



US011419620B2

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

(10) **Patent No.:** **US 11,419,620 B2**
(45) **Date of Patent:** **Aug. 23, 2022**

(54) **MINIMALLY INVASIVE THROMBECTOMY**

(71) Applicant: **The University of Toledo**, Toledo, OH (US)

(72) Inventors: **Christopher J. Cooper**, Perrysburg, OH (US); **Mohammad H. Elahinia**, Toledo, OH (US); **Rajesh Gupta**, Saline, MI (US); **Hamdy Ibrahim**, Toledo, OH (US)

(73) Assignee: **The University of Toledo**, Toledo, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 452 days.

(21) Appl. No.: **15/919,513**

(22) Filed: **Mar. 13, 2018**

(65) **Prior Publication Data**

US 2018/0256177 A1 Sep. 13, 2018

Related U.S. Application Data

(63) Continuation-in-part of application No. 14/433,278, filed as application No. PCT/US2013/062998 on Oct. 2, 2013, now abandoned.

(Continued)

(51) **Int. Cl.**

A61B 17/221 (2006.01)
A61F 2/01 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC .. **A61B 17/221** (2013.01); **A61B 2017/00862** (2013.01); **A61B 2017/00867** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC **A61B 17/221**; **A61B 17/22031**; **A61B 17/12168**; **A61B 17/12172**;

(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,706,671 A 11/1987 Weinrib
5,885,258 A 3/1999 Sachdeva et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO 0222028 3/2002
WO 201307277 A2 5/2013
WO 2014055609 A1 4/2014

OTHER PUBLICATIONS

Extended European Search Report, Application No. 19162401.4, dated Jul. 2, 2019.

(Continued)

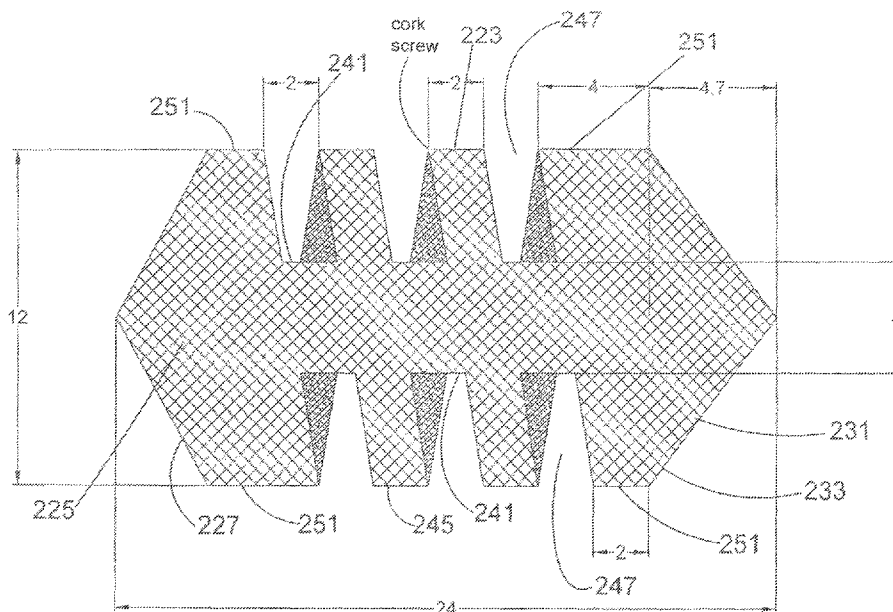
Primary Examiner — Katherine H Schwiker

(74) *Attorney, Agent, or Firm* — MacMillan, Sobanski & Todd, LLC

(57) **ABSTRACT**

A minimally invasive blood clot capturing invention made of nitinol. The nitinol is shaped into a plurality of fingers to form a frame for a basket and funnel to capture and remove blood clots. The basket and funnel being delivered to the blood clot by a catheter. The basket and funnel are capable of being collapsed within a catheter, capable of being deployed into a blood vessel, and capable of being retracted into the catheter for removal from the blood vessel.

14 Claims, 21 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/709,202, filed on Oct. 3, 2012.

(51) **Int. Cl.**

A61B 17/00 (2006.01)
A61B 17/22 (2006.01)

(52) **U.S. Cl.**

CPC *A61B 2017/2212* (2013.01); *A61B 2017/2215* (2013.01); *A61B 2017/2217* (2013.01); *A61B 2017/22038* (2013.01); *A61B 2017/22079* (2013.01); *A61F 2002/018* (2013.01); *A61F 2230/0067* (2013.01); *A61F 2230/0091* (2013.01); *A61F 2250/0039* (2013.01)

(58) **Field of Classification Search**

CPC *A61B 2017/2215*; *A61B 2017/2217*; *A61B 2017/2212*; *A61B 2017/22031*; *A61B 2017/22035*; *A61B 2017/22081*; *A61B 2017/22038*; *A61B 17/22032*; *A61B 17/22034*; *A61F 2/01*; *A61F 2/013*; *A61F 2002/015*; *A61F 2002/016*; *A61F 2002/018*; *A61F 2/0103-0108*; *A61F 2/012*; *A61F 2/014*
USPC 606/200
See application file for complete search history.

8,784,434 B2	7/2014	Rosenbluth et al.	
8,968,330 B2	3/2015	Rosenbluth et al.	
9,259,237 B2	2/2016	Quick et al.	
9,408,620 B2	8/2016	Rosenbluth	
9,526,864 B2	12/2016	Quick	
9,526,865 B2	12/2016	Quick	
2002/0123765 A1*	9/2002	Sepetka	<i>A61B 17/22031</i> 606/192
2003/0153943 A1	8/2003	Michael et al.	
2004/0073243 A1	4/2004	Sepetka et al.	
2004/0133232 A1	7/2004	Rosenbluth et al.	
2005/0119668 A1	6/2005	Teague et al.	
2007/0112371 A1*	5/2007	Cangialosi	<i>A61F 2/013</i> 606/200
2007/0167974 A1	7/2007	Cully et al.	
2007/0208367 A1*	9/2007	Fiorella	<i>A61B 17/320725</i> 606/198
2008/0269774 A1	10/2008	Garcia et al.	
2008/0312681 A1	12/2008	Ansel et al.	
2009/0299393 A1	12/2009	Martin et al.	
2010/0268265 A1	10/2010	Krolik et al.	
2011/0152920 A1*	6/2011	Eckhouse	<i>A61B 17/221</i> 606/200
2011/0202088 A1	8/2011	Eckhouse et al.	
2011/0213403 A1*	9/2011	Aboytes	<i>A61M 29/02</i> 606/194
2014/0005714 A1	1/2014	Quick et al.	
2014/0303667 A1	10/2014	Cox et al.	
2017/0071614 A1	3/2017	Vale et al.	
2017/0119408 A1	5/2017	Ma	
2019/0269424 A1*	9/2019	Morsi	<i>A61B 17/221</i>

(56)

References Cited

U.S. PATENT DOCUMENTS

6,146,404 A	11/2000	Kim et al.
6,203,561 B1	3/2001	Ramee et al.
6,383,205 B1	5/2002	Samson et al.
6,605,102 B1	8/2003	Mazzocchi et al.
7,306,618 B2	12/2007	Demond et al.
8,025,668 B2	9/2011	McCartney

OTHER PUBLICATIONS

Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration dated Feb. 21, 2014.
The extended European search report is enclosed. dated Aug. 12, 2016.

