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(54) **THROMBECTOMY TREATMENT SYSTEM AND METHOD**

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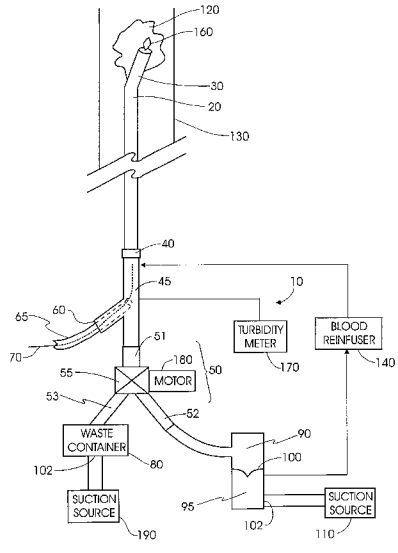
(57) **ABSTRACT**

A thrombectomy treatment system and method are provided. The system includes a catheter for insertion into the vascular system of a patient so that a tip of the catheter is positioned in the vicinity of a blood clot to be removed from the patient. A suction source is provided to withdraw the blood clot from the patient through the catheter. A filtration device functions to remove the blood clot from the accompanying blood. The filtered blood is collected in a blood collection device. A blood reinfuser communicates with the blood collection device to reinfuse the filtered blood back into the patient.

6 Claims, 3 Drawing Sheets



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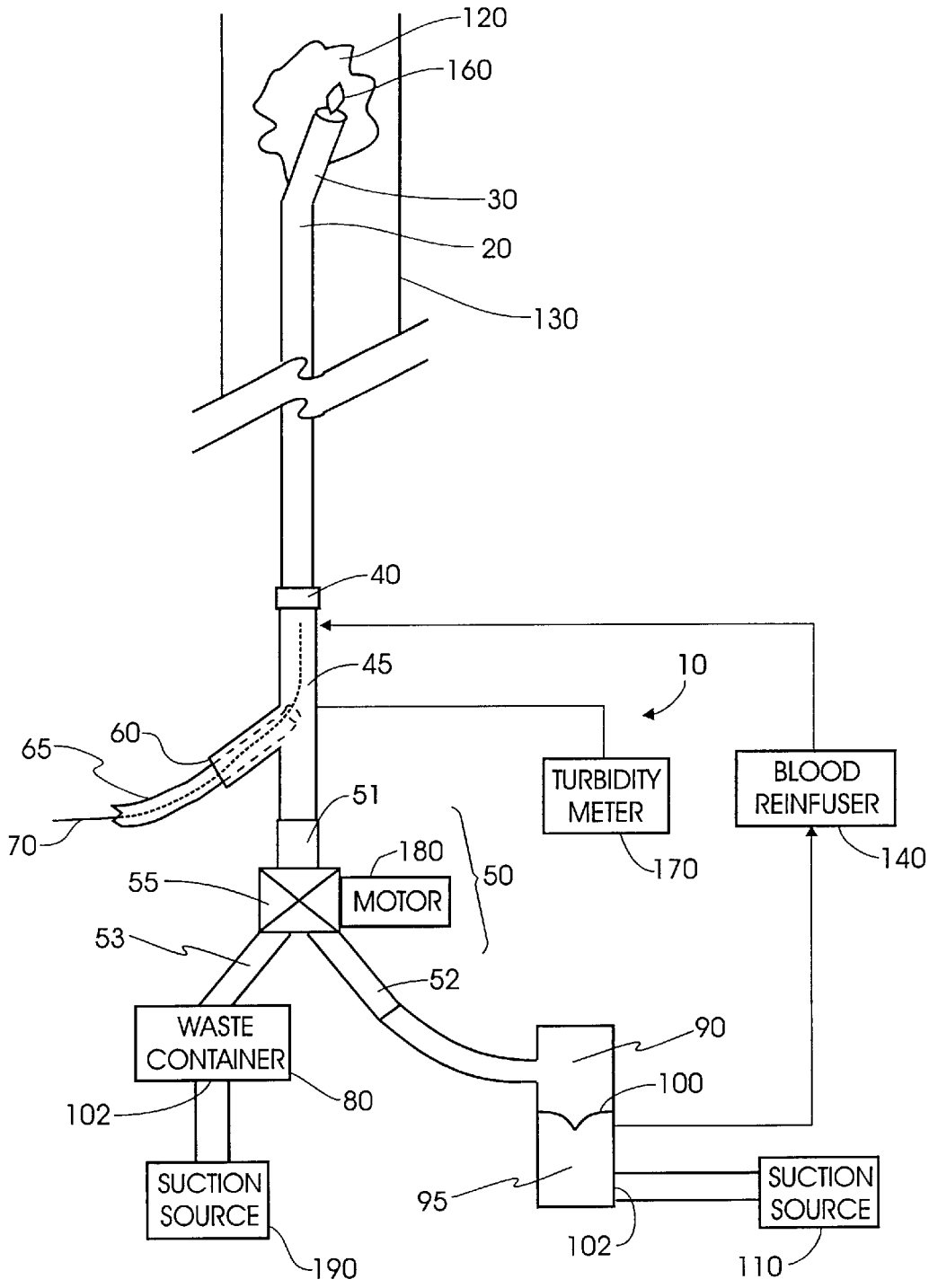
120
160
30
20
130
40
45
10
65
60
TURBIDITY METER
BLOOD REINFUSER
51
70
180
55
MOTOR
50
53
52
WASTE CONTAINER
90
100
80
102
SUCTION SOURCE
95
SUCTION SOURCE
102
190
110
170
140

