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(54) **ULTRASOUND ENHANCED CENTRAL VENOUS CATHETER**

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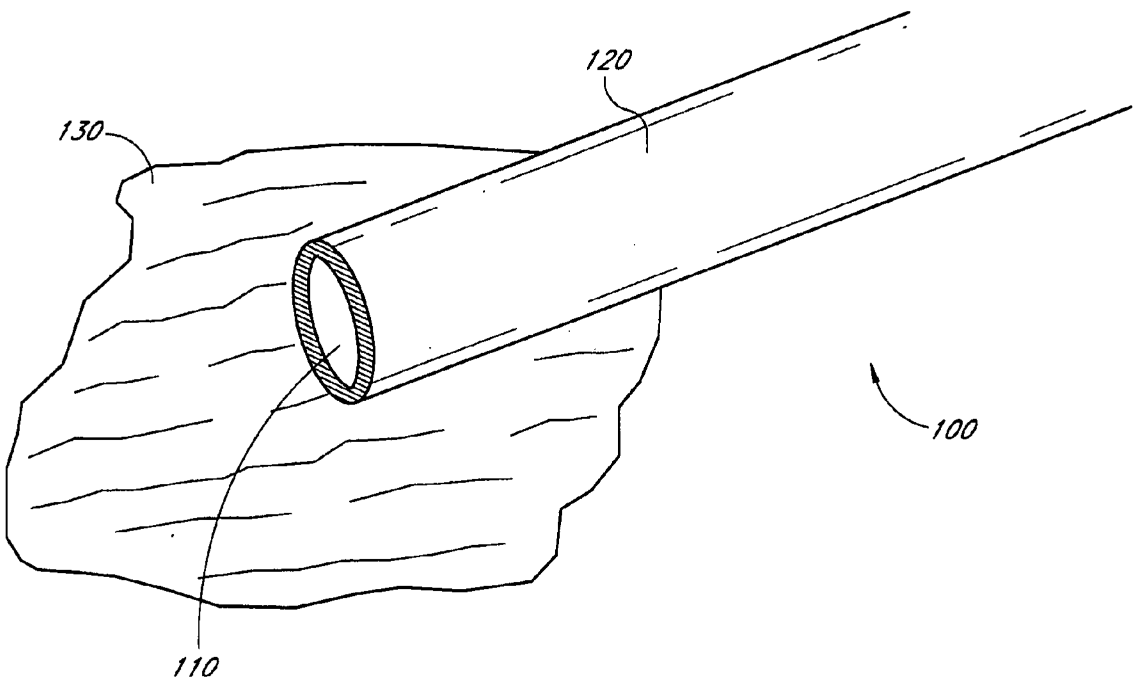
(57) **ABSTRACT**

A central venous catheter comprises an ultrasound assembly. In one arrangement, the radiating member is used to remove a blockage from the central venous catheter. In another arrangement, inserting an ultrasound assembly into a central venous catheter. The ultrasound assembly comprises an ultrasound radiating member mounted on an elongate support structure. The method further comprises positioning the ultrasound assembly within the central venous catheter such that the ultrasound radiating member is adjacent to a deposited material formed on a portion of the central venous catheter. The method further comprises supplying an electrical current to the ultrasound radiating member to expose the deposited material to ultrasonic energy. The method further comprises passing a therapeutic compound through the central venous catheter to expose the deposited material to the therapeutic compound simultaneously with ultrasonic energy.