* cited by examiner

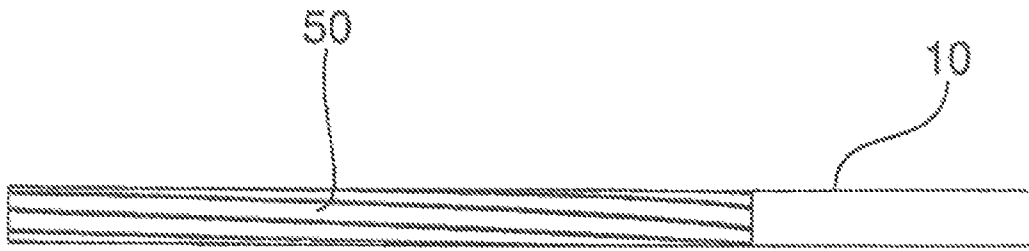


FIG 1

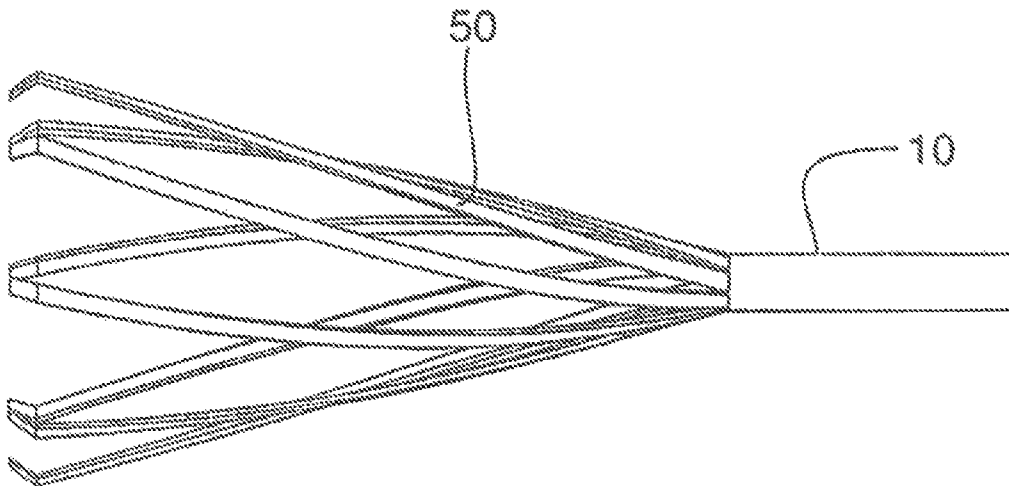


FIG 2

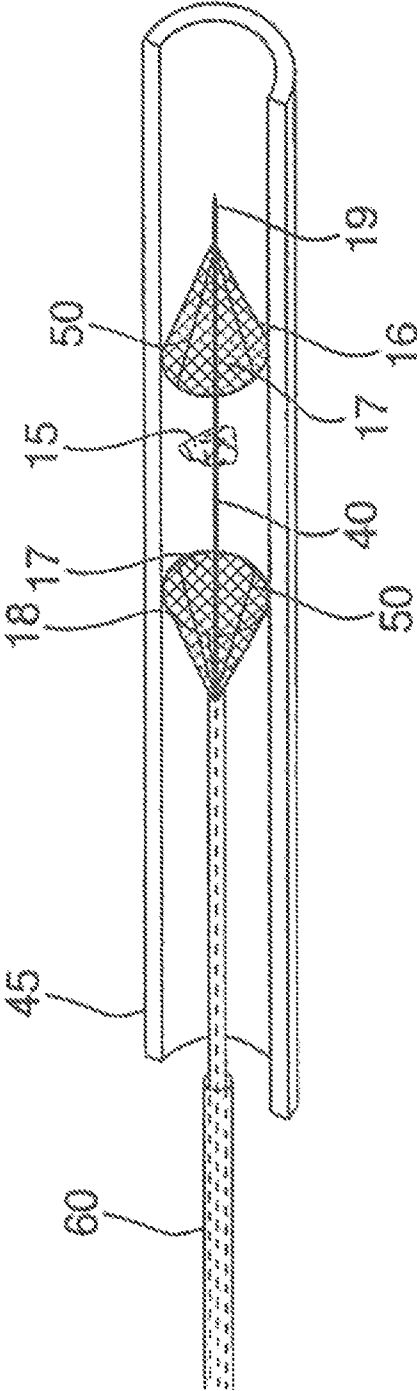


FIG 3

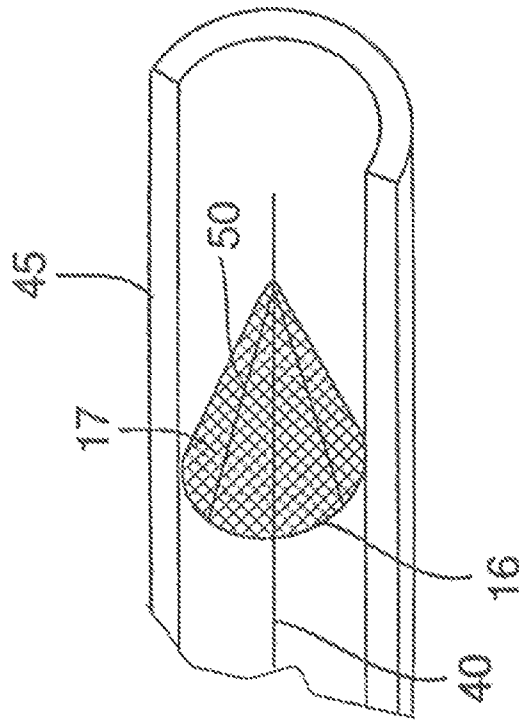


FIG 4

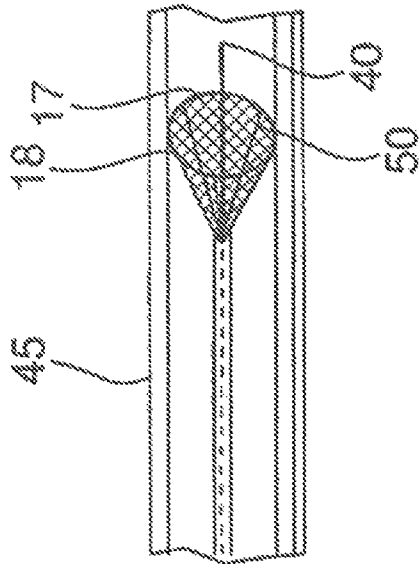


FIG 5

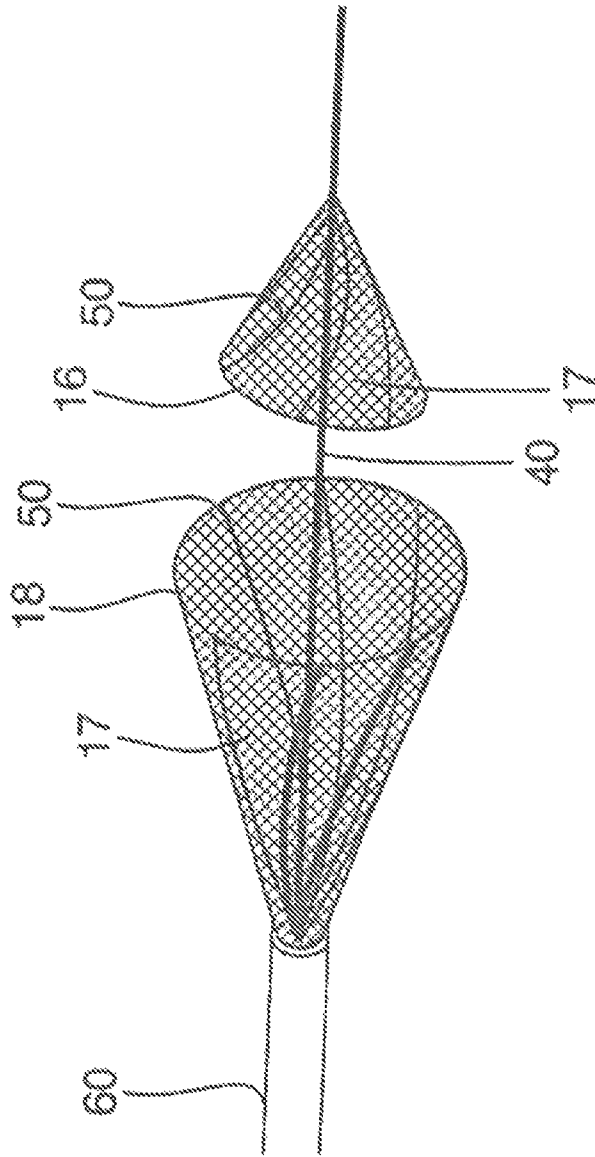


FIG 6

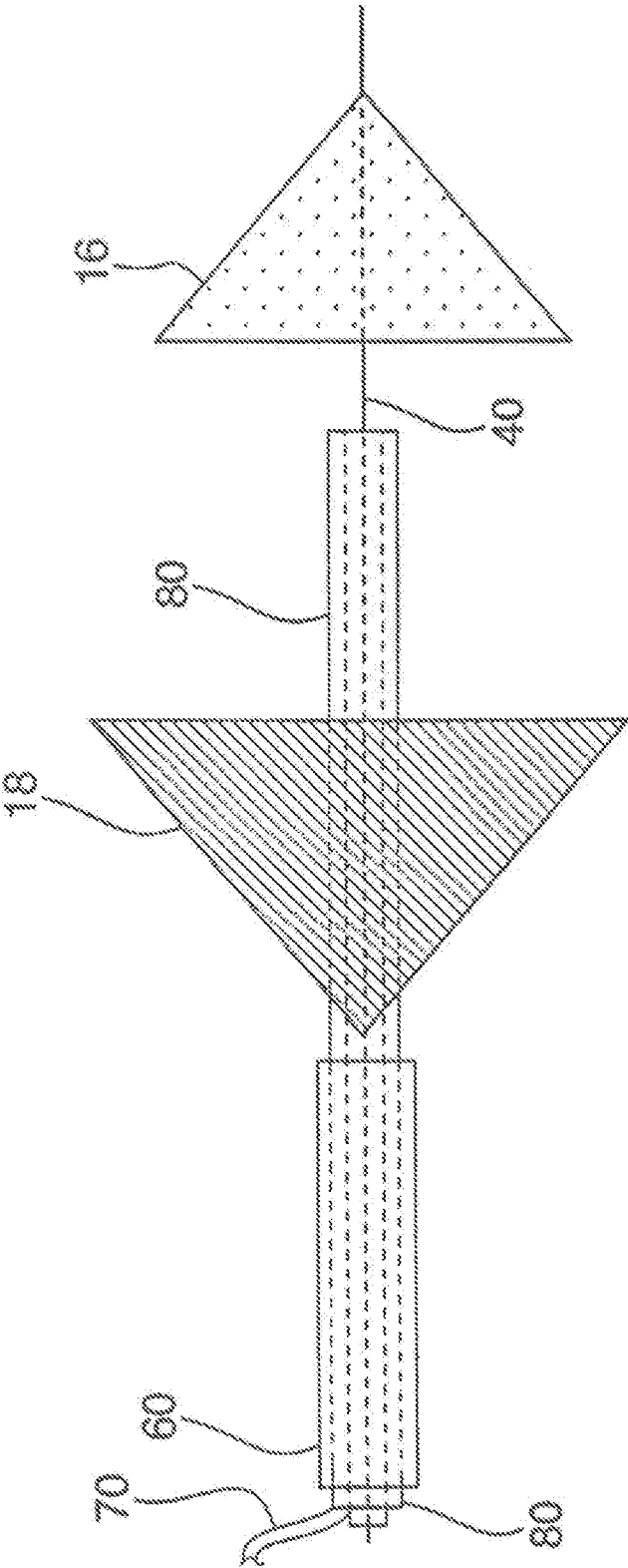


FIG 7

Average Filter Mass Increase

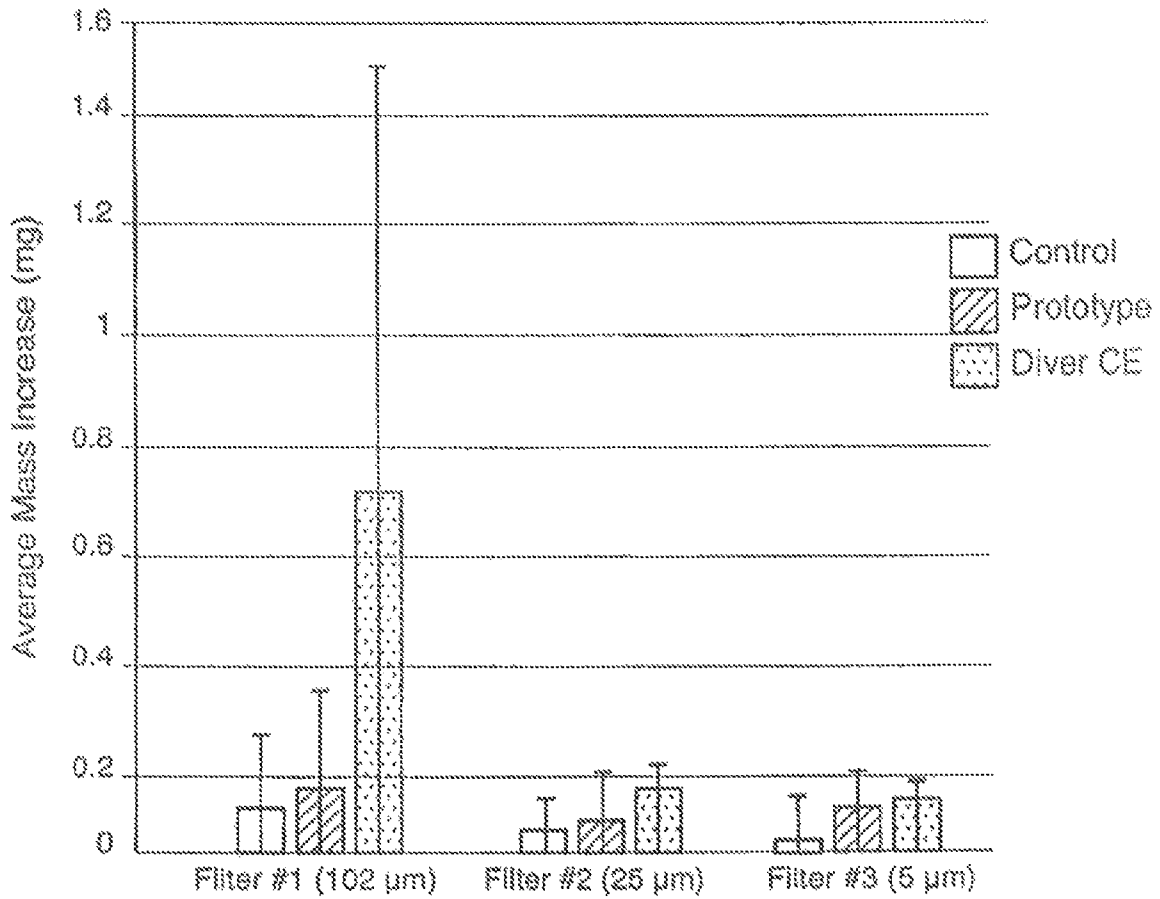
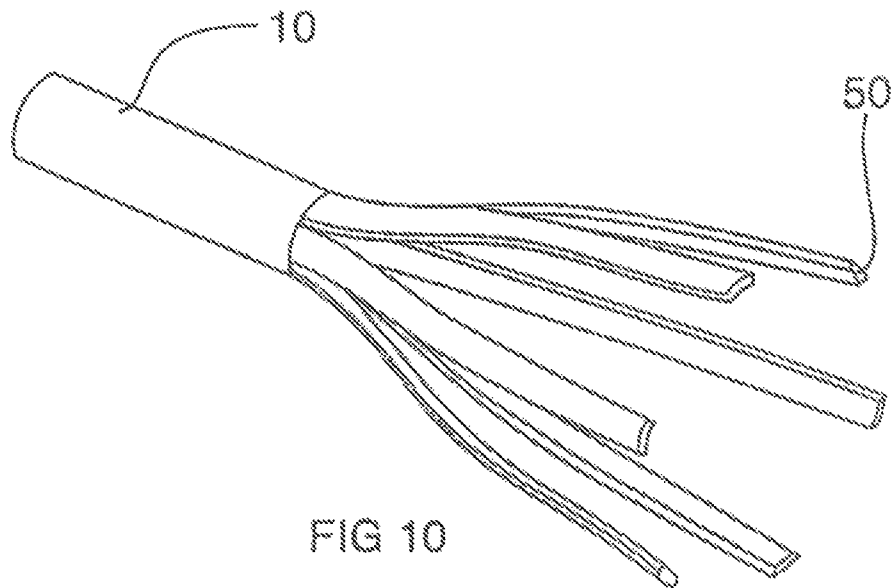
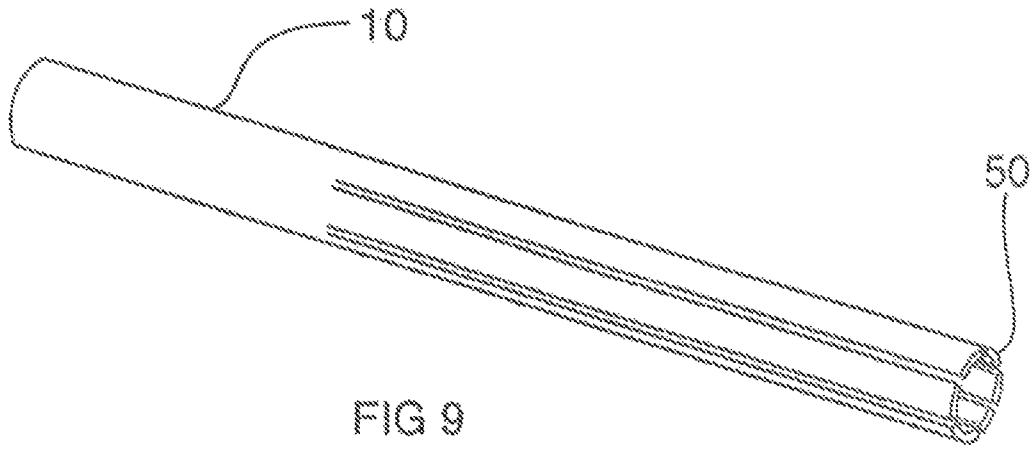


