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(54) **APPARATUS AND METHOD FOR AN ULTRASONIC MEDICAL DEVICE TO TREAT DEEP VEIN THROMBOSIS**

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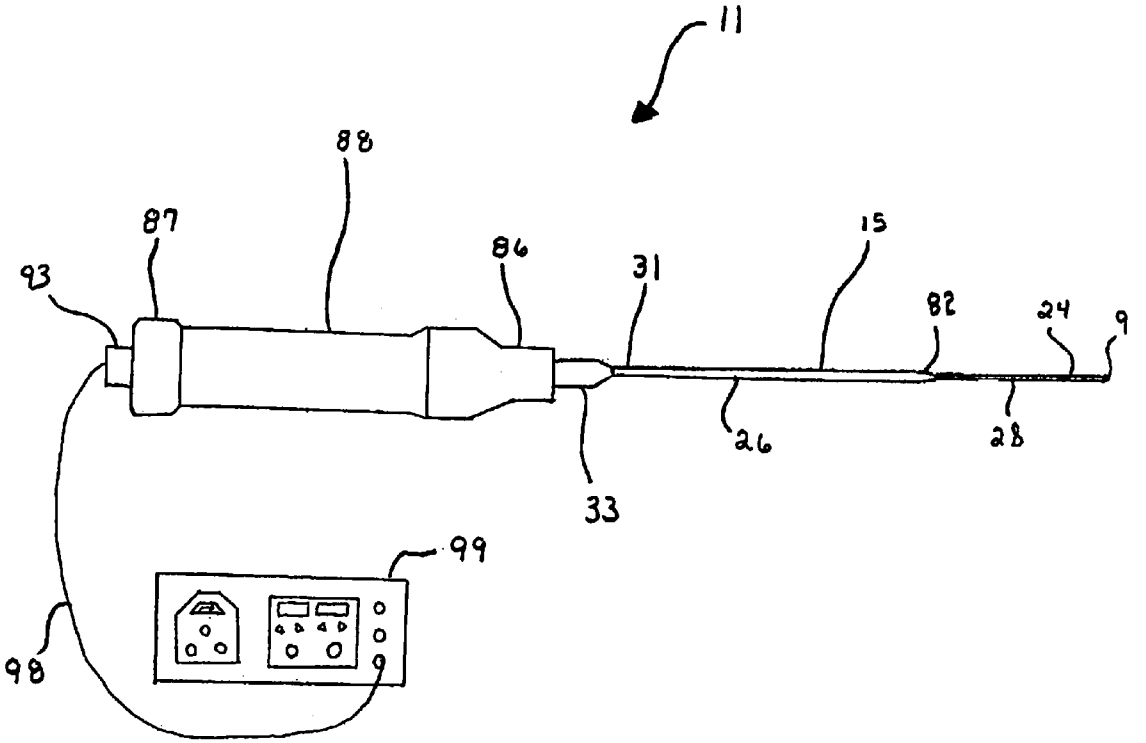
(57) **ABSTRACT**

An apparatus and method for an ultrasonic medical device to treat deep vein thrombosis. The ultrasonic medical device comprises an ultrasonic probe having a proximal end, a distal end and a longitudinal axis therebetween. The ultrasonic probe is inserted into a deep vein of a leg, navigated adjacent to a thrombus in the deep vein and placed in communication with the thrombus. An ultrasonic energy source is activated to generate a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the ultrasonic probe. The transverse ultrasonic vibration creates a plurality of transverse nodes and a plurality of transverse anti-nodes along the longitudinal axis of the ultrasonic probe, generating cavitation in a medium surrounding the ultrasonic probe to ablate the thrombus and treat deep vein thrombosis.



