through the balloon, through the blood and vessel wall to the calcified lesion where the energy will break the hardened plaque without the application of excessive pressure by the balloon on the walls of the artery.

FIG. **3** is a schematic of the high voltage pulse generator **30**. FIG. **3**A shows a resulting waveform. The voltage needed will depend on the gap between the electrodes and generally 100 to 3000 volts. The high voltage switch **32** can be set to control the duration of the pulse. The pulse duration will depend on the surface area of the electrodes **22** and **24** and needs to be sufficient to generate a gas bubble at the surface of the electrode causing a plasma arc of electric current to jump the bubble and create a rapidly expanding and collapsing bubble, which creates the mechanical shock wave in the balloon. Such shock waves can be as short as a few microseconds.

FIG. **4** is a cross sectional view of the shockwave catheter **20** showing an arc **25** between the electrodes **22** and **24** and simulations of the shock wave flow **28**. The shock wave **28** will radiate out from the electrodes **22** and **24** in all directions and will travel through the balloon **26** to the vessel where it will break the calcified lesion into smaller pieces.

FIG. **5** shows another dilating catheter **40**. It has insulated electrodes **42** and **44** within the balloon **46** displaced along the length of the balloon **46**.

FIG. **6** shows a dilating catheter **50** with an insulated electrode **52** within the balloon **56**. The electrode is a single electrode pole in the balloon, a second pole being the ionic fluid **54** inside the balloon. This unipolar configuration uses the ionic fluid as the other electrical pole and permits a smaller balloon and catheter design for low profile balloons. The ionic fluid is connected electrically to the HV pulse generator **30**.

FIG. **7** is another dilating **60** catheter with electrodes **62** and **64** within the balloon **66** and studs **65** to reach the calcification. The studs **65** form mechanical stress risers on the balloon surface **67** and are designed to mechanically conduct the shock wave through the intimal layer of tissue of the vessel and deliver it directly to the calcified lesion.

FIG. **8** is another dilating catheter **70** with electrodes **72** and **74** within the balloon **76** and with raised ribs **75** on the surface **77** of the balloon **76**. The raised ribs **75** (best seen in FIG. **8**A) form stress risers that will focus the shockwave energy to linear regions of the calcified plaque.

FIG. **9** is a further dilating catheter **80** with electrodes **82** and **84** within the balloon **86**. The catheter **80** further includes a sensor **85** to detect reflected signals. Reflected signals from the calcified plaque can be processed by a processor **88** to determine quality of the calcification and quality of pulverization of the lesion.

FIG. **10** is a pressure volume curve of a prior art balloon breaking a calcified lesion FIG. **10**B shows the build up of energy within the balloon (region A to B) and FIG. **10**C shows the release of the energy (region B to C) when the calcification breaks. At region C the artery is expanded to the maximum dimension of the balloon. Such a dimension can lead to injury to the vessel walls. FIG. **10**A shows the initial inflation of the balloon.

FIG. **11** is a pressure volume curve showing the various stages in the breaking of a calcified lesion with shock waves according to the embodiment. The balloon is expanded with a saline fluid and can be expanded to fit snugly to the vessel wall (Region A)(FIG. **11**A) but this is not a requirement. As the High Voltage pulses generate shock waves (Region B and C) extremely high pressures, extremely short in duration will chip away the calcified lesion slowly and controllably expanding the opening in the vessel to allow blood to flow un-obstructed (FIG. **11**B).

FIG. **12** shows, in a cutaway view, shock waves **98** delivered in all directions through the wall **92** of a saline filled balloon **90** and intima **94** to a calcified lesion **96**. The shock waves **98** pulverize the lesion **96**. The balloon wall **92** may be formed of non-compliant or compliant material to contact the intima **94**.

FIG. **13** shows calcified plaque **96** pulverized by the shock waves. The intima **94** is smoothed and restored after the expanded balloon (not shown) has pulverized and reshaped the plaque into the vessel wall.