FIG 8



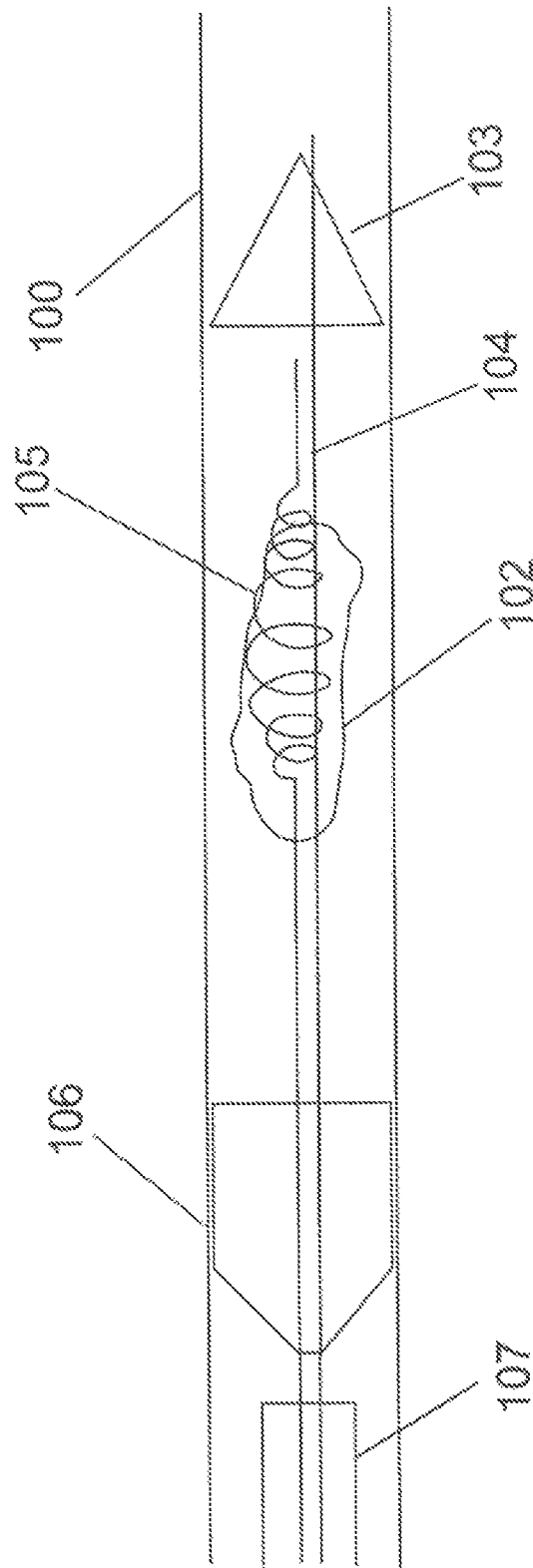


FIG. 11

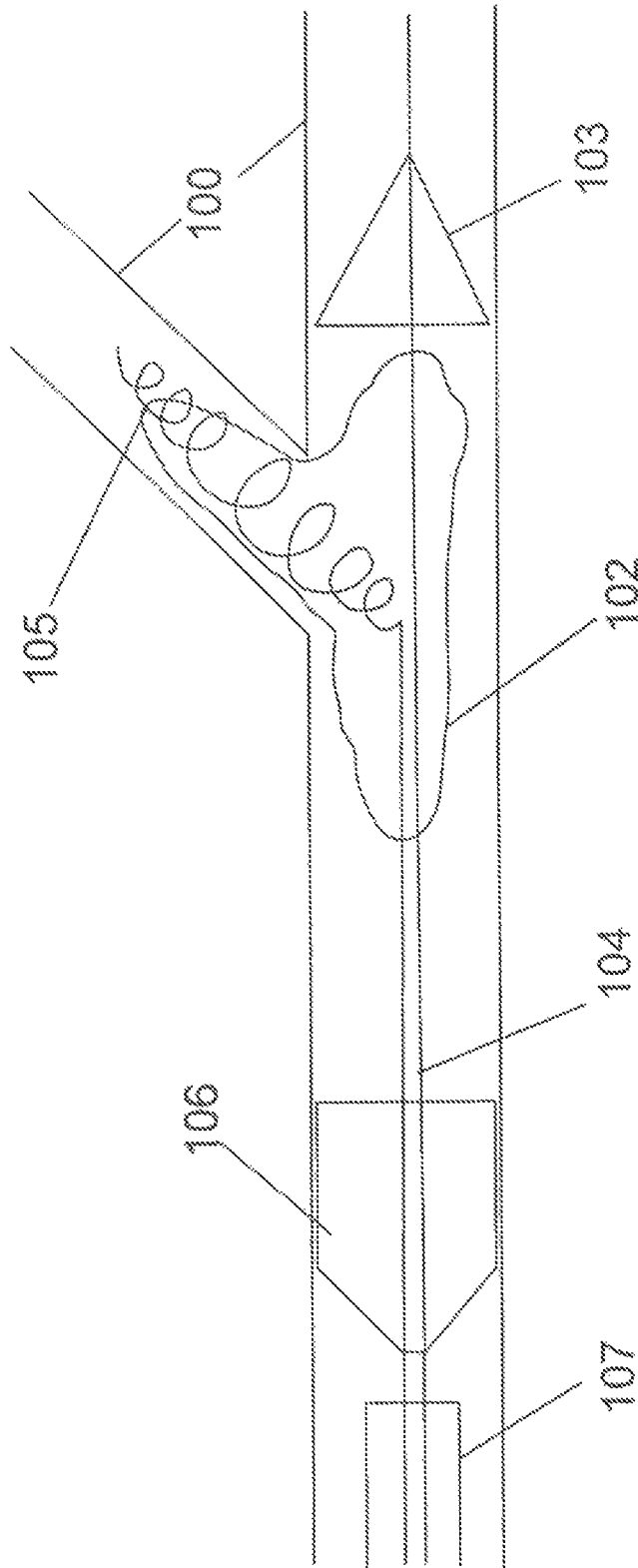


FIG. 12

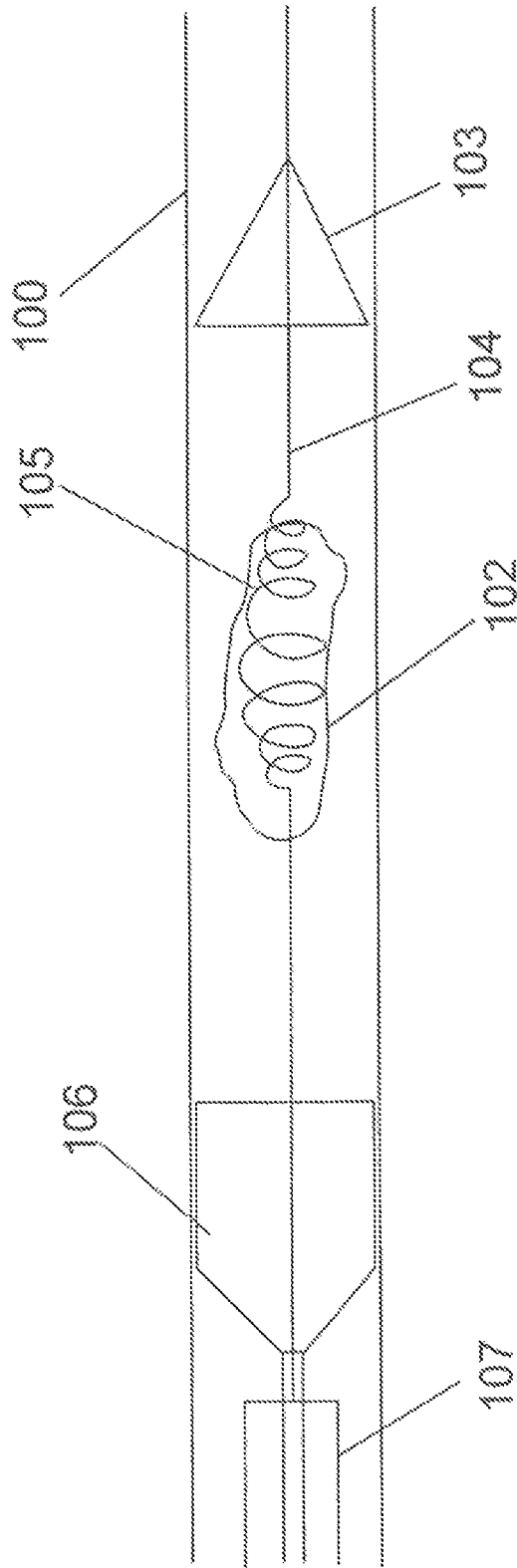


FIG. 13

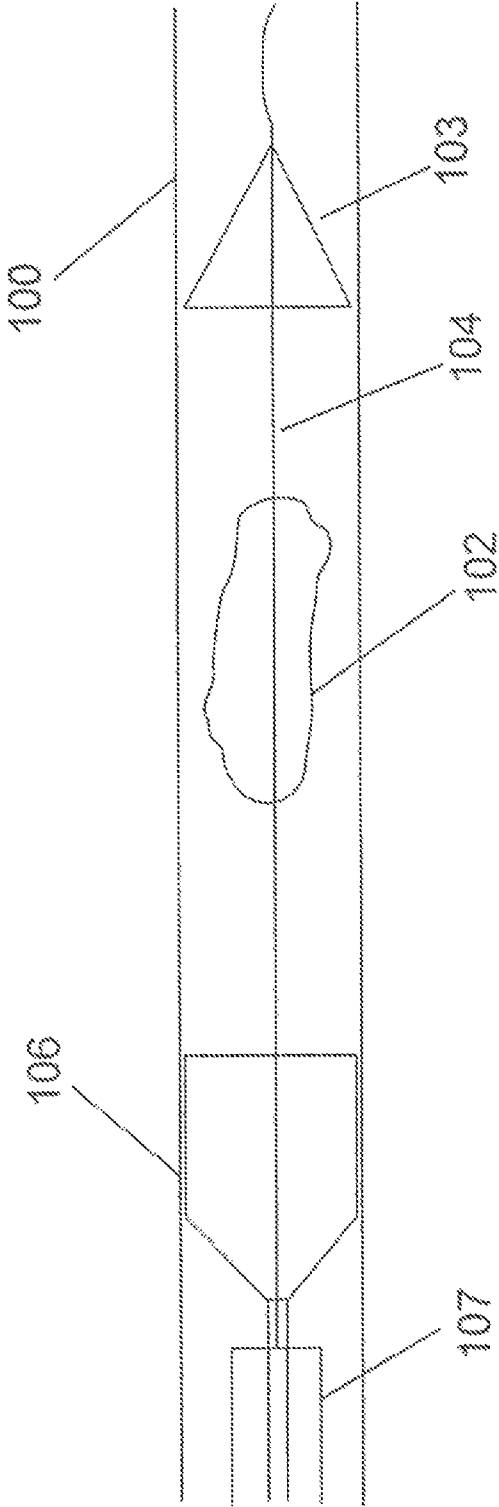


FIG. 14

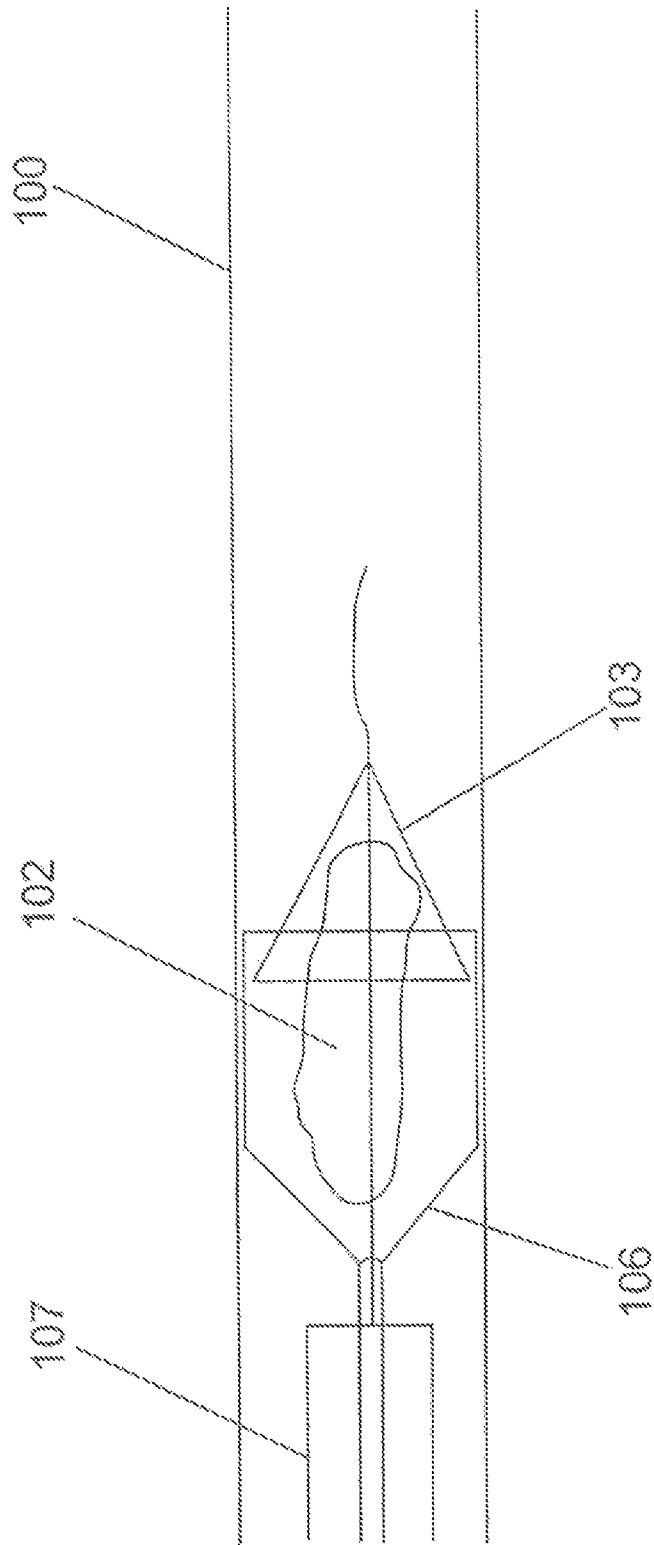


FIG. 15

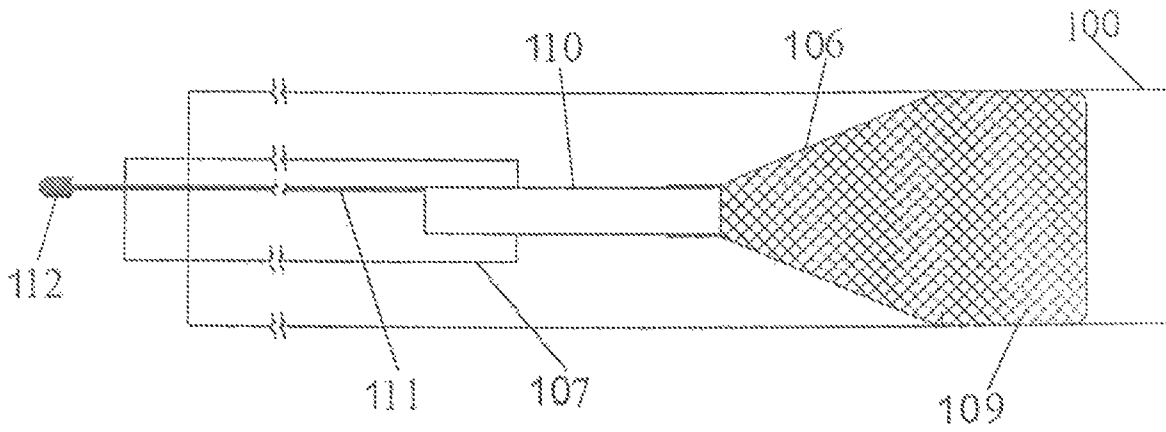


FIG. 16

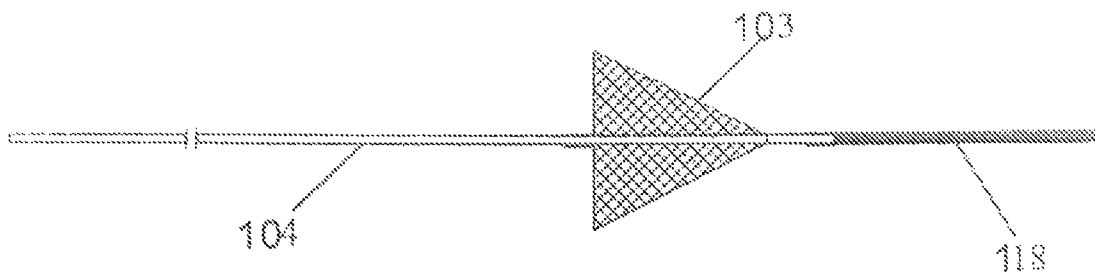


FIG. 17