FIG. 1

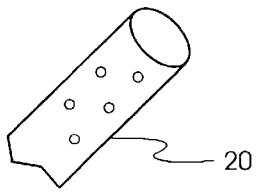

FIG. 2A

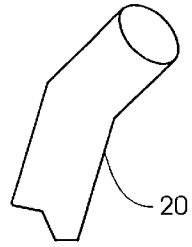

FIG. 2B

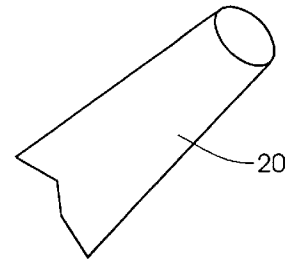

FIG. 2C

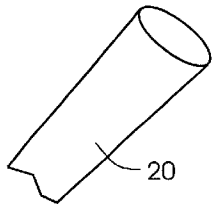

FIG. 2D

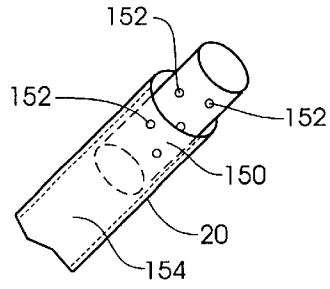

FIG. 2E

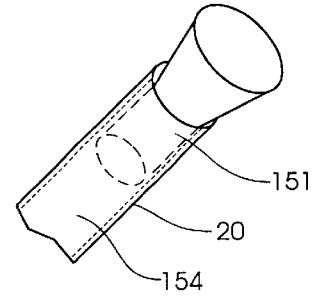

FIG. 2F

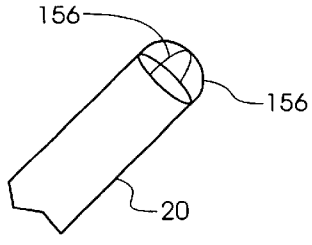

FIG. 2G

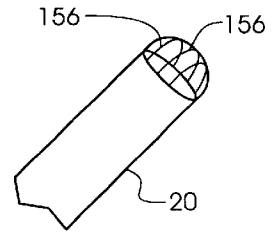

FIG. 2H

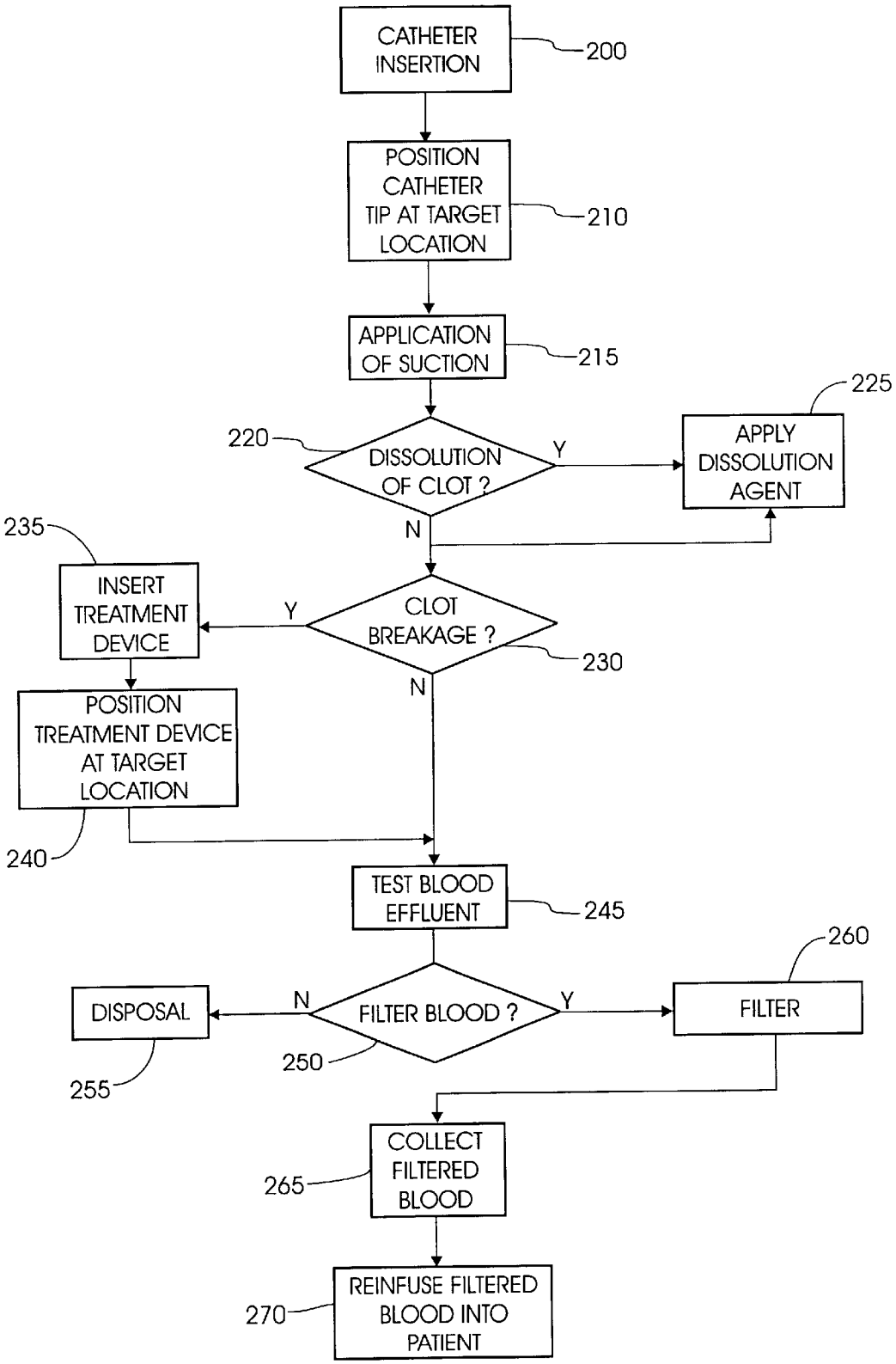
CATHETER INSERTION
200
POSITION CATHETER TIP AT TARGET LOCATION
210
APPLICATION OF SUCTION
215
225
220
DISSOLUTION OF CLOT ?
Y
APPLY DISSOLUTION AGENT
N
235
INSERT TREATMENT DEVICE
Y
CLOT BREAKAGE ?
230
N
POSITION TREATMENT DEVICE AT TARGET LOCATION
240
TEST BLOOD EFFLUENT
245
260
DISPOSAL
N
FILTER BLOOD ?
Y
FILTER
250
255
COLLECT FILTERED BLOOD
265
REINFUSE FILTERED BLOOD INTO PATIENT
270

FIG. 3

THROMBECTOMY TREATMENT SYSTEM AND METHOD

FIELD OF THE INVENTION

The present invention relates generally to a thrombectomy treatment system and method, and more particularly to a percutaneous thrombectomy system and method providing reinfusion of treated blood that is free of blood clots.

BACKGROUND OF THE INVENTION

Blood clots, such as emboli and thrombi, can pose serious health risks, making treatment and removal of the clots highly desirable. Blood clots may form on the interior surface of a blood vessel and grow in size to occlude the blood vessel at the point of clot formation. Alternately, a portion of the clot may break free forming an embolus capable of occluding a blood vessel anywhere within the vascular system.