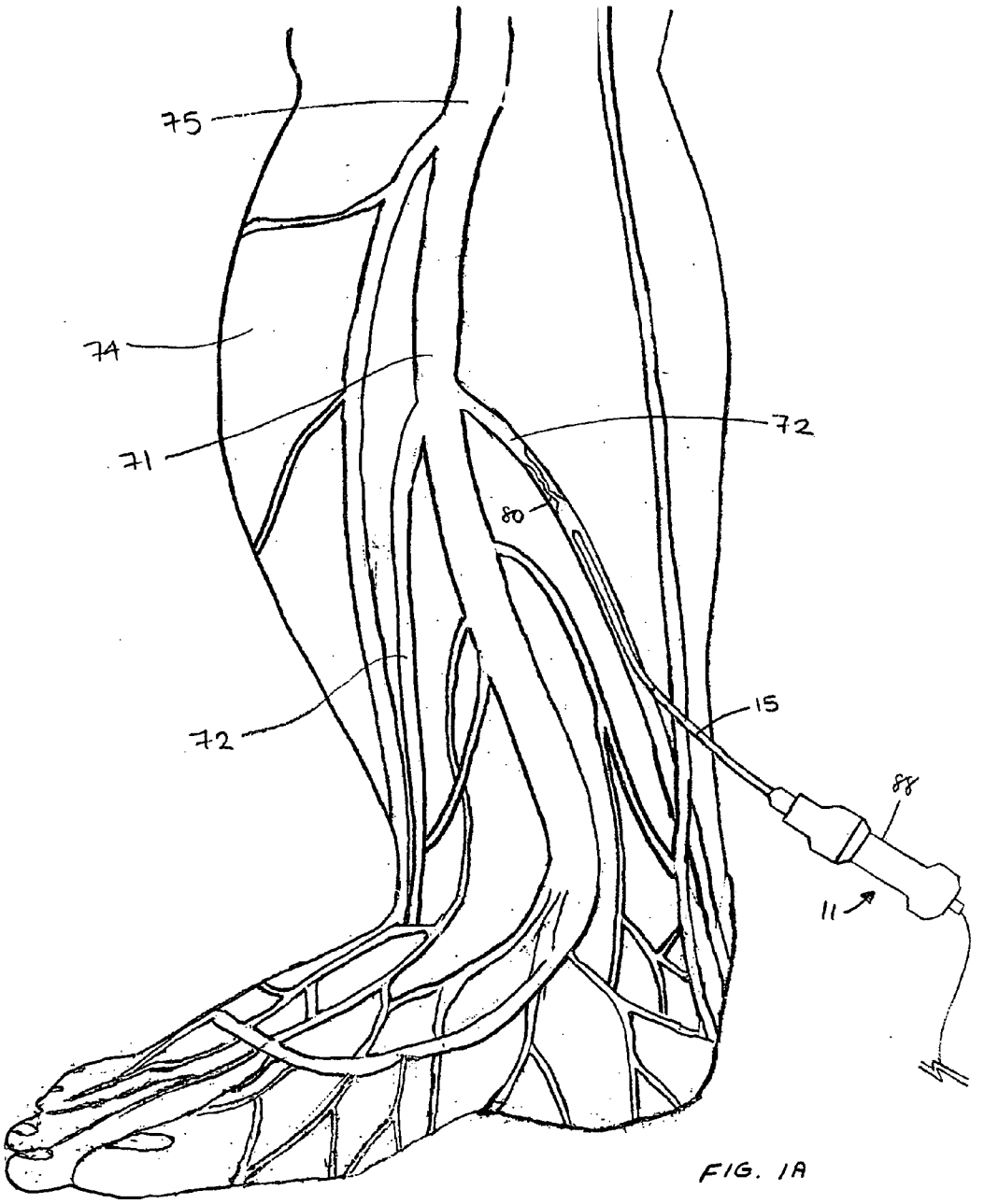


FIG. 1A

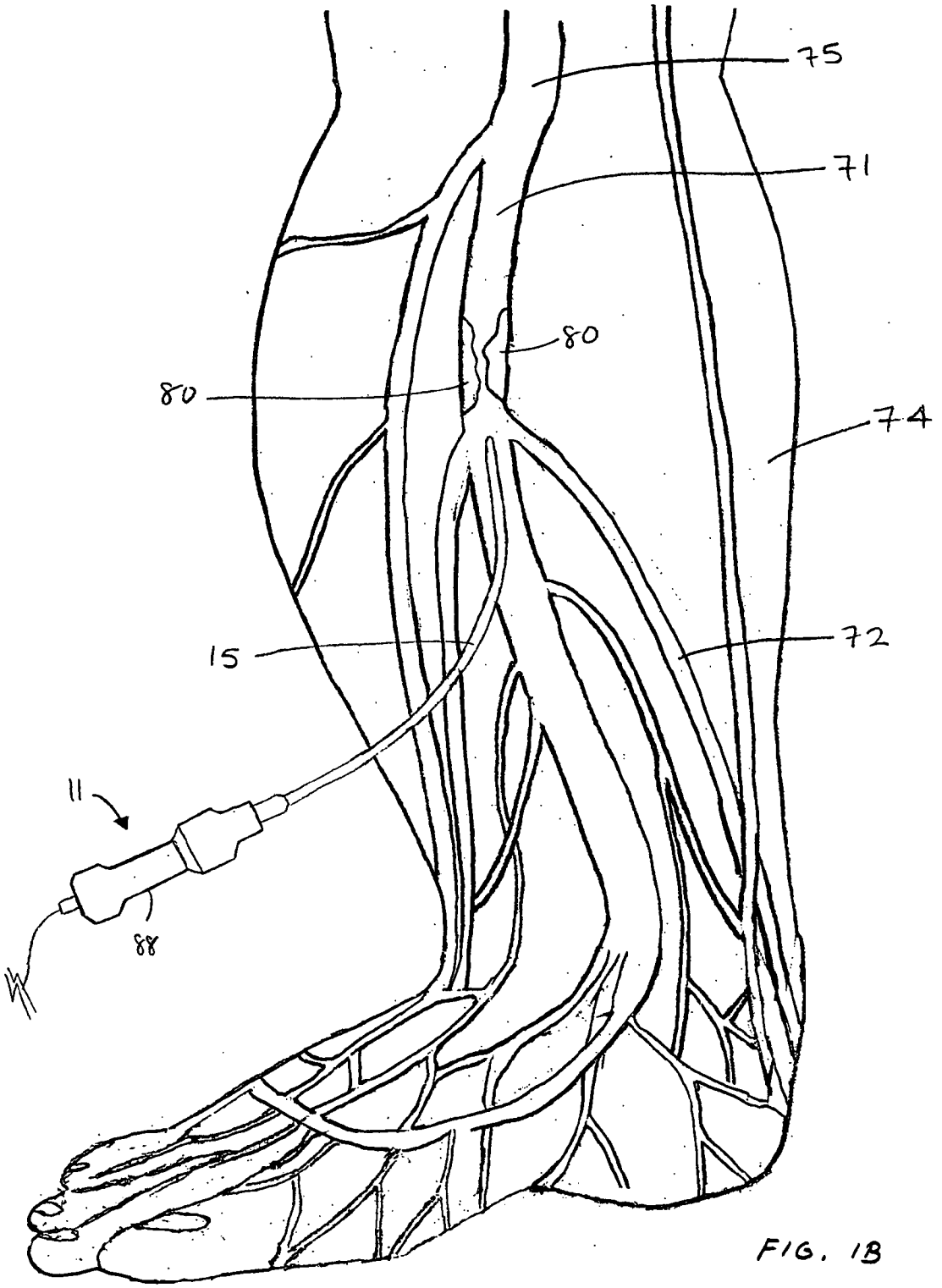


FIG. 1B

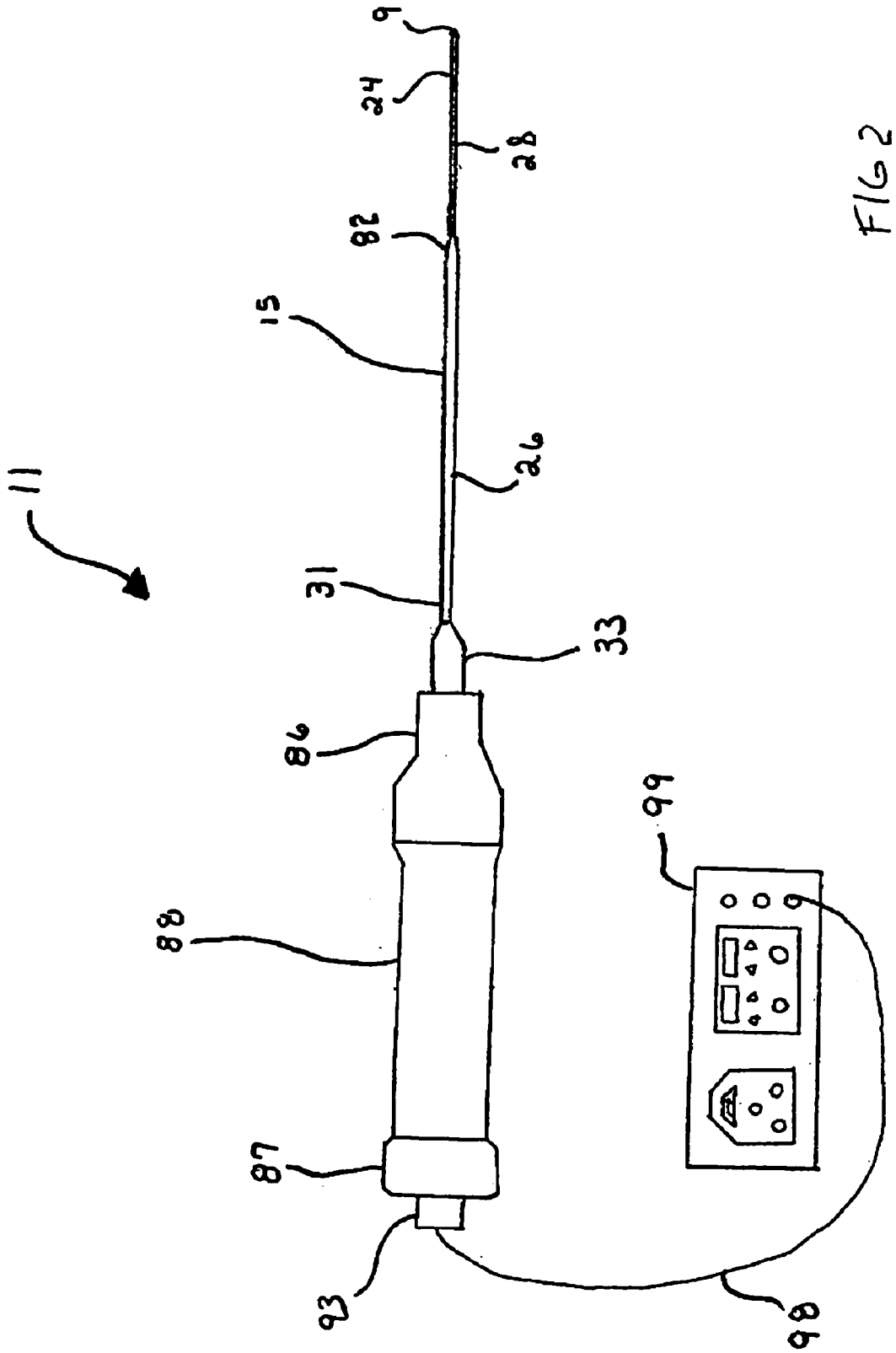


FIG 2

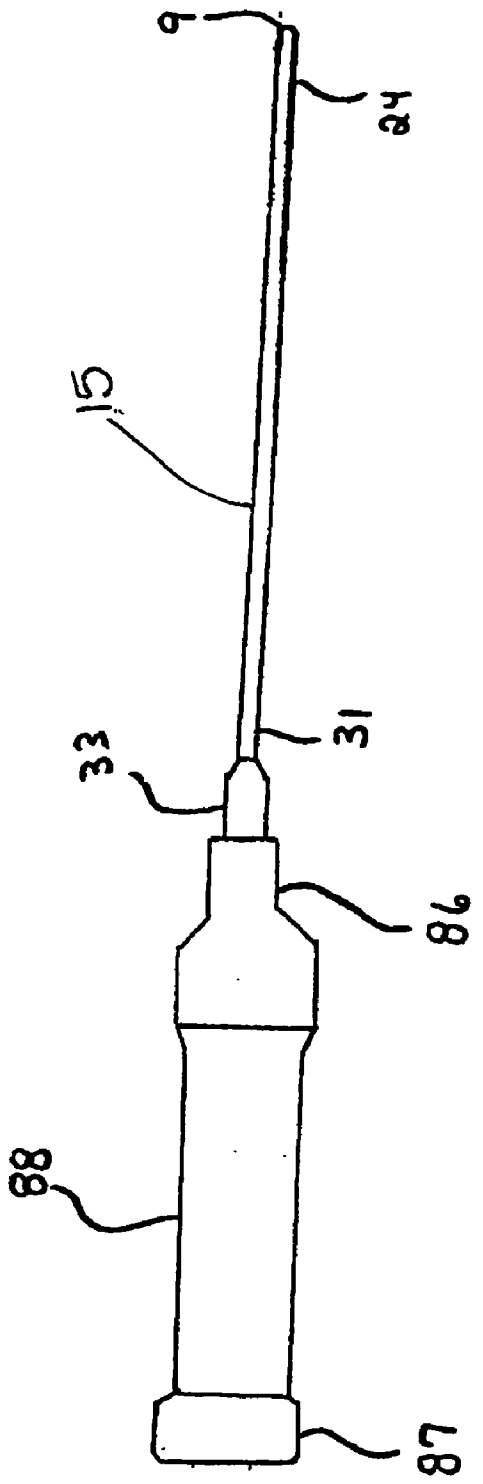


Fig 3

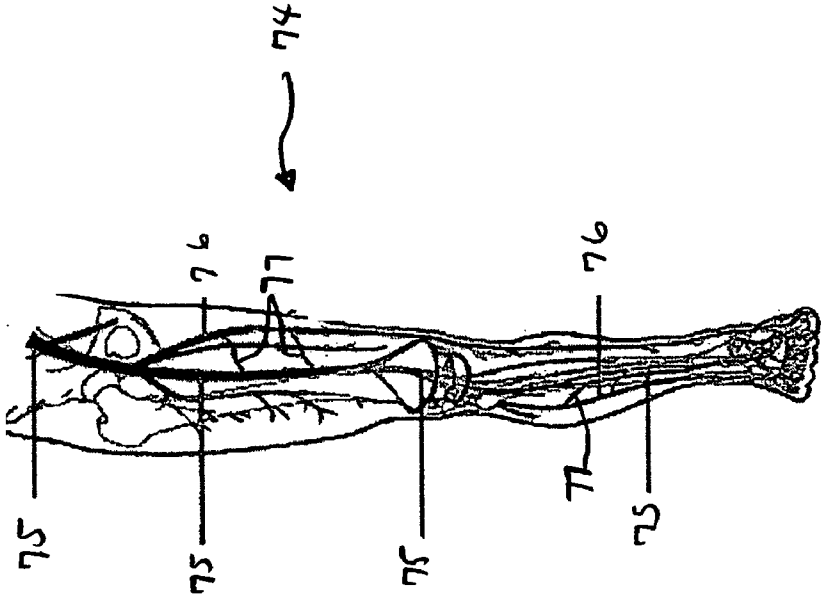
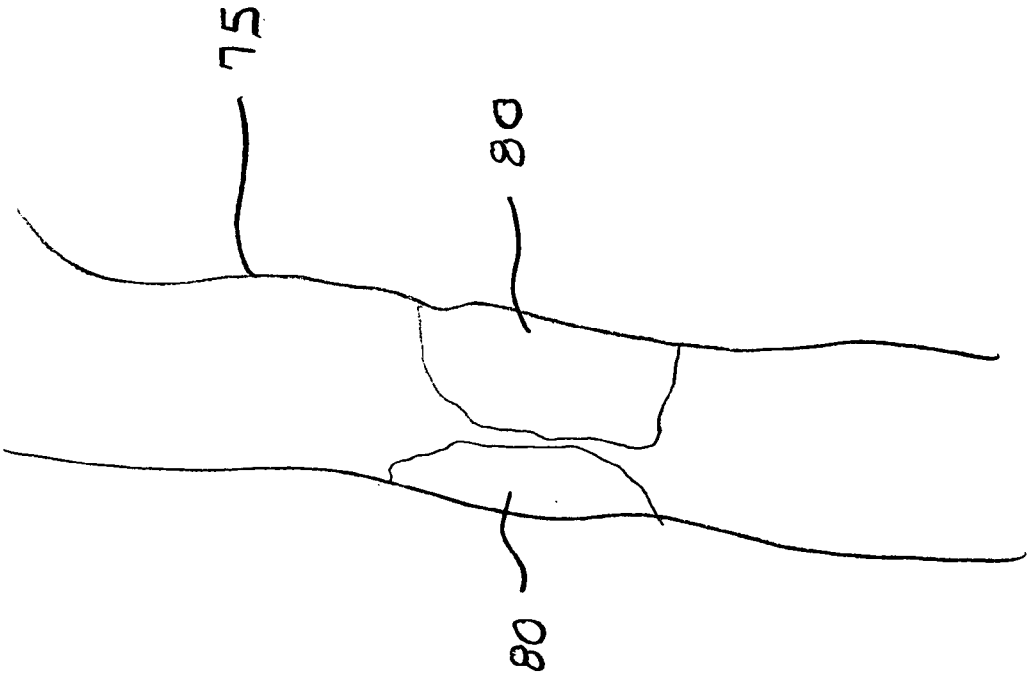