FIG. **14** is a schematic of a circuit **100** that uses the generator circuit **30** of FIG. **3** and a surface EKG **102** to synchronize the shock wave to the "R" wave for treating vessels near the heart. The circuit **100** includes an R-wave detector **102** and a controller **104** to control the high voltage switch **32**. Mechanical shocks can stimulate heart muscle and could lead to an arrhythmia. While it is unlikely that shockwaves of such short duration as contemplated herein would stimulate the heart by synchronizing the pulses (or bursts of pulses) with the R-wave, an additional degree of safety is provided when used on vessels of the heart or near the heart. While the balloon in the current drawings will provide an electrical isolation of the patient from the current, a device could be made in a non-balloon or non-isolated manner using blood as the fluid. In such a device, synchronization to the R-wave would significantly improve the safety against unwanted arrhythmias.

FIG. **15** shows a still further dilation catheter **110** wherein a shock wave is focused with a parabolic reflector **114** acting as one electrode inside a fluid filled compliant balloon **116**. The other electrode **112** is located at the coaxial center of the reflector **114**. By using the reflector as one electrode, the shock wave can be focused and therefore pointed at an angle (45 degrees, for example) off the center line **111** of the catheter artery. In this configuration, the other electrode **112** will be designed to be at the coaxial center of the reflector and designed to arc to the reflector **114** through the fluid. The catheter can be rotated if needed to break hard plaque as it rotates and delivers shockwaves.

While particular embodiments of the present invention have been shown and described, modifications may be made. For example, instead of manual actuation and spring loaded return of the valves used herein, constructions are possible which perform in a reversed manner by being spring actuated and manually returned. It is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by those claims.

What is claimed is:

1. An angioplasty catheter comprising:

an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough;

an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon; and

an arc generator including a pair of electrodes, said electrodes being positioned within and in non-touching relation to the balloon, said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shock wave.

2. The catheter of claim **1**, wherein the pair of electrodes includes a pair of metallic electrodes.

3. The catheter of claim **2**, wherein the electrodes are radially displaced from each other.

4. The catheter of claim **2**, wherein the electrodes are longitudinally displaced from each other.

5. The catheter of claim **2**, wherein the pair of electrodes is disposed adjacent to and outside of the guide wire lumen.

6. The catheter of claim **2**, wherein the catheter has a distal end and wherein the pair of electrodes is disposed proximal to the distal end of the catheter.

7. The catheter of claim **1**, wherein the balloon is formed of non-compliant material.

8. The catheter of claim **1**, wherein the balloon is formed of compliant material.

9. The catheter of claim **1**, wherein the balloon has a surface, and wherein the catheter further comprises at least one stress riser carried on the surface of the balloon.

10. The catheter of claim **1**, further comprising a sensor that senses reflected energy.

11. The catheter of claim **1**, further comprising a reflector within the balloon that focuses the shock waves.

12. The catheter of claim **1**, wherein the balloon electrically insulates the pair of electrodes from tissue external to the catheter.

13. The catheter of claim **1**, wherein the pair of electrodes includes a first electrode and a second electrode, the second electrode being arranged to form an electrical arc with the first electrode to generate the mechanical shock wave and to reflect the mechanical shock wave in a desired pattern.

14. The catheter of claim **1**, wherein the balloon has a center axis and the guide wire lumen has a center axis in common with the balloon center axis; and

wherein at least one electrode of the electrode pair is disposed in non-intersecting relation with respect to the balloon center axis.

15. A system comprising:

an angioplasty catheter including an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough, an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon, and an arc generator including a pair of electrodes being positioned within and in non-touching relation to the balloon; and

a power source configured to provide a high voltage pulse to the arc generator, said high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shock wave.

16. The system of claim **15**, wherein the power source is arranged to provide high voltage pulses having at least one of selectable pulse durations, selectable voltage amplitudes, and selectable pulse repetition rates.

17. The system of claim **15**, further comprising an R wave detector that synchronizes the mechanical shock waves with a cardiac R waves.

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