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(71) Applicant: **BIO2 MEDICAL, INC.** [US/US]; 18618  
Tuscany Stone Drive, Suite 100, San Antonio, TX 78258  
(US).

(72) Inventors: **ANGEL, Luis, F.**; 18114 Liscum Hill, San  
Antonio, TX 78258 (US). **STEINMETZ, Jeffrey, N.**;  
10842 West 54th Place, Arvada, CO 80002 (US). **SIMS,  
Daniel, D.**; 8967 West 77th Place, Arvada, CO 80005  
(US).

(74) Agents: **ROSENBAUM, David, G.** et al.; Rosenbaum IP,  
1480 Techny Road, Northbrook, IL 60062 (US).

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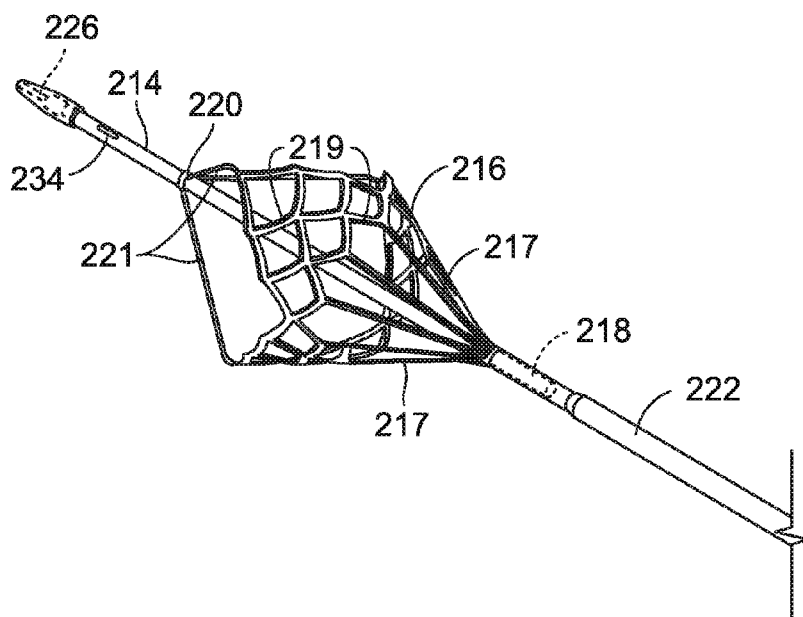


FIG. 19

(57) Abstract: A combined multi-lumen central access catheter and an embolic filter, further comprising an imaging modality to facilitate intravascular imaging of the filter.



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**Title:**

[001] IVC FILTER CATHETER WITH IMAGING MODALITY

**Background of the Invention**

[002] The present invention pertains generally to the field of vascular filters for capturing  
5 embolic material in the blood flow.

[003] The accepted standard of care for patients with venous thromboembolism (VTE) is  
anticoagulant therapy. Inferior vena cava (IVC) filters are reserved for those patients who fail  
anticoagulant therapy, or have a complication or contraindication to anticoagulant therapy. Until  
the early 1970's, the only method of IVC interruption was surgical, either by clipping, ligation or  
10 plication. The first clinical experience of an endoluminally-placed device to interrupt IVC flow  
was reported by Mobin-Uddin et al. in 1969. However, it was not until the introduction of a  
stainless steel umbrella-type filter by Greenfield et al. in 1973 that an effective method of  
endoluminally trapping emboli while simultaneously preserving IVC flow became possible.  
Indeed, for many years, the Greenfield filter set a benchmark by which newer filters were  
15 measured. Early generations of filters were inserted by surgical cut-down and venotomy.  
Eventually filters were able to be inserted percutaneously: initially through large 24 Fr sheaths,  
though newer generations of filters are able to be delivered through 6 Fr systems.

[004] Despite the safety and efficacy of modern day filters, systemic anticoagulation remains  
the primary treatment for VTE. Either unfractionated or low molecular weight heparin followed  
20 by three months of oral anticoagulation in patients with proximal deep venous thrombosis (DVT)  
is approximately 94% effective in preventing pulmonary embolism (PE) or recurrent DVT. The  
routine placement of IVC filters in addition to anticoagulation in patients with documented DVT  
was investigated by Decousus et al. in a randomized trial. Decousus H, Leizorovicz A, Parent F,  
et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients  
25 with proximal deep-vein thrombosis. *N Engl J Med* 1998; 338:409–415. This study revealed  
that the use of a permanent filter in addition to heparin therapy significantly decreased the  
occurrence of PE within the first 12 days compared to those without a filter. However, no effect  
was observed on either immediate or long-term mortality, and by 2 years, the initial benefit seen

in the group of patients with filters was offset by a significant increase in the rate of recurrent DVT.

[005] Despite the efficacy of anticoagulant therapy in the management of VTE, there are certain situations and conditions in which the benefits of anticoagulation are outweighed by the risks of instituting such a therapy. These include contraindications and complications of anticoagulant therapy. In such circumstances, there may be absolute or relative indications for filter insertion

[006] Currently, there are several different types of permanent cava filters that are FDA approved. These include the Bird's Nest filter (Cook Incorporated, Bloomington, IN), Vena Tech LGM filter (B. Braun, Bethlehem PA), Vena Tech LP (B. Braun), Simon Nitinol filter (Bard, Covington, GA), Titanium Greenfield filter (Boston Scientific, Natick MA), Over-the-Wire Greenfield filter (Boston Scientific), TrapEase filter (Cordis Corp.), SafeFlo filter (Rafael Medical Technologies, Inc.), and the Günther Tulip filter (Cook Medical).

[007] Well-founded concerns over the long-term complications of permanent IVC filters, particularly in younger patients in need of PE prophylaxis with a temporary contraindication to anticoagulation, has led to the development of temporary and retrievable filters. Temporary filters remain attached to an accessible transcutaneous catheter or wire. These have been used primarily in Europe for PE prophylaxis during thrombolytic therapy for DVT. Currently these devices are not approved for use in the United States. Retrievable filters are very similar in appearance to permanent filters, but with modifications to the caval attachment sites and/or hooks at one end that can facilitate their removal. Retrievable filters are currently available in the United States, examples of these as set forth in *Endovascular Today's 2012 Buyer's Guide* include the ALN Optional Filter (ALN), Option (Argon Medical Devices) Günther Tulip (Cook Inc.), Celect and Opt Ease (Cordis Corp.), and Eclipse and Meridian nitinol filters (Bard Peripheral Vascular, Tempe, AZ). 2012 Buyer's Guide, *Endovascular Today* 2011; Dec.: 98. The time limit of retrievability is in part dependant on the rate of endothelialization of the device, which typically occurs within 2 weeks. However, differences in design may extend the time period in which the filter may be safely retrieved.

[008] Currently no consensus exists as to which patients have an indication for a retrievable filter. However, it is generally accepted that patients at high risk for pulmonary embolism or with documented PE and with a temporary contraindication to anticoagulation are candidates.

[009] Certain circumstances preclude the placement of a filter in the infrarenal IVC. This includes thrombus extending into the infrarenal IVC, renal vein thrombosis or pregnancy. The safety of suprarenal placement of IVC filters is well documented, with no reported instances of renal dysfunction and no differences in the rates of filter migration, recurrent PE or caval thrombosis.

[010] The rate of upper extremity DVT is on the rise. This is predominantly due to an increasing number of patients having short- and long-term upper extremity central venous access catheters. In one study, 88% of patients found to have an upper extremity DVT had a central venous catheter present at the site of thrombosis at the time of diagnosis or within the previous two weeks. Pulmonary embolism may complicate upper extremity DVT in 12–16% of cases. In patients who have such a complication or contraindication to anticoagulation, a filter can be safely placed immediately below the confluence of the brachiocephalic veins. However, misplacement of an SVC filter is theoretically more likely than with an IVC filter because of the relatively short target area for deployment.

[011] The most common imaging modality used for filter insertion is fluoroscopy, performed either in an interventional suite or an operating room. Bedside placement of filters has inherent advantages, particularly for critically ill patients in intensive care settings where transport can be avoided. Portable fluoroscopy, surface duplex ultrasound and intravascular ultrasound (IVUS) have all been used to assist with bedside filter placement.

[012] Vena cava filter placement frequently occurs concomitantly with central access line placement or in critically ill patients that already have a central access line in place. Heretofore, however, there have been no devices which combine the function of a central access catheter and a removable vena cava filter.

### **Summary of the Invention**

[013] The present invention relates to multi-lumen central access catheter having a proximal end and a distal end thereof relative to the longitudinal axis of the catheter, a vena cava filter

near the distal end of the central access catheter, at least one of a port proximal the vena cava filter or a port distal the vena cava filter. The proximal and distal ports, which may be positioned entirely or partially distant from an open area bounded by the filter member, and lumens associated therewith, are also open to fluid flow to provide means for introducing fluids, such as an anticoagulant, thrombolytic or other bioactive agents, contrast medium, blood transfusions, intravenous fluids or other medications. Alternatively, the proximal and distal ports may be used for withdrawal or evacuation of fluids or other material through the catheter.

[014] The present invention may be configured for either a femoral approach or a jugular approach to the inferior vena cava. Vena cava filters are typically deployed infrarenally, but may also be deployed suprarenally. It will be understood that within the inferior vena cava blood flow is superior, i.e., toward the patients head. Thus, in all embodiments, the vena cava filter will be positioned so that it opens inferiorly, i.e., away from the patient's head and toward the direction of the blood flow. It will be appreciated, therefore, that in the present invention, the vena cava filter will have a different axial orientation on the central access catheter depending upon whether the device is intended for use in a femoral approach or a jugular approach.

[015] Accordingly, it is an objective of the present invention to provide a multi-lumen catheter coupled to a vena cava filter that is useful both as a central venous access catheter for administration of intravenous fluids, bioactive agents, contrast agents, flushing agents, pressurized fluids for mechanical thrombolysis and/or withdrawal of blood samples and for capture of thrombus or emboli.

[016] Another aspect of the present invention is to provide a filter geometry in which the proximal portion of the filter, relative to the axis of blood flow, has larger interstitial openings to permit thrombus or embolic material to flow into the filter, while the distal portion of the filter, again relative to the axis of blood flow, has relatively smaller interstitial openings that capture the thrombus or embolic material within the filter. Another way to view this aspect is that the structure of the filter includes a greater open surface area exposed to the flow of embolic material into the filter at its proximal end, while the distal end has smaller open surface area exposed to the flow of embolic material to capture the embolic material in the distal end of the filter member. More specifically, regardless of whether the present invention is delivered by a jugular

approach or a femoral approach, the filter geometry is such that the larger interstitial openings of the filter are positioned inferiorly along a longitudinal axis of the filter.

[017] Each of the foregoing embodiments of the present invention may further be adapted for use with an imaging modality to facilitate intravascular imaging beyond or within the region of the filter member. In this manner, as opposed to the prior art, the condition of the filter member may be visualized from within the filter member, rather than via a traditional external imaging modality such as fluoroscopy, venography, or ultrasound. Additionally, in some embodiments, the imaging modality may pass entirely through the distal tip of the multi-lumen catheter, and enable an operator to use the intravascular imaging modality to visualize the origins of the renal veins. This could allow the operator to place the catheter without use of external imaging (i.e. fluoroscopy, trans-abdominal duplex ultrasound, CT, etc.).