FIG. 4

FIG 5



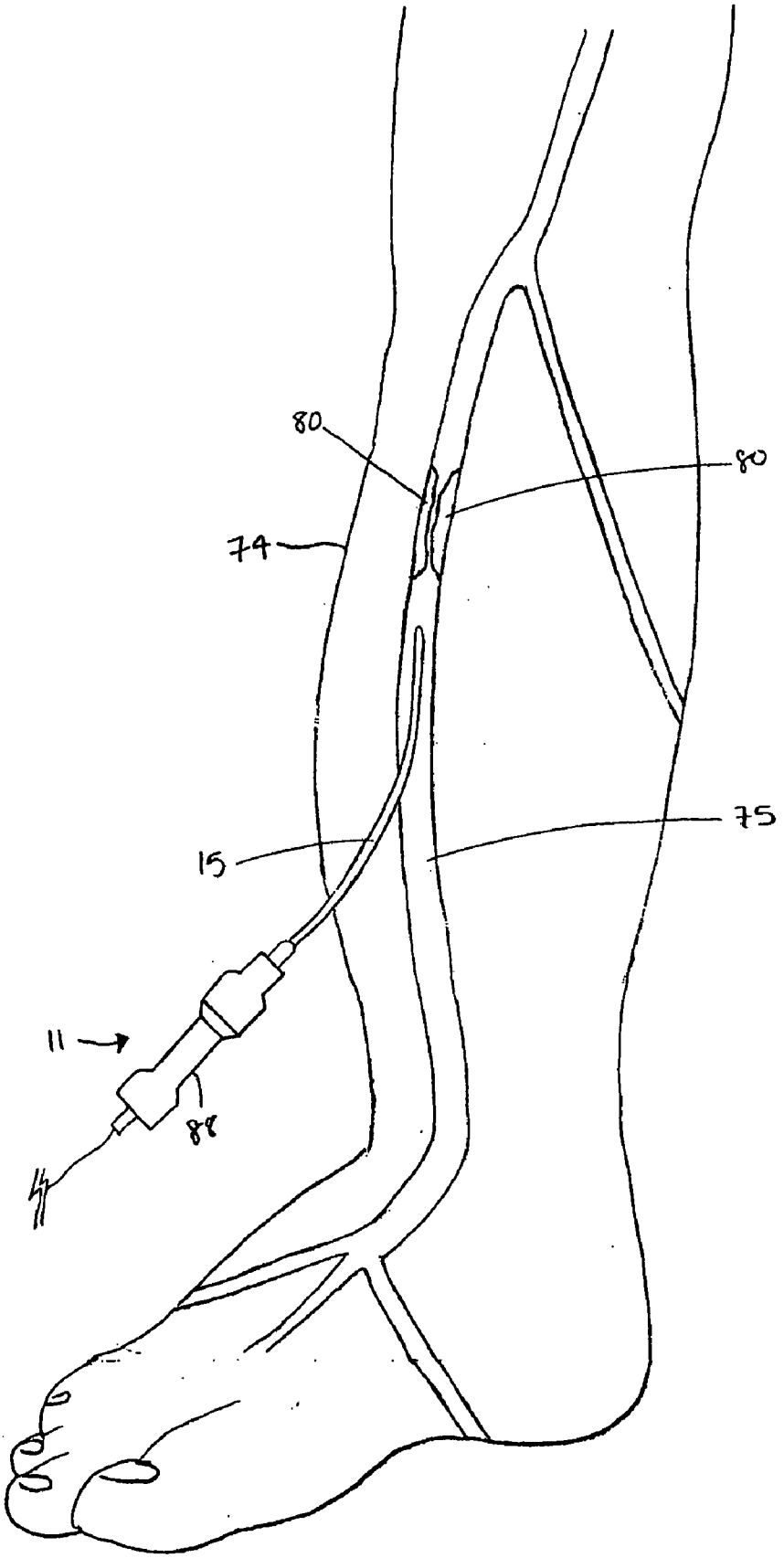


FIG. 6

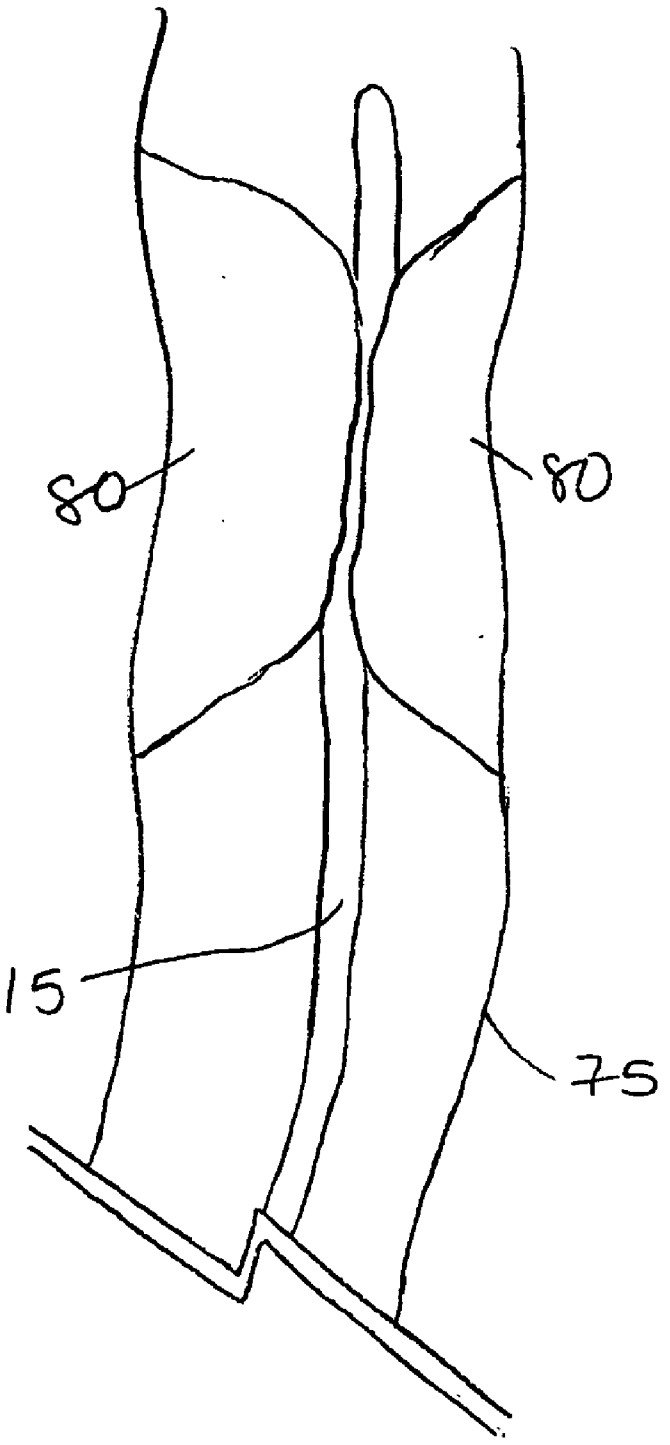


FIG. 7

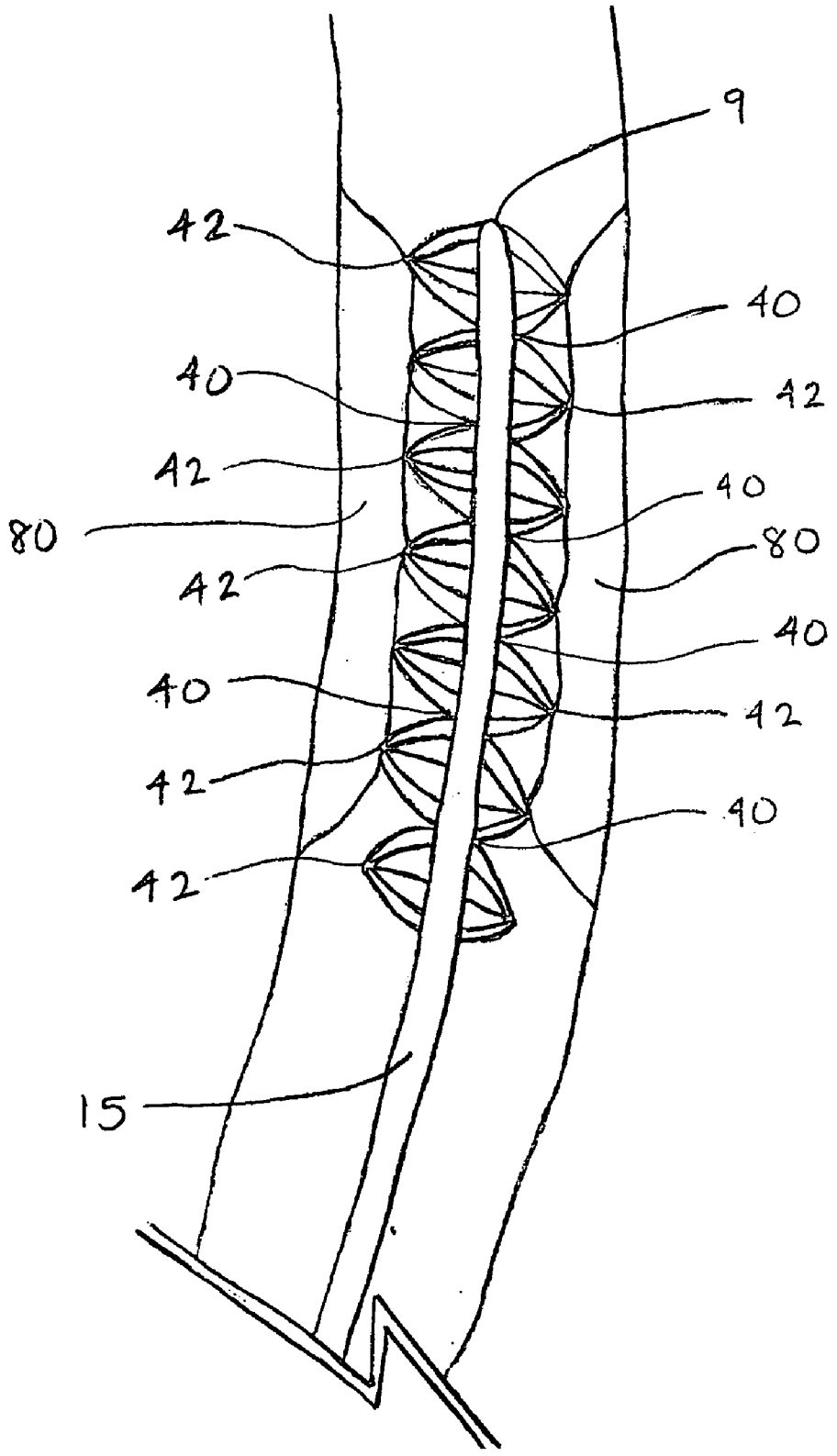


FIG. 8

APPARATUS AND METHOD FOR AN ULTRASONIC MEDICAL DEVICE TO TREAT DEEP VEIN THROMBOSIS

RELATED APPLICATIONS

[0001] This application is a continuation-in-part of application Ser. No. 10/665,445, filed Sep. 19, 2003, which is a continuation of application Ser. No. 09/776,015, filed Feb. 2, 2001, now U.S. Pat. No. 6,652,547, which is a continuation-in-part of application Ser. No. 09/618,352, filed Jul. 19, 2000, now U.S. Pat. No. 6,551,337, which claims benefit of Provisional Application Serial No. 60/178,901, filed Jan. 28, 2000, and claims benefit of Provisional Application Serial No. 60/157,824, filed Oct. 5, 1999, the entirety of all these applications are hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to medical devices, and more importantly to an apparatus and a method for an ultrasonic medical device to treat deep vein thrombosis.

BACKGROUND OF THE INVENTION

[0003] The formation of a blood clot or a thrombus in a deep vein of a body, a condition known as deep vein thrombosis (DVT), presents many problems to the individual suffering from the condition. The blood clot or thrombus can lead to various complications, including decreased blood flow and death. The thrombus in the deep vein interferes with blood circulation in the area of the thrombus and can break away and travel in the vein, ultimately blocking a blood vessel in the lungs, brain, heart or other critical areas of the body, a condition known as pulmonary embolism (PE). DVT can also damage the valves in the vein by inhibiting upward flow of blood, causing the blood to pool in the leg. DVT most commonly occurs in the lower leg, upper leg and thigh area.

[0004] DVT is a condition characterized by a reduction in blood flow, with several factors increasing the susceptibility of developing DVT. A person who has had a previous DVT condition is more likely to have a subsequent DVT condition. Immobility, such as prolonged sitting, long travel, surgical procedures or the subsequent bed rest recovery from a surgical procedure, increases the probability of developing DVT. The probability of a DVT condition is increased by pregnancy, childbirth and the use of medications such as estrogen and birth control pills. People undergoing cancer treatments or having a history of polycythemia vera, malignant tumors and inherited or acquired hypercoagulability have a higher probability of developing DVT. The incidence of DVT is more common in people over 40 years of age in addition to individuals who are obese.

[0005] Many scientific studies have analyzed DVT. A study of passengers who took a long haul flights over a six week period was performed by New Zealand researchers. Subjects traveled for at least ten hours per flight and each subject flew an average of about thirty-nine hours over the study. The results of the study showed that nine of the nearly nine hundred passengers developed a blood clot. (Hughes et al., (Dec. 20, 2003) *The Lancet,* 362: 2039-2044). In a separate case, a twenty-eight year old female British passenger on a twenty hour flight from Australia to London died as a result of the DVT condition. A separate study in the United Kingdom found that approximately one in two thousand people develop DVT per year.

[0006] The prior art has discussed various ways of preventing and treating DVT and pulmonary embolism. Prior art attempts to prevent and treat DVT have used intermittent pressure on a leg of a patient to help blood circulation. Through the application of intermittent pressure to the leg, blood flow is directed through the leg and into the torso.

[0007] U.S. Pat. No. 6,615,080 to Unsworth et al. discloses a single channel neuromuscular electrical stimulation device for the prevention of deep vein thrombosis, pulmonary embolism, lower extremity edema and other associated conditions by electrical stimulation of the muscles of the foot. Surface electrodes positioned over the foot muscles are attached to a stimulator that stimulates the foot muscles to reduce pooling of the blood in the soleal veins of the calf. The Unsworth et al. disclosure is limited to the soleal veins of the calf. The Unsworth et al. device does not engage the area of the blood clot or thrombus, but rather relies on electrical stimulation of the muscles to prevent DVT, pulmonary embolism and lower extremity edema.

[0008] U.S. Pat. No. 6,290,662 to Morris et al. discloses an apparatus for deep vein thrombosis prophylaxis and other conditions comprising an inflatable/deflatable bladder disposed against an extremity such as the upper calf, foot or hand of a patient. An inelastic member of the Morris et al. device fully encloses the bladder and body part while compressive forces are directed against the body part when the bladder expands. The Morris et al. device does not directly engage the area of the blood clot or thrombus, but relies on the compressive forces to increase blood circulation and translate to the problematic area of the blood clot or thrombus. The Morris et al. device relies on a range of pressures that may be too high or too low depending on the patient and may not directly translate to increased blood flow.