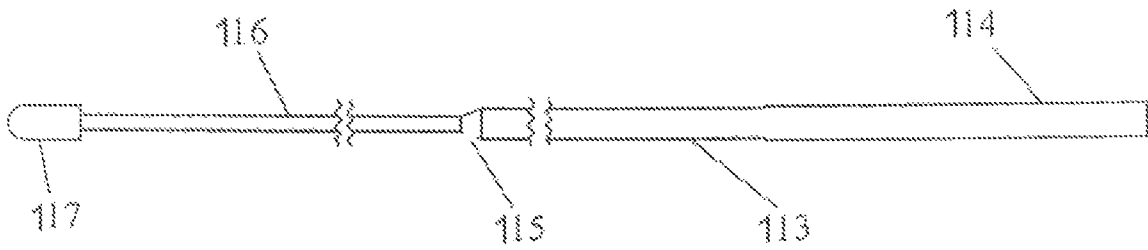


FIG. 18

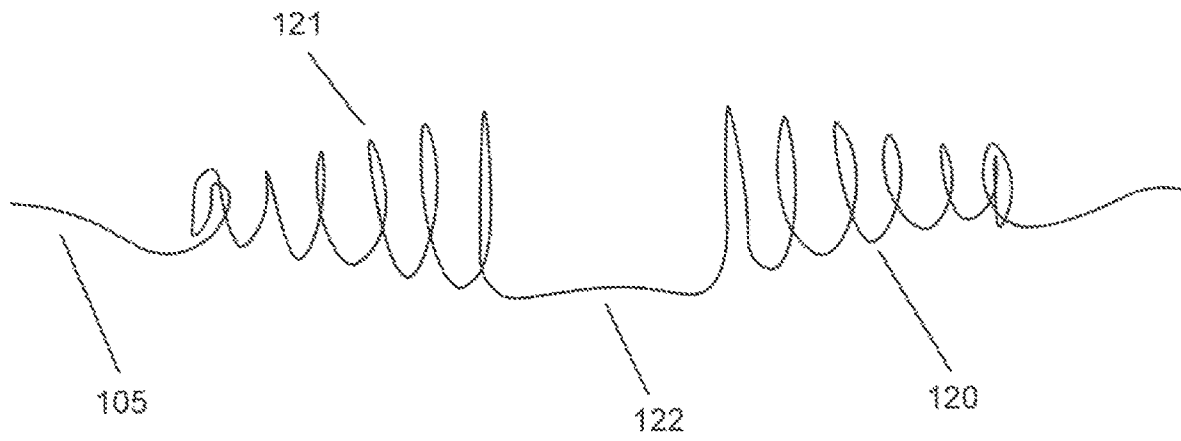


FIG. 19

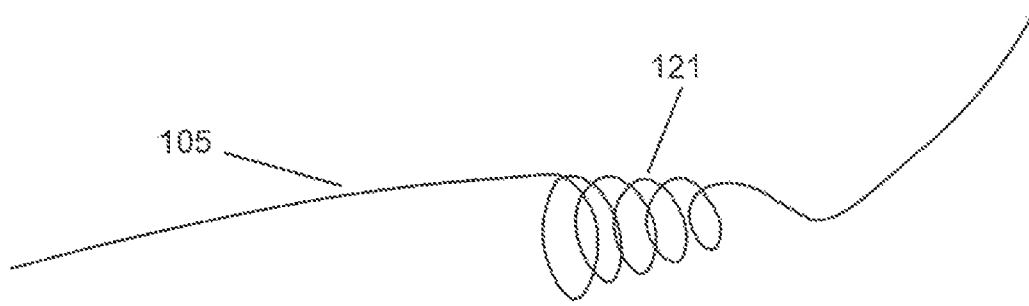


FIG. 20

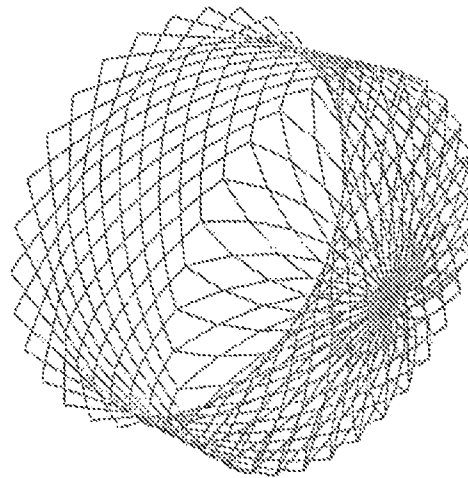


FIG. 21

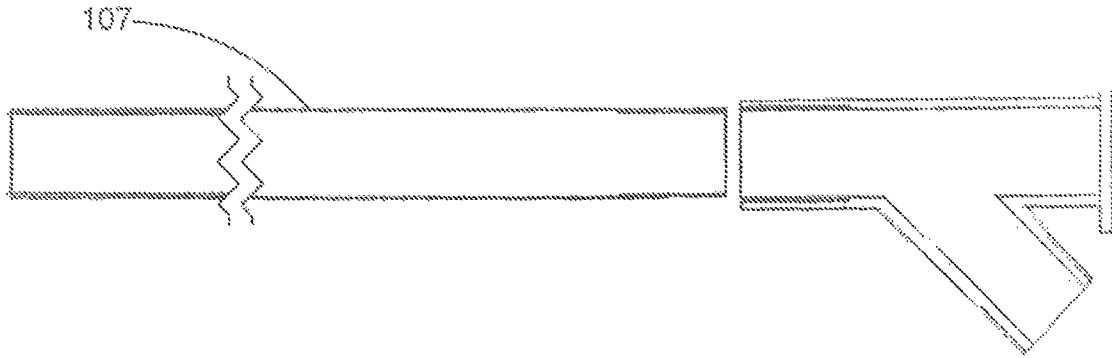


FIG. 22

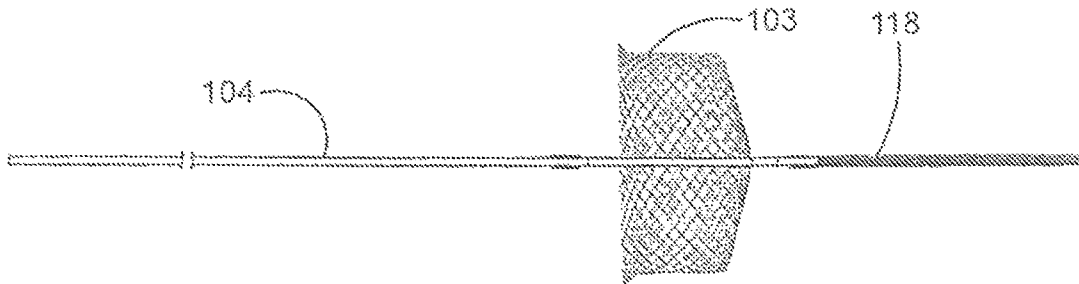
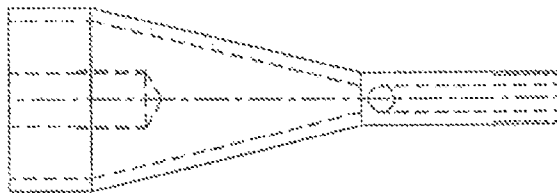
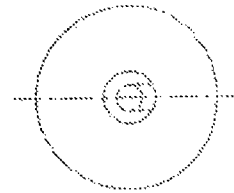


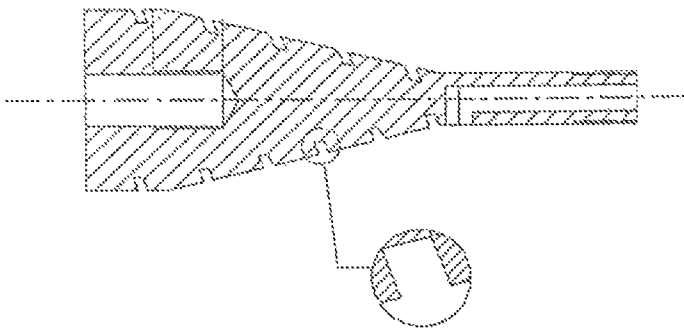
FIG. 23



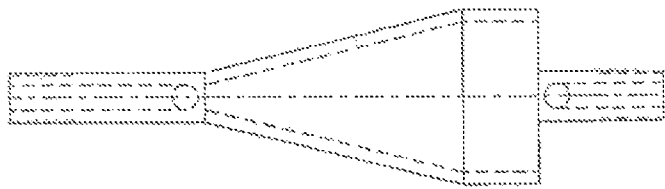
Front View
FIG. 24



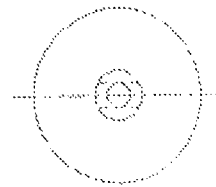
Side View
FIG. 25



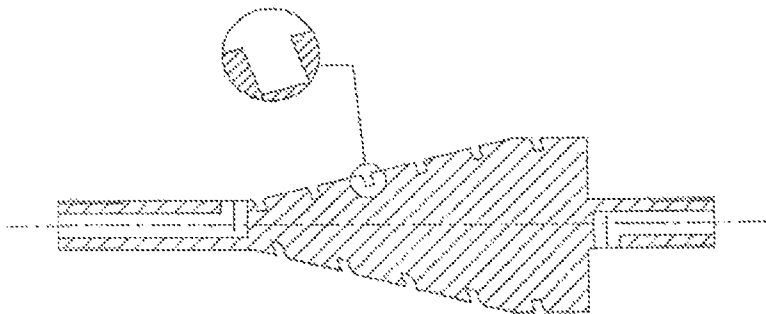
Top (Section A-A)
FIG. 25



Front View
FIG. 27



Side View
FIG. 29



Top (Section A-A)
FIG. 28

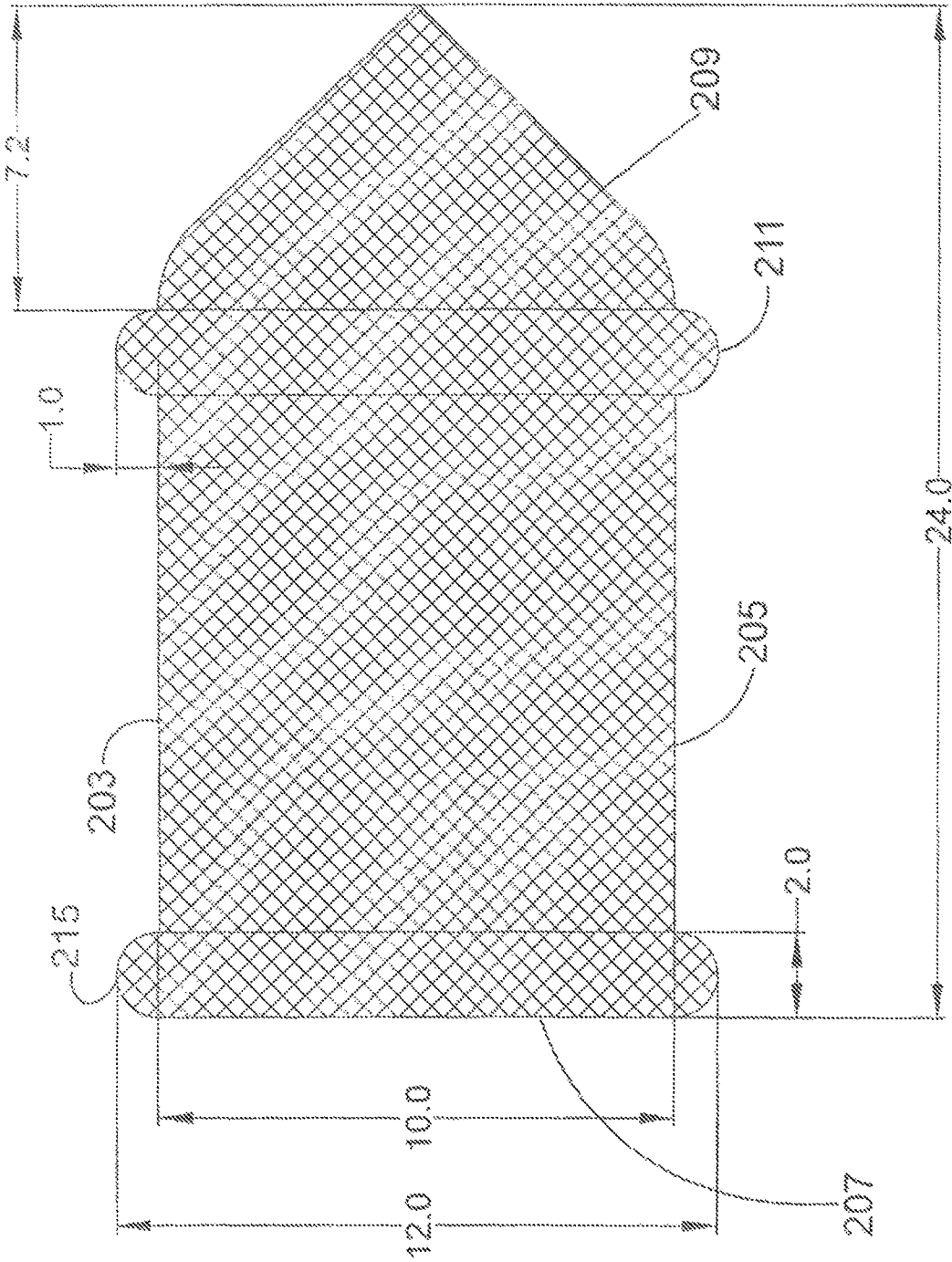


FIG. 30

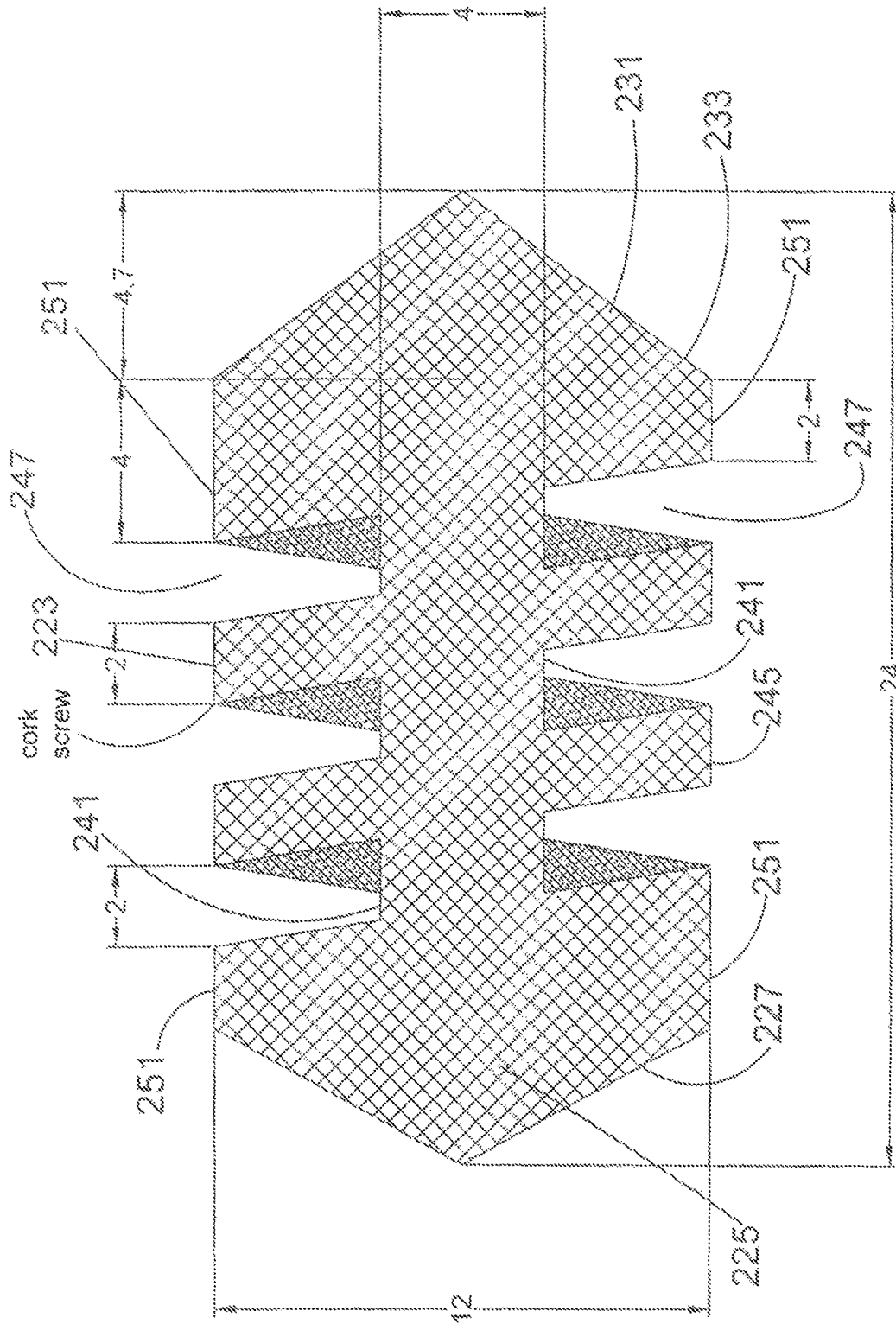


FIG 31

MINIMALLY INVASIVE THROMBECTOMY**CROSS REFERENCE TO RELATED APPLICATIONS**

This is a continuation in part of U.S. application Ser. No. 14/433,278 filed on Apr. 2, 2015. This application also claims the benefit of U.S. provisional patent application Ser. No. 61/709,202 filed Oct. 3, 2012 and PC17US13/62998 filed on Oct. 2, 2013.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

The invention was not made with any government support and the government has no rights in the invention.

BACKGROUND OF THE INVENTION

This invention relates to a minimally invasive thrombectomy device for the removal of thrombi (clots) located in blood vessels at different anatomical locations, particularly for pulmonary arteries in the lung.

Many vascular system problems stem from insufficient blood flow. One of the main causes is a blockage within veins known as a blood clot, or thrombus. This can occur after trauma, surgery, or other phenomenological reasons. The ultimate goal of any percutaneous modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This can be achieved by thrombus dissolution, fragmentation, thrombus aspiration, en bloc removal, or a combination of these methods.

Pulmonary embolism (PE) is a fatal condition that occurs when clots move to pulmonary arteries causing blockage of the arteries leading to respiratory failure, right ventricular failure, and death. Pulmonary embolism is the third most common cause of death for hospitalized patients.

Intravenous and oral anticoagulation are the most common modalities for treating PE. For patients with more severe PE, such as massive (5% of patients) and submassive PE (40% of patients), these medications may not resolve the thrombus burden in a rapid enough fashion, and additional therapies are needed to remove the clot and restore the blood flow.

Other treatments that are used less frequently in open heart surgery for manual removal of the clot (surgical embolectomy), thrombolytic medications, and catheter-directed treatments. Each of these carries substantial risks for patient outcomes, particularly open-heart surgery, while thrombolytic medications can cause bleeding throughout the body and in the brain, and catheter-directed treatments require long treatment periods, and large catheters. Percutaneous thrombectomy of thrombus is a new approach that has been recently introduced to mechanically remove an embolus from blood vessels. Thrombectomy devices involve the use of catheters to minimally-invasively reach and remove a thrombus. Percutaneous thrombectomy is the removal of thrombus using non-surgical methods. Percutaneous thrombectomy can be used to remove thrombus from arteries, veins and vascular grafts and can be used alone, as a primary procedure, or in combination with transcatheter thrombolysis or angioplasty and stenting.