When the obstruction occludes a vessel supplying blood to the brain, a stroke may result causing temporary or lasting paralysis of a part of the body or, in severe cases, death. Obstruction of the pulmonary artery or one of its branches can create difficulty in breathing and can potentially cause the patient to die. Blockage of other blood vessels can occur as well causing attendant health concerns. Given the potentially irreversible and destructive nature of such blockage, safe and effective procedures are needed to eliminate clots from the vascular system.

Many factors can contribute to the likelihood of clot formation, including injury to a blood vessel, alterations from normal blood flow, changes in the coagulability of the blood, and formation of fatty plaques on the lining of a blood vessel (atherosclerosis). An abrupt, abnormal change in diameter of a blood vessel wall, such as an aneurysm, increases the potential for blood coagulation. Other factors such as confinement in bed may also result in more sluggish blood flow in the veins and consequent formation of a clot.

Dialysis grafts can disrupt blood flow to an extent that increases the risk of clot formation within the vicinity of the graft junction. Additionally, surface character and compliance mismatch of some graft materials may cause turbulence in the blood flow, which in turn may lead to hemolysis of red cells, provide sites for mural bacterial adhesion and subsequent colonization, and, in areas of blood stasis, promote thrombosis and blood coagulation. Accordingly, dialysis patients are at increased risk for the formation of blood clots in the vicinity of the dialysis graft.

The present invention addresses these concerns by providing a system and a method for removing clots from the vascular system of a patient by withdrawing blood and clots from the patient, filtering the blood to remove the clots, and reinfusing the filtered blood back into the patient.

SUMMARY OF THE INVENTION

An apparatus for removal of blood clots from the blood vessel system of a patient is provided whereby clots such as thrombi and/or emboli are extracted from the patient with some of the patient's blood. As used herein "blood vessel system" includes grafts as well as naturally occurring blood vessels. The blood containing emboli or thrombi is then filtered in a filter unit and collected in a blood collection container. A blood reinfuser communicates with the blood collection container to enable the filtered blood to be reinfused back into the patient. As a result, the reinfusion of filtered blood that is free from blood clots is safely effected.

More specifically, the system comprises a percutaneous catheter assembly, a blood filtration device, a suctioning source, and a reinfuser. The catheter assembly comprises a main catheter for insertion into a selected blood vessel of a patient to permit blood and blood clots to be removed from the patient. The catheter end is positioned at a selected target site to effect removal of a blood clot. The catheter assembly may include a port through which a guidewire, a declotting device such as a thrombolytic device or a balloon, may be inserted to assist in the dislodgement and removal of the blood clot. The end of the catheter may comprise one of various differently configured tips suited to the removal of blood clots. In a selected arrangement, the catheter assembly is in fluid communication with a Y-junction adapter which has one branch in fluid communication with the filtering device to permit the blood to be filtered and a second branch in fluid communication with a waste container to permit disposal of the removed clots.

The main catheter is in fluid communication with a blood filtration device. The filtration device comprises a filter suitable for separating blood clots from the blood and a blood collection device for collecting the filtered blood. The filtration device is in communication with a suctioning source, such as a motorized pump, which provides suction to the main catheter through the filtration device. Application of suction causes blood clots and any accompanying blood from the patient to be withdrawn from the target site through the main catheter and into the filtration device, where the accompanying blood is separated from the blood clots. A reinfuser is in fluid communication with the blood collection device and comprises a delivery device, such as an intravenous (IV) needle and tubing, to reinfuse the filtered blood back into the patient.

In one arrangement, the blood collection device may be separated from the filtration device and attached to the reinfuser for reinfusion of the filtered blood into the patient. In an alternate arrangement, the reinfuser may function to reinfuse the filtered blood to the patient while the blood collection device remains attached to the filtration device.

By the method of the present invention, a catheter is inserted into a graft or a selected blood vessel of a patient and is advanced until the distal end of the catheter is located at a selected target site at a blood clot. Suction is applied to a blood filtration device which is in fluid communication with the proximal end of the catheter. The suction draws the blood clot and any accompanying blood into the distal end of the catheter removing the clot from the patient. The removed blood and blood clot are transported through the catheter into the filtration device where the blood is filtered to separate the clot from the blood. The collected, filtered blood is then reinfused back into the patient through the reinfuser. The filtered blood may be reinfused into the patient while the catheter remains in place. Alternatively, the reinfusion may be effected subsequent to the suctioning to remove the blood clot. Optionally, the reinfusion may be effected through the catheter.