[0009] The prior art does not provide a solution for preventing and treating deep vein thrombosis in a safe, effective and time efficient manner. The prior art does not provide a solution for engaging the blood clot or the thrombus. Prior art instruments are limited in that they rely upon electrical stimulation of the muscles and transmission of the electrical simulation to the area of the blood clot or thrombus. Prior art instruments use high compressive forces to attempt to increase blood circulation. Therefore, there remains a need in the art for an apparatus and a method for an apparatus and a method of preventing and treating deep vein thrombosis that engages the blood clot or thrombus while not compromising the health of the patient.

SUMMARY OF THE INVENTION

[0010] The present invention provides an apparatus and a method for an ultrasonic medical device to treat deep vein thrombosis. The present invention is an ultrasonic medical device comprising a flexible, ultrasonic probe having a proximal end, a distal end and a longitudinal axis therebetween. The ultrasonic medical device includes a transducer for creating a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the flexible, ultrasonic probe. A coupling engages the proximal end of the flexible, ultrasonic probe to a distal end of the transducer. An ultrasonic energy source engaged to the transducer produces

an ultrasonic energy. The transverse ultrasonic vibration generates a plurality of transverse nodes and a plurality of transverse anti-nodes along at least a portion of the longitudinal axis of the flexible, ultrasonic probe, creating cavitation in a medium surrounding the flexible, ultrasonic probe to ablate a thrombus and treat deep vein thrombosis.

[0011] The present invention is an ultrasonic medical device for treating deep vein thrombosis comprising an ultrasonic probe having a proximal end, a distal end terminating in a probe tip and a longitudinal axis between the proximal end and the distal end. The ultrasonic medical device includes a transducer that converts electrical energy into mechanical energy, creating a transverse ultrasonic vibration along the longitudinal axis of the ultrasonic probe. A coupling engages the proximal end of the ultrasonic probe to the distal end of the transducer. The transverse ultrasonic vibration produces a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe.

[0012] The present invention is a method of resolving deep vein thrombosis comprising: providing an ultrasonic medical device comprising an ultrasonic probe having a proximal end, a distal end and a longitudinal axis therebetween; navigating the ultrasonic probe adjacent to a thrombus; placing the ultrasonic probe in communication with the thrombus; and activating an ultrasonic energy source engaged to the ultrasonic probe to generate a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the ultrasonic probe, wherein the transverse ultrasonic vibration creates a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe.

[0013] The present invention is a method of ablating a thrombus in a deep vein of a body comprising providing an ultrasonic medical device comprising an ultrasonic probe having a proximal end, a distal end terminating in a probe tip and a longitudinal axis between the proximal end and the distal end. The ultrasonic probe is inserted into an insertion point in the deep vein and moved to place the ultrasonic probe in communication with the thrombus. An ultrasonic energy source engaged to the ultrasonic probe is activated to produce an electric signal to drive a transducer of the ultrasonic medical device to generate a transverse ultrasonic vibration of the ultrasonic probe. The transverse ultrasonic vibration produces cavitation in a medium surrounding the ultrasonic probe to ablate the thrombus.

[0014] The present invention provides an apparatus and a method for an ultrasonic medical device to treat deep vein thrombosis. An ultrasonic probe is used to ablate a thrombus in a deep vein of the leg, preventing the thrombus, or a portion of the thrombus, from being carried with the blood to the heart and obstructing the flow of blood to one or more arteries in the lungs. The present invention provides an ultrasonic medical device that is simple, user-friendly, time efficient, reliable and cost effective.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The present invention will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the present invention.

[0016] **FIG. 1A** is a side plan view of an ultrasonic probe of the present invention inserted into a tibial deep vein of a leg where the probe is moving toward a thrombus in the tibial vein.

[0017] **FIG. 1B** is a side plan view of an ultrasonic probe of the present invention inserted into a popliteal deep vein of a leg where the probe is moving toward a thrombus in the popliteal vein.

[0018] **FIG. 2** is a side plan view of an ultrasonic medical device of the present invention capable of ablating a thrombus to treat deep vein thrombosis.

[0019] **FIG. 3** is a side plan view of an ultrasonic probe of the present invention having an approximately uniform diameter from a proximal end of the ultrasonic probe to the distal end of the ultrasonic probe.

[0020] **FIG. 4** is a view of a leg of a patient with deep veins, superficial veins and short veins.

[0021] **FIG. 5** is a view of a thrombus in a deep vein of a leg of a patient.

[0022] **FIG. 6** is a perspective view of an ultrasonic probe of the present invention inserted in a deep vein of a leg and being moved toward a thrombus in the deep vein.

[0023] **FIG. 7** is an enlarged view of an ultrasonic probe of the present invention in communication with a thrombus in a deep vein of a body.