[018] Generally, intravascular imaging systems utilize a sheath through which a signal is transmitted and received. In the present invention, the multi-lumen catheter with associated filter member may serve as the sheath for introduction of an intravascular imaging system, permitting improved imaging of the condition of the filter member while in use. In particular, the use of an intravascular imaging system with the multi-lumen catheter with associated filter member will permit a medical professional to monitor the condition of the filter member, and utilize appropriate techniques to lyse a collected thrombus. Because of the improved imaging, the lysing techniques may be more specifically and accurately targeted, as compared to lysing techniques applied without the benefit of imaging the condition of the filter member. In other, alternative, embodiments, the intravascular imaging system may also enable a medical professional to visualize the filter catheter for placement within a patient.

[019] Some non-limiting examples of imaging systems include intravascular ultrasound (IVUS), optical coherence tomography (OCT), side looking OCT, ultrasound, thermography, IR imaging, Florence imaging, luminescent imaging, MRI, videography, photoacoustic, and other similar imaging technologies. These systems may permit 360 degree imaging, or be side looking and rotatable to image through 360 degrees. In one embodiment, the system generally includes an imaging core drive cable and an imaging probe. The imaging probe may be a tip, cone, and/or the like disposed at a distal end of the imaging core drive cable, wherein the imaging

probe and/or the drive cable are operably connected to an external system for operating the imaging system.

[020] In one embodiment, the imaging probe may be disposed within a portion of the central lumen bounded by the filter member. Thus, the imaging probe may be operated to help a user  
5 detect the presence of a thrombus captured by the filter member. Further, the imaging probe may also help detect the size and/or position of a captured thrombus. The imaging probe may be rotated and/or translated within the lumen, so as to permit imaging of the entire filter member. Alternatively, the imaging probe may be adapted to permit 360 degree imaging through the wall of the catheter lumen without requiring rotation. In a further embodiment, the imaging probe  
10 may be adapted to permit imaging of the length of the filter member without distal or proximal translation. Preferably, the imaging probe is operable to image the filter member in an expanded state.

[021] In another embodiment, the imaging system may be disposed within a lumen of a multi-lumen sheath associated with a multi-lumen or single lumen filter catheter.

[022] In one embodiment, the position of the imaging probe relative to the filter member is  
15 determined. In one embodiment, the imaging probe may further comprise a radiopaque material to permit external imaging of the probe to determine its location relative to the filter. In an alternative embodiment, the drive cable may have measured markings disposed thereon to permit determination of the position of the imaging probe relative to the filter, based on the relationship  
20 between the markings on the drive cable and the conduit into which the imaging probe and drive cable are inserted.

[023] In order to monitor the condition of the filter member, the imaging probe may transmit and receive an imaging signal through a wall of the lumen. The imaging signal may depend upon the particular imaging system utilized, and generally comprises a transmitted signal, wave,  
25 energy, or the like that is emitted from the imaging probe in order to image or visualize the filter member. In one embodiment, the relevant portion of the lumen is a section of the catheter body bounded by the proximal and distal ends of the filter member. The dimensions and/or material of any or all of the catheter body may be selected to maximize imaging signal transmission and/or imaging signal clarity.



[024] Alternatively, in some embodiments the filter may be attached to an end of a single or a multi-lumen catheter. In these embodiments, the region bounded by the proximal and distal ends of the filter is open and free of imaging obstruction.

5 [025] Generally, the imaging system may be used with the filter member to monitor the condition of the filter member and to capture a thrombus within a blood vessel. This may be accomplished by introducing the multi-lumen catheter, having the filter member coupled thereto, into the blood vessel. The catheter may then be deployed within the blood vessel such that the filter has an enlarged diametric opening facing a patient's blood flow. The imaging system may then be translated through a lumen of the multi-lumen catheter and be operable to image or  
10 visualize the condition of the filter member. Alternatively, the imaging system may be used to visualize the filter catheter to assist a medical professional in placement of the filter catheter within a patient.

[026] In another embodiment, the imaging system may be used with a multi-lumen sheath coupled to a filter catheter, such that the imaging system is disposed within a lumen of the multi-  
15 lumen sheath.

[027] In one embodiment disclosed herein is a method of capturing thrombus within a blood vessel, comprising the steps of: introducing a catheter having a filter member coupled thereto; deploying the catheter within a blood vessel such that the filter has an enlarged diametric opening which opens facing a patient's blood flow; and imaging the filter member with an  
20 imaging system operable to detect a condition of the filter member.

[028] In one embodiment disclosed herein is a multi-lumen filter catheter, comprising: a multi-lumen catheter body having a plurality of lumens; a filter member coupled to the catheter body; and an imaging system operable to detect a condition of the filter member.

25 [029] In one embodiment disclosed herein is a medical device, comprising: a catheter body having a filter member coupled to the catheter body; a multi-lumen sheath, wherein the catheter body is disposed within a lumen of the multi-lumen sheath; and an imaging system operable to detect a condition of the filter member.

**Brief Description of the Drawings**

[030] Fig. 1 is a perspective view of a central venous access vena cava filter catheter in accordance with a first embodiment of the present invention with the vena cava filter in an unexpanded state.

5 [031] Fig. 2 is a side elevational view of a central venous access vena cava filter catheter in accordance with the first embodiment of the present invention.

[032] Fig. 3 is a cross-sectional view taken along line 3-3 of Fig. 2.

[033] Fig. 4 is a cross-sectional view taken along line 4-4 of Fig. 2.

[034] Fig. 5 is a cross-sectional view taken along line 5-5 of Fig. 2.

10 [035] Fig. 6 is a perspective view of a central venous access vena cava filter catheter in accordance with a second embodiment of the present invention illustrating the vena cava filter in an unexpanded state.

[036] Fig. 7 is a side elevational view of a central venous access vena cava filter catheter in accordance with the second embodiment of the present invention.

15 [037] Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 7.

[038] Fig. 9 is a cross-sectional view taken along line 9-9 of Fig. 7.

[039] Fig. 10 is a cross-sectional view taken along line 10-10 of Fig. 7.

[040] Fig. 11 is a cross-sectional view taken along line 11-11 of Fig. 7.

20 [041] Fig. 12 is a perspective view of the central venous access vena cava filter catheter of Fig. 1 illustrating the vena cava filter in a diametrically expanded state.

[042] Fig. 13A is a perspective view of a vena cava filter member in accordance with a first embodiment thereof.

[043] Fig. 13B is a first side elevational view thereof.

[044] Fig. 13C is an end elevational view thereof.

25 [045] Fig. 13D is a second side elevational view thereof.

[046] Figs. 14A-14H are perspective views of alternative embodiments of a vena cava filter member in accordance with the present invention.

[047] Figs. 15A-15H are fragmentary side elevational views of the alternative embodiments of the vena cava filter member illustrated in Figs. 14A-14H.

5 [048] Fig. 16A is a side elevational view of the vena cava central line catheter in its undeployed state.

[049] Fig. 16B is a side elevational view of the vena cava central line catheter in its deployed state.

10 [050] Fig. 17 is a side elevational view of a vena cava filter member in its expanded state in accordance with one embodiment of the present invention.

[051] Fig. 18 is a perspective view of a vena cava filter member in its expanded state in accordance with an alternative embodiment of the present invention.

[052] Fig. 19 is a perspective view of a vena cava filter member in its expanded state in accordance with yet another embodiment of the present invention.

15 [053] Fig. 20 is a perspective view of a vena cava filter member in its expanded state in accordance with still another embodiment of the present invention.

[054] Figs. 21A and 21B are perspective views of a vena cava filter member mounted at a distal end of a central line catheter having a distal balloon.

20 [055] Figs. 22A and 22B are perspective views of an alternative embodiment of a vena cava filter member mounted at a distal end of a central line catheter having a distal balloon.

[056] Fig. 23 is a side cross sectional view of an embodiment of the vena cava filter member mounted at a distal end of a central line catheter in its expanded state, further comprising an imaging modality disposed within a lumen of the catheter.

### **Detailed Description of the Preferred Embodiments**

25 [057] In the accompanying Figures like structural or functional elements are designated by like reference numerals, e.g., 16, 116, 216, 316, 416 represent similar structural or functional elements across different embodiments of the invention. With particular reference to Figs. 1-5, according to a first embodiment of the invention, there is disclosed a central venous access filter

(“CVAF”) 10 that is composed generally of a multi-lumen central venous access catheter body 12 having a proximal port 32 associated with a first lumen 44 and a distal port 34 associated with a second lumen 42, a filter member 16, having a first end 18 and a second end 20, is positioned generally intermediate the distal port 34 and the proximal port 32 and is generally concentric relative to the catheter body 12. An outer sheath 22 is concentrically disposed over the catheter body 12 such that relative movement of the catheter body 12 and the outer sheath 22 either exposes the filter member 16 or captures the filter member 16 within the outer sheath 22. The outer sheath 22 terminates in an annular opening at a distal end thereof and at first hub member 225 as depicted in Figures 16A and 16B. The proximal hub 225 will be described more fully hereinafter. The catheter body 12 extends through a central bore in the proximal hub 225 and passes through a central lumen of the outer sheath 22. A second hub member 227, as depicted in Figures 16A and 16B, is coupled to a proximal end of the catheter body 12. The second hub member 227 and the first hub member 225 are removably engageable with each other as will also be described further hereinafter.

[058] Depending upon the orientation of the filter member 16, the first end 18 or the second end 20 may either be fixed or moveable relative to the catheter body 12. Alternatively, as will be discussed further hereinafter, the filter member 16 may have only a first end 18 which is fixed to the catheter body 12

[059] To facilitate percutaneous introduction of the inventive CVAF 10, a physician may optionally elect to employ an introducer sheath (not shown) as vascular access conduit for the CVAF 10. The presence of the filter member 16 at the distal end of the catheter body 12 creates a region of relatively lower flexibility and the practitioner may determine it beneficial to employ an introducer sheath for vascular access.

[060] As used in this application, unless otherwise specifically stated, the terms “proximal” and “distal” are intended to refer to positions relative to the longitudinal axis of the catheter body 12. Those skilled in the art will understand that the catheter body 12 has a distal end which is first inserted into the patient and a proximal end which opposite the distal end. Additionally, the terms “inferior” or “inferiorly” are intended to refer to the anatomic orientation of being in a direction away from the patient’s head while the terms “superior” or “superiorly” are intended to refer to the anatomic orientation of being toward the patient’s head.

[061] The multi-lumen aspect of the inventive central venous access filter catheter 10 is shown more clearly in Figs. 2-5. The catheter body 12 has a proximal section 13 and a distal section 14, which is longitudinally opposite the proximal section 13, and which may have a relatively smaller diametric profile than the proximal section 13. As described above, the first lumen 44 terminates at the proximal port 32, while the second lumen 42 terminates at the distal port 34. A central guidewire lumen 30 may be provided that extends the entire longitudinal length of the catheter body 12 and terminates at the distal end of the catheter body 12 at a distal guidewire opening 31 that permits the catheter body to track along a guidewire during a procedure. The central guidewire lumen 30 may also be used to introduce fluids, such as bioactive agents, intravenous fluids or blood transfusions.

[062] Additionally, at least one of a plurality of infusion lumens 40 are provided, each having at least one infusion port 36 that passes through a wall of the catheter body 12. Bioactive agents, flushing fluids for flushing or under elevated pressures for mechanical thrombolysis of thrombus in the filter member 16, contrast agents or other fluids may be infused through the infusion lumens 40 and out of the at least one infusion port 36 to pass into the patient's venous system for either local or systemic effect. In accordance with one embodiment of the invention, plural infusion ports 36 are provided with multiple ports 36 being provided in communication with a single infusion lumen 40 and spaced along a longitudinal axis of the catheter body 12.

Additionally, plural infusion ports 36 may be provided in a circumferentially spaced manner to provide for fluid infusion at points spaced around the circumference of the catheter body 12. In this manner, fluid infusion is provided along both the longitudinal axis and the circumferential axis of the catheter body 12 within the spatial area defined by and bounded by the filter member 16. Because the plural infusion ports 36 communicate with the spatial area defined by and bounded by filter member 16, fluids introduced through the infusion lumens 40 are directed immediately at thrombus caught within the filter member 16. This permits thrombolytic agents, high pressure mechanical thrombolysis using a pressurized saline flush to be introduced directly to the situs of thrombus capture within filter member 16. Alternatively, thermal, ultrasound or other types of thrombolysis may be employed to disrupt thrombus captured by the filter member 16. For example, the annular space between the outer sheath 22 and the catheter body 12 may be used to introduce a thrombolytic to the filter and shower the filter to disrupt thrombus caught by the filter member 16. Additionally, the balloon depicted in Figures 21 and 22 may be positioned

adjacent the filter member 16 and be provided with plural openings oriented in the direction of the filter member 16 to facilitate thrombolysis.

[063] It will be understood, by those skilled in the art, that alternative arrangements of the first lumen 44, the second lumen 42, the guidewire lumen 30, or the infusion lumens are possible and contemplated by the present invention. The number and arrangement of lumens in the catheter body 12 is a function of the desired number of operable ports passing through the walls of the catheter body 12, the relative position of the operable ports, the desired position and geometry of the guidewire lumen 30, the desired longitudinal flexibility of the catheter body 12, the desirable degree of kink resistance of the catheter body 12, and other factors which are known to one of ordinary skill in the catheter arts.

[064] While the present invention is not limited to specific dimensional sizes of either the catheter body member 12, the outer sheath 22, lumen diameter or port dimension, an exemplary outer diameter size of the outer sheath 22 is between 8 Fr (2.7 mm) and 9 Fr (3.0mm) while an exemplary outer diameter size of the catheter member 12 is between 6 Fr (2.0 mm) and 7 Fr. A diametric transition taper 15 may be provided between the proximal portion 13 and the distal portion 14 of the catheter body 12 corresponding to the thickness of the filter member 16. In this manner, the outer surface of the filter member 16 is substantially co-planar with the outer diameter of the proximal portion 13 of the catheter body 12 about its entire circumference. Alternatively, the catheter body member 12 may have a constant diameter and the filter member 16 coupled to an outer surface of the catheter body member 12, with the outer sheath 22 having a luminal diameter sufficient to fit over the filter member 16. Moreover, the fixed first end 18 of filter 16 is positioned adjacent and in abutting relationship with the diametric transition 15, while the moveable second end 20 of filter member 16 is concentrically positioned around the distal section 14 of catheter body 12 and is reciprocally moveable thereupon to accommodate diametric expansion of the filter member 16. Lumen diameter and port dimension are a function of design requirements and are variable depending upon the desired purpose and function of the lumen or port, e.g., pressure sensing, infusion, evacuation, guidewire, flow sensing, or flow conduit.

[065] In order to aid a physician in visualizing the CVAF 10 *in vivo*, at least one radio-opaque or other viewable marker may be provided. A first marker 24 is provided at the distal end of the outer sheath 22 and a second marker 26 may be provided at a distal tip 33 of the catheter body

12. It will be understood that when the outer sheath 22 is in its non-retracted delivery position, that the filter 16 will be covered and the marker 24 and the second marker 26 will be adjacent or in close proximity with one another. Alternatively, the outer sheath 22 may, itself, be made of or include a radio-opaque or other viewable material, such as a metal braid or metal reinforcement within or applied to a polymeric sheath. The first and second markers 24, 26 or the material of the outer sheath 22 may enhance visualization of the CVAF 10 under fluoroscopy, ultrasound or other visualization or guidance technique.

[066] Figs. 6-11 illustrate a second embodiment of the CVAF 50. Unlike CVAF 10, CVAF 50 does not include the central guidewire lumen 30 of CVAF 10. Rather, while the general construct of CVAF 50 is similar to that of CVAF 10, a different configuration of the inner lumens is employed.

[067] CVAF 50, like CVAF 10, consists generally of a multi-lumen central venous access catheter body 12 having a proximal port 32 associated with a first lumen 54 and a distal port 34 associated with a second lumen 58, a filter member 16, having a fixed first end 18 and a moveable second end 20, is positioned generally intermediate the distal port 34 and the proximal port 32 and is generally concentric relative to the catheter body 12. Use of the term “generally intermediate” is intended to mean that at least a substantial portion of the filter member 16 resides intermediate the distal port 34 and the proximal port 32. Thus, the filter member 16 may partially overlay either or both of the proximal port 32 or the distal port 34.

[068] The catheter body 12 has a proximal section 13 and distal section 14, which is longitudinally opposite the proximal section 13 which may have a relatively smaller diametric profile than the proximal section 13. As described above, the first lumen 54 terminates at the proximal port 32, while the second lumen 58 terminates at the distal port 34. An atraumatic tip 52 terminates the catheter body 12 at its distal end. The atraumatic tip 52 preferably includes a radio-opaque marker to aid in positional visualization of the distal end of the catheter body 12.

[069] A plurality of infusion lumens 56 are provided, each having at least one infusion port 36, preferably plural infusion ports 36, that passes through a wall of the catheter body 12 and communicates with a space defined within an area bounded by the filter member 16. Bioactive agents, flushing fluids, pressurized mechanical thrombolytic fluids, or other fluids may be infused through the infusion lumens 56 and out of the at least one infusion port 36 to pass into

the space defined by the filter member 16 and ultimately into the patient's venous system for either local or systemic effect. In accordance with one embodiment of the invention, the each of the plural infusion lumens 56 are in fluid communication with plural ports 36 arrayed along both the longitudinal axis and the circumferential axis of the catheter body. This configuration provides for fluid infusion along both the longitudinal axis and the circumferential axis of the catheter body 12 and in direct communication with the space defined by the filter member 16 that captures thrombus.

[070] The infusion lumens 56, the first lumen 54 and the second lumen 58 are bounded by and separated from each other by first catheter septum 51 and second catheter septum 56 which also aid in providing structural support for the catheter body 12. First catheter septum 51 is a generally diametrically and longitudinally extending member that divides the first lumen 54 from the second lumen 58 along the longitudinal axis of the catheter body 12. Second catheter septum 56 may comprise a generally U-shaped member that intersects the first catheter septum 51 at a lower aspect of the septum and is connected with an inner wall surface of the catheter body 12 at upper aspects of the septum 51 to define two infusion lumens in lateral regions of the catheter body 12.

[071] The filter member 16 has two general configurations. A first configuration consists generally of two opposing generally open conical sections formed by plural interconnected structural elements defining the lateral surfaces of each open conical section, wherein the two opposing generally open conical sections each have open bases facing each other which are interconnected by a generally cylindrical section of the filter member 16. Each open conical section has an open base and an apex, wherein the apices project in opposing directions, with one apex projecting proximally and another apex projecting distally relative to the axis of the catheter. The plural interconnected structural elements forming the lateral surfaces of each generally open conical section may be strut-like structural members extending generally axially along the longitudinal axis of the filter member 16. The axially extending strut-like structural members may be linear members or may be curved members. The apices of each of the generally open conical sections are formed either of a generally cylindrical collar that serves to couple the filter member 16 to the catheter body 12. The generally cylindrical collar is concentrically engaged about the catheter body 12 and may be axially movable thereupon, or is formed by connections between adjacent pairs of longitudinal strut-like structural members



which circumscribe a circumference of the catheter body 12. The generally cylindrical section of the filter member 16 is formed by a generally open lattice of interconnected structural elements which connect the base of a first open conical section to the base of a second open conical section. The generally cylindrical section of the filter member 16 lies in apposition with a vascular wall upon deployment of the filter member 16 with a vascular lumen.

[072] A second general configuration of the filter member 16 consists generally of a single generally open conical section in which a plurality of longitudinal strut-like structural members form the lateral surfaces of the conical section and are connected to a generally cylindrical collar which couples the filter member 16 to the catheter body 12 at an apex of the generally open conical section. The base of the generally open conical section is formed by opposing ends of the longitudinal strut-like structural members. A generally cylindrical section of the filter member 16, formed of a generally open lattice of interconnected structural elements, extends from the longitudinal strut-like structural members forming the base of the generally open conical section, to provide a region of the filter member 16 which is in apposition to the vascular wall upon deployment of the filter member.

[073] One embodiment of the filter member 16 is illustrated in its diametrically expanded configuration in Figs. 12-13D. In this embodiment, filter member 16 consists generally of a first end 18 and a second end 20, each of which consists generally of a tubular structure which is circumferentially positioned about a section of the catheter body 12. One of the first end 18 and second end 20 are fixedly coupled to the catheter body 12, while the other is movable relative to the catheter body 12. At least one of a plurality of first strut members 62, are coupled at their first end to the first end 18 of filter member 16 and each extends axially relative to the longitudinal axis of the catheter body 12. Each of the first strut members 62 is an elongate member that, upon diametric expansion of the filter member 16, flares away from the central longitudinal axis of the catheter body 12, in a generally tapered conical manner, and terminates in an end section 63 that bends generally parallel to and along the longitudinal axis of the catheter body 12. A plurality of second strut members 64 are coupled at an end to the second end 20 of filter member 16 and each extends parallel relative to the longitudinal axis of the catheter body 12. A plurality of third strut members 66 are coupled at ends thereof to an end of the filter member and each extends parallel relative to the longitudinal axis of the catheter body 12.

[074] It will be appreciated, by those skilled in the art, that the number of struts employed as the first strut members 62, the second strut members 64 and the third strut members 66 forming the filter member 16 may be evenly distributed about a 360 degree circumference and define the lateral wall surfaces of the filter member 16. A circumferential member 70 extends  
5 circumferentially to define a circumferential axis of the filter member 16 and has a series of continuous undulations defining peaks a series of peaks 75 and valleys 77 about the circumference of filter member 16. Each of the plurality of first strut members 62, the plurality of second strut members 64 and the plurality of third strut members 66 are coupled to the circumferential member 70 at different points about its circumferential axis and intermediate the  
10 proximal end 18 and the distal end 20 of the filter member 16. In its unexpanded state the filter member 16 has a generally tubular shape, while in its expanded state the filter member 16 assumes one of the general configurations discussed above, i.e., either oppositely extending generally open conical sections or a single generally open conical section.

[075] The plurality of first strut members 62 are preferably offset from each other by  
15 approximately 120 degrees about the circumference of the catheter body 12. The plurality of second strut members 64 are also preferably offset from each other by approximately 120 degrees. Finally, the plurality of third strut members 66 are also preferably offset from each other by approximately 120 degrees. Each of the plurality of first strut members 62 couple at a junction 76 to the circumferential member 70 at a peak thereof. Similarly, each of the plurality  
20 of third strut members 66 couple at junction 76 to the circumferential member 70 at a peak thereof. In this manner, a first strut member 62 and a third strut member 66 are each coupled to circumferential member 70 at junction 76 and, in this relationship, form a generally linear member that extends along the longitudinal axis of the catheter body and connects between the proximal end 18 of the filter member 16 and the distal end 20 of the filter member 16. Each of  
25 the second strut members 64 couple, at their proximal ends to a valley 77 of the circumferential member 70 and connects at a junction 79. Unlike the connections at junction 76 between the plurality of first strut members 62 and the plurality of second strut members, in this embodiment of the filter member 16, there is no member that connects to junction 79 and extends from the first end 18 of the filter member 16. In this configuration, the circumferential member 70  
30 assumes a generally circumferential tri-leaflet ring having three peaks 75 and three valleys 77 which circumferentially circumscribe a central opening 72 which faces inferiorly relative to the

patient's blood flow such that the blood flow first passes into the central opening 72 and past the third strut members 66 and the second strut members 64 then past the first strut members 62.

[076] To facilitate bending and folding of the circumferential member 70 between the expanded and unexpanded states, generally U-shaped hinge members 74 may be provided at each of the valleys 77 of the circumferential member 70. It will be understood that each of the plurality of first strut members 62, plurality of second strut members 64, plurality of third strut members 66 and the circumferential member 70 are preferably fabricated of biocompatible materials, such as shape memory alloys, superelastic materials or elastic materials, including, without limitation, titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, such as zirconium-titanium-tantalum alloys, cobalt-chromium-molybdenum alloys, nitinol, and stainless steel.

[077] Figs. 14A-14H and corresponding Figs. 15A-15H depict alternative embodiments of the filter member 16, labeled 80, 90, 100, 110, 120, 130, 140 and 150, respectively. Like filter member 16, each of filter members 80, 90, 100, 110, 120, 130, 140 and 150 having a first end 18 and a second end 20 that each consist of a generally ring-like structure intended to circumferentially couple to a catheter body 12 (not shown), with the first end 18 being fixed and the second end 20 being reciprocally moveable axially along the distal portion 14 of catheter body 12. Like filter member 16, each of the alternative filter member embodiments depicted in Figs. 14A-14H and 15A-15H, consist of a plurality of first strut members 81, 91, 101, 111, 121, 131, 141 and 151, respectively, extending distally from the first end 18 of the filter member and a plurality of second strut members 83, 93, 103, 113, 123, 133, 143 and 153, respectively, extending proximally from the distal end 20 of the filter member, with a diametrically expandable circumferential member 87, 97, 107, 117, 127, 137, 147, 157, respectively, interconnecting the distally extending strut members 81, 91, 101, 111, 121, 131, 141 and 151, respectively, with the proximally extending strut members 83, 93, 103, 113, 123, 133, 143 and 153. In the alternative embodiments of filter members 100, 110 and 120, at least some distally extending strut members and at least some of the proximally extending strut members form linear elements that extend along the entire longitudinal axis of the respective filter member, with the circumferential member being comprised of at least one undulating or serpentine ring structure.

[078] In the alternative embodiments of filter members 80, 90, 130, 140 and 150, a plurality of distally extending strut members are provided spaced approximately 120 degrees apart from one and other about the circumference of the filter members, and the distally extending strut members bifurcating once or twice distally in a generally Y-shaped manner as in filter members 80, 130, 140 or 150, or the proximally extending strut members bifurcating proximally in a generally Y-shaped manner and interconnecting with the distally extending generally Y-shaped strut members to form a diamond-like pattern as in filter member 90. In filter members 90 and 140, the circumferential member is formed by the diamond-like pattern formed by the intersection of the plurality of struts. In contrast, in filter members 80, 130 and 150, the circumferential member is formed by at least one undulating or serpentine ring structure which is diametrically expansible. As illustrated in filter members 110, 120 and 130, apical portions of each undulating or serpentine ring structure is interconnected by an interconnecting member 114, 124, 134, respectively, either with an adjacent ring structure, as in filter member 110 or to a distal end 20 of the filter member itself. A longitudinally serpentine section 132 in filter 32 may be provided in conjunction with the interconnecting member 134, to afford greater expansive properties to the circumferential member 137.

[079] According to some embodiments particularly well-suited for placement by femoral or other infrarenal approach, the filter member 16 is characterized by a generally conical filter member 16 having a greater open surface area exposed to the flow of embolic material into the filter at its proximal end, while the distal end has smaller open surface area exposed to the flow of embolic material to capture the embolic material in the distal end of the filter member.

[080] In other embodiments particularly well-suited for placement by a jugular or suprarenal approach, the filter member 16 is characterized by a generally conical filter member 16 having a greater open surface area exposed to the flow of embolic material into the filter at its distal end, which the proximal end of the filter member 16 has a smaller open surface area exposed to the flow to capture smaller embolic material in the distal end of the filter member 16.

[081] Additionally, in all of the embodiments the filter member 16 is self-centering to provide proper apposition against the vascular walls and centering within the lumen of a blood vessel. This maximizes the flow dynamics of the filter member 16 within the blood vessel for purposes

of capturing embolic material within the struts of the filter and centers the catheter body member 12 within the vascular lumen.

[082] As noted above, the proximal 32 and distal 34 ports serve as means for measuring flow rates or pressure differentials across the filter 16. This may be accomplished by including flow sensors and/or pressure transducers 19 in operable association with each port 32, 34, with the associated electrical connections to the flow sensors and/or pressure transducers 19 passing through the respective lumens associated with each port 32, 34 and terminating at the proximal end of the catheter body 12. Where flow sensors 19 are employed, a single flow sensor associated with proximal port 32, the distal port 34 or the distal end of outer sheath 22 may be sufficient to detect fluid flow rate at the position of the catheter body 12. By providing a flow sensor at the distal end of sheath 22, the clinician will be able to determine flow velocity at the distal end of the outer sheath 22 prior to introducing the catheter body 12 and make fine adjustments to the placement of the distal end of the outer sheath 22 to ensure proper placement for the filter member 16. Plural flow sensors 19 may be employed and operably associated with each of proximal port 32 and distal port 34 to sense changes in flow velocity across the filter member 16. Alternatively, the flow sensors and/or pressure transducers 19 may reside in communication with the lumens respectively associated with each port 32, 34 at the proximal end of the catheter body 12, thereby eliminating the need for electrical connectors resident with the associated lumens. Furthermore, wireless flow sensors and/or pressure transducers may be provided in communication with each port 32, 34, and be operably coupled to a power source and a transmitter to wirelessly transmit telemetry data from the transducers to a wireless receiver in communication with the transmitter, as is known in the art.

[083] Alternatively, the proximal 32 and distal ports 34 may be used for monitoring or sensing other conditions in the body that are detectable in the blood. For example, analyte sensors may be introduced to either the lumens communicating with the proximal 32 or distal ports 34 or to the ports themselves to monitor and/or sense chemical or biochemical conditions in the body. An example of this application is monitoring or sampling blood glucose levels for diabetes control. Further, the proximal 32 and distal ports 34 may be used for fluid infusion or for withdrawal or evacuation of fluids or other material through the catheter body 12. In this later instance, where the proximal port 32 is positioned to underlay the filter member 16, thrombus collected in the filter member 16 may be capable of being lysed, either by thrombolysis through the

infusion ports 36 or under the influence of thermal or mechanical lysis, such as by introducing a laser, ultrasound or other system capable of lysing thrombus, which may be introduced through the lumen communicating with the proximal port 32, or the distal port 34 or the guidewire lumen 30, or introduced separately from the CVAF 10, positioned within the space bounded by the filter member 16, lysing thrombus collected in the filter member 16 and evacuating the lysed thrombus through the proximal port 32

[084] It is known that flow rate increases proximally within the venous system. For example a flow rate of 1 L/min is typical in one femoral vein, increases to 2 L/min in the inferior vena cava and increasing another 0.7 to 1 L/min proximate the renal veins. Knowing the typical flow velocities in vessels of different transverse cross-sectional areas, coupled with a flow sensor 19 associated with the multi-lumen catheter body 12 may serve to supplement or replace the requirements for fluoroscopy or sonography in placement of the CVAF 10, 50.

[085] Other sensors, such as, for example, chemosensors, color sensors, electrical sensors or biosensors, may be employed in lieu of or in addition to pressure transducer and/or a flow sensor 19 in order to detect other changes or conditions within the patient's vasculature. For example, color sensors exist that sense color changes in thrombus, such color changes may be displayed and interpreted by the medical practitioner as an indication of thrombus staging. Analyte sensors, such as a glucose sensor or an oxygen saturation sensor may also be employed.

[086] The filter member 16, or its alternative embodiments described above, may be fixed to the catheter body 12 or may be removably coupled to the catheter body 12 for deployment as either a permanent filter or as a temporary and retrievable vena cava filter. Removable coupling of the filter member to the catheter body 12 may be accomplished with a variety of release and retrieval mechanisms operably associated the catheter body 12 and proximate the diametric transition 15. Non-limiting examples of such release and retrieval mechanisms include a wire release that engages with a the first end 18 of the filter, a cooperating indexed detent and projection interaction between the catheter body 12 and the first end 18 of the filter, such as a detent in the proximal end of the filter and a cooperating projection in the multi-lumen catheter that is positionally indexed to the detent and releasable from the detent, or, alternatively, a helical slot or threads may be formed in the proximal end 18 of the filter and indexed and cooperating

projection in the multi-lumen catheter than permits engagement and disengagement with the helical slot or threads.

[087] In use, an introducer sheath is first placed into the body in a normal manner for introducing a central venous line, such as by the Seldinger technique. Specifically, after

5 accessing a vein using a large bore needle, under local anesthesia, a guidewire is inserted through the needle bore and passed into the vein. Once the guidewire is positioned, the needle is withdrawn, and a dilator together with the introducer sheath introduced over the guidewire.

Once the introducer sheath is positioned at a desired location within the venous system under radiography, the dilator may be removed from the patient. Radiopaque markers associated with

10 the introducer sheath may be employed to assist in positional visualization of the distal end of the introducer sheath. The outer sheath 22 covering the filter 16 is removed while introducing the filter member 16 and catheter body 12 into the introducer sheath. The outer sheath 22 constrains the filter member 16 during its passage through the introducer sheath and positioning the distal end of the catheter within the patient's vasculature. Once the distal end of the catheter body 12

15 reaches the distal end of the introducer sheath, the filter is deployed. If the filter therapy alone is desired, the filter member 16 is detached from the catheter body 12 and the catheter body 12, introducer sheath and guidewire is withdrawn from the patient. Where both central venous access and filter therapy is desired, the introducer sheath and catheter body 12 with the filter member 16 is left in the patient until withdrawal is required.

20 [088] Retrieval and removal of a detached filter member 16 is accomplished using a second procedure under local anesthesia which substantially replicates the placement of the CVAF, with a capture sheath (not shown), similar to introducer sheath, being introduced, a retrieval catheter being introduced through the sheath, and engaging the filter member 16, then withdrawn into the capture sheath to collapse the filter member 16, with the entire assembly of the filter member 16, 25 catheter body 12, outer sheath 22 and guidewire, if used, is withdrawn from the patient.

[089] As depicted in Figs. 16A and 16B, which depict the undeployed state (Fig. 16A) and the deployed state (Fig. 16B) of the filter member 216, respectively, common to each of the embodiments of the present invention 200 is an inner catheter 214 that carries the vena cava filter 216 at a distal end thereof. The inner catheter 214 is concentrically and reciprocally engaged 30 within an outer sheath 222 such that relative axial movement of the inner catheter 214 and the

outer sheath 222 either exposes the vena cava filter 216 for deployment or captures the vena cava filter 216 for retrieval. A first hub member 225 is coupled to a proximal end of the outer sheath 222 and a second hub member 227 is coupled to a proximal end of the inner catheter 214. First hub member 225 and second hub member 227 are engageable, such as by a threaded, bayonet, snap fit, friction fit or interference fit fitting, to secure the inner catheter 214 within the outer sheath 222 and restrict relative axial movement of the two elements after deployment of the vena cava filter 216. A flush line 229 communicates with the first hub member 225 and is in fluid communication with a luminal space within the outer sheath 222. A plurality of fluid lines 231, 233, 235, 237 communicate with the second hub member 227 and are each in fluid communication with one of the plural lumens within the inner catheter member 214, e.g., lumens communicating with the proximal, distal or infusion ports (not shown). A distal tip 26 is provided at a distal end of the inner catheter.

[090] A jugular approach necessitates that the catheter be introduced retrograde relative to the vector of blood flow within the vena cava, i.e., the catheter is introduced through the jugular vein and directed inferiorly toward an infrarenal position. Additionally, since the blood flow opposes the distal end of the catheter and passes toward the proximal end, the vena cava filter must open inferiorly such that its largest diametric section in apposition to the vessel walls opens toward the distal end of the catheter rather than toward the proximal end of the catheter as with the femoral approach.

[091] Figures 17-20 depict alternative embodiments of vena cava filter members in accordance with the present invention. Figure 17 illustrates a filter orientation for a femoral approach, while Figures 18-20 illustrate a filter orientation for a jugular approach. As illustrated in Figure 17, filter member 216 defines a relatively larger volume open space 201 and a relatively smaller volume open space 203. Open spaces 201 and 203 are bounded by structural members of the filter member 216 and are both open toward the direction of blood flow indicated by arrow 5, with larger open space 201 being relatively upstream the blood flow relative to smaller open space 203 in both the femoral or the jugular orientation of filter member 216.

[092] As with all previous embodiments described of the filter member, filter member 216 is formed of plural interconnected structural elements. In accordance with the preferred embodiments of the filter members of the present invention, and as particularly exemplified by



filter member 216, the filter member has a first end 218 and a second end 220, at least one of which is attached to the distal section 214 of the catheter body 212. First structural members 217 extend generally axially, either proximally as shown in Fig. 17 or distally as shown in Fig. 18, along the longitudinal axis of the filter member 216. Again, it is understood that use of the terms “proximal” or “proximally” and “distal” or “distally” are intended to refer to positions relative to the longitudinal axis of the catheter body 212. The first structural members 217 are connected to either the first end 218 or the second end 220 of the filter member 216. Second structural members 219 are connected to the first structural members 217 at an end of the first structural members 217 which is opposite that connected to either the first end 218 or the second end 220 of the filter member 216. In accordance with a preferred embodiment of the invention, the second structural members 219 form at least two successive zigzag shaped structures which are connected to an end of the first structural members and at opposing apices 223 to form conjoined ring-like structures about the circumference of the filter member 216. In this manner the second structural members 219 generally define lattice-like pattern upon diametric expansion of the filter member 216. The lattice-like pattern formed by the second structural members 219 projects axially along the longitudinal axis of the catheter 214 tapering to form at least one petal-like projection 225 that terminates in a terminal apex member 227. As will be appreciated by those skilled in the art, Fig. 17 depicts three petal like projections 225, with one being behind the plane of the figure and, therefore, not shown. Each of the petal-like projections 225 act to engage and oppose vascular wall surfaces to seat the filter member 216 against the vessel wall, and center the filter member and catheter 214 within the vascular lumen. As illustrated in Fig. 17, third structural members 221 are provided and are connected to each of the terminal apex members 227 and extend axially relative to the catheter 214 and connect with a second end 218 of the filter member 216.

[093] In the embodiment illustrated in Fig. 17, which is an orientation of the filter member 216 for a femoral approach, and in the embodiment illustrated in Fig. 19, which is an orientation of the filter member 216 for a jugular approach, the first end 218 of the filter member 216 is fixedly connected to the catheter 212, while the second end 220 of the filter member 216 is movably coupled to the catheter 212 and moves axially along the catheter 216 upon expansion or contraction of the filter member 216.

[094] Fig. 18 depicts an embodiment of the filter member 216 identical to that illustrated in Fig. 19, with the sole exception that the third structural members 219 and the second end 220 of the filter member 216 are omitted. In this embodiment, the terminal apex member 227 of each petal-like member 225 are not connected to a second end 220 of the filter member 216 by the third structural members 219.

[095] Fig. 20 depicts an alternative embodiment of the filter member 216 which is similar to that depicted in Fig. 18, except that at least one circumferential ring member 252 is connected to the terminal apex member 227 of each of the petal-like members 225 at a juncture 253 with the terminal apex member 227. The addition of the additional circumferential ring member 252 results in a relative elongation over the length L1 of the filter member 216 depicted in Fig. 18 by a length L2 which facilitates additional apposition between the filter member 216 and the vascular wall and stabilization of the petal-like members 225.

[096] Figs. 21A and 21B depict an alternative embodiment of the filter member 216 in Fig. 18, having first end 318, first structural elements 317 and second structural elements 319 all analogously arranged as in the embodiment of Fig. 18. Filter member 300, however, employs a modified distal end 314 of the catheter 312 to include an expansive balloon 360. The guidewire lumen of the multi-lumen catheter 312 may be used in place of a distal port for condition sensing, flushing, infusion or the like. The expansive balloon 360 may be used to break up thrombus captured within the filter member 316, either by mechanical force through serial dilatation or by infusion of a thrombolytic agent through openings in the balloon 360. Fig. 21A depicts the balloon 360 in its collapsed state, whereas Fig. 21B depicts the balloon in its expanded state.

[097] Alternatively, an expansive balloon 360 may be placed proximal the filter member 300 and serve to temporarily occlude the vessel to facilitate aspiration or evacuation of thrombus from the filter member 30.

[098] Figs. 22A and 22B depict an alternative embodiment of the filter member 216 in Fig. 20 having first end 418, first structural elements 417 and second structural elements 419, at least one circumferential ring member 452 connected to the terminal apex member 427 of each of the petal-like members 425 at a juncture 453 with the terminal apex member 427; all analogously arranged as in the embodiment of Fig. 20. Filter member 400, however, employs a modified

distal end 414 of the catheter 412 to include an expansive balloon 460. The guidewire lumen of the multi-lumen catheter 412 may be used in place of a distal port for condition sensing, flushing, infusion or the like. The expansive balloon 460 may be used to break up thrombus captured within the filter member 416, either by mechanical force through serial dilatation or by infusion of a thrombolytic agent through openings in the balloon 460. Fig. 22A depicts the balloon 460 in its collapsed state, whereas Fig. 22B depicts the balloon in its expanded state.

[099] Again, an expansive balloon 460 may be positioned proximal the filter member 416 to permit temporary occlusion of the blood vessel and permit aspiration or evacuation of thrombus from the filter member 416.

[0100] Each of the foregoing embodiments of the present invention may further be adapted for use with an imaging modality to facilitate intravascular imaging of the filter member from beyond or within a lumen of the multi-lumen catheter. Additionally, in some embodiments, the imaging modality may pass entirely through the distal tip of the multi-lumen catheter, and enable an operator to use the intravascular imaging modality to visualize the origins of the renal veins.

This could allow the operator to place the catheter without use of external imaging (i.e. fluoroscopy, trans-abdominal duplex ultrasound, CT, etc.).

[0101] Generally, intravascular imaging systems utilize a sheath through which a signal is transmitted and received. In the present invention, the multi-lumen catheter with associated filter member may serve as the sheath for introduction of an intravascular imaging system, permitting improved imaging of the condition of the filter member while in use. In particular, the use of an intravascular imaging system with the multi-lumen catheter with associated filter member will permit a medical professional to monitor the condition of the filter member, and utilize appropriate techniques to lyse a collected thrombus. Because of the improved imaging, the lysing techniques may be more specifically and accurately targeted, as compared to lysing techniques applied without the benefit of imaging the condition of the filter member. In other, alternative, embodiments, the intravascular imaging system may also enable a medical professional to visualize the filter catheter for placement within a patient.

[0102] Fig. 23 depicts a cross-sectional side view of one embodiment of the expanded filter member and catheter assembly of Fig. 12, further comprising an imaging modality. In this embodiment, filter member 516 consists generally of a first end 518 and a second end 520, each

of which consists generally of a tubular structure which is circumferentially positioned about a section of the catheter body 512. One of the first end 518 and second end 520 are fixedly coupled to the catheter body 512, while the other is movable relative to the catheter body 512. The filter member is structurally analogous to that discussed above, such as in relation to Fig. 12 above. In its unexpanded state the filter member 516 has a generally tubular shape, while in its expanded state the filter member 516 assumes one of the general configurations discussed above, i.e., either oppositely extending generally open conical sections or a single generally open conical section. The assembly may further comprise an outer sheath 522 disposed over the catheter body 512.

[0103] The catheter body 512 includes a distal portion 514 about which the filter member 516 is disposed. Catheter body 512 further includes at least one lumen 530, such as a central guidewire lumen, which may extend the entire longitudinal length of the catheter body 512 and may terminate at the distal end of the catheter body 512 at a distal opening 531. The central lumen 530 may be used to house and/or introduce elements of an imaging system. In another embodiment, the lumen into which the imaging system is disposed is not the central lumen, but another lumen of the multi-lumen catheter body 512, so long as the imaging system is able to image the filter member 516. Some non-limiting examples of imaging systems include intravascular ultrasound (IVUS), optical coherence tomography (OCT), side looking OCT, ultrasound, thermography, IR imaging, Florence imaging, luminescent imaging, MRI, videography, photoacoustic, and other similar imaging technologies. These systems may permit 360 degree imaging, or be side looking and rotatable to image through 360 degrees. In one embodiment, the system generally includes an imaging core drive cable 630 and an imaging probe 650. The imaging probe 650 may be a tip, cone, and/or the like disposed at a distal end of the imaging core drive cable 630, wherein the imaging probe 650 and/or the drive cable 630 are operably connected to an external system (not shown) for operating the imaging system.

[0104] In one embodiment, the imaging probe 650 may be disposed within a portion 600 of the central lumen 530 bounded by a proximal end 518 and a distal end 520 of the filter member 516. Thus, the imaging probe 650 may be operated to help a user detect the presence of a thrombus captured by the filter member 516. Further, the imaging probe 650 may also help detect the size and/or position of a captured thrombus. The imaging probe 650 may be rotated and/or translated within the lumen 530, so as to permit imaging of the entire filter member 516. Alternatively, the

imaging probe 650 may be adapted to permit 360 degree imaging of the filter member 516 without requiring rotation. In a further embodiment, the imaging probe 650 may be adapted to permit imaging of the length of the filter member 516 without distal or proximal translation. Preferably, the imaging probe 650 is operable to image the filter member 516 in an expanded state.

[0105] In one embodiment, the position of the imaging probe 650 relative to the filter member 516 may be determined. In one embodiment, the imaging probe 650 may further comprise a radiopaque material to permit external imaging of the probe 650 to determine its location relative to the filter 516, which as described above may have its own radiopaque markers. In another embodiment, the drive cable 630 may have measured markings disposed thereon to permit determination of the position of the imaging probe 650 relative to the filter 516, based on the relationship between the markings on the drive cable 630 and the conduit into which the imaging probe 650 and drive cable 630 are inserted.

[0106] In order to monitor the condition of the filter member 516, the imaging probe 650 may transmit and receive an imaging signal through a wall of the lumen 530. The imaging signal may depend upon the particular imaging system utilized, and generally comprises a transmitted signal, wave, energy, or the like that is emitted from the imaging probe 650 in order to image or visualize the filter member 516. In a preferred embodiment, the relevant portion of the lumen 530 is a section 600 of the distal portion 514 of the catheter body 512 bounded by the proximal end 518 and distal end 520 of the filter member 516. The dimensions and/or material of any or all of either the bounded portion 600 or the distal portion 514 may be selected to maximize imaging signal transmission and/or imaging signal clarity. Examples of appropriate materials include, but are not limited to, polyethylene, PTFE, and other polymers.

[0107] Alternatively, in some embodiments the filter 516 may be attached to a distal end of a single or a multi-lumen catheter 512. In these embodiments, the region bounded by the proximal and distal ends of the filter 516 is open and free of imaging obstruction. The imaging modality may be disposed through the lumen of the catheter 512 and translated such that it extends beyond the distal end of the lumen and into the open region between the proximal and distal ends of the filter 516.

[0108] Where the imaging system is an IVUS system, preferably the portion of the catheter body 512 from which the imaging probe 650 images is acoustically transparent to allow for the transmission of the imaging signal, ultrasound waves for IVUS, through the body 512. The imaging probe 650 may comprise an ultrasound transducer connected to the distal end of a drive cable 630, which extends through the lumen 530 of the catheter body 512. The drive cable 630 is used to rotate and translate the transducer of the imaging probe 650 within the catheter lumen 530. The drive cable 630 may possess a high torsional stiffness so that the drive cable 630 can transmit torque from a drive motor (not shown) to the transducer to rotate the transducer. In another embodiment, rotation of the transducer is not necessary, such as when the imaging probe 650 is capable of 360 degree imaging. The drive cable 630 may also possess a low bending stiffness allowing the drive to bend along a tortuous path of a blood vessel. The imaging probe 650 is operably connected to ultrasound electronics (not shown) external a patient. In one embodiment, the operable connection may be via a wire that runs along the drive cable 630.

[0109] As an optical analog of ultrasound, intravascular OCT uses a high-bandwidth light source instead of an ultrasound-emitting crystal to create high-resolution images. OCT is an interferometric technique, typically employing near-infrared light, where an optical beam is directed at tissue, and a small portion of this light that reflects from sub-surface features is collected. Where the imaging system is an OCT system, preferably the portion of the catheter body 512 from within which the imaging probe 650 images is optically transparent to allow for the transmission of the imaging signal, light waves for OCT, through the portion of the catheter body 512. The imaging probe 650 may comprise an optical emitter connected to the distal end of a drive cable 630, which extends through the lumen 530 of the catheter body 512. The drive cable 630 is used to rotate and/or translate the optical emitter of the imaging probe 650 within the catheter lumen 530. The imaging probe 650 is operably connected to OCT electronics (not shown) external a patient. In one embodiment, the operable connection may be via a wire that runs along the drive cable 630. In another embodiment, the operable connection may be via an optical waveguide that runs along the drive cable 630.

[0110] Further, the imaging modality may generally be incorporated into any of the above disclosed embodiments of the multi-lumen catheter and filter member assembly.

[0111] In another embodiment, an imaging probe may be disposed within a lumen of the IVC filter catheter, without an imaging catheter coupled thereto.

[0112] In still another embodiment, an imaging catheter, housing an imaging probe therein, may be disposed within a lumen of the IVC filter catheter. In this embodiment, the imaging catheter is not coupled to the IVC filter catheter, and may be disposed within an appropriately sized lumen of the IVC filter catheter. The imaging modality may thus be positioned within or beyond a lumen of the IVC filter catheter, as a self contained system.

[0113] In another embodiment, an imaging catheter, housing an imaging core therein, is integral with a lumen of the IVC filter catheter. The imaging core may be translated proximally and/or distally relative to the imaging catheter and/or the IVC filter catheter.

[0114] In another embodiment, a medial filter port may be used as a conduit to deliver an imaging catheter to the caval space within the filter. The imaging catheter may be coupled to the proximal hub of the catheter, by any one of the proximal hubs as disclosed US provisional patent application serial number 61/584,716, filed January 9, 2011, US patent application serial number 13/083,053, filed April 8, 2011, which are hereby incorporated by reference in their entirety.

[0115] In another embodiment, the imaging probe 650 may be disposed within a lumen of a multi-lumen catheter sheath, such as that disclosed in commonly owned and co-pending US provisional patent application serial number 61/668,308, filed July 5, 2012, which is hereby incorporated by reference in its entirety. In this embodiment, the imaging probe 650 may be disposed in the lumen of the multi-lumen sheath rather than the filter catheter. The imaging probe 650 may be translated so as to be disposed within a region bounded by the proximal end 518 and distal end 520 of the filter member 516. The structure and operation of this embodiment is analogous to those disclosed above.

[0116] Generally, the imaging system may be used with the filter member to monitor the condition of the filter member and to capture a thrombus within a blood vessel. This may be accomplished by introducing the multi-lumen catheter, having the filter member coupled thereto, into the blood vessel. The catheter may then be deployed within the blood vessel such that the filter has an enlarged diametric opening facing a patient's blood flow. The imaging system may then be translated through a lumen of the multi-lumen catheter and be operable to image or visualize the condition of the filter member. If a thrombus is detected, then a fluid may be

infused through at least one lumen in the multi-lumen catheter in communication with at least one infusion port passing through the multi-lumen catheter and open to an inner spatial area bounded by the filter member. Alternatively, other means of lysing a detected thrombus may be utilized, such as thermal or mechanical lysis, such as by introducing a laser, ultrasound, or other system capable of lysing thrombus.

[0117] In another embodiment, the imaging system may be used with a multi-lumen sheath coupled to a filter catheter, such that the imaging system is disposed within a lumen of the multi-lumen sheath and images the filter member.

[0118] It will be appreciated by those skilled in the art that in all embodiments of the described central venous access filter, the filter member has a relatively larger opening that is open inferiorly in a direction that opposes the blood flow vector and employs structural elements that taper superiorly along the direction of the blood flow vector to reduce the open surface area of the filter member and capture thrombus.

[0119] Thus there has been described a central venous access filter in accordance with the foregoing embodiments of the invention which include, generally, a multi-lumen catheter body, a filter member and an introducer sheath. The multi-lumen catheter body has a plurality of ports each of which are in fluid flow communication with at least one lumen in the multi-lumen catheter body. Lumens may include a central guidewire lumen useful for tracking over a guidewire and/or larger volume infusion of bioactive agents, intravenous fluids, blood transfusions, or other fluids; infusion lumens in communication with infusion ports positioned to direct fluids to the space bounded by the filter member for introducing bioactive agents, including thrombolytic agents or flushing agents, including pressurized fluids for mechanical thrombolysis directly to the capture site of the thrombus in the filter member; and lumens communicating with proximal and distal ports which may also be used for fluid introduction and/or may house or communicate with sensors, such as pressure transducers, flow sensors, analyte sensors, color sensors, optical sensors or the like. The filter member may be detachable from the multi-lumen catheter body to permit temporary filter placement and later retrieval by a detachment mechanism that cooperates between the filter and the multi-lumen catheter body. These and other aspects of the present invention are provided by way of non-limiting examples,



with the claims appended hereto serving to define the scope of the subject matter regarded as the invention.

**Claims**

What is claimed is:

1. A method of capturing thrombus within a blood vessel, comprising the steps of:
  - a. introducing a catheter having a filter member coupled thereto;
  - b. deploying the catheter within a blood vessel such that the filter has an enlarged diametric opening which opens facing a patient's blood flow; and
  - c. imaging the filter member with an imaging system operable to detect a condition of the filter member.
2. The method according to claim 1, wherein the step of imaging the filter member further comprises confirming the presence of a thrombus captured by the filter member.
3. The method according to claim 1, wherein the imaging system is selected from the group comprising an intravascular ultrasound system and an optical coherence tomography system.
4. The method according to claim 1, wherein the step of imaging the filter member further comprises inserting the imaging system into a lumen of the catheter and disposing an imaging probe of the imaging system in a region of the catheter bounded by a proximal end and a distal end of the filter member.
5. The method according to claim 4, wherein the imaging probe is adapted to be translated at least one of proximally or distally relative to the filter member.
6. The method according to claim 4, wherein the imaging probe is adapted to be rotated relative to the filter member.
7. The method according to claim 1, wherein the step of introducing a catheter further comprises disposing the catheter in a lumen of a multi-lumen sheath, and introducing the multi-lumen sheath having the catheter disposed therein.

8. The method according to claim 7, wherein the imaging system is disposed within a lumen of the multi-lumen sheath.

5 9. A multi-lumen filter catheter, comprising:

- a. a multi-lumen catheter body having a plurality of lumens;
- b. a filter member coupled to the catheter body; and
- c. an imaging system operable to detect a condition of the filter member.

10 10. The multi-lumen filter catheter according to claim 9, wherein the imaging system is selected from the group comprising an intravascular ultrasound system and an optical coherence tomography system.

11. The multi-lumen filter catheter according to claim 9, wherein the imaging system is  
15 disposed within a lumen of the multi-lumen catheter body, and the imaging system is configured to image the filter member from within said lumen of the multi-lumen catheter body.

12. The multi-lumen filter catheter according to claim 9, wherein the imaging system further  
20 comprises a drive cable and an imaging probe.

13. The multi-lumen filter catheter according to claim 12, wherein the imaging probe is adapted to be positioned within the multi-lumen catheter body in a region bounded by a  
25 proximal end and a distal end of the filter member.

14. The multi-lumen filter catheter according to claim 13, wherein the bounded region of the multi-lumen catheter body has at least one of dimensions or material selected to optimize an imaging signal transmission and an imaging signal clarity therethrough.

15. The multi-lumen filter catheter according to claim 12, wherein the imaging probe is adapted to be translated at least one of proximally or distally relative to the filter member.

16. The multi-lumen filter catheter according to claim 12, wherein the imaging probe is adapted to be rotated relative to the filter member.

5 17. The multi-lumen filter catheter according to claim 12, wherein the imaging system further comprises an imaging catheter.

18. The multi-lumen filter catheter according to claim 17, wherein the imaging catheter is disposed within a lumen of the multi-lumen catheter body.

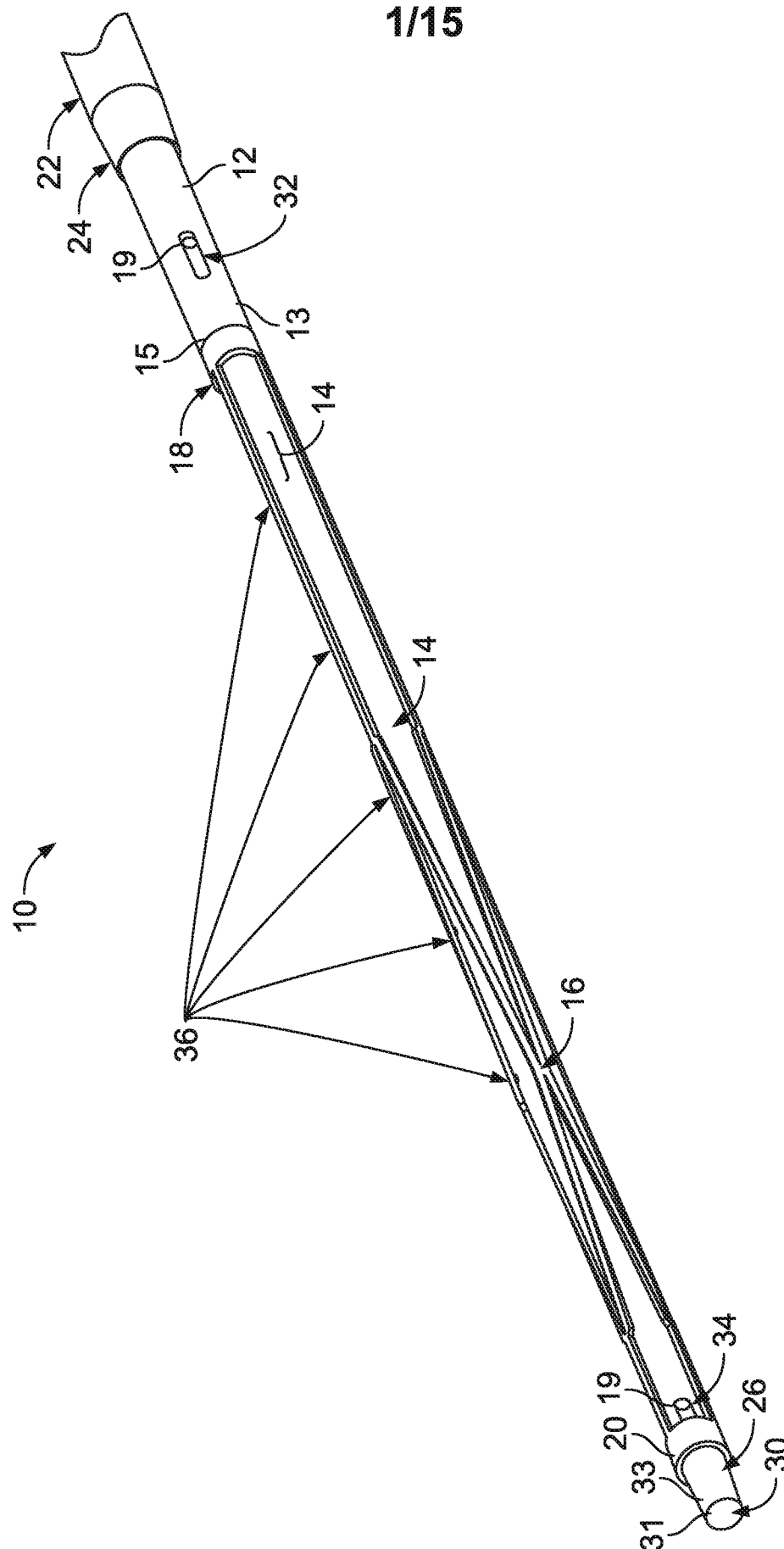
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19. The multi-lumen filter catheter according to claim 17, wherein the imaging catheter is integral with a lumen of the multi-lumen catheter body.

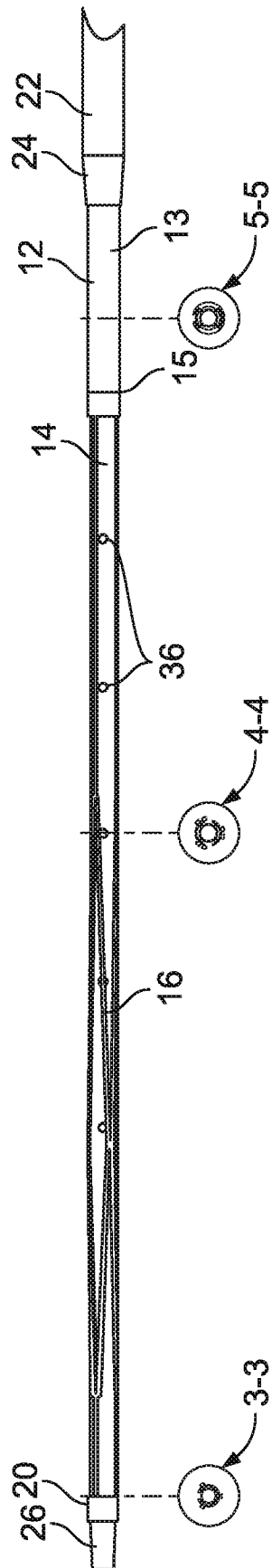
20. A medical device, comprising:

- 15
- a. a catheter body having a filter member coupled to the catheter body;
  - b. a multi-lumen sheath, wherein the catheter body is disposed within a lumen of the multi-lumen sheath; and
  - c. an imaging system operable to detect a condition of the filter member.

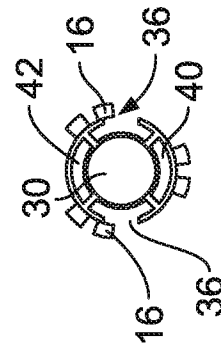
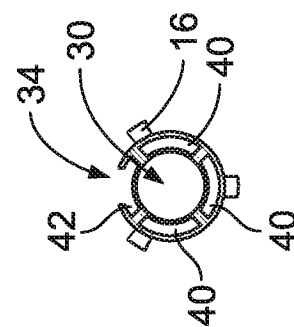
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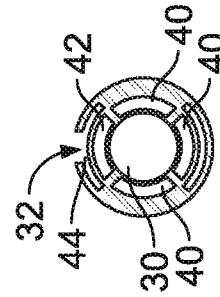
தலை



## 2. Goal



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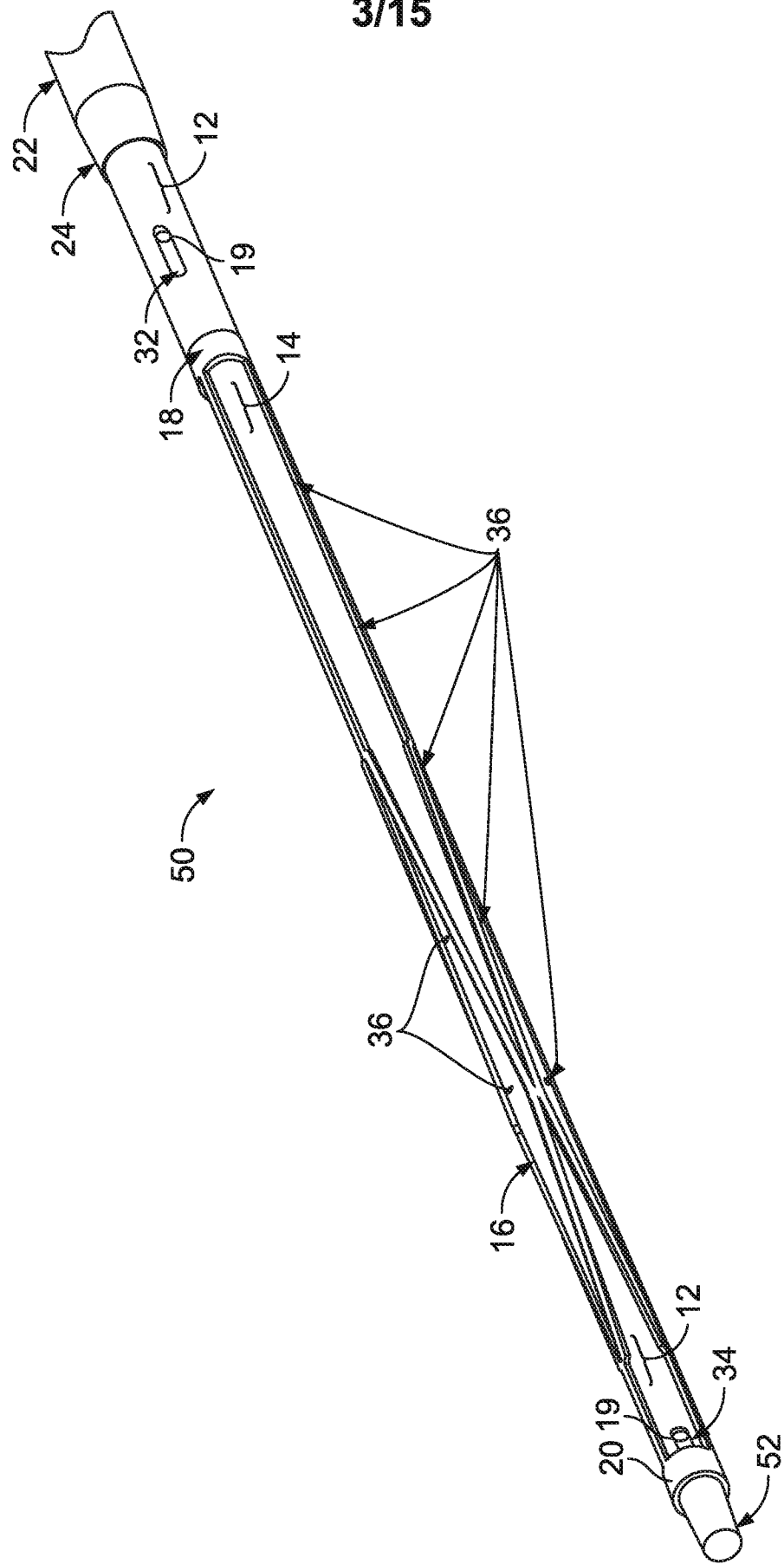


FIG. 6

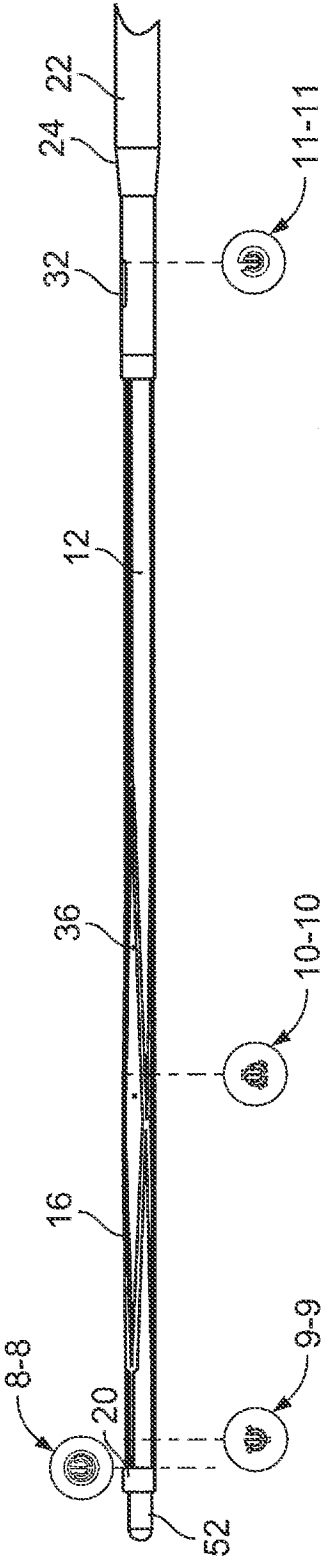


FIG. 7

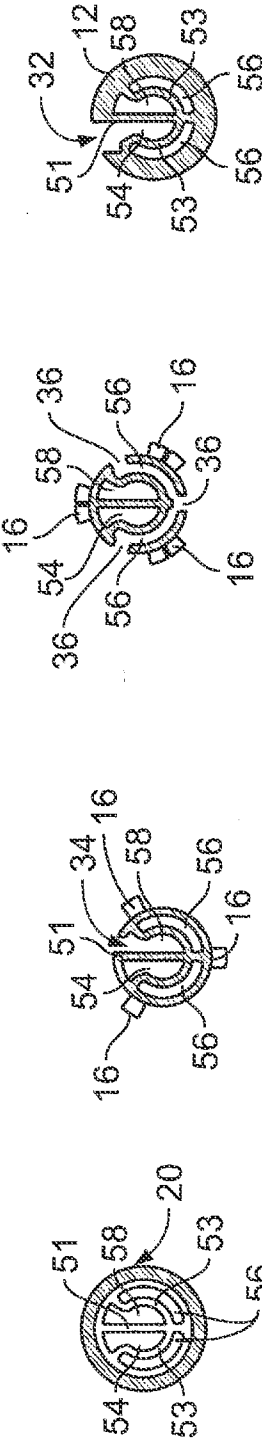


FIG. 8

FIG. 9

FIG. 10

FIG. 11



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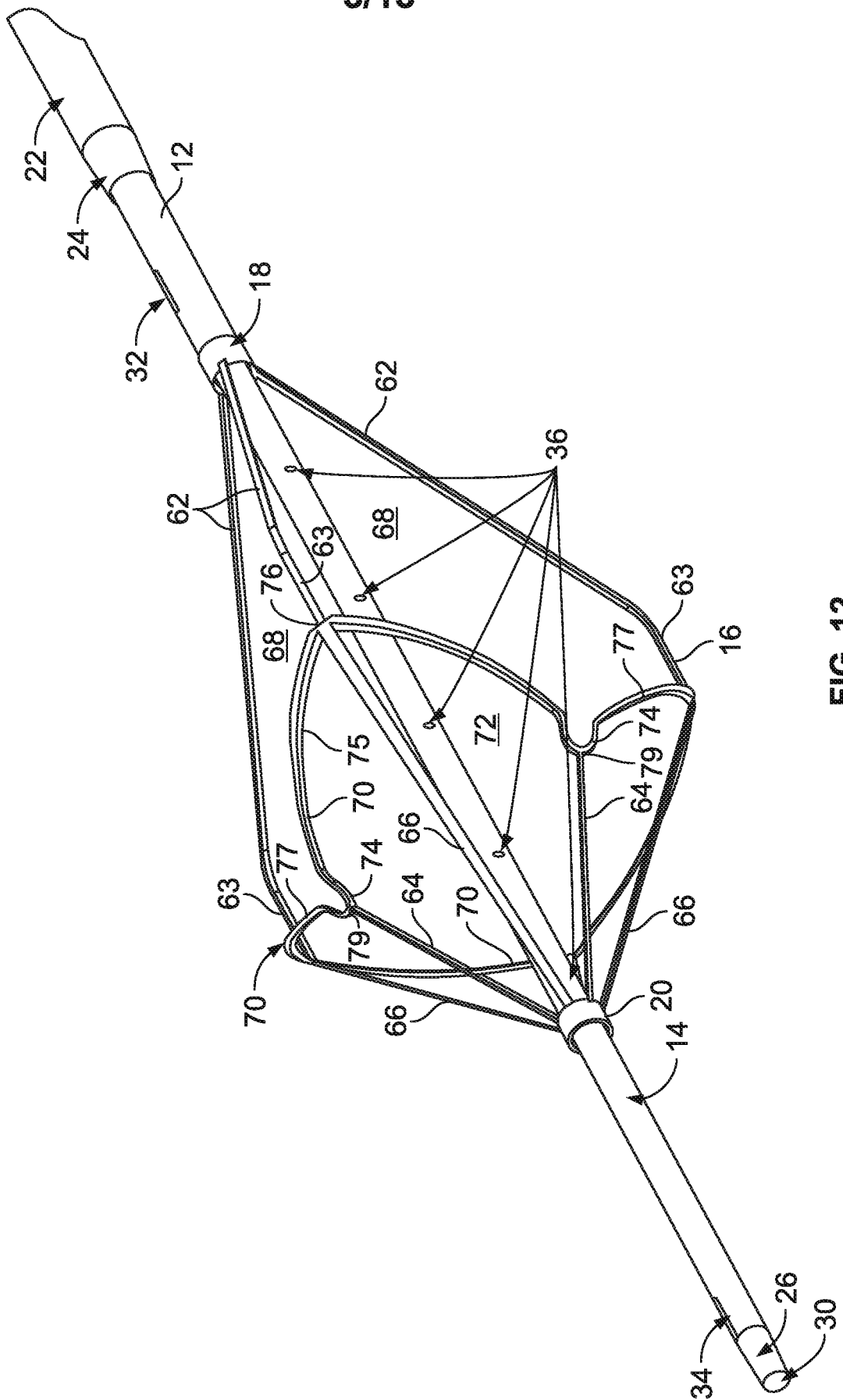


FIG. 12

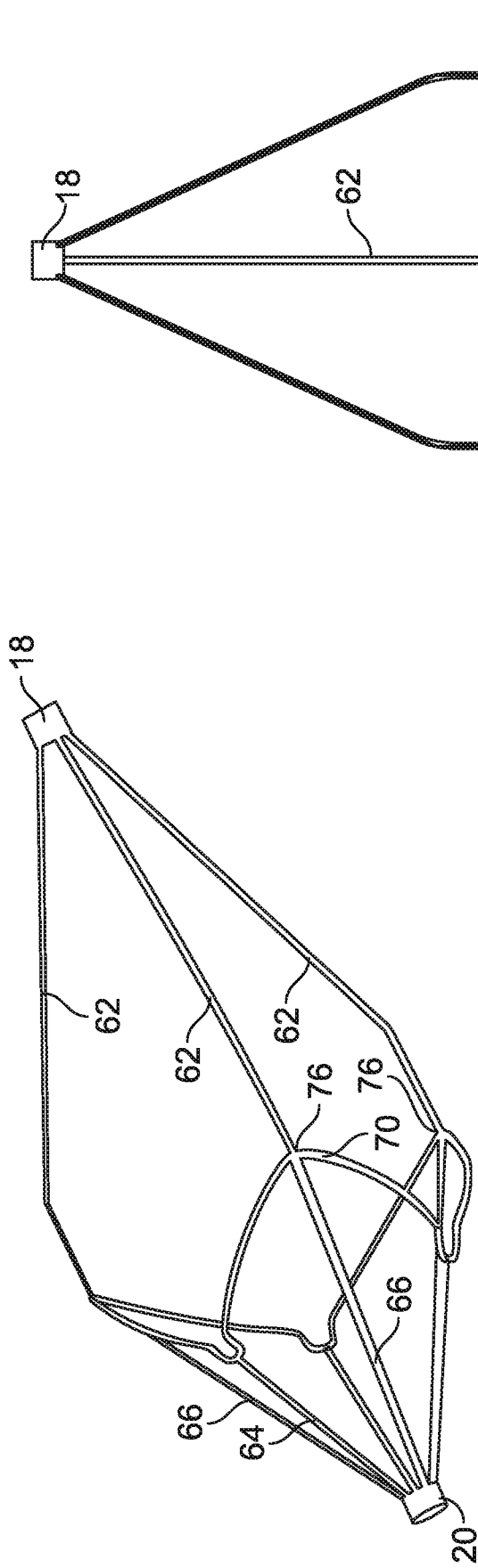


FIG. 13A

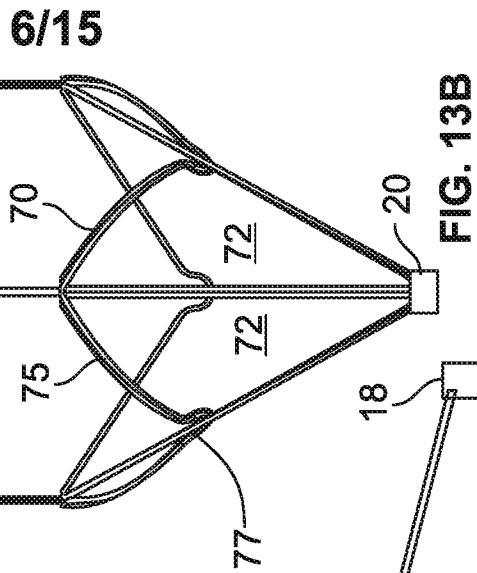


FIG. 13B

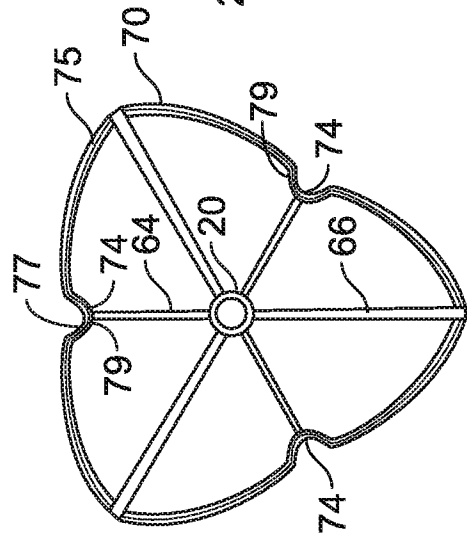


FIG. 13C

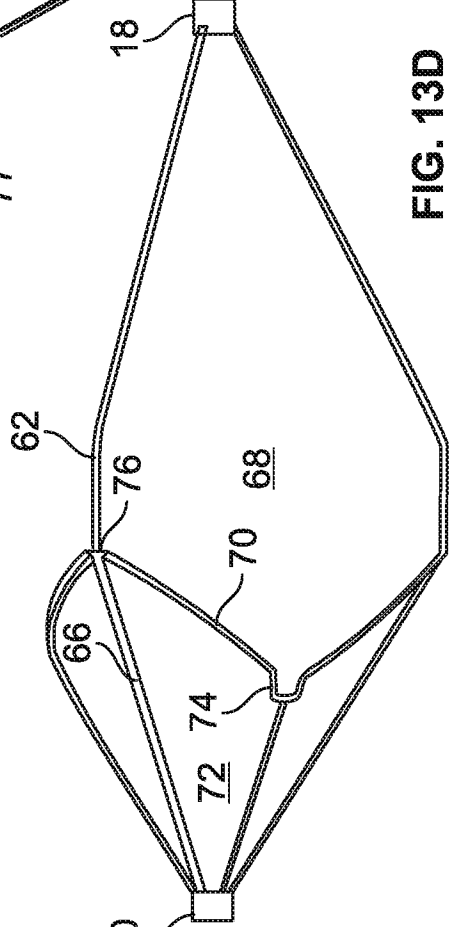