In a selected mode of operation of the current invention, a device, such as a thrombolytic device, is inserted into the catheter and is used to break up the blood clot at the distal end of the catheter prior to removal of the blood clot fragments by suction through the catheter. Optionally, a thrombolytic agent may be introduced through the catheter or systemically to aid in dissolution of the clot prior to removal. In applications where it is not desirable to filter the suctioned clot, the suctioned blood, or a portion of the suctioned blood, may be diverted into a waste container.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary and the following detailed description of the preferred embodiments of the present

invention will be best understood when read in conjunction with the appended drawings, in which:

FIG. **1** is a schematic view, partially in section, showing the system of the present invention for treating blood clots;

FIGS. **2** A–H are schematic perspective views of alternate catheter tips for use in treating blood clots in accordance with the present invention; and

FIG. **3** is a flow chart showing a method for treating blood clots in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, a percutaneous thrombectomy treatment system **10** is provided for enabling the removal of blood clots from a patient's body. The blood clot is removed from the patient's body by dislodging the clot and suctioning the clot with any accompanying blood from the patient's body. The suctioned blood and clot are then filtered external to the body to extract the clots from the filtered blood. Reinfusion of the filtered blood back into the patient's body is then effected.

The treatment system **10** comprises a first flexible, longitudinally elongated tubular member, such as a catheter **20**, suitable for insertion into the vascular system of a patient for the withdrawal of blood clots **120** and accompanying blood. Catheter **20** is formed of a suitable pliable material and includes a distal tip **30** for insertion into a selected lumen of the patient and a proximal end for connection with a source of suction **110**.

The proximal end of catheter **20** is in fluid communication with a blood filtration device **90** so that the blood clot and the accompanying blood is drawn through the catheter and into the filtration device **90** by the source of suction **110**. The filtration device **90** comprises a filter **100** suitable for capturing and separating blood clots **120** from the withdrawn blood. The filtration device **90** is in fluid communication with a blood collection device **95** for collecting the filtered blood. The filtration device **90** is further in gaseous communication with a suction source **110** which provides suction to the catheter **20** through the filtration device **90**. Application of suction withdraws blood clots **120** and any accompanying blood from the patient through the catheter **20** into the filtration device **90**, where the accompanying blood is separated from blood clots **120** by filter **100**. A valve or safety seal **102** may be utilized to prevent the flow of the filtered blood from blood collection device **95** into suction source **110**. The source of suction is preferably connected with the blood collection device **95** at a position vertically higher than the highest level of collected blood to prevent any blood flow into the source of suction **110**. The blood may be drawn through filter **100** by the force of gravity, the force of suction, by centrifugal force or by any combination of such forces. When centrifugal force is used, a centrifuge unit may be incorporated in or connected with the filtration device **90**.

The proximal end of catheter **20** is operably connected to filtration device **90** via an adapter **45** and rotating hub connector **40**. The hub **40** is rotatably mounted on the adapter and functions to rotatably connect the catheter with the adapter in a fluidly sealed manner. The adaptor **45** includes a side branch **60** through which a guidewire **70** or other suitable device such as a thrombolytic device or balloon may be inserted into the catheter. From the side branch **60**, the guidewire **70**, for example a 0.035" or a 0.018" guidewire, extends through the main lumen of the adapter **45** and into the lumen of catheter **20**. In a particular embodiment, a selected treatment device may be inserted onto guidewire **70** and introduced into the vascular system of the patient through the catheter **20**. The treatment device may be a percutaneous thrombolytic device, or a balloon device or some other device, useful to dislodge or break up blood clots **120**. Other devices not employing the guidewire may be utilized.

A secondary catheter **65** may be inserted over the guidewire and advanced until the distal end of the secondary catheter **65** is positioned at the blood clot **120**. A thrombolytic agent, such as a tissue plasminogen activator, may be delivered to the blood clot **120** through the secondary catheter **65** or systemically to promote dissolution of the clot **120** as an aid to withdrawal of the clot **120** through the catheter **20**.