[0024] **FIG. 8** is a view of an ultrasonic probe of the present invention showing a plurality of transverse nodes and a plurality of transverse anti-nodes while in communication with a thrombus in a deep vein of a body.

[0025] While the above-identified drawings set forth preferred embodiments of the present invention, other embodiments of the present invention are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments of the present invention by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the present invention.

DETAILED DESCRIPTION

[0026] The present invention provides an apparatus and a method for using an ultrasonic medical device to ablate a thrombus to treat deep vein thrombosis. The ultrasonic medical device comprises an ultrasonic probe, a transducer, a coupling engaging a proximal end of the ultrasonic probe to a distal end of the transducer and an ultrasonic energy source engaged to the transducer. The ultrasonic probe is inserted into a deep vein and placed in communication with the thrombus. The ultrasonic energy source produces an ultrasonic energy that is transmitted to the transducer, where the transducer creates a transverse ultrasonic vibration along the ultrasonic probe. The transverse ultrasonic vibration creates a plurality of transverse nodes and a plurality of transverse anti-nodes along the longitudinal axis of the ultrasonic probe, creating cavitation along a portion of the longitudinal axis of the ultrasonic probe to ablate the thrombus and treat deep vein thrombosis. By ablating the throm-

bus in the deep vein, the thrombus or a portion of the thrombus is not carried with the blood to the heart or the arteries of the lungs where a pulmonary embolism can occur.

[0027] The following terms and definitions are used herein:

[0028] "Ablate" as used herein refers to removing, clearing, destroying or taking away a thrombus. "Ablation" as used herein refers to a removal, clearance, destruction, or taking away of the thrombus.

[0029] "Anti-node" as used herein refers to a region of a maximum energy emitted by an ultrasonic probe at or proximal to a specific location along a longitudinal axis of the ultrasonic probe.

[0030] "Node" as used herein refers to a region of a minimum energy emitted by an ultrasonic probe at or proximal to a specific location along a longitudinal axis of the ultrasonic probe.

[0031] "Probe" as used herein refers to a device capable of propagating an energy emitted by the ultrasonic energy source along a longitudinal axis of the probe, resolving the energy into an effective cavitational energy at a specific resonance (defined by a plurality of nodes and a plurality of anti-nodes along an "active area" of the probe) and is capable of an acoustic impedance transformation of electrical energy to a mechanical energy.

[0032] "Thrombus" as used herein refers to a collection of a matter including, but not limited to, a group of similar cells, intravascular blood clots, occlusions, plaque, biological material, fibrin, calcified plaque, calcium deposits, occlusional deposits, atherosclerotic plaque, fatty deposits, adipose tissues, atherosclerotic cholesterol buildup, fibrous material buildup, arterial stenoses, minerals, high water content tissues, platelets, cellular debris, wastes and other occlusive materials.

[0033] "Transverse" as used herein refers to a vibration of a probe not parallel to a longitudinal axis of the probe. A "transverse wave" as used herein is a wave propagated along the probe in which a direction of a disturbance at a plurality of points of a medium is not parallel to a wave vector.

[0034] An ultrasonic probe of an ultrasonic medical device of the present invention capable of ablating a thrombus **80** to treat deep vein thrombus is illustrated generally at **15** in **FIG. 1**A and **FIG. 1B**. **FIG. 1A** shows the ultrasonic probe **15** inserted at a lower calf of a leg **74** into a deep vein **75** of the leg **74** and adjacent to the thrombus **80** in the deep vein **75**. In **FIG. 1**A, the ultrasonic probe **15** is inserted into a popliteal vein **72** in the lower calf area of the leg **74**. A flexibility of the ultrasonic probe allows the ultrasonic probe **15** to be navigated within the deep vein **75**.

[0035] **FIG. 1B** shows the ultrasonic probe **15** inserted at a calf area into the deep vein **75** of the leg **74** and adjacent to the thrombus **80** in the deep vein **75**. In **FIG. 1**B, the ultrasonic probe **15** is inserted into the tibial vein **72**.

[0036] **FIG. 2** shows an ultrasonic medical device capable of ablating a thrombus to treat deep vein thrombosis and prevent the thrombus from obstructing a vasculature in the body. In a preferred embodiment of the present invention, the ultrasonic probe **15** is used to ablate a thrombus in a deep vein of a leg or a deep vein of a pelvis. The ultrasonic medical device **11** includes an ultrasonic probe **15** which is coupled to an ultrasonic energy source or generator **99** for the production of an ultrasonic energy. A handle, **88**, comprising a proximal end **87** and a distal end **86**, surrounds a transducer within the handle **88**. The transducer, having a proximal end engaging the ultrasonic energy source **99** and a distal end coupled to a proximal end **31** of the ultrasonic probe **15**, transmits the ultrasonic energy to the ultrasonic probe **15**. A connector **93** and a connecting wire **98** engage the ultrasonic energy source **99** to the transducer. The ultrasonic probe **15** includes the proximal end **31**, a distal end **24** that ends in a probe tip **9** and a longitudinal axis between the proximal end **31** and the distal end **24**. In a preferred embodiment of the present invention shown in **FIG. 2, a** diameter of the ultrasonic probe decreases from a first defined interval **26** to a second defined interval **28** along the longitudinal axis of the ultrasonic probe **15** over a transition **82**. A coupling **33** that engages the proximal end **31** of the ultrasonic probe **15** to the transducer within the handle **88** is illustrated generally in **FIG. 2**. In a preferred embodiment of the present invention, the coupling is a quick attachment-detachment system. An ultrasonic medical device with a quick attachment-detachment system is described in the Assignee's co-pending patent applications U.S. Ser. No. 09/975,725; U.S. Ser. No. 10/268,487 and U.S. Ser. No. 10/268,843, and the entirety of all these applications are hereby incorporated herein by reference.

[0037] **FIG. 3** shows an alternative embodiment of the ultrasonic probe **15** of the present invention. In the embodiment of the present invention shown in **FIG. 3**, the diameter of the ultrasonic probe **15** is approximately uniform from the proximal end **31** of the ultrasonic probe **15** to the distal end **24** of the ultrasonic probe **15**.

[0038] In a preferred embodiment of the present invention, the ultrasonic probe **15** is a wire. In an embodiment of the present invention, the ultrasonic probe **15** is elongated. In an embodiment of the present invention, the diameter of the ultrasonic probe **15** changes at greater than two defined intervals. In an embodiment of the present invention, the transitions **82** of the ultrasonic probe **15** are tapered to gradually change the diameter from the proximal end **31** to the distal end **24** along the longitudinal axis of the ultrasonic probe **15**. In another embodiment of the present invention, the transitions **82** of the ultrasonic probe **15** are stepwise to change the diameter from the proximal end **31** to the distal end **24** along the longitudinal axis of the ultrasonic probe **15**. Those skilled in the art will recognize there can be any number of defined intervals and transitions, and the transitions can be of any shape known in the art and be within the spirit and scope of the present invention.

[0039] In an embodiment of the present invention, the gradual change of the diameter from the proximal end **31** to the distal end **24** occurs over the at least one transition **82**, with each transition **82** having an approximately equal length. In another embodiment of the present invention, the gradual change of the diameter from the proximal end **31** to the distal end **24** occurs over a plurality of transitions **82** with each transition **82** having a varying length. The transition **82** refers to a section where the diameter varies from a first diameter to a second diameter.

[0040] In a preferred embodiment of the present invention, the ultrasonic probe **15** has a small diameter. In a preferred

embodiment of the present invention, the cross section of the ultrasonic probe is approximately circular. In an embodiment of the present invention, the diameter of the distal end **24** of the ultrasonic probe **15** is about 0.004 inches. In another embodiment of the present invention, the diameter of the distal end **24** of the ultrasonic probe **15** is about 0.015 inches. In other embodiments of the present invention, the diameter of the distal end **24** of the ultrasonic probe **15** varies between about 0.003 inches and about 0.025 inches. Those skilled in the art will recognize an ultrasonic probe **15** can have a diameter at the distal end **24** smaller than about 0.003 inches, larger than about 0.025 inches, and between about 0.003 inches and about 0.025 inches and be within the spirit and scope of the present invention.

[**0041**] In an embodiment of the present invention, the diameter of the proximal end **31** of the ultrasonic probe **15** is about 0.012 inches. In another embodiment of the present invention, the diameter of the proximal end **31** of the ultrasonic probe **15** is about 0.025 inches. In other embodiments of the present invention, the diameter of the proximal end **31** of the ultrasonic probe **15** varies between about 0.003 inches and about 0.025 inches. Those skilled in the art will recognize the ultrasonic probe **15** can have a diameter at the proximal end **31** smaller than about 0.003 inches, larger than about 0.025 inches, and between about 0.003 inches and about 0.025 inches and be within the spirit and scope of the present invention.

[**0042**] The probe tip **9** can be any shape including, but not limited to, rounded, bent, a ball or larger shapes. In a preferred embodiment of the present invention, the probe tip **9** is smooth to prevent damage to the deep veins **75** and the valves in the deep veins **75**. In one embodiment of the present invention, the ultrasonic energy source **99** is a physical part of the ultrasonic medical device **11**. In another embodiment of the present invention, the ultrasonic energy source **99** is not an integral part of the ultrasonic medical device **11**. The ultrasonic probe **15** is used to ablate a thrombus and may be disposed of after use. In a preferred embodiment of the present invention, the ultrasonic probe **15** is for a single use and on a single patient., In a preferred embodiment of the present invention, the ultrasonic probe **15** is disposable. In another embodiment of the present invention, the ultrasonic probe **15** can be used multiple times.

[**0043**] The ultrasonic probe **15** is designed, constructed and comprised of a material to not dampen the transverse ultrasonic vibration, and thereby supports a transverse vibration when flexed. In a preferred embodiment of the present invention, the ultrasonic probe **15** comprises titanium or a titanium alloy. In a preferred embodiment of the present invention, the ultrasonic probe **15** comprises titanium alloy Ti-6Al-4V. The elements comprising Ti-6Al-4V and the representative elemental weight percentages of Ti-6Al-4V are titanium (about 90%), aluminum (about 6%), vanadium (about 4%), iron (maximum about 0.25%) and oxygen (maximum about 0.2%). Titanium is a strong, flexible, low density, low radiopacity and easily fabricated metal that is used as a structural material. Titanium and its alloys have excellent corrosion resistance in many environments and have good elevated temperature properties. In another embodiment of the present invention, the ultrasonic probe **15** comprises stainless steel. In another embodiment of the present invention, the ultrasonic probe **15** comprises an alloy of stainless steel. In another embodiment of the present invention, the ultrasonic probe **15** comprises aluminum. In another embodiment of the present invention, the ultrasonic probe **15** comprises an alloy of aluminum. In another embodiment of the present invention, the ultrasonic probe **15** comprises a combination of titanium and stainless steel. Those skilled in the art will recognize that the ultrasonic probe can be comprised of many other materials known in the art and be within the spirit and scope of the present invention.