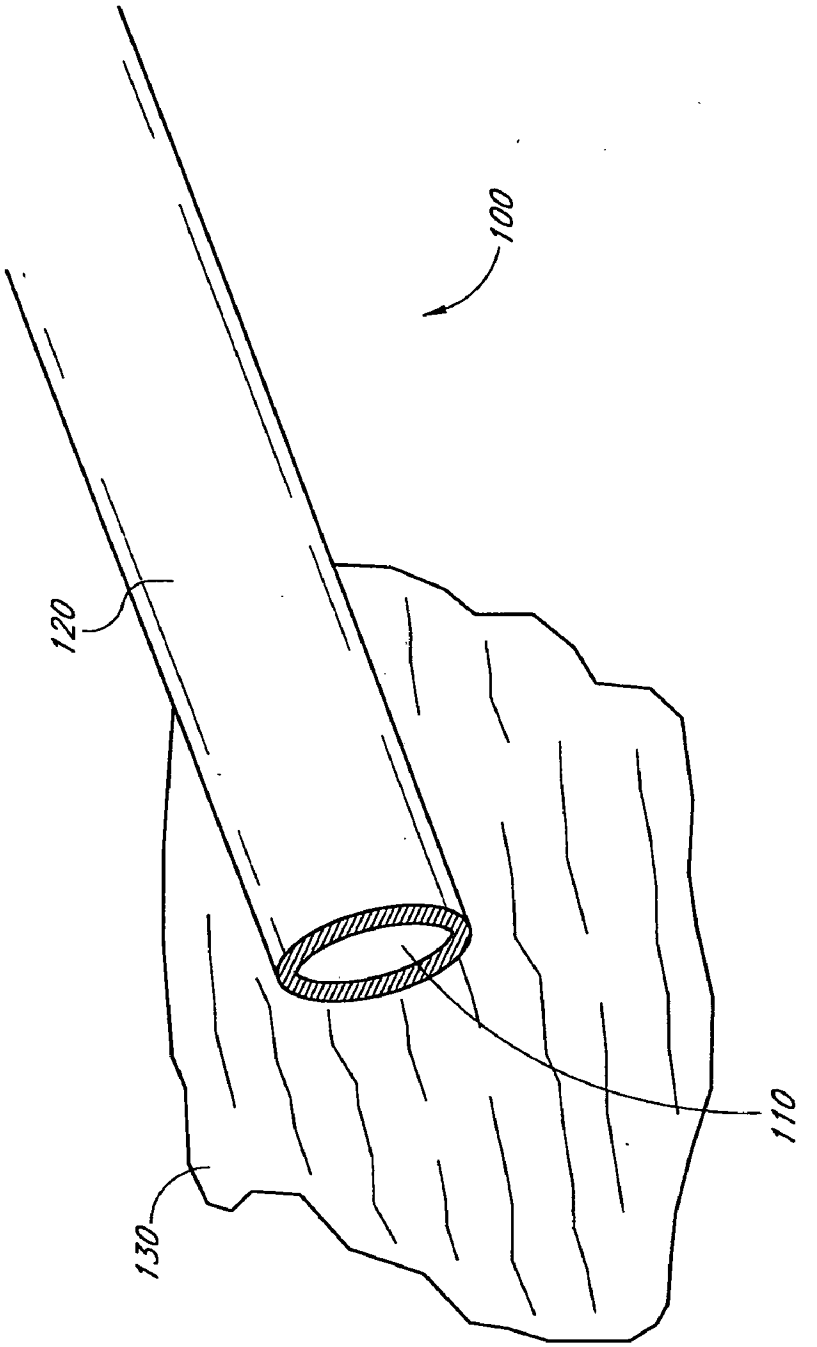


FIG. 1

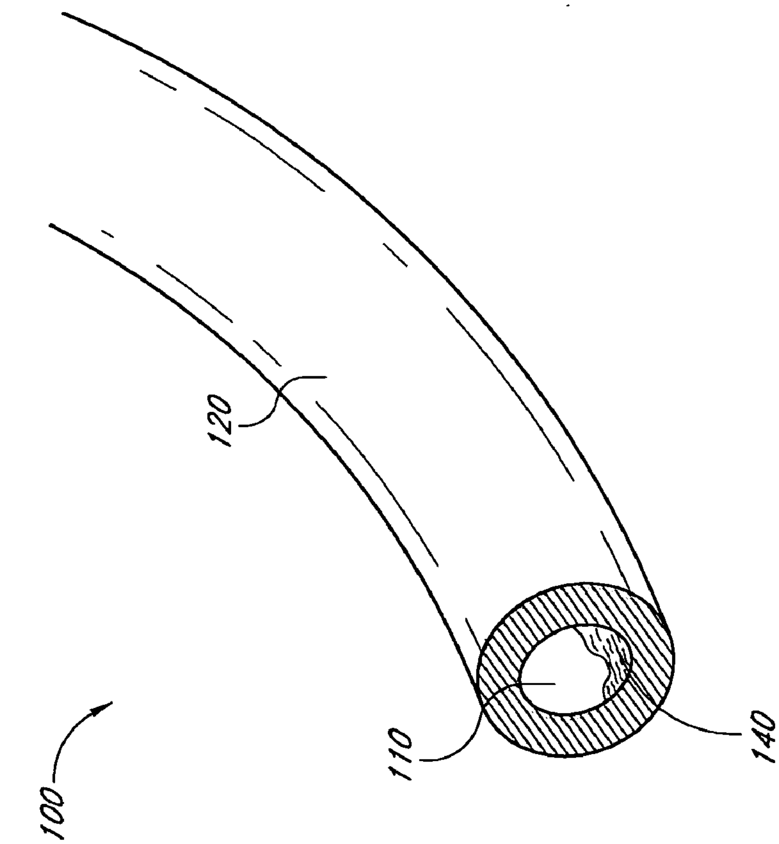


FIG. 2

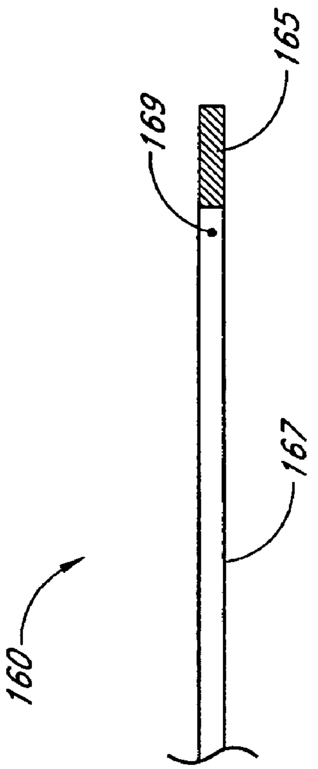


FIG. 4

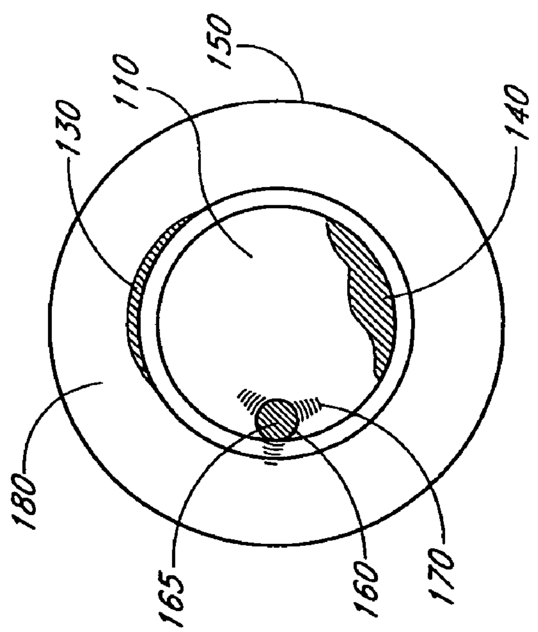


FIG. 3

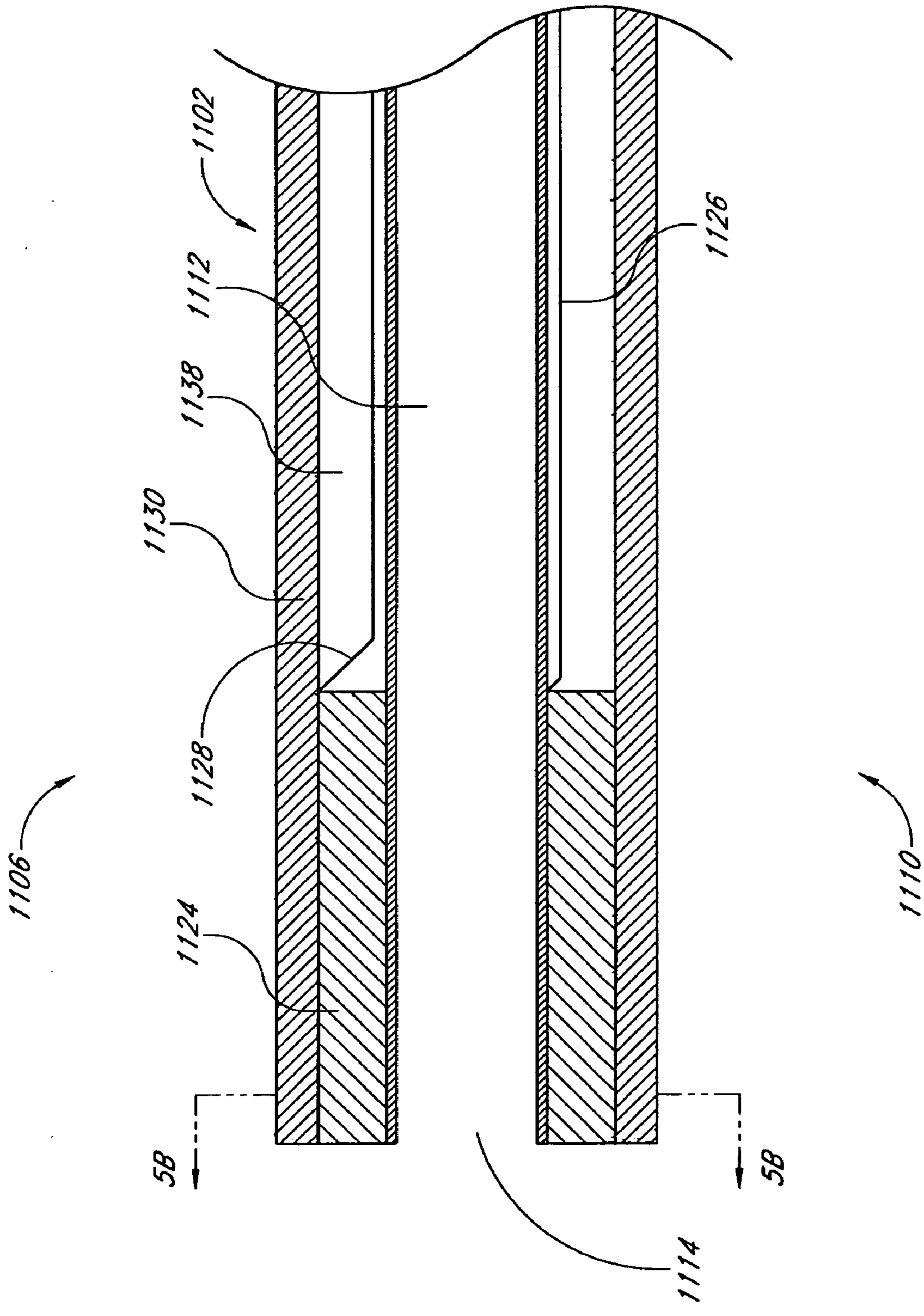


FIG. 5A

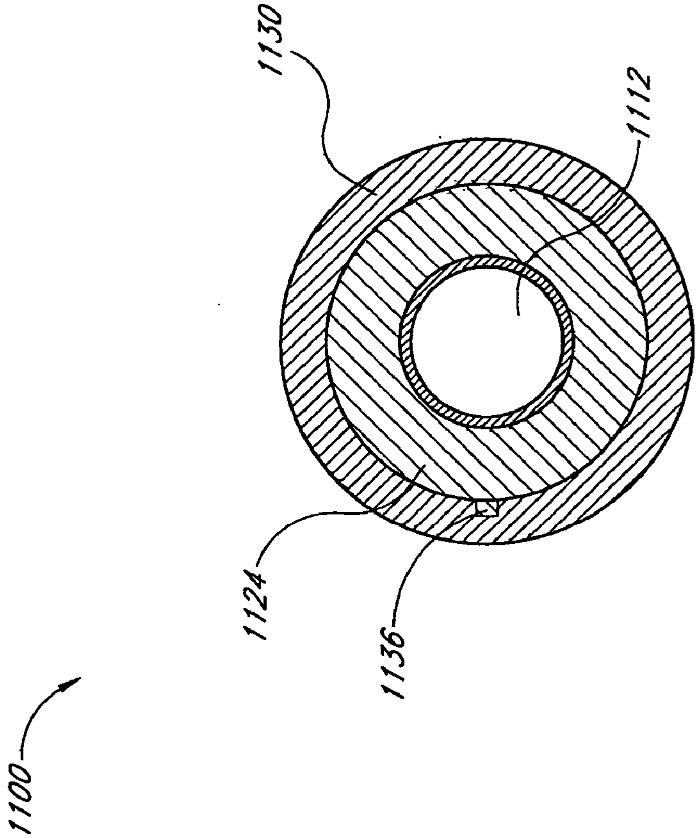


FIG. 5B

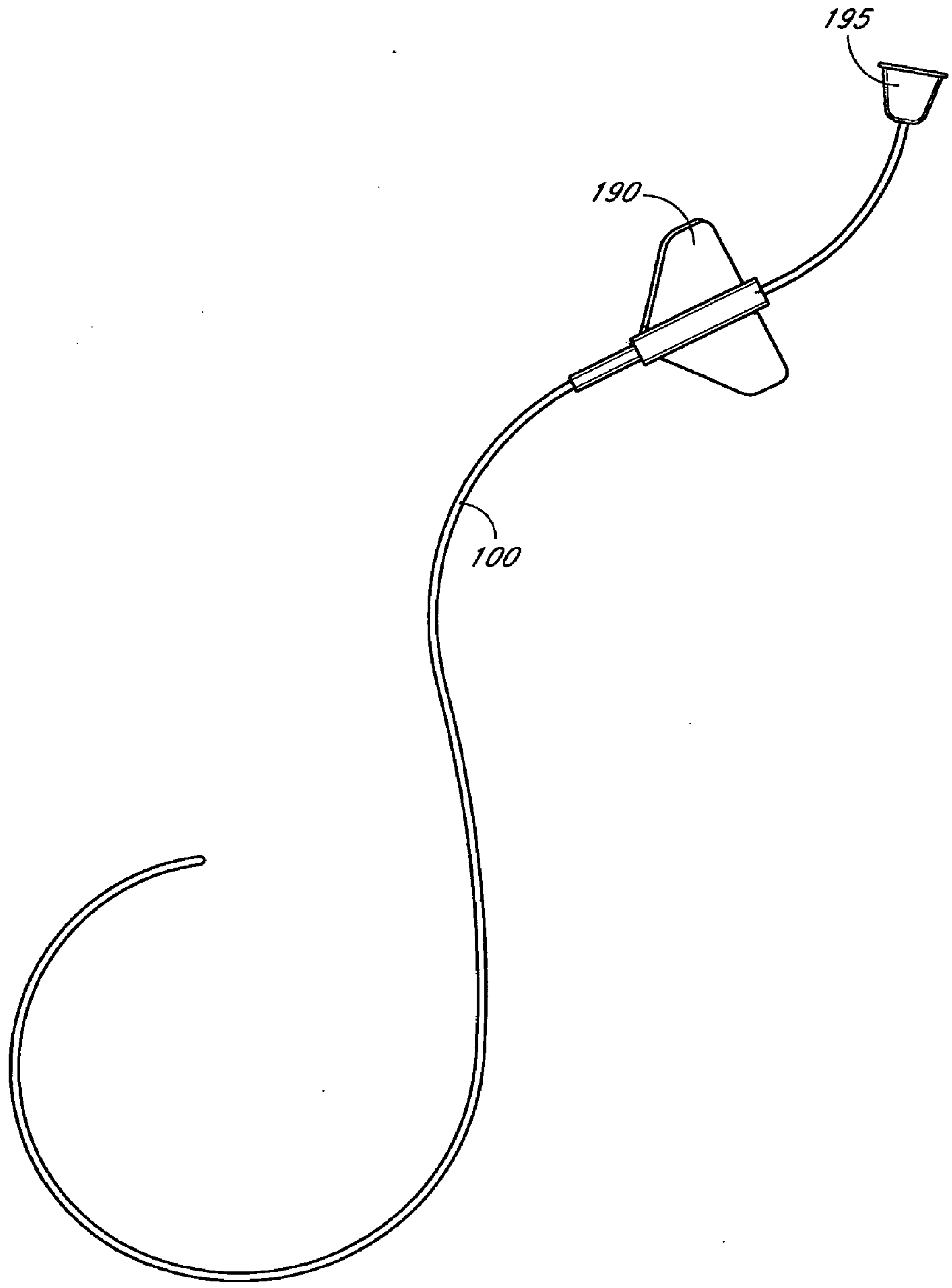


FIG. 6

ULTRASOUND ENHANCED CENTRAL VENOUS CATHETER

PRIORITY CLAIM

[0001] This is a continuation of International Application PCT/US2004/012362 (filed 22 Apr. 2004), which claims the benefit of U.S. Provisional Application No. 60/464,673 (filed 22 Apr. 2003), the entire disclosure of which is hereby incorporated in its entirety by reference herein.

FIELD OF THE INVENTION

[0002] The present invention relates generally to use of an ultrasound assembly with a central venous catheter, and more specifically to using ultrasonic energy to enhance the efficacy of a central venous catheter.

BACKGROUND OF THE INVENTION

[0003] The term "central venous catheter" or "CVC," refers generally, in addition to its ordinary meaning, to a catheter that has been inserted into a vein of the vascular system. Although CVCs have many varied applications, CVCs are frequently used when a patent requires frequent or continuous injections of medications or fluids for nutritional support. Common CVC applications include, but are not limited to, chemotherapy, long-term intravenous antibiotics, long-term pain medications, long-term intravenous nutrition, frequent blood draws, dialysis, and plasmapheresis. Therefore, a CVC can be used to deliver fluids to, or extract fluids from, the cardiovascular system.