Catheter directed thrombectomy and thrombolysis is less traumatic and avoids the morbidity and mortality associated with conventional surgical techniques. It also has the advantage of providing diagnostic information about associated

vascular diseases and to treat coexisting lesions. As a result, there has been a push for the use of percutaneous mechanical thrombectomy (PMT) devices. These devices offer a key advantage over surgical thrombectomy or thrombolysis. The concept of the mechanical thrombectomy is attractive, however, developing a miniature device that can quickly and atraumatically restore patency to a vessel without creating some degree of distal embolization is a goal that still eludes the medical community.

An invention based on the use of super-elastic alloy nitinol has been developed that offers several advantages over PMT devices currently on the market. This invention provides a higher degree of authority and maneuverability for capturing and removing blood clots. A major issue with existing PMT inventions is shearing off of smaller particles (embolic particles) during the process of dot removal. The thrombi of PE are often larger in diameter than the catheters used for PMT, and there is often fragmentation and further embolization of thrombus during the removal process. Distal Embolization occurs when either the dot itself or the embolic particles travel downstream and occlude another vessel in the body. Distal embolization is known to lead to fatal complications in the treatment of pulmonary embolism, when the secondary clots move to pulmonary arteries in the lungs, or a stroke, when the secondary clots occlude the vessels in the brain. In the U.S., the number of fatalities due to pulmonary embolism alone is known to be approximately 200,000 per year. The invention is capable of removing a thrombus while minimizing distal embolization and therefore reducing the risk of secondary clot formation and the related complications and fatalities.

This invention is capable of removing different sizes en bolus safer, quicker and more efficiently than currently available procedures.

SUMMARY OF THE INVENTION

The present invention generally refers to a minimally invasive blood clot capturing device made of nitinol. The invention is deployed by a catheter that is introduced into the body using the modified Seldinger technique. The catheter is driven to a blood clot and the operator deploys the invention out of the catheter. The invention evacuates thrombus without shearing the blood clot into smaller pieces. Current PMT devices that operate to pull-back and capture a thrombus have no way of guiding a blood clot into an exiting catheter without shearing pieces of blood clot which can escape downstream and create, in some instances, problems that are worse than the initial obstruction. Due to practical limitations regarding catheter sizes that are appropriate for accessing human vessels, in most cases, the blood clot has a diameter that is larger than that of the aspiration catheter. This invention specially addresses this critical design challenge by using a nitinol proximal basket to encircle the thrombus during the aspiration and removal phase. With the introduction of this invention, loss of emboli is drastically reduced most situations.

Accordingly, an object of subject invention is to provide a method and system that completely removes thrombus in blood vessels safely and efficiently.

Still another object of the present invention is to minimally-invasively treat patients with pulmonary embolism by completely and quickly removing different sizes and shapes of thrombus from the pulmonary arteries without causing any trauma to the blood vessels. Various aspects of this invention will become apparent to those skilled in the art

from the following detailed description of the preferred embodiments, when read in light of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the laser spiral cut nitinol tube prior to shape setting.

FIG. 2 is a perspective view of the laser spiral cut nitinol tube after shape setting.

FIG. 3 is a perspective view of the invention, showing both elements of the invention, the basket and funnel, deployed to capture a blood clot between the two elements.

FIG. 4 is an expanded perspective view of the collection basket.

FIG. 5 is an expanded perspective view of the funnel.

FIG. 6 is a perspective view of the invention.

FIG. 7 is a schematic view of FIG. 3.

FIG. 8 is a graph showing the results of testing, error bars show \pm standard deviation.

FIG. 9 is a perspective view of the laser straight cut nitinol tube prior to shape setting.

FIG. 10 is a perspective view of the laser straight cut nitinol tube after shape setting.

FIG. 11 is a side elevational view of the invention.

FIG. 12 is a side elevational view of an alternative structure of the device.

FIG. 13 is a side elevational view.

FIG. 14 is a partial side elevational view.

FIG. 15 is a partial side elevational view.

FIG. 16 is a partial side elevational view.

FIG. 17 is a partial side elevational view.

FIG. 18 is a partial side elevational view.

FIG. 19 is a side elevational view of a part of the device.

FIG. 20 is a side elevational view of a part of the device.

FIG. 21 is a perspective view of a part of the device.

FIG. 22 is a side elevational view of a component of the device.

FIG. 23 is a side elevational view of another feature of the device.

FIG. 24 is a side elevational view of a feature of the invention.

FIG. 25 is a top view of the feature of FIG. 24.

FIG. 26 is an end view of the feature of FIG. 24.

FIG. 27 is a side elevational view of a feature of the invention.

FIG. 28 is a top view of the feature of FIG. 27.

FIG. 29 is an end view of the feature of FIG. 27.

FIG. 30 is a partial side elevational view.

FIG. 31 is a partial side elevational view.

DETAILED DESCRIPTION

Specific embodiments of the invention will now be described with reference to the accompanying drawings. The invention provides a novel method and system to conduct a thrombectomy using a combination of trapping, snaring and aspiration mechanisms to remove different sizes of thrombus from a blood vessel, particularly pulmonary arteries treating patients with pulmonary embolism. Throughout this disclosure, various publications, patents and published patent specifications are referenced by an identifying citation. The disclosures of these publications, patents and published patent specifications are hereby incorporated by reference into the present disclosure to more fully describe the state of the art to which this invention pertains.

Before the instant invention is described further, it is to be understood that the invention is not limited to the particular embodiments of the invention described below, as variations of the particular embodiments may be made and still fall within the scope of the appended claims. It is also to be understood that the terminology employed is for the purpose of describing particular embodiments and is not intended to be limiting, instead, the scope of the present invention will be established by the appended claims.

It must be noted that, as used in this specification and the appended claims, the singular forms “a,” “an” and “the” include plural reference unless the context clearly dictates otherwise. Unless defined otherwise all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges, and such embodiments are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Throughout the entire specification including the claims, the word “comprise” and variations of the word, such as “comprising” and “comprises,” as well as “have,” “having,” “includes,” “include,” and “including,” and variations thereof, means that the named steps, elements or materials to which it refers are essential, but other steps elements, or materials may be added and still form a construct with the scope of the claim or disclosure. When recited in describing the invention and in a claim, it means that the invention and what is claimed is considered to what follows and potentially more. These terms, particularly when applied to claims, are inclusive or open-ended and do not exclude additional, unrecited elements or methods steps.

The term “nitinol” herein is used to describe a metal alloy comprised of nickel and titanium where the two elements are present in approximately equiatomic percentages. The term superelastic herein is used to describe a property of nitinol of a certain chemical composition in which a deformation is recovered without it being necessary to heat the nitinol alloy.

Thrombus is used to describe a blood clot, the final product of a blood coagulation step in hemostasis. As such the terms thrombus and clots are used interchangeably.

Referring now to FIGS. 1-3 the invention is a percutaneous catheter-based device that uses a pair of superelastic nitinol capturing elements to aid in the collection of a thrombus and minimize distal embolization. The invention, being made of nitinol and once it is unrestricted by the catheter, changes shape to create a basket 16. The invention has two components of a superelastic nitinol tube 10 that have been partially laser cut longitudinally and shape set to create a cone of superelastic fingers. FIG. 1 shows the nitinol tube 10 as cut by the laser cutting process prior to shape setting. This same cutting process, illustrated in FIG. 1, is used to create both, the basket 18 and a funnel 18. FIG. 2 illustrates how a plurality of fingers 50 are shape set into the expanded position. FIGS. 11-12 illustrate the preferred embodiment wherein the plurality of fingers 50 of the basket 16 and the funnel 18 can be spiraled or have a helix shape to maximize contact the nitinol fingers of the basket 16 and

funnel **18**. To further ensure contact of the nitinol fingers, the plurality of fingers **50** are spiraled in opposite directions. The basket **16** and the funnel **18** are covered in a blood permeable membrane **17** such as expanded Polytetrafluoroethylene (ePTFE), BioWeb, or other membranes, capable of allowing blood flow while capturing blood clots, or may omit such a membrane and use a nitinol mesh with designed pore sizes. To reduce the risk of puncturing a blood vessel **45**, the plurality of fingers **50** may be rounded, further, the tips of the fingers **50** may be flattened and/or curved inward **51** as illustrated in FIG. 2. The basket **16** and the funnel **18** may be made from superelastic nitinol or other metal alloy exhibiting superelastic properties. The spiral orientation of the plurality of fingers **50** also reduces the risk of tearing the membrane **17**.

In the preferred embodiment the invention is deployed using an outer catheter **60** and an inner catheter **80**. The invention is deployed by constricting the basket **16** within the inner catheter **80** and by constricting the tunnel **18** with the outer catheter **60**. The outer catheter is directed to the blood clot **15**. The outer catheter is partially retracted to deploy and expand the funnel **18**. The inner catheter **80** and the basket **16** are guided to the distal end of the blood clot **15** and the inner catheter is fully removed to deploy and expand the basket **16**. A guide wire **40** is used to draw the basket **18** to the blood clot **15**. Pulling the basket **16** through the blood clot **15** will cause the blood clot to lodge into the basket **16**. A guide wire **40** is withdrawn to guide the basket **16** into the funnel **18**. The funnel **18** and the basket **16** are drawn into the outer catheter **60** collapsing the funnel **18** onto the basket **16** and thus collapsing the basket inside the funnel and trapping the blood clot within. In other embodiments additional catheters **70** may be used to provide suction, deploy multiple baskets, or other devices to dislodge the blood clot **15**.

In the preferred embodiment the funnel **18** and the basket **16** are used in conjunction, however it is envisioned that the funnel or basket could be deployed individually, or in combination with other PMT devices.

The basket **16** may have a probe **19** located on the end to assist in moving the basket to the distal end of the blood clot **15**. The catheter can be withdrawn leaving behind and deploying the basket **16**. Once the catheter is withdrawn the plurality of fingers **30** of the basket **16** expand to the predetermined shape. A similar process takes place proximal to the blood clot **15**. The funnel **18** is advanced out of a constraining catheter where it expands to nearly the diameter of the vessel lumen. The superelastic property of nitinol assists in expanding the nitinol material that forms the basket **16** and the funnel **18**. The guide wire **40** extends to the basket **18** and through the funnel **15**. The guide wire **40** is advanced in a direction towards the funnel moving the basket towards the funnel. This movement brings the basket **16** into contact with the blood clot **15** whereby the basket can remove the blood clot from the blood vessel by trapping the blood clot within the basket **16**.

FIGS. 9 and 10 illustrate different embodiments of the invention wherein the plurality of fingers **50**, are straight and not spiral shaped. Other shapes may be used for the plurality of fingers **50**.

In some applications it may be preferable to have control wires that extend through the funnel **18** and engage the outer periphery of the basket **16**. The control wires can be moved individually or as a group to position the outer periphery in a position adjacent to the clot **15**. The control wires can help to position the basket **16** in the best position to capture the

clot. In some instances, the control wires can be used to assist the basket in removing the clot from the wall of the blood vessel.

A source of suction may be directed to the portion of the blood vessel that is located between the basket **16** and the funnel **18**. The suction is used to remove fluid and particles from the blood vessel during the time that the blood clot **16** is being removed from the blood vessel. The basket is withdrawn capturing the blood clot **15**. The basket **16** can be withdrawn and nested in the funnel **18**. Aspiration of the blood clot **15** can be performed if desired by applying manual suction with a syringe on the funnel **18** catheter. Once nested, the two nitinol components of the invention collapse by withdrawing the funnel **18** catheter within the outer catheter **60** taking the basket **16** and clot with it.

In some applications the funnel **18** and the basket **16** can be positioned using separate catheters or the same catheter. Suction can be provided through a catheter that positions the basket **16**, the funnel **18**, or a separate catheter **70** may be used to provide the suction. It should also be appreciated that either the basket **15** or the funnel **18** may be deployed or opened first in the blood vessel depending on how the blood clot **15** is to be removed.

The basket **16** and the funnel **18** are made of a material which is opaque for medical imaging equipment to allow for monitoring of the placement of the basket and funnel relative to the blood clot **15**. In some procedures it may be desirable to use a balloon on the distal or proximal side of the blood clot. The balloon can be used to stop or control the flow of blood through the vessel during the Clot removal procedure.

Two components of superelastic nitinol tube **10** have been partially laser cut longitudinally and shape set to create a cone of superelastic fingers FIG. 2. A Techne FB-08 fluidized alumina furnace may be used for the shape setting. Alternatively, the baskets may be formed from woven nitinol wires and then heat-set for the desired shapes.

Different embodiments of the invention can include varying diameters of nitinol tubing **10** as well as varying diameter of the final shape set size of collection basket **16** and/or funnel **18**. Since the human circulatory system includes vessels of many different sizes, the invention may be scalable to be used in various locations of the body.