[**0044**] The physical properties (i.e., length, cross sectional shape, dimensions, etc.) and material properties (i.e., yield strength, modulus, etc.) of the ultrasonic probe **15** are selected for operation of the ultrasonic probe **15** in the transverse mode. The length of the ultrasonic probe **15** of the present invention is chosen to be resonant in a transverse mode. In an embodiment of the present invention, the ultrasonic probe **15** is between about 30 centimeters and about 300 centimeters in length. Those skilled in the art will recognize an ultrasonic probe can have a length shorter than about 30 centimeters, a length longer than about 300 centimeters and a length between about 30 centimeters and about 300 centimeters and be within the spirit and scope of the present invention.

[**0045**] The handle **88** surrounds the transducer located between the proximal end **31** of the ultrasonic probe **15** and the connector **93**. In a preferred embodiment of the present invention, the transducer includes, but is not limited to, a horn, an electrode, an insulator, a backnut, a washer, a piezo microphone, and a piezo drive. The transducer converts electrical energy provided by the ultrasonic energy source **99** to mechanical energy and sets the operating frequency of the ultrasonic medical device **11**. The transducer is capable of engaging the ultrasonic probe **15** at the proximal end **31** with sufficient restraint to form an acoustical mass that can propagate the ultrasonic energy provided by the ultrasonic energy source **99**.

[**0046**] **FIG. 4** shows the main veins in the leg **74** including deep veins **75**, superficial veins **76** and short veins **77**. The deep veins **75** of the leg **74** pass through the center of the leg **74** and are surrounded by muscles. The superficial veins **76** of the leg **74** are located in a fatty layer underneath the skin. The short veins **77** of the leg **74**, also known as connecting veins, link the deep veins **75** and the superficial veins **76**.

[**0047**] The deep veins **75** of the leg **74** are important for the upward flow of blood to the heart. The deep veins **75** comprise one way valves that prevent the blood from flowing backward. The deep veins **75** lie deep within the muscle and carry most of the blood out of the leg **74** and to the heart for oxygenation. Muscles surrounding the deep veins **75**, including the quadriceps, thigh muscles, gastrocnemius, soleus, abductors, peroneus muscles, plantaris muscles and popliteud muscles, compress the one way valves to help force the blood in an upward direction toward the heart. The deep veins **75** carry approximately ninety percent of the blood from the legs **74** to the heart. Various deep veins **75** in the leg **74** include, but are not limited to the common iliac, the femoral, the popliteal **71** and the tibial veins **72**.

[**0048**] The deep veins generally follow the course of the associated arteries. The tibial veins **72**, also known as the

peroneal veins, are located in the calf. The anterior tibial veins **72** pass between the tibia and the fibula along the leg **74**. The anterior tibial veins **72** receive blood from the knee joint, muscles of the thigh, and upper calf and the join the posterior tibial vein **72** and the popliteal vein **71**. The popliteal vein **71** is formed by the junction of the anterior and posterior tibial veins **72** and ascends to the femoral vein. The popliteal vein **71** usually has four valves to assist with the transportation of blood.

[**0049**] The superficial veins **76** of the leg **74** play a minor role in carrying the blood to the heart. While the superficial veins **76** comprise one way valves that are similar to those in the deep veins **75**, the one way valves in the superficial veins **76** are not surrounded by muscle. The superficial veins **76** lie above the muscles of the leg **74**. Because the one way valves in the superficial veins **76** are not surrounded by muscle, the flow of blood upward in the superficial veins **76** is much slower when compared to the blood flow in the deep veins **75**. A majority of the blood that flows up the superficial veins **76** is diverted into the deep veins **75** through the short veins **77**. Valves in the short veins **77** of the leg **74** allow the blood to flow from the superficial veins **76** to the deep veins **75**, but not vice versa. Various superficial veins **76** in the leg **74** include, but are not limited to, the great saphenous and the lesser saphenous veins.

[**0050**] As discussed above, the deep veins **75**, the superficial veins **76** and the short veins **77** all have valves that allow blood to flow in one direction only, and prevent the blood from flowing back towards the capillaries and collecting or puddling in the lower leg. Disruption, inversion or damage to the valves can cause the blood to flow down the veins in the wrong direction and puddle in the lower leg. This disruption or damage to the valves causes the veins to enlarge (varicose veins) or cause pain, leg swelling, hypergigmentation and skin ulcers in the part of the leg **74** around the ankle.

[**0051**] The valves in the veins are filamentous and composed of two leaflets that allow blood to flow in only one direction to prevent the blood from falling back into the leg after the leg muscles have helped to propel the blood toward the heart. The ultrasonic probe **15** of the present invention is atraumatic and does not damage, disrupt or invert the valves. The small diameter of the ultrasonic probe **15** allows the ultrasonic probe **15** to be transited through an opening in the valve without damaging the valve. The small diameter of the ultrasonic probe **15** allows the ultrasonic probe **15** to minimize contact with the valves as the ultrasonic probe **15** is fed through the deep vein **75** and valves. The combination of the flexibility of the ultrasonic probe **15** and the smooth probe tip **9** allows the ultrasonic probe **15** to be moved through the valve without perforating the membrane comprising the valve while maintaining the integrity of the valve. The flexibility of the ultrasonic probe **15** allows the ultrasonic probe **15** to be deflected, flexed and bent through the deep vein **75** and the valves. The smooth probe tip **9** also prevents damage, disruption or inversion of the valves upon retraction of the ultrasonic probe **15** from the deep vein **75**.

[**0052**] **FIG. 5** shows a thrombus **80** in the deep vein **75** of the leg **74**. The presence of the thrombus **80**, or blood clot, in the deep veins **75** of the leg presents a major risk to a patient. Since the blood from the deep veins travels to the heart and ultimately to the lungs, the thrombus **80** or at least a portion of the thrombus **80** in the deep veins **75** of the leg **74** can pass through the heart and obstruct the flow of blood to one or more arteries in the lungs, a condition known as pulmonary embolism. The degree of severity of the pulmonary embolism depends on the size of the thrombus **80** and the number of thrombi. A small thrombus **80** can block a small artery in the lungs, causing a small piece of lung tissue to die, a condition known as pulmonary infarction. A larger thrombus **80** presents a life threatening condition since the larger thrombus **80** can obstruct all or at least a majority of the blood travelling from the right side of the heart to the lungs, thereby causing a quick death. Therefore, removal of the thrombus **80** to treat deep vein thrombosis is critical to the well being of the patient.

[**0053**] **FIG. 6** shows the ultrasonic probe **15** inserted in the deep vein **75** of the leg **74** being moved toward the thrombus **80**. The ultrasonic probe **15** has a stiffness that gives the ultrasonic probe **15** a flexibility allowing the ultrasonic probe **15** to be deflected, flexed and bent through the tortuous paths of the vasculature, including the deep vein **75**. The ultrasonic probe **15** can be bent, flexed and deflected to reach the thrombus **80** in the deep veins **75** of the leg **74** that would otherwise be difficult to reach.

[**0054**] **FIG. 7** shows an enlarged view of a portion of the longitudinal axis of the ultrasonic probe **15** in communication with the thrombus **80** in the deep vein **75** of the leg **74**. With the ultrasonic probe **15** in communication with the thrombus **80**, the ultrasonic energy source **99** is activated to provide a low power electric signal of between about 2 watts to about 6 watts to the transducer that is located within the handle **88**. The transducer converts electrical energy provided by the ultrasonic energy source **99** to mechanical energy. The operating frequency of the ultrasonic medical device **11** is set by the transducer and the ultrasonic energy source **99** finds the resonant frequency of the transducer through a Phase Lock Loop. By an appropriately oriented and driven cylindrical array of piezoelectric crystals of the transducer, the horn creates a longitudinal wave along at least a portion of the longitudinal axis of the ultrasonic probe **15**. The longitudinal wave is converted to a transverse wave along at least a portion of the longitudinal axis of the ultrasonic probe **15** through a nonlinear dynamic buckling of the ultrasonic probe **15**.

[**0055**] As the transverse wave is transmitted along the longitudinal axis of the ultrasonic probe **15**, a transverse ultrasonic vibration is created along the longitudinal axis of the ultrasonic probe **15**. The ultrasonic probe **15** is vibrated in a transverse mode of vibration. The transverse mode of vibration of the ultrasonic probe **15** differs from an axial (or longitudinal) mode of vibration disclosed in the prior art. The transverse ultrasonic vibrations along the longitudinal axis of the ultrasonic probe **15** create a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe **15**.

[**0056**] **FIG. 8** shows the ultrasonic probe **15** of the present invention having a plurality of transverse nodes **40** and a plurality of transverse anti-nodes **42** along a portion of the longitudinal axis of the ultrasonic probe **15** and in communication with the thrombus **80**. The transverse nodes **40** are areas of minimum energy and minimum vibration. The transverse anti-nodes **42**, or areas of maximum energy and maximum vibration, also occur at repeating intervals along

the portion of the longitudinal axis of the ultrasonic probe **15**. The number of transverse nodes **40** and transverse anti-nodes **42**, and the spacing of the transverse nodes **40** and transverse anti-nodes **42** of the ultrasonic probe **15** depend on the frequency of energy produced by the ultrasonic energy source **99**. The separation of the transverse nodes **40** and transverse anti-nodes **42** is a function of the frequency, and can be affected by tuning the ultrasonic probe **15**. In a properly tuned ultrasonic probe **15**, the transverse anti-nodes **42** will be found at a position exactly one half of the distance between the transverse nodes **40** located adjacent to each side of the transverse anti-nodes **42**.