[0004] In a wide variety of medical applications, the tip of a CVC is advanced into the superior vena cava ("SVC") from an upper extremity jugular vein or subclavian vein. Other approaches and deployment locations can be used in other applications. CVCs are used in a wide variety of applications; one common application is in the provision of a therapeutic compound into a patient's vascular system.

[0005] When a CVC is used for an extended period, blockages can form within the CVC, or can form outside the CVC in the vein between the CVC and the blood vessel wall. For example, a blockage inside the CVC can be caused by drug precipitate or thrombus. Additionally, platelet aggregation or fibrin deposition can completely encase the surface of the CVC, or can form a sac around the distal end of the CVC. Conventionally, such blockages were removed, if at all, either by removing and replacing/cleaning the CVC or while the CVC is in place passing a clot-dissolving compound through the CVC to dissolve the blockage. However, removing the CVC catheter is generally not desirable and introducing a large quantity of clot-dissolving compounds into the vascular system can have negative side effects.

SUMMARY OF THE INVENTION

[0006] Therefore, a device capable of removing blockages or other materials from within or around a CVC, without removing the CVC and/or causing the negative side effects associated with the introduction of large quantities of clot-dissolving compounds into the vascular system, has been developed. In addition, an improved CVC that is capable of being outfitted with an ultrasound assembly is also provided.