The proximal end of the catheter **20** is in fluid communication with the base **51** of a Y-shaped adapter **50**. More specifically the adapter **45** is sealably connected to the base **51** of the Y-shaped adapter **50** thereby connecting the catheter with the Y-shaped adapter **51**. First and second branches **52**, **53** of the Y-shaped adapter **50** are in fluid communication with the filtration device **90** and a waste container **80**, respectively. The Y-shaped adapter **50** includes a valve **55**, such as a manually actuatable valve, capable of selecting either the first branch **52** or the second branch **53** so that the fluid flow of withdrawn blood can be selectably directed into the filter **90** or the waste container **80**. As an alternative to manual actuation, valve **55** may be actuated by a motor **180**.

The waste container **80** is further in gaseous communication with a waste suction source **190** which provides suction to the catheter **20**. Application of suction withdraws blood clots **120** and any accompanying blood from the patient through the catheter **20** into the waste container **80**. A valve or safety seal **102** may be utilized to prevent the flow of the blood from waste container **80** into waste suction source **190**.

The distal end of the catheter **20** comprises a suitable tip for the removal of blood clots **120**. Depending upon the particular application or procedure to be performed, for example, as shown in FIG. **2**A, the tip of the catheter **20** may contain at least one hole in its side wall or optionally a plurality of side apertures through which blood may be withdrawn to prevent the blockage of suction by an inadvertent occlusion of the tip end.

As shown in FIG. **2**B, the tip of the catheter **20** may be formed to extend at an angle from the longitudinal axis of catheter **20** to enable easier positioning of the tip in selected applications.

As shown in FIG. **2**C, the tip of catheter **20** may be inwardly tapered toward the tip end so that the diameter of the catheter decreases towards the distal end of the catheter **20** to provide a tip end nozzle. The tapered tip may be preferable for use with smaller clots or where more precise positioning of the tip end is desired.

As shown in FIG. **2**D, the catheter **20** may flare outwardly at the tip so that the catheter increases in diameter towards the tip end of the catheter **20**. The outwardly flared end tip may be useful to encapture clot fragments that might otherwise flow by a narrower tip.

As shown in FIG. **2**E, the distal end of the catheter **20** may be adapted to contain a hollow tubular insert **150** coaxially disposed within the distal end of the catheter **20**. The tubular insert **150** is capable of slidable movement along the longitudinal direction of catheter **20** so that the tip of the insert may be moveable to extend outside of the catheter **20**

beyond the distal end of catheter **20** or withdrawn back into the catheter. To effect movement of the tubular insert, a device may be attached to insert **150** as desired, such as a positioning catheter **154**, which may be inserted through branch **60**. Optionally, insert **150** may contain one or more holes **152** in the side wall of the insert **150**. As the insert **150** extends beyond the distal end of catheter **20**, a blood clot **120** may be drawn through the tip end while the side apertures function to prevent the blockage of suction.

As shown in FIG. **2**F, a slidably extendable and retractable inner coaxial insert tube **151** may be provided wherein the tip end may expand in diameter as it extends beyond the distal end of catheter **20** to provide a flare tipped end. The flare tip of tube **151** may expand when deployed outside the catheter **20** and may collapse as the flare tip is retracted back into the catheter **20**. The flare tip is useful to encompasses a greater diameter of the inside of a vessel to prevent clot fragments from by-passing the suction at the tip end.

As shown in FIG. **2**G, the distal end of catheter **20** includes at least one strut **156** which traverses the distal end of the catheter **20**. Optionally, a pair of criss-crossed struts **156** may be employed so that the struts **156** overlap or intersect at their midpoints. The struts **156** may bow outwardly beyond the distal end of catheter **20** to inhibit the occlusion of the distal end of the catheter **20**. The struts may also function to facilitate the dislodgement and/or grinding of a clot to effect extraction. As shown in FIG. **2**H, a plurality of struts **156** may be arranged to form a mesh.

A reinfuser **140**, such as the Cell Saver type of device, is provided to reinfuse the filtered blood collected in the blood collection device **95** back into the patient. The reinfuser **140** may include a suitable blood injection assembly to deliver filtered blood back into the patient. The reinfuser **140** is in fluid communication with a suitable catheter, and reinfusion occurs through such catheter. The reinfuser **140** may communicate with catheter **20** via branch **60**. In a particular arrangement, the blood collection device **95** is removable from the filtration device **90** so that the filtration device may be operably connected to the reinfuser **140** for reinfusion of the filtered blood into the patient. Alternatively, the blood collection device **95** may remain attached to the filtration device **90**. In such an arrangement the reinfuser **140** must then be operably connected to the blood collection device **95** by appropriate tubing so that the reinfuser **140** reinfuses the filtered blood back into the patient while the blood collection device **95** remains attached to the filtration device **90**.