[**0057**] The transverse wave is transmitted along the longitudinal axis of the ultrasonic probe **15** and the interaction of the surface of the ultrasonic probe **15** with the medium surrounding the ultrasonic probe **15** creates an acoustic wave in the surrounding medium. As the transverse wave is transmitted along the longitudinal axis of the ultrasonic probe **15**, the ultrasonic probe **15** vibrates transversely. The transverse motion of the ultrasonic probe **15** produces cavitation in the medium surrounding the ultrasonic probe **15** to ablate the thrombus **80**. Cavitation is a process in which small voids are formed in a surrounding medium through the rapid motion of the ultrasonic probe **15** and the voids are subsequently forced to compress. The compression of the voids creates a wave of acoustic energy which acts to dissolve the matrix binding the thrombus **80**, while having no damaging effects on healthy tissue. Action of the ultrasonic probe **15** results in fibrinolysis and surface erosion of the thrombus **80**.

[**0058**] The thrombus **80** in the deep vein **75** is resolved into a particulate having a size on the order of red blood cells (approximately 5 microns in diameter). The size of the particulate is such that the particulate is easily discharged from the body through conventional methods or simply dissolves into the blood stream. A conventional method of discharging the particulate from the body includes transferring the particulate through the blood stream to the kidney where the particulate is excreted as bodily waste. By resolving the thrombus **80** in the deep vein **75** to a particulate, the particulate will travel with the blood to the heart and ultimately to the arteries of the lungs without any risk of obstructing the arteries and causing a pulmonary embolism or a pulmonary infarction.

[**0059**] The transverse ultrasonic vibration of the ultrasonic probe **15** results in a portion of the longitudinal axis of the ultrasonic probe **15** vibrated in a direction not parallel to the longitudinal axis of the ultrasonic probe **15**. The transverse vibration results in movement of the longitudinal axis of the ultrasonic probe **15** in a direction approximately perpendicular to the longitudinal axis of the ultrasonic probe **15**. Transversely vibrating ultrasonic probes for biological material ablation are described in the Assignee's U.S. Pat. No. 6,551,337; U.S. Pat. No. 6,652,547; and U.S. Pat. No. 6,660,013 and Assignee's co-pending patent application U.S. Ser. No. 09/917,471, which further describe the design parameters for such an ultrasonic probe and its use in ultrasonic devices for ablation, and the entirety of these patents and patent applications are hereby incorporated herein by reference.

[**0060**] As a consequence of the transverse ultrasonic vibration of the ultrasonic probe **15**, the thrombus destroying effects of the ultrasonic medical device **11** are not limited to those regions of the ultrasonic probe **15** that may come into contact with the thrombus **80**. Rather, as a section of the longitudinal axis of the ultrasonic probe **15** is positioned in proximity to the thrombus **80**, the thrombus **80** is removed in all areas adjacent to the plurality of energetic transverse nodes **40** and transverse anti-nodes **42** that are produced along the portion of the length of the longitudinal axis of the ultrasonic probe **15**, typically in a region having a radius of up to about **6** mm around the ultrasonic probe **15**.

[**0061**] A novel feature of the present invention is the ability to utilize ultrasonic probes **15** of extremely small diameter compared to prior art probes, without loss of efficiency, because the thrombus fragmentation process is not dependent on the area of the probe tip **9**. Highly flexible ultrasonic probes **15** can therefore be designed to mimic device shapes that enable facile insertion into thrombus areas or extremely narrow interstices that contain the thrombus **80**. Another advantage provided by the present invention is the ability to rapidly move the thrombus **80** from large areas within cylindrical or tubular surfaces.

[**0062**] The number of transverse nodes **40** and transverse anti-nodes **42** occurring along the longitudinal axis of the ultrasonic probe **15** is modulated by changing the frequency of energy supplied by the ultrasonic energy source **99**. The exact frequency, however, is not critical and the ultrasonic energy source **99** run at, for example, about 20 kHz is sufficient to create an effective number of thrombus destroying transverse anti-nodes **42** along the longitudinal axis of the ultrasonic probe **15**. The low frequency requirement of the present invention is a further advantage in that the low frequency requirement leads to less damage to healthy tissue. Those skilled in the art understand it is possible to adjust the dimensions of the ultrasonic probe **15**, including diameter, length and distance to the ultrasonic energy source **99**, in order to affect the number and spacing of the transverse nodes **40** and transverse anti-nodes **42** along a portion of the longitudinal axis of the ultrasonic probe **15**.

[**0063**] The present invention allows the use of ultrasonic energy to be applied to the thrombus **80** selectively, because the ultrasonic probe **15** conducts energy across a frequency range from about 10 kHz through about 100 kHz. The amount of ultrasonic energy to be applied to a particular treatment site is a function of the amplitude and frequency of vibration of the ultrasonic probe **15**. In general, the amplitude or throw rate of the energy is in the range of about 25 microns to about 250 microns, and the frequency in the range of about 10 kHz to about 100 kHz. In a preferred embodiment of the present invention, the frequency of ultrasonic energy is from about 20 kHz to about 35 kHz.

[**0064**] The present invention also provides a method of preventing deep vein thrombosis. A medical professional gains access to the deep vein **75** in the leg **74** through an insertion point in the deep vein **75**. A device including, but not limited to, a vascular introducer can be used to create an insertion point in the deep vein **75** to gain access to the deep vein **75**. A vascular introducer for use with an ultrasonic probe is described in Assignee's co-pending patent application U.S. Ser. No. 10/080,787, and the entirety of this application is hereby incorporated herein by reference.

[**0065**] After gaining access to the deep vein **75** in the leg **74**, the ultrasonic probe **15** is moved through the insertion

point of the deep vein **75**, navigated through the deep vein **75** and placed adjacent to the thrombus **80**. In a preferred embodiment of the present invention, the ultrasonic probe **15** is inserted in the deep vein **75** below the thrombus **80** and navigated upward with the flow of blood in the deep vein **75** toward the thrombus **80**. Less force is required in moving the ultrasonic probe **15** with the flow of blood because there is less friction and viscous drag. In an alternative embodiment of the present invention, the ultrasonic probe **15** is inserted in the deep vein above the thrombus **80** and navigated downward against the flow of blood in the deep vein **75** toward the thrombus **80**. While a greater force is required to navigate the ultrasonic probe **15** against the flow of blood, the strength of the ultrasonic probe **15** permits movement against the flow of blood. Whether the ultrasonic probe **15** enters above or below the thrombus **80** is often dictated by anatomical considerations of the patient.

[**0066**] The ultrasonic probe **15** is placed in communication with the thrombus **80** by sweeping, twisting or rotating the ultrasonic probe **15** along the thrombus **80**. Those skilled in the art will recognize the ultrasonic probe can be placed in communication with the thrombus in many ways known in the art and be within the spirit and scope of the present invention.

[**0067**] The ultrasonic probe **15** is placed in communication with the thrombus **80** and the ultrasonic energy source **99** engaged to the ultrasonic probe **15** is activated to generate a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the ultrasonic probe **15**. The ultrasonic probe may then be swept, twisted or rotated along the thrombus **80**. The transverse ultrasonic vibration creates a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe **15**, causing a thrombus destroying effect along the portion of the length of the longitudinal axis of the ultrasonic probe **15**.

[**0068**] The present invention also is a method of ablating the thrombus **80** in the deep vein **75** of the body. Access to the deep vein **75** in the leg **74** is gained by creating an insertion point in the deep vein **75** using a device such as a vascular introducer. The ultrasonic probe **15** having the proximal end **31**, the distal end **24** terminating in the probe tip **9** and a longitudinal axis between the proximal end and the distal end **24** is inserted through the insertion point of the deep vein **75** and moved through the deep vein **75** and placed in communication with the thrombus **80**. A stiffness of the ultrasonic probe **15** of the ultrasonic medical device **11** gives the ultrasonic probe **15** a flexibility allowing the ultrasonic probe **15** to be deflected, flexed and bent through the tortuous paths of the vasculature, including the deep vein **75**. The ultrasonic energy source **99** engaged to the ultrasonic probe **15** is activated to produce an electric signal to drive the transducer of the ultrasonic medical device **11** to produce a transverse vibration of the ultrasonic probe **15**. The transverse ultrasonic vibration of the ultrasonic probe **15** produces cavitation in a medium surrounding a portion of the length of the longitudinal axis of the ultrasonic probe **15** to ablate the thrombus **80**.

[**0069**] A method of resolving deep vein thrombosis comprising providing an ultrasonic medical device **11** comprising an ultrasonic probe **15** having a proximal end **31**, a distal end **24** and a longitudinal axis therebetween; navigating the ultrasonic probe **15** proximal to a thrombus **80**; placing the ultrasonic probe **15** in communication with the thrombus **80**; activating an ultrasonic energy source **99** engaged to the ultrasonic probe **15** to generate a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the ultrasonic probe **15**, wherein the transverse vibration creates a plurality of transverse nodes **40** and a plurality of transverse anti-nodes **42** along a portion of the longitudinal axis of the ultrasonic probe **15**.

[**0070**] A method of ablating a thrombus **80** in a deep vein **75** of a body comprising providing an ultrasonic medical device **11** comprising an ultrasonic probe **15** having a proximal end **31**, a distal end **24** terminating in a probe tip **9**, and a longitudinal axis between the proximal end **31** and the distal end **24**; inserting the ultrasonic probe **15** in an insertion point of the deep vein **75**; moving the ultrasonic probe **15** to place the ultrasonic probe **15** in communication with the thrombus **80**; activating an ultrasonic energy source **99** engaged to the ultrasonic probe **15** to produce an electric signal that drives a transducer of the ultrasonic medical device **11** to produce a transverse ultrasonic vibration of the ultrasonic probe **15**, wherein the transverse ultrasonic vibration produces cavitation in a medium surrounding the ultrasonic probe **15** to ablate the thrombus **80**.