[0007] Accordingly, one embodiment of the present invention comprises an elongate central venous catheter. The elongate central venous catheter having a distal region configured for insertion into a patient's vasculature. The elongate central venous catheter also has a fluid delivery lumen configured to allow a fluid to be delivered through the central venous catheter to the patient's vasculature. The apparatus further comprises an ultrasound assembly configured to be positioned adjacent to the central venous catheter distal region. The apparatus further comprises a temperature sensor configured to measure a temperature in a region adjacent to the ultrasound assembly.

[0008] According to one embodiment of the present invention, a method for removing a blockage from a central venous catheter comprises inserting an ultrasound assembly into a central venous catheter. The ultrasound assembly comprises an ultrasound radiating member mounted on an elongate support structure. The method further comprises positioning the ultrasound assembly within the central venous catheter such that the ultrasound radiating member is adjacent to a deposited material formed on a portion of the central venous catheter. The method further comprises supplying an electrical current to the ultrasound radiating member to expose the deposited material to ultrasonic energy. The method further comprises passing a blockage removal compound through the central venous catheter to expose the deposited material to the blockage removal compound simultaneously with ultrasonic energy.

[0009] According to another embodiment of the present invention, a method comprises exposing a deposited material formed on a central venous catheter to ultrasonic energy while the central venous catheter is positioned in a patient and exposing the deposited material to a blockage removal compound while the central venous catheter is positioned in a patient.

[0010] According to another embodiment of the present invention, a method for removing a deposited material from a catheter comprises supplying a blockage removal compound to the deposited material. The method further comprises exposing the deposited material to ultrasonic energy generated by an ultrasound radiating member positioned within the catheter. The method further comprises measuring a temperature on the catheter to provide an indication of progression of the removal of the deposited material from the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Exemplary embodiments of the CVCs disclosed herein, and exemplary methods for using said CVCs are illustrated in the accompanying drawings, which are for illustrative purposes only. The drawings comprise the following figures, in which like numerals indicate like parts.

[0012] **FIG. 1** is a perspective view of an exemplary embodiment of a distal end of a CVC structure having a fibrin sleeve formed thereover.

[0013] **FIG. 2** is a perspective view of an exemplary embodiment of a distal end of a CVC structure having a intraluminal thrombus or clot formed therein.

[0014] **FIG. 3** is a cross-sectional view of a CVC disposed within a patient's vasculature, wherein an ultrasound assembly is positioned within the CVC.

[0015] **FIG. 4** is a side view of the ultrasound assembly positioned within the CVC of **FIG. 3**.

[0016] **FIG. 5A** is a cross-sectional view of a CVC having an embedded ultrasound radiating member.

[0017] **FIG. 5B** is a cross-sectional view of the CVC of **FIG. 5A**, taken along line **5B-5B**.

[0018] **FIG. 6** is a perspective illustration of a CVC elongate body having a suture wing in the catheter proximal region.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0019] As described above, material can be deposited in and around a CVC during extended use. Such deposition can adversely affect operation of the CVC, making it difficult or impossible to deliver therapeutic compounds or other materials through the CVC to the patient's vasculature. Therefore, improvements have been developed to mitigate the adverse affects associated with material deposition in or around a CVC. Exemplary embodiments of these improvements are disclosed herein.

[0020] A wide variety of CVC structures exist, and the improvements described herein are not intended to be limited to a particular CVC structure. Rather, the improvements are described in connection with a generic CVC structure, with the understanding that these improvements are not limited to use with that particular CVC structure. For example, CVCs can be configured with multiple lumens, rather than a single central lumen. For example, in one embodiment, a CVC catheter has been one lumen and five lumens. Multiple lumens can be used for introducing and withdrawing fluids and devices, such as a guidewire. Likewise, the improvements disclosed herein can be used with catheters other than CVC catheters, such as with catheters configured to be inserted into other regions of the vascular system.

[0021] Accordingly, the term "central venous catheter" refers generally, in addition to its ordinary meaning, to a catheter that has been inserted into a vein of the vascular system. In a wide variety of medical applications, the tip of a CVC is advanced into the superior vena cava ("SVC") from an upper extremity jugular vein or subclavian vein. Other approaches and deployment locations can be used in other applications. CVCs are used in a wide variety of applications; one common application is in the provision of a therapeutic compound into a patient's vascular system.

[0022] As used herein, the term "therapeutic compound" refers broadly, without limitation, to a drug, medicament, dissolution compound, genetic material or any other substance capable of effecting physiological functions. Additionally, any mixture comprising any such substances is encompassed within this definition of "therapeutic compound", as well as any substance falling within the ordinary meaning of these terms.

[0023] As used herein, the term "ultrasound energy" is a broad term and is used in its ordinary sense and means, without limitation, mechanical energy transferred through pressure or compression waves with a frequency greater than about 20 kHz. In one embodiment, the waves of the ultrasound energy have a frequency between about 500 kHz and 20 MHz and in another embodiment between about 1 MHz and 3 MHz. In yet another embodiment, the waves of the ultrasound energy have a frequency of about 3 MHz.

[0024] As used herein, the term "catheter" is a broad term and is used in its ordinary sense and means, without limitation, an elongate flexible tube configured to be inserted into the body of a patient, such as, for example, a body cavity, duct or vessel.

[0025] A distal region of a generic CVC structure is illustrated in **FIGS. 1 and 2**. As illustrated, a generic CVC comprises a flexible, elongate body **100** that forms a central lumen **110**. The elongate body **100** has an outer surface **120**, and is dimensioned to facilitate its passage through the peripheral vascular system. Generally, suitable materials and dimensions for the CVC can be selected readily based on the natural and anatomical dimensions of the particular treatment site and percutaneous access site. Examples of suitable CVC materials include, but are not limited to, extruded polytetrafluoroethylene ("PTFE"), polyethylenes ("PE"), polyamides and other similar materials. In CVCs configured for long term implantation, soft materials such as urethanes and silicones can be used to form the catheter body. Additionally, a CVC optionally includes a coating, such as a silver coating, to reduce the likelihood of infection.

[0026] In certain embodiments, the proximal region of the CVC is reinforced by braiding, mesh or other internal or external structures to provide increased kink resistance and pushability, thereby facilitating passage of the CVC through the patient's vasculature. In other embodiments, the CVC body can be reinforced by including a stylet in the CVC body, which serves to maintain rigidity of the CVC during passage through the patient's vasculature. In such embodiments, a thin, elongate wire can be used as a stylet.

[0027] In one embodiment, a CVC has an outer diameter between approximately 6 French and approximately 14 French.

[0028] A CVC optionally includes a suture wing or cuff in the catheter proximal region, which can be used to attach the proximal end of the CVC to the patient. For example, **FIG. 6** illustrates a CVC elongate body **100** having a suture wing **190** in the catheter proximal region. The suture wing **190** can be constructed of a material suitable for attachment to a patient's body. In other embodiments, a cuff that may be made out of a material such as Dacron can be used. As illustrated, the CVC optionally includes a proximal hub **195** that can be used to supply fluid, such as a therapeutic compound, through a CVC lumen.

[0029] As described above, material often deposits in and around a CVC that has been positioned within a patent's vasculature for an extended period of time. Such blockages can be caused by therapeutic compound precipitate, platelet aggregation, or fibrin deposition. For example, **FIG. 1** illustrates the formation of a fibrin sleeve **130** at the distal region of the CVC, and **FIG. 2** illustrates the formation of a thrombus or clot **140** within the CVC central lumen **110**. Either of these conditions can adversely affect the operation of the CVC, making it difficult or impossible to pass therapeutic compounds or other materials through the CVC and into the patient's vasculature.

[0030] The blockages described above, whether formed inside or outside the CVC, often become coated with a protein substance that provides a shield for bacteria. This protein "shield" makes it difficult to treat bacterial growth within the blockage using antibiotics. Therefore, because of the bacteria-resistant shield, bacterial growth within the blockage can proliferate, increase the size of the blockage, and cause infection. This process is a significant contributing factor to upper extremity deep vein thrombosis ("DVT").