EXAMPLE

A simulated circulatory system was built to test the present invention along with a commercially available PMT device. The setup features a reservoir physiologic saline solution pumped through a system of tubing using a peristaltic pump. The network of tubes splits into a testing branch and a bypass branch. The testing branch has an acrylic chamber that is tapered to simulate an arterial or venous stenosis. This section of the testing environment was designed such that an artificial clot would become stuck in this section and the inventions could be used as they would be clinically. A three-stage cascading filtration system was installed downstream from the testing chamber to capture any embolic particles.

A peristaltic pump (Ismatec MCP Standard) was programmed to simulate the pulsate flow from the heart. The maximum pressure was approximately 120 mmHg, the minimum pressure was approximately 80 mmHg, and the maximum velocity was about.

A 10 mL sample of fresh blood was transferred to an intermediate 15 mL test tube. A pipette was then used to transfer 9 mL of blood to twelve, 2 mL test tubes creating

twelve samples of 750 μL of blood. These twelve samples were allowed to incubate at 22° C. for 24 hours. This procedure was done twice: once to create twelve clots to test the present invention and once to create twelve clots to test a commercially available PMT device.

A DiverCE Rapid Exchange Clot Extraction Catheter (INVATEC S.p.A. Roncadelle (Bs) Italy) was chosen as the commercially available PMT to test under the same conditions as the present invention. The DiverCE is an aspiration invention that uses manual suction with a syringe to evacuate a clot. There are two version of the DiverCE, one for “organized thrombus” and one for “fresh thrombus”. The version for fresh thrombus was used for this test.

Blood Clots were created and placed in the system. The system was then sealed, and the pump was activated. The present invention was introduced via percutaneous puncture of the laboratory tubing. The invention was withdrawn and the blood clot **15** was captured and removed. This procedure was repeated twelve times. The DiverCE catheter was operated as outlined by the manufacturer’s instructions for use in each of the twelve trials.

Data was collected using the three-stage cascading filtration system. Stainless steel filters were used to capture any embolic material. Filter #1 closest to the clot had a pore opening size of 102 μm . Filter #2, the middle filter, had a pore opening size of 25 μm . The last filter, Filter #3, had a pore size of 5 μm . A set of three filters (#1, #2, and #3) were weighed prior to performing a capturing trial with either the present in or the DiverCE. The filters were installed into the designed flanges and the test was conducted. After the capturing procedure Was completed and the pump deactivated, the tubing was evacuated of saline via a laboratory vacuum such that all possible particles would be captured by the filtration system. The filters were removed and allowed to dry for 24 hours. The filters were reweighed, and any mass gain was recorded. New filters were used for each trial.

A control study was also conducted. Saline solution was allowed to flow over a series of three filters (#1, #2, and #3) for a period of twenty seconds. Filters were weighed nor to saline flow and after 24 hours of drying time. Any mass increase was recorded, and results are shown in FIG. 8. As illustrated by FIG. 8, the present invention outperformed the commercially available DiverCE at each stage and drastically reduced embolic particles.

Referring to FIGS. 11-31, additional features of the invention are shown. The basic operation of the invention is essentially the same as previously described. The apparatus comprises of three primary devices made of superelastic nitinol that can be positioned inside a blood vessel **1**: (i) an expandable basket **103** connected to a guide wire **104** positioned on the distal side of the thrombus **102**, (ii) a wire **101** with a spiral counter-rotating conical tip **105**, and (iii) an expandable funnel **106** positioned on the proximal side of the thrombus **102**.

The wire **100** with a spiral counter-rotating conical tip **105** independent of the expandable basket **103** and guide wire **104** system which gives the physician or user the freedom to remove thrombus in different branches simultaneously such as in the case of saddle pulmonary embolism (saddle thrombus **108**), see FIG. 12.

The wire **101** with a spiral counter-rotating conical tip **105**, alternatively, may be connected to the expandable basket **103**, in which case, the wire and basket can work as a single device. This eliminates the need for wire **104** which reduces the complexity of the procedure especially when the apparatus is used for removing a normal thrombus located in

one blood vessel, see FIG. 13. In some applications, the wire **101** may not be necessary and the wire **104** will be used separately with basket **103**.

The wire **101** with a spiral counter-rotating conical tip **105** and the expandable basket **103** independent from each other or as one device, are disposed and pulled towards the distal side of thrombus **102** to capture and move the thrombus into the funnel **106** disposed of a main sheath **107**.

The first step for using the invention includes positioning a guidewire at the proximal side of the thrombus **102** or **108**. One example of a guide wire is a flexible 0.035" nitinol guidewire. The guidewire is positioned using a common technique called “Seldenger Technique”. For instance, the guidewire is positioned in the pulmonary artery by firstly placing it into the femoral vein using percutaneous puncture and then up vena cave and through the right atrium and right ventricle into the pulmonary artery to the location of the thrombus.

Using a dilator, the main sheath **107** is guided over the guidewire in place to the proximal side of the thrombus **102** or **108**. The end of the main sheath is inside the body at the proximal side of the thrombus, while the beginning of the sheath is outside the body with a hemostatic valve that is used to insert the apparatus into the body. The end of the main sheath stays inside the body during the procedure until the complete removal of the thrombus. The feature of the main sheath **107** are shown in FIG. 22. The sheath shown is an example of a deliver/system that can be used with the clot removal device of the invention.

The funnel **106** is firstly constricted and inserted through the main sheath **101** all the way until the end of the main sheath **107**. Once the funnel **106** is outside the main sheath **107** at the proximal side of the thrombus **102** or **108**, it expands to a predetermined shape and expands to a diameter at the open end of the funnel that is essentially the diameter of the blood vessel. The funnel **106** been uniquely designed to achieve thrombus capture and retrieval en bloc. The funnel has a conical section **106** and a cylindrical section **109**. The conical section has a length from about 15 mm to about 50 mm. The cylindrical section extends from the conical section and forms the opening for the funnel. The opening in the funnel has a diameter from about 10 mm to about 50 mm, the size of the opening is dependent on the size of the vessel where the funnel is deployed. The central problem of percutaneous thrombectomy is that the thrombus is often larger in diameter than the orifice of the sheath used for aspiration. Most often, this results in shearing and fragmentation of thrombus with minimal thrombus capture. The funnel **106** has been designed to specially address this critical challenge. It is designed with an elongated cylindrical extension **109** at the open end of the funnel, of at least 5 mm and up to 100 mm in length with a preferred length from about 20 mm to about 40 mm. The extension designed to be in contact with the inner walls of the blood vessel **101**, see FIG. 16. The funnel is enlarged and elongated to entirely encompass the basket **103**, wire with spiral counter-rotating conical tip **105**, and the thrombus. By encircling the thrombus and then constraining the thrombus during the removal process as the baskets are withdrawn into the outer sheath, the proximal basket is able to contain the thrombus and prevent embolization of thrombus during the removal process. This allows the device to retrieve larger thrombi without any loss of thrombus as the device is retrieved back into the main sheath **107**. In addition, the cylindrical extension **109** results in a longer contact surface with the inner walls of the blood vessel **101** which reduces the forces on the blood vessel and possible blood vessel trauma. The cylin-

drical extension **109** also engages the wads of the blood vessel and acts as a barrier for allowing the thrombus or any portion of the thrombus from moving past the funnel as the thrombus is removed. The funnel **106** is connected to a small cylindrical tube “cuff” **110** to allow for maximum lumen diameter during aspiration, see FIG. **16**. The end of the cuff **110** is connected to a stiff metallic mandrel **111** with a handle grip **112** at its end, outside the body, for a better maneuverability and control of the funnel system. The tube cuff **110** is positioned in the main sheath **107** during insertion into the patient.

After the funnel **106** is placed through the main sheath **107** at the proximal side of the thrombus **102** or **108**, a small delivery catheter **113** constricting the basket **103** is inserted through the main sheath **107**, the tube cuff **110** and the funnel **106** past the thrombus. Once the delivery catheter **113** is in location, the basket **103** is then released and deployed to a predetermined shape and diameter by retrieving its constraining delivery catheter **113** while keeping the basket **103** and wire **104** in location. The basket can have a generally conical or cylindrical shape. FIG. **23** shows the cylindrical shape for the basket **103**. The length of the basket is from about 5 mm to about 50 mm and the opening of the basket has a diameter from about 10 mm to about 40 mm. The diameter of the opening being dependent on the size of the vessel where the basket is deployed. When the basket **103** has a cylindrical shape, the sidewall of the cylindrical basket will engage or be close to the wall of the blood vessel. The sidewalls of the cylindrical basket can engage the thrombus and assist in removing the thrombus from the blood vessel. FIG. **13** shows that the wire **104** is connected to the basket **103** from its distal end. Both the wire **101** with spiral counter-rotating conical tip **105** and the wire **104** have a soft and flexible distal tip **118** to allow for easy shaping and maneuvering, see FIG. **17**. The details of the delivery catheter **113** for basket **106** are shown in FIG. **18**. The catheter has an enlarged atraumatic expansion tip **114** to house the constricted basket **103**. At the connection between the catheter **113** and a stiff metallic mandrel **116**, there is an opening **115** that is used as a “rapid exchange” to allow for a quick delivery and deployment of the basket **103**. The end of the mandrel, outside the body, has a handle grip **117** for a better maneuverability and control of the basket delivery catheter.

Another delivery catheter **119** constricting the wire **101** with a spiral counter-rotating conical tip **105** is inserted through the main sheath **107**, the tube cuff **110** and the funnel **106** to the location of the thrombus **102** or **108**. The wire with a spiral counter-rotating conical tip **105** is then released and deployed by retrieving its constraining delivery catheter **119** while keeping the wire with a spiral counter-rotating conical tip **105** in location in the blood vessel. FIG. **19** shows the design of the wire **101** with a spiral counter-rotating conical tip **105**. At the first end **121** and the second end **122**, the wire spirals conically in different opposite directions, with the middle of the wire then having a finger-like loop **122**. The first and second ends of the wire **101** have a length from about 10 mm to about 50 mm with a referred length from about 15 mm to about 30 mm. the finger-like loop **122** has a length of from about 5 mm to about 30 mm with a preferred length from about 7 mm to about 15 mm. it should be appreciated, however, that the length of the loop **122** and the first and second ends is dependent on the size of the blood vessel where the device is used. The counter rotation of the wire has sever unique properties. During the initial deployment, the first end **120** is deployed distally to the thrombus and prevents distal migration of the thrombus.

With further deployment, it creates a space between the first and second ends for the thrombus to fit into. At the place of change of direction, a loop **122** is formed. The finger-like loop **122** in the middle is designed to be positioned along the inside of the vessel wall **100** and mechanically scrape or remove the thrombus **102** or **108** from the vessel wall as the proximal deployment occurs, effectively encircling the thrombus **102** or **108** within the wire **105**. This could be very useful for removing very chronic thrombi that are adherent to blood vessel walls. If the thrombus **102** or **108** is not encircled during deployment, the central finder-like loop **122** can be rotated, with the rotation of the wire **105** itself, to scrape the thrombus **102** or **108** off the vessel wall **100** and entrain it into the middle of the spiraled wire **105**. Finally, during retrieval, the conical first and second ends of the spiral wire effectively form a capture spiral to retain the thrombus **102** or **108** during the removal. The wire **101** is also designed to allow it to easily be retracted into the funnel **106** and prevent distal embolization of the thrombus **102** or **108** during the terminal stages of thrombus retrieval. The conical shape of the first and second ends is designed, to unwind during retrieval into the sheath.

The basket **103**, wire **104**, wire **101** with a spiral counter-rotating conical tip **105** are withdrawn in the blood vessel capturing (snaring) the thrombus **102** or **108** until these components are nested in the deployed funnel **106**. The funnel **106** (encompassing the basket **103**, wire **104**, wire **101** with a spiral counter-rotating conical tip **105**, and thrombus **102** or **108**) is retrieved through the main sheath **107**. A continuous aspiration can be applied through a (large) side port with a male-threaded end (18-18 Fr) connected to an aspiration syringe with: a female-threaded end (16-18 Fr) during the retrieval of funnel **106**. Once the thrombus is retrieved, the funnel **106** is collapsed and withdrawn within the main sheath **107** and the thrombus **102** or **108** is removed.

The basket **103** and funnel **106** are made of braided superelastic nitinol wires shape-set in a way to have an open cell design, while being in a deployable state, without the need for any membrane or filament. This allows for maintenance of blood flow during the deployment, operation, and retrieval.

The braided superelastic nitinol wires are shape-set in a way to allow for the basket **103** to change its shape by allowing the opening in the basket to fold backward, see FIG. **21**. By folding backwards, the opening of the basket engages the thrombus and can assist in removing the thrombus from the wall of the blood vessel. The longer funnel **106** with wider opening diameter creates more surface area for contact with thrombus at the extension **109** at the opening and this is beneficial in capturing the emboli. This design results in a strengthened funnel structure and an increased maximum dragging force, while remaining atraumatic, during thrombus removal.

The basket **103**, funnel **106**, and wire **101** with a spiral counter-rotating conical tips **105** can have differential surfaces. These components can have an outside that is finely polished and an inside that is either rough, or has microscopic surfaces, like shark skin, that unidirectionally latches onto objects, like thrombus **102** or **108**, to retain the object as it being pulled back, against the current of blood, to be retained into a sheath **107** catheter or other devices.

In alternative preferred embodiments, the basket **103**, funnel **106**, and wire **101** with a spiral counter-rotating conical tip **105** may be coated with biologic products that specifically adhere to the materials we desire to retrieve (thrombus). As an example, the Fab fragment of anti-bodies

can be used, specifically directed against human proteins such as fibrin, activated platelet receptors (IIb/IIIa), or other materials found in thrombi. These antibody fragments attached to the retrieval devices will form a biologic locking mechanism to hold the thrombus **102** or **106** to the basket **103**, funnel **106** and wire **101**, selectively retrieving only the desired biologic products from the body.

Another shape of the wire with a spiral counter-rotating conical tip is shown in FIG. **20**. The wire **130** has a first end **133** and a second end **135**. A conical section **137** is disposed on the wire between the first end and the second end. The conical section is disposed to engage and retrieve a thrombus with the basket **103** and funnel **106** as previously described. This is a simpler structure for the wire where it is not necessary to have two counter rotating sections. The shape and size of the single conical section **137** is the same as the previously described conical sections on the first and second ends of the wire **101**.

FIG. **22** shows a schematic representation of the design of the needed mandrill to make the spiral counter-rotating conical tip **105**. The needed mandrill consists of two parts, right and left that can be assembled together. The superelastic nitinol wire **105** is then inserted from one end through the center hole and guided through the cortical grooves all the way to the second center hole at the other end. Finally, the wire **105** is constrained and shape set into the desired shape and dimensions.

FIG. **30** shows another configuration for a basket that can be used to remove a thrombus from a blood vessel. The basket **203** has a cylindrical section **205** having an opening **207** and a conical section **209** that is joined to the end of the cylindrical section **205** that is spaced apart from the opening **207**. The conical section **209** functions to close the cylindrical section **205**. A raised rib **211** is formed in the cylindrical section **205** adjacent the end where the conical section **209** is connected to the cylindrical section **205**. A raised rib **215** is located on the cylindrical section **205** adjacent the opening **207**. The basket **203** is made of a braided superelastic nitinol wires that are shape-set as previously described in this application. The ribs **211** and **215** are reinforcing elements that provide additional structural rigidity for the basket **203**. In particular, a rib **215** assists in maintaining the opening **207** in a desired fully extended position while the basket **203** is used to remove and collect the thrombus from a blood vessel. The rib **211** provides structural rigidity for an end of the basket **203** that is spaced apart from the opening **207**. The rib **211** and the rib **215** act to keep the basket **203** in a fully extended position as it is pulled along the blood vessel towards the funnel **106** which is the other element of the thrombus capture device. The fully extended orientation for the basket **203** assist in positioning the basket where it can engage as completely as possible the thrombus and remove the thrombus from the walls of the blood vessel. The basket is used in the same manner as the basket **103** to remove a thrombus.

FIG. **31** shows another feature of the invention where a plug **223** can be used in place of the basket **103**, **203** to assist in removing the thrombus from a blood vessel. The plug **223** is attached to the wire **104** or wire **101** with the spiral counter-rotating conical tip **105** as previously discussed in this application. The plug **223** is made of braided superelastic nitinol wires that are shaped-set in a way to have an open cell design, while in the deployed state, without the need for any membrane or filament as previously discussed in this application. The plug can be deployed in a compressed state and when the constraining sheath used to deliver the plug is removed the plug expands to its full extended shape set stage

as shown in FIG. **31**. The plug has a first conical end **225** located on the first end **227** and a second conical end **231** located on the second end **233** of the plug. A reinforcing member **241** extends along the longitudinal axis of a plug from the first conical end **225** to the second conical end **231**. The reinforcing member **241** is positioned on each side of the plug **223**. The reinforcing member has a height that is approximately one third of the diameter of the first and second conical sections. A spiral section **245** of braided superelastic nitinol wires extends from the first conical end **225** to the second conical end **231** of the plug **223**. The spiral section **245** has a diameter that is substantially the same as the diameter of the first and second conical ends of the plug. The spiral section **245** creates a cylindrical spiral that extends from the first end **227** to the second end **233** of the plug **223**. Openings **247** are positioned between the spiral sections **245** and the openings provide access to the interior of the plug **223**. The spiral sections **245** form a cylindrical band **251** that engage the outer diameter of the first and second conical sections located on the first and second ends respectively of the plug **223**.

The plug **223** is deployed in the blood vessel in the same manner as the basket **103**, **203** on the distal side of the thrombus as previously described: Once the plug is in the desired location it is deployed by removing the delivery sheath and allowing the plug to expand due to the shape-set characteristics of the plug. The plug is then advanced towards the thrombus and the funnel **106**. The first conical end **227** engages the thrombus and advances it towards the funnel **106**. The cylindrical band **251** adjacent the first cylindrical section **227** is designed to be adjacent the wall of the blood vessel and to retain the thrombus adjacent the first end **225** of the plug **223**. If the thrombus is secured to the walls of the blood vessel, the cylindrical bands **251** will abrade against the thrombus and, hopefully, break the thrombus free from the walls of the blood vessel. Pieces of the thrombus that are removed from the walls of the blood vessel by the cylindrical bands **261** will fall into the openings **247** between the spiral sections **245** and enter the interior of the plug **223**. If the cylindrical bands **251** do not remove all of the portions of the thrombus that are attached to the walls of the blood vessel, the following spiral section **245** will engage and, hopefully, displace the thrombus from the walls of the blood vessel. Again, the displaced pieces of the thrombus can pass through the openings **247** into the interior of the plug **223**. Pieces from the thrombus that enter the plug **223** from the openings **247** will be retained in the plug by the spiral sections **245** and the walls of the blood vessel. The pieces of the thrombus that are so dislodged and positioned in the interior of the plug **223** will also be confined by the second cylindrical section **231** on the second end **233** of the plug. The plug **223** will be advanced into the funnel **106** in the manner previously described so that the thrombus will be between the plug **223** and the funnel **106**. The cylindrical section **109** on the funnel **106** has a length that is at least as long as the length of the plug **223** so that the plug **223** will be fully enclosed within the funnel **106**.

To assist in positioning the basket and funnel in the blood vessel, the superelastic material can have a shape memory that is dependent on the temperature of the material. The superelastic material can be maintained in a compressed state at a lower temperature, such as the temperature in an operating room, and then expand to its shape set expanded shape at a higher temperature, such as the temperature on the interior of a human body. The temperature shape memory can be designed for the nitinol superelastic material and be part of the shape setting process for the funnel, basket and

13

wires used to remove a thrombus. The shape memory feature assists in having the components inserted into the body of the patient stay in a compressed state until the components are deployed from the delivery sheath. Once the components are deployed, the components are subject to the higher body temperature and expand to the desired expanded shape set orientation.

The principle and mode of operation of this invention have been explained and illustrated in its preferred embodiments. However, it must be understood that this invention may be practiced otherwise than as specifically explained and illustrated without departing from its spirit or scope.

We claim:

1. An apparatus for conducting a thrombectomy in a blood vessel of a patient comprising:

an expandable basket designed for positioning in the blood vessel on a distal side of or adjacent to the thrombus, the expandable basket configured to expand once it is in position on the distal side of or adjacent to the thrombus, the expandable basket made from a superelastic or a shape memory material, having a mesh pattern that can retain the thrombus;

a guide wire connected to the expandable basket for positioning the expandable basket in position on the distal side of or adjacent to the thrombus and for removing the expandable basket from the blood vessel; and

an expandable funnel designed for positioning in the blood vessel on a proximal side of the thrombus, the expandable funnel having a cylindrical section, the expandable funnel configured to expand once it is in position on the proximal side of the thrombus with an open side of the expandable funnel facing the thrombus, the cylindrical section being designed to engage the wall of the blood vessel, the expandable funnel made from a superelastic or shape memory material, having a mesh pattern that can retain the thrombus, the apparatus having a deployed state wherein the expandable basket and expandable funnel expand and engage an internal wall of the blood vessel and a delivery state wherein the expandable basket and expandable funnel have a contracted configuration to allow insertion in the blood vessel within a delivery sheath, the expandable basket being designed to fit within the cylindrical section of the expandable funnel when the expandable basket is advanced towards the expandable funnel by the guide wire to remove the thrombus, the expandable funnel designed to encircle and constrain the thrombus during a removal process as it is withdrawn into an aspiration catheter, the apparatus having the ability to change shape and diameter as it is withdrawn into the aspiration catheter;

wherein the expandable basket is a plug having a first conical end located on a first end and a second conical end located on a second end, wherein spiral sections extend from the first conical end to the second conical end, the spiral sections forming a cylindrical band that has a diameter substantially the same as a diameter of the first and second conical ends, and a reinforcing member extending parallel to a longitudinal axis of the plug from the first conical end to the second conical end, wherein the reinforcing member has a height that is approximately one third of the diameter of the first and second conical ends, wherein openings are positioned between the spiral sections, the openings being disposed to allow pieces from the thrombus to pass through the openings and into an interior of the plug.

14

2. The apparatus of claim 1 wherein a wire with a spiral orientation extends between the expandable basket and the expandable funnel, the spiral orientation of the wire being designed to engage the thrombus to assist in positioning the thrombus in a desired location for removal.

3. The apparatus of claim 2 wherein the wire has a first spiral section and a second spiral section, the first and second spiral sections having opposing spiral orientations.

4. The apparatus of claim 3 wherein an offset section is positioned between the first and second spiral sections, the offset section extending outwardly and being disposed to engage the wall of the blood vessel when the wire is rotated whereby the offset section can assist in dislodging the thrombus from the wall of the blood vessel.

5. The apparatus of claim 4 wherein the offset section has a length from about 5 mm to about 30 mm.

6. The apparatus of claim 4 wherein each of the first and second spiral sections has a length from about 10 mm to about 50 mm.

7. The apparatus of claim 3, the openings of the plug being disposed to allow pieces from the thrombus to pass through the openings of the plug and into an interior of the plug.

8. The apparatus of claim 1 wherein the cylindrical section has a length from about 5 mm to about 20 mm.

9. The apparatus of claim 1 wherein the cylindrical section has a length from about 15 mm to about 50 mm.

10. The apparatus of claim 1, wherein the cylindrical section has a length that is at least as long as a length of the plug.

11. The apparatus of claim 1, wherein the reinforcing member is integrally formed with the first conical end and the second conical end.

12. An apparatus for conducting a thrombectomy in a blood vessel of a patient comprising:

an expandable basket made from a superelastic or a shape memory material, wherein the expandable basket has a mesh pattern;

a guide wire connected to the expandable basket; and an expandable funnel connected to the guide wire, wherein the expandable funnel is made from a superelastic or shape memory material and has a mesh pattern, wherein the expandable funnel comprises a cylindrical section;

wherein the apparatus has a deployed state wherein the expandable basket and the expandable funnel have an expanded configuration, and a delivery state wherein the expandable basket and the expandable funnel have a contracted configuration;

wherein the expandable basket in the contracted configuration fits within the cylindrical section of the expandable funnel; and

wherein the expandable basket is a plug having a first conical end located on a first end and a second conical end located on a second end, wherein spiral sections extend from the first conical end to the second conical end, the spiral sections forming a cylindrical band that engages an outer diameter of the first and second conical ends, and a reinforcing member extending parallel to a longitudinal axis of the plug from the first conical end to the second conical end, wherein the reinforcing member has a height that is approximately one third of the outer diameter of the first and second conical ends, wherein openings are positioned between the spiral sections.

13. The apparatus of claim 12, wherein the cylindrical section has a length that is at least as long as a length of the plug.

14. The apparatus of claim 12, wherein the reinforcing member is integrally formed with the first conical end and the second conical end.

* * * * *