[**0071**] In an alternative embodiment of the present invention, the ultrasonic probe **15** is vibrated in a torsional mode. In the torsional mode of vibration, a portion of the longitudinal axis of the ultrasonic probe **15** comprises a radially asymmetric cross section and the length of the ultrasonic probe **15** is chosen to be resonant in the torsional mode. In the torsional mode of vibration, a transducer transmits ultrasonic energy received from the ultrasonic energy source **99** to the ultrasonic probe **15**, causing the ultrasonic probe **15** to vibrate torsionally. The ultrasonic energy source **99** produces the electrical energy that is used to produce a torsional vibration along the longitudinal axis of the ultrasonic probe **15**. The torsional vibration is a torsional oscillation whereby equally spaced points along the longitudinal axis of the ultrasonic probe **15** including the probe tip **9** vibrate back and forth in a short arc about the longitudinal axis of the ultrasonic probe **15**. A section proximal to each of a plurality of torsional nodes and a section distal to each of the plurality of torsional nodes are vibrated out of phase, with the proximal section vibrated in a clockwise direction and the distal section vibrated in a counterclockwise direction, or vice versa. The torsional vibration results in an ultrasonic energy transfer to the biological material with minimal loss of ultrasonic energy that could limit the effectiveness of the ultrasonic medical device **11**. The torsional vibration produces a rotation and a counterrotation along the longitudinal axis of the ultrasonic probe **15** that creates the plurality of torsional nodes and a plurality of torsional anti-nodes along a portion of the longitudinal axis of the ultrasonic probe **15** resulting in cavitation along the portion of the longitudinal axis of the ultrasonic probe **15** comprising the radially asymmetric cross section in a medium surrounding the ultrasonic probe **15** that ablates the biological material. An apparatus and method for an ultrasonic medical device operating in a torsional mode is described in Assignee's co-pending patent application U.S. Ser. No. 00/000,000 (Attorney Docket No. 20563/2422), filed Feb. 9, 2004, and the entirety of this application is hereby incorporated herein by reference.

[0072] In another embodiment of the present invention, the ultrasonic probe **15** is vibrated in a torsional mode and a transverse mode. A transducer transmits ultrasonic energy from the ultrasonic energy source **99** to the ultrasonic probe **15**, creating a torsional vibration of the ultrasonic probe **15**. The torsional vibration induces a transverse vibration along an active area of the ultrasonic probe **15**, creating a plurality of nodes and a plurality of anti-nodes along the active area that result in cavitation in a medium surrounding the ultrasonic probe **15**. The active area of the ultrasonic probe **15** undergoes both the torsional vibration and the transverse vibration.

[0073] Depending upon physical properties (i.e., length, diameter, etc.) and material properties (i.e., yield strength, modulus, etc.) of the ultrasonic probe **15**, the transverse vibration is excited by the torsional vibration. Coupling of the torsional mode of vibration and the transverse mode of vibration is possible because of common shear components for the elastic forces. The transverse vibration is induced when the frequency of the transducer is close to a transverse resonant frequency of the ultrasonic probe **15**. The combination of the torsional mode of vibration and the transverse mode of vibration is possible because for each torsional mode of vibration, there are many close transverse modes of vibration. By applying tension on the ultrasonic probe **15**, for example by bending the ultrasonic probe **15**, the transverse vibration is tuned into coincidence with the torsional vibration. The bending causes a shift in frequency due to changes in tension. In the torsional mode of vibration and the transverse mode of vibration, the active area of the ultrasonic probe **15** is vibrated in a direction not parallel to the longitudinal axis of the ultrasonic probe **15** while equally spaced points along the longitudinal axis of the ultrasonic probe **15** in a proximal section vibrate back and forth in a short arc about the longitudinal axis of the ultrasonic probe **15**. An apparatus and method for an ultrasonic medical device operating in a transverse mode and a torsional mode is described in Assignee's co-pending patent application U.S. Ser. No. 00/000,000 (Attorney Docket No. 20563/2432), filed Feb. 9, 2004, and the entirety of this application is hereby incorporated herein by reference.

[0074] While the above discussion and figures focus on the venous removal of the thrombus **80**, the present invention can also be used for the arterial removal of the thrombus **80**. The ultrasonic probe **15** of the present invention can not only be used in the deep veins of the leg for venous removal of thrombus **80**, but the ultrasonic probe **15** can also be adapted for use in the arteries of the leg for arterial removal of thrombus **80**.

[0075] The present invention provides and apparatus and a method for an ultrasonic medical device to treat deep vein thrombosis. An ultrasonic probe is used to ablate a thrombus in a deep vein of the leg, preventing the thrombus, or a portion of the thrombus, from being carried with the blood to the heart and obstructing the flow of blood to one or more arteries in the lungs. The present invention provides an ultrasonic medical device to treat deep vein thrombosis that is simple, user-friendly, time efficient, reliable and cost effective.

[0076] All patents, patent applications, and published references cited herein are hereby incorporated herein by reference in their entirety. While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

What is claimed is:

1. An ultrasonic medical device for treating deep vein thrombosis comprising:

a flexible, ultrasonic probe having a proximal end, a distal end and a longitudinal axis therebetween;

a transducer creating a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the flexible, ultrasonic probe;

a coupling engaging the proximal end of the flexible, ultrasonic probe to a distal end of the transducer;

an ultrasonic energy source engaged to the transducer that produces an ultrasonic energy,

wherein the transverse ultrasonic vibration generates a plurality of transverse nodes and a plurality of transverse anti-nodes along at least a portion of the longitudinal axis of the flexible, ultrasonic probe, creating cavitation in a medium surrounding the flexible, ultrasonic probe to ablate a thrombus and treat deep vein thrombosis.

2. The ultrasonic medical device of claim 1 wherein the flexible, ultrasonic probe comprises a material that allows the flexible, ultrasonic probe to be bent, deflected and flexed.

3. The ultrasonic medical device of claim 1 wherein the flexible, ultrasonic probe comprises a diameter that enables insertion into a vein.

4. The ultrasonic medical device of claim 1 wherein a diameter of the flexible, ultrasonic probe has a uniform diameter from the proximal end to the distal end.

5. The ultrasonic medical device of claim 1 wherein a diameter of the flexible, ultrasonic probe varies from the proximal end to the distal end.

6. The ultrasonic medical device of claim 1 wherein a cross section of the flexible, ultrasonic probe is approximately circular.

7. The ultrasonic medical device of claim 1 wherein the transverse ultrasonic vibration generates acoustic energy in a medium surrounding the flexible, ultrasonic probe.

8. The ultrasonic medical device of claim 1 wherein the ultrasonic energy source delivers ultrasonic energy in a frequencey range from about 10 kHz to about 100 kHz.

9. The ultrasonic medical device of claim 1 wherein the ultrasonic energy source provides an electrical energy to the transducer at a resonant frequency of the transducer by finding the resonant frequency of the transducer.

10. The ultrasonic medical device of claim 1 wherein the flexible, ultrasonic probe is disposable.

11. An ultrasonic medical device for treating deep vein thrombosis comprising:

an ultrasonic probe having a proximal end, a distal end terminating in a probe tip and a longitudinal axis between the proximal end and the distal end;

a transducer that converts electrical energy into mechanical energy, creating a transverse ultrasonic vibration along the longitudinal axis of the ultrasonic probe; and

a coupling engaging the proximal end of the ultrasonic probe to a distal end of the transducer,

wherein the transverse ultrasonic vibration produces a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe.

12. The ultrasonic medical device of claim 11 wherein the ultrasonic probe supports the transverse ultrasonic vibration when flexed.

13. The ultrasonic medical device of claim 11 wherein the ultrasonic probe has a flexibility allowing the ultrasonic probe to be deflected and articulated.

14. The ultrasonic medical device of claim 11 wherein a transverse wave from the transverse ultrasonic vibration is transmitted along the longitudinal axis of the ultrasonic probe, creating an interaction of a surface of the ultrasonic probe with a medium surrounding the ultrasonic probe to create an acoustic wave in the medium.

15. The ultrasonic medical device of claim 11 wherein the transverse ultrasonic vibration of the ultrasonic probe produces cavitation in a medium surrounding the ultrasonic probe to ablate a thrombus to treat deep vein thrombosis.

16. The ultrasonic medical device of claim 11 wherein an ultrasonic energy source is engaged to the transducer and provides the electrical energy to the transducer.

17. A method of resolving deep vein thrombosis comprising:

providing an ultrasonic medical device comprising an ultrasonic probe having a proximal end, a distal end and a longitudinal axis therebetween;

navigating the ultrasonic probe adjacent to a thrombus;

placing the ultrasonic probe in communication with the thrombus;

activating an ultrasonic energy source engaged to the ultrasonic probe to generate a transverse ultrasonic vibration along at least a portion of the longitudinal axis of the ultrasonic probe,

wherein the transverse ultrasonic vibration creates a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe.

18. The method of claim 17 further comprising generating acoustic energy in a medium surrounding the ultrasonic probe through the transverse ultrasonic vibration of the ultrasonic probe.

19. The method of claim 17 further comprising sweeping the ultrasonic probe along the thrombus.

20. The method of claim 17 further comprising moving the ultrasonic probe back and forth along the thrombus.

21. The method of claim 17 further comprising rotating the ultrasonic probe along the thrombus.

22. The method of claim 17 further comprising providing an electrical energy to a transducer at a resonant frequency of the transducer by the ultrasonic energy source determining the resonant frequency of the transducer.

23. The method of claim 17 further comprising delivering ultrasonic energy in a frequency range from about 10 kHz to about 100 kHz by the ultrasonic energy source.

24. The method of claim 17 further comprising providing the ultrasonic probe having a flexibility allowing the ultrasonic probe to be deflected and articulated.

25. A method of ablating a thrombus in a deep vein of a body comprising:

providing an ultrasonic medical device comprising an ultrasonic probe having a proximal end, a distal end terminating in a probe tip, and a longitudinal axis between the proximal end and the distal end;

inserting the ultrasonic probe in an insertion point of the deep vein;

moving the ultrasonic probe to place the ultrasonic probe in communication with the thrombus;

activating an ultrasonic energy source engaged to the ultrasonic probe to produce an electric signal that drives a transducer of the ultrasonic medical device to produce a transverse ultrasonic vibration of the ultrasonic probe,

wherein the transverse ultrasonic vibration produces cavitation in a medium surrounding the ultrasonic probe to ablate the thrombus.

26. The method of claim 25 further comprising transmitting a transverse wave from the transverse ultrasonic vibration along the longitudinal axis of the ultrasonic probe to create an acoustic wave in the medium surrounding the ultrasonic probe.

27. The method of claim 25 further comprising producing a plurality of transverse nodes and a plurality of transverse anti-nodes along a portion of the longitudinal axis of the ultrasonic probe by the transverse ultrasonic vibration.

28. The method of claim 27 wherein the plurality transverse nodes are points of a minimum transverse ultrasonic vibration.

29. The method of claim 27 wherein the plurality of transverse anti-nodes are points of a maximum transverse ultrasonic vibration.

30. The method of claim 25 wherein the ultrasonic probe is for a single use on a single patient.

31. The method of claim 25 further comprising delivering ultrasonic energy in a frequency range of about 10 kHz to about 100 kHz by the ultrasonic energy source.

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