[0031] An obstruction within a CVC can be cleaned while in the patient by using a brush and a small amount of a therapeutic compound, such as a lytic solution. However, it is difficult or impossible to clean the outer surface of a CVC using a brush. In an exemplary embodiment, ultrasonic energy is used to clean one or more portions of a CVC, such as the central lumen **110**, the elongate body outer surface **120**, or both. Preferably, the ultrasonic energy is used in combination with a blockage removal compound to clean the one or more portions of the CVC. In such embodiments, the ultrasonic energy is preferably configured to enhance the therapeutic effects and/or delivery of the blockage removal compound. For example, the ultrasonic energy can be used to penetrate the protein shield that often covers an occlusion, thereby allowing a blockage removal compound, such as a solution containing an antibacterial agent and/or a thrombus removing compound (e.g., Heparin, Uronkinase, Streptokinase, TPA and other thrombolytics or anti-thrombus agents) to be delivered directly to the occlusion. The ultrasonic energy can be delivered independent of, or simultaneously with, the blockage removal compound. In another use of the system disclosed herein, a CVC is exposed to ultrasonic energy periodically to reduce or prevent accumulation of protein thereon. Preferably, in these embodiments, the ultrasound and/or the blockage removal compound applied while the central venous catheter is positioned in a patient.

[0032] One system for using ultrasonic energy to clean a CVC is illustrated in **FIG. 3**. **FIG. 3** is a cross-sectional illustration of the elongate body **100** of a CVC that has been positioned within a patient's vasculature **150**. As illustrated, this system can be used to clean deposited material from within the CVC outer surface **120** (such as a fibrin sleeve **130**), or from the CVC inner lumen **110** (such as a thrombus or clot **140**), or both. Similarly, this system can be used to clean deposited material from the distal end of the CVC, or from an intermediate position on the CVC.

[0033] Still referring to **FIG. 3**, to expose the deposited material to ultrasonic energy, an ultrasound assembly **160** is inserted into, and passed through the elongate body **100**. The ultrasound assembly **160**, a side view of which is illustrated in **FIG. 4**, comprises an ultrasound radiating member **165** positioned at the distal end of an elongate support member **167**. In an exemplary embodiment, the ultrasound radiating member comprises lead zirconate titanate ("PZT"), although other materials capable of generating mechanical vibrations when exposed to electronic signals can also be used. Although the ultrasound assembly **160** illustrated in **FIG. 4** comprises one ultrasound radiating member **165**, in a modified embodiment, multiple ultrasound radiating members are positioned along the elongate support member **167**. The multiple ultrasound radiating members can be controlled independently of each other. In another modified embodiment, the ultrasound radiating member is mechanically connected to an ultrasound oscillator positioned at the proximal end of the CVC, outside the patient's body; additional information regarding this configuration is provided U.S. Pat. No. 6,524,251, issued on 25 Feb. 2003, and entitled "Ultrasonic Device for Tissue Ablation and Sheath for Use Therewith."

[0034] Additional information regarding controlling a plurality of ultrasound radiating members are provided in U.S. Patent Application Publication US 2004/0024347 A1, published on 5 Feb. 2004 and entitled "Catheter with Multiple Ultrasound Radiating Members," the entire disclosure of which is hereby incorporated herein by reference herein. Additional information regarding mounting one or more ultrasound radiating members on an elongate support structure are provided in U.S. patent application Ser. No. 10/751,843, filed on 5 Jan. 2004 and entitled "Ultrasonic Catheter with Axial Energy Field," the entire disclosure of which is hereby incorporated by reference herein.

[0035] A temperature sensor **169** is optionally positioned in a distal region of the elongate support member **169**. In other embodiments, the temperature sensor **169** is positioned directly on the ultrasound radiating member **165**. In such embodiments, the ultrasound radiating member **165**, and optionally the temperature sensor **169**, are electrically connected to control circuitry at a proximal end of the ultrasound assembly **160**. The temperature sensor can be used to monitor and control the progression of the cleaning procedure. In particular, when removing a blockage from within or around a CVC, a decrease in the temperature at the treatment site can indicate that the blockage has been at least partially removed or dissolved, and that flow has been at least partially reestablished at the treatment site. In addition, the temperature sensor may be used to determine that the radiating member is positioned 165 within the blockage. Additional information regarding using temperature measurements to monitor the progression of an ultrasound-enhanced treatment are provided in U.S. Patent Application Publication 2003/0220568 A1, published on 27 Nov. 2003 and entitled "Blood Flow Reestablishment Determination," as well as in U.S. Provisional Pat. Applications Nos. 60/540,900 (filed 29 Jan. 2004) and 60/540,703 (filed 30 Jan. 2004); the entire disclosure of these three applications is hereby incorporated by reference herein.

[0036] As described above, the ultrasound assembly **160** is passed through the CVC to a point that the ultrasound radiating member **165** is positioned adjacent to a blockage. The blockage is located either within the CVC elongate body **100**, or outside the CVC elongate body **100**. When the ultrasound radiating member **165** is activated via the control circuitry, ultrasonic vibrations are generated, thereby exposing the blockage to ultrasonic energy **170**. The blockage can also optionally be exposed to a blockage removal compound to assist in breaking down or dissolving the blockage, such as a thrombolytic solution or an antibacterial solution. The blockage removal compound can be delivered through the CVC itself, or can be independently supplied to the treatment site by, for example, a secondary delivery catheter or a delivery lumen formed integrally with the central venous catheter. In an exemplary embodiment, the ultrasonic energy enhances the effect of the blockage removal compound, as described previously.

[0037] In a modified embodiment, the CVC is configured to facilitate the delivery of ultrasonic energy to blockages that form on or within the elongate body. For example, in one embodiment, the elongate body, or optionally only a distal region of the elongate body, is formed from a material that is substantially transparent to ultrasonic energy. This configuration advantageously allows ultrasonic energy generated by an ultrasound radiating member positioned within the central lumen **110** to pass through the elongate body **100** and be absorbed by a blockage outside the CVC.

[0038] The ultrasound radiating member **165** need not be positioned within the CVC central lumen **110**. For example, the ultrasound assembly can be passed along the outer surface **120** of the CVC in a region **180** (see **FIG. 3**) between the patient's vasculature **150** and the CVC. In another embodiment, the ultrasound radiating member **150** is embedded within the walls of the CVC, as illustrated in **FIG. 5A and 5B**.

[0039] As shown in **FIGS. 5A and 5B**, a modified ultrasound catheter **1100**, such as a CVC, generally comprises a multi-component tubular body **1102** having a proximal region (not shown) and a distal region **1106**. Suitable materials and dimensions for the ultrasound catheter **1100** can be selected based on the natural and anatomical dimensions of the treatment site and of the percutaneous access site.

[0040] The elongate, flexible tubular body **1102** comprises an outer sheath **1130** that is positioned upon an inner core **1110**. In an exemplary embodiment, the outer sheath **1130** comprises extruded PEBAX, PTFE, PEEK, PE, polymides, braided polymides and/or other similar materials that are substantially transparent to ultrasonic energy. In an exemplary embodiment, the inner core **1110** comprises polymide or a similar material which, in some embodiments, can be braided to increase the flexibility of the tubular body **1102**. The inner core **1110** at least partially defines a delivery lumen **1112** that extends longitudinally along the catheter **1100**. The delivery lumen **1112** includes a distal exit port **1114**. At a proximal end of the catheter **1100**, the delivery lumen **1112** optionally includes a Luer fitting to facilitate the passage of a fluid therethrough.

[0041] Still referring to the exemplary embodiment illustrated in **FIGS. 5A and 5B**, the tubular body distal region **1106** includes the ultrasound radiating member **1124**. In a modified embodiment, the ultrasonic energy can be generated by an ultrasound radiating member that is remote from the treatment site; in such embodiments the ultrasonic energy can be transmitted via, for example, a wire to the treatment site, as described above.

[0042] As illustrated in **FIGS. 5A and 5B**, the ultrasound radiating member **1124** is configured as a hollow cylinder. As such, the inner core **1110** extends through the ultrasound radiating member **1124**. The ultrasound radiating member **1124** is secured to the inner core **1110** in a suitable manner, such as with an adhesive. A potting material is optionally used to further secure the mounting of the ultrasound radiating member **1124** along the inner core **1110**.

[0043] In other embodiments, the ultrasound radiating member **1124** is configured with a different shape. For example, the ultrasound radiating member can be configured as a solid rod, a disk, a solid rectangle, a curved element (such as a split cylinder or a curved rectangular element), or a thin block. In such embodiments. the ultrasound radiating members are configured with dimensions that allow them to be embedded within the walls of the CVC, as the ultrasound radiating member **1124** illustrated in **FIGS. 5A and 5B** is embedded in the CVC wall. In other embodiments, wherein the CVC includes a plurality of lumens formed within the catheter, the ultrasound radiating members can be embedded in the catheter walls between the lumens. Because relatively soft materials are often used to form the CVC body, as described above, the catheter walls can be configured with a relatively large thickness, thereby providing ample space to support one or more embedded ultrasound radiating members. Particular characteristics of the ultrasound radiating member can be optimized with routine experimentation based on the particular physical configuration of the CVC body, including the CVC body materials, dimensions, and shape.

[0044] Still further, the ultrasound radiating member can comprise a plurality of smaller ultrasound radiating members. However, the illustrated arrangement advantageously provides for enhanced cooling of the ultrasound radiating member **1124**. For example, in embodiments wherein a therapeutic compound is delivered through the delivery lumen **1112**, the therapeutic compound advantageously serves as a heat sink for removing heat generated by the ultrasound radiating member **1124**. In another embodiment, a return path can be formed in the region **1138** between the outer sheath **1130** and the inner core **1110**, such that coolant from a coolant system can be directed through the region **1138**.

[0045] In a modified embodiment, the CVC is configured to caused the ultrasonic energy generated by the ultrasound radiating member to radiate outward from the CVC or inward toward the central lumen. This can be accomplished, for example, by positioning a chamber of high ultrasonic impedance material on the opposite side of the ultrasound radiating member from where the ultrasonic energy is to be directed. This modification can be made with a variety of different ultrasound radiating member configurations, including hollow cylindrical configurations and rectangular configurations. Additional information regarding the use of a backing to direct ultrasonic energy is provided is U.S. Pat. No. 6,676,626, issued on 13 Jan. 2004, and entitled "Ultrasound Assembly with Increased Efficacy," and in U.S. Pat. No. 6,582,392, issued on 24 Jun. 2003, and entitled "Ultrasound Assembly for Use with a Catheter", which are hereby incorporated by reference herein in their entirety.

[0046] In an exemplary embodiment, the ultrasound radiating member **1124** is selected to produce ultrasonic energy in a frequency range that is well suited for removal of deposited material from the catheter **1100**. Suitable frequencies of ultrasonic energy include, but are not limited to, from about 20 kHz to about 20 MHz. In one embodiment, the frequency is between about 500 kHz and 20 MHz, and in another embodiment the frequency is between about 1 MHz and about 3 MHz. In yet another embodiment, the ultrasonic energy has a frequency of about 3 MHz.

[0047] As described above, ultrasonic energy is generated from electrical power supplied to the ultrasound radiating member **1124**. The electrical power can be supplied through a pair wires **1126**, **1128** that extend through the tubular body **1102**. In an exemplary embodiment, the electrical wires **1126**, **1128** are secured to the inner core **1110**, lay along the inner core **1110**, and/or extend freely in the region **1138** between the inner core **1110** and the outer sheath **1130**. In the illustrated arrangement, the first wire **1126** is connected to the hollow center of the ultrasound radiating member **1124**, while the second wire **1128** is connected to the outer periphery of the ultrasound radiating member **1124**.

[0048] With continued reference to the exemplary embodiment illustrated in **FIG. 5B**, the catheter **1100** includes at least one temperature sensor **1136** along the tubular body distal region **1106**. The temperature sensor **1136** is located on or near the ultrasound radiating element **1124**. Suitable temperature sensors include but are not limited to, diodes, thermistors, thermocouples, resistance temperature detectors ("RTDs"), and fiber optic temperature sensors that used thermalchromic liquid crystals. In such embodiments, the temperature sensor is operatively connected to control circuitry through a control wire that extends through the tubular body **1102**.