Referring to FIG. **3**, a catheter **20** is inserted, at step **200**, percutaneously into a selected blood vessel of the vascular system of the patient and is advanced until the distal end of the catheter **20** is located, at step **210**, at a blood clot **120** selected for removal. The catheter **20** may be introduced into the body through a vein or an artery, such as a femoral artery or vein or jugular vein so that the distal end of the catheter may be properly positioned at the target site for removal of the clot. The distal end of the catheter **20** may be located within the lumen of the blood vessel **130** or within the lumen of an organ, such as the heart. Further, the distal end of catheter **20** may be located within the lumen of a graft, such as an arterial bypass graft, a dialysis graft, or venous bypass graft.

Once the distal end of catheter **20** is positioned at the desired target location, suction is applied, at step **215**, to the proximal end of catheter **20** by the suction source **110** via the blood filtration device **90** which is in fluid communication with the catheter **20**. The suction is created by a suitable suction source **110**, such as wall suction or a portable pump, which is in gaseous communication with the blood filtration device **90**. The suction from the suction source **110** draws the blood clot **120** and any accompanying blood into the distal end of the catheter **20** thereby removing the clot **120** from the patient.

If dissolution of the clot is desired prior to removal at step **220**, then a thrombolytic agent, such as tissue plasminogen activator, is delivered to clot **120**, at step **225**, through the catheter **20** or systemically to promote dissolution of the clot prior to its removal through the catheter **20**. For this purpose, a secondary catheter **65** may be inserted over the guidewire **70** and advanced until the distal end of the secondary catheter **65** is at the blood clot **120**. The thrombolytic agent, such as a tissue plasminogen activator, is delivered to the blood clot **120** through the secondary catheter **65** to promote at least partial dissolution of the clot as an aid to withdrawal of the clot through the catheter **20**.

In a particular mode of operation where clot breakage or dislodgement is desired at step **230**, a treatment device **160** is used to break up or dislodge the blood clot **120** prior to its removal. For example, a guidewire **70** may be inserted through branch **60** and advanced through the catheter **20** until the distal end of the guidewire **70** reaches the distal end of catheter **20**. The treatment device **160** is positioned at the distal end of the guidewire **70** and is advanced into catheter **20**, at step **235**, until the treatment device **160** is in close proximity to the clot **120** at the target site at step **240**. Alternatively, a treatment device may be used without a guidewire. The treatment device **160** may be a percutaneous thrombolytic device, a balloon device or some other suitable device useful to break up blood clots **120**. The treatment device **160** is manipulated to effect the breakup of the blood clot **120**.

The removed blood and blood clot **120** are transported through the catheter **20** and Y-shaped adapter **50** into the filtration device **90**. In a first method of operation, the clarity of the blood is observed visually or otherwise tested at step **245**, and any suctioned aliquot judged to contain too much clot to allow safe filtration, at step **250** is diverted into waste container **80** by actuation of valve **55** for disposal, at step **255**. In an alternative method of operation, the clarity of the blood may be observed using a turbidity meter **170**, and blood determined to be too turbid is diverted into waste container **80** using valve **55** which is actuated by a controller motor **180**.

Blood having acceptable characteristics is transported through the Y-shaped adapter **50** into the filtration device **90** where the blood is filtered at step **260** to separate the clots **120** from the blood. The filtered blood is collected at step **265** and is then reinfused back into the patient.

In a first reinfusion method, the blood collection device **95** is removed from the filtration device **90** and operably connected to the reinfuser **140** for reinfusion of the filtered blood into the patient. In a second reinfusion method, the blood collection device **95** remains attached to the filtration device **90**, and the reinfuser **140** is operably connected to the blood collection device **95**.

The reinfuser **140** includes a delivery system for delivering the filtered blood-back into the patient. For this purpose, an IV needle and IV tubing may be provided. The tubing is connected at one end with the blood collection device and the IV needle is inserted into the vascular system of the patient. The reinfuser **140** draws the filtered blood from the blood collection device **95** and delivers it into the vascular system of the patient through the delivery device. In a preferred method, the delivery device of the reinfuser **140**

includes catheter **20**. The reinfuser **140** draws the filtered blood from the blood collection device **95** and delivers it to the patient through catheter **20**. The reinfuser **140** may communicate with catheter **20** via branch **60**. Optionally, the reinfusion step may be performed simultaneously with the suctioning step.

These and other advantages of the present invention will be apparent to those skilled in the art. Accordingly, it will be recognized by those skilled in the art that changes or modifications may be made to the above-described embodiments without departing from the broad inventive concepts of the invention. It should therefore be understood that this invention is not limited to the particular embodiments described herein, but is intended to include all changes and modifications that are within the scope and spirit of the invention as set forth in the claims.

What is claimed is:

1. A method for removal of a clot in a blood vessel system of a patient using a thrombectomy treatment system, comprising the steps of:

(a) introducing a catheter into a blood vessel system of a patient, the catheter having proximal and distal extremities;

(b) advancing the catheter through a portion of the blood vessel system to position the distal extremity of the catheter at a desired location within the blood vessel system;

(c) providing a filtration device in fluid communication with the proximal extremity of the catheter, the filtration device separable from the catheter;

(d) applying suction from a suction source to the catheter near its proximal extremity to suction blood into the distal extremity of the catheter and through the filtration device without suctioning blood into the suction source;

(e) diverting a portion of the suctioned blood into a waste container when the diverted blood does not meet a selected criteria of clarity;

(f) filtering the suctioned blood with the filtration device to remove clots to provide a source of filtered blood; and

(g) drawing the filtered blood from the source of filtered blood into a reinfuser and reinfusing the drawn filtered blood back into the patient.

2. A method for removal of a clot in a blood vessel system using a thrombectomy treatment system, comprising the steps of:

(a) introducing a catheter into a blood vessel system of a patient, the catheter having proximal and distal extremities;

(b) advancing the catheter through a portion of the blood vessel system to position the distal extremity of the catheter at a desired location within the blood vessel system;

(c) applying suction from a suction source to the catheter near its proximal extremity to suction blood into the distal extremity of the catheter without suctioning blood into the suction source;

(d) diverting a portion of the suctioned blood into a waste container;

(e) filtering the suctioned blood to remove the clots; and reinfusing the filtered blood into the patient through the distal extremity of the catheter,

wherein the non-diverted blood meets a selected criteria of clarity.

3. A thrombectomy treatment system comprising:

(a) a catheter having proximal and distal extremities, the distal extremity for insertion into a blood vessel system of a patient;

(b) a filtration device in fluid communication with the proximal extremity of the catheter for receiving suctioned blood from the catheter, the filtration device removable from the catheter and capable of filtering the blood to provide a source of filtered blood;

(c) a suction source in gaseous communication with the filtration device for applying suction to the proximal extremity of the catheter, the suction source adapted to suction blood from the blood vessel system into the distal extremity of the catheter and into the filtration device without suctioning blood into the suction source;

(d) a reinfuser removably connected in fluid communication with the filtration device for reinfusing the filtered blood back into the patient, the reinfuser having a drawing means for drawing blood from the source of filtered blood into the reinfuser, and

(e) a turbidity meter for detecting the turbidity of the suctioned blood.

4. The system according to claim **3** comprising a valve in communication with the catheter and wherein the turbidity meter is operably connectable to a motor for causing actuation of the motor to move the valve to direct a flow of blood through the catheter.

5. The system according to claim **4** wherein the turbidity meter actuates the motor when the detected turbidity meets a predetermined value.

6. A thrombectomy treatment system comprising:

(a) a catheter having proximal and distal extremities, the distal extremity for insertion into a blood vessel system of a patient;

(b) a filtration device in fluid communication with the proximal extremity of the catheter for receiving suctioned blood from the catheter, the filtration device removable from the catheter and capable of filtering the blood to provide a source of filtered blood:

(c) a suction source in gaseous communication with the filtration device for applying suction to the proximal extremity of the catheter, the suction source adapted to suction blood from the blood vessel system into the distal extremity of the catheter and into the filtration device without suctioning blood into the suction source; and

(d) a reinfuser removably connected in fluid communication with the filtration device for reinfusing the filtered blood back into the patient, the reinfuser having a drawing means for drawing blood from the source of filtered blood into the reinfuser,

wherein the filtration device includes a centrifuge.

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