[**0049**] In other embodiments, a vibrational element is embedded in the wall of a CVC. In such embodiments, the vibrational element comprises a metallic compound that can be vibrated by application of an oscillating electromagnetic field from outside the body. For example, an externally-applied electromagnetic field can be used to vibrate a ferro-metallic ring or cylinder embedded in the wall of the catheter **1100**. In such embodiments, wires and electrodes used to supply power to an ultrasound radiating member can be eliminated. In certain embodiments, the vibrational element embedded is configured to vibrate upon application of an externally-applied oscillating electric field, or magnetic field, or upon application of externally-applied ultrasonic energy.

Scope of the Invention

[**0050**] For purposes of describing the invention and the advantages achieved over the prior art, certain features, objects and advantages of the invention have been set forth herein. Not necessarily all such features, objects or advantages may be used or achieved in accordance with a particular embodiment of the invention. Thus, for example, the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein. In addition, various methods and procedures have been described above. It should be understood that those methods and procedures should not be limited to the sequence described but may be performed in different orders and that not necessarily all of the steps of a method or procedure needs to be performed. Furthermore, the present invention is not limited to any particular disclosed embodiment, but is limited only by the claims set forth below.

We claim:

1. An apparatus comprising:

an elongate central venous catheter having a distal region configured for insertion into a patient's vasculature, and a fluid delivery lumen configured to allow a fluid to be delivered through the central venous catheter to the patient's vasculature;

an ultrasound assembly configured to be positioned adjacent to the central venous catheter distal region; and

a temperature sensor configured to measure a temperature in a region adjacent to the ultrasound assembly.

2. The apparatus of claim 1, wherein the ultrasound assembly comprises an ultrasound radiating member mounted on an elongate support structure configured to be passed through the central venous catheter.

3. The apparatus of claim 1, wherein the ultrasound assembly comprises an ultrasound radiating member mounted on the central venous catheter.

4. The apparatus of claim 1, wherein the ultrasound assembly comprises a plurality of ultrasound radiating members.

5. The apparatus of claim 1, wherein the temperature sensor is a thermocouple.

6. The apparatus of claim 1, wherein central venous catheter has an outer diameter between approximately 6 French and approximately 14 French.

7. A method for removing a blockage from a central venous catheter comprising:

inserting an ultrasound assembly into a central venous catheter, the ultrasound assembly comprising an ultrasound radiating member mounted on an elongate support structure;

positioning the ultrasound assembly within the central venous catheter such that the ultrasound radiating member is adjacent to a deposited material formed on a portion of the central venous catheter;

supplying an electrical current to the ultrasound radiating member to expose the deposited material to ultrasonic energy; and

passing a blockage removal compound through the central venous catheter to expose the deposited material to the blockage removal compound simultaneously with ultrasonic energy.

8. The method of claim 7, wherein the ultrasound assembly comprises a plurality of ultrasound radiating members.

9. The method of claim 7, wherein the ultrasound assembly comprises a plurality of ultrasound radiating members, and wherein the plurality of ultrasound radiating members are individually controllable.

10. The method of claim 7, further comprising measuring a temperature in a region adjacent to the ultrasound radiating member.

11. The method of claim 7, further comprising:

measuring a temperature in a region adjacent to the ultrasound radiating member; and

adjusting the electrical current supplied to the ultrasound radiating member based on the measured temperature.

12. The method of claim 7, wherein the blockage removal compound is also passed through the central venous catheter before ultrasonic energy is supplied to the deposited material.

13. A method comprising exposing a deposited material formed on a central venous catheter to ultrasonic energy while the central venous catheter is positioned in a patient and exposing the deposited material formed on the central venous catheter to a blockage removal compound while the central venous catheter is positioned in a patient.

14. The method of claim 13, wherein the blockage removal compound comprises an antibacterial solution.

15. The method of claim 13, wherein the ultrasonic energy has a frequency between about 20 kHz and about 20 MHz.

16. The method of claim 13, the blockage removal compound comprises a thrombus removing agent.

17. The method of claim 13, wherein the blockage removal compound is also delivered to the deposited material before ultrasonic energy is supplied to the deposited material.

18. The method of claim 13, wherein the ultrasonic energy is also delivered to the deposited material after termination of the delivery of blockage removal compound to the deposited material.

19. The method of claim 13, wherein the ultrasonic energy is delivered from an ultrasound assembly positioned within a central lumen of the central venous catheter.

20. The method of claim 13, wherein the ultrasonic energy is delivered from an ultrasound assembly positioned within a central lumen of the central venous catheter, and wherein the ultrasound assembly comprises an ultrasound radiating member mounted on an elongate support structure.

21. The method of claim 13, wherein the ultrasonic energy is delivered from an ultrasound assembly positioned within a central lumen of the central venous catheter, and wherein the ultrasound assembly comprises a plurality of ultrasound radiating members mounted on an elongate support structure.

22. The method of claim 13, further comprising measuring a temperature adjacent to the deposited material.

23. The method of claim 13, further comprising:

measuring a temperature adjacent to the deposited material; and

adjusting the amount of ultrasonic energy delivered to the deposited material based on the measured temperature.

24. The method of claim 13, wherein the ultrasonic energy is delivered from an ultrasound radiating member embedded in an elongate body of the central venous catheter.

25. The method of claim 13, wherein the blockage removal compound is delivered to the deposited material through the central venous catheter.

26. The method of claim 13, wherein the blockage removal compound is delivered to the deposited material through a delivery lumen formed integrally with the central venous catheter.

27. A method for removing a deposited material from a catheter comprising:

supplying a therapeutic compound to the deposited material;

exposing the deposited material to ultrasonic energy generated by an ultrasound radiating member positioned within the catheter; and

measuring a temperature on the catheter to provide an indication of progression of the removal of the deposited material from the catheter.

28. The method of claim 27, wherein the therapeutic compound comprises an antibacterial solution.

29. The method of claim 27, wherein the deposited material is exposed to ultrasonic energy and therapeutic compound simultaneously.

30. The method of claim 27, wherein the catheter comprises a central venous catheter.

31. The method of claim 27, wherein the ultrasound radiating member is positioned within a central lumen of the catheter.

32. The method of claim 27, wherein the ultrasound radiating member is embedded within an elongate body of the catheter.

33. The method of claim 27, further comprising adjusting the amount of ultrasonic energy delivered to the deposited material based on the measured temperature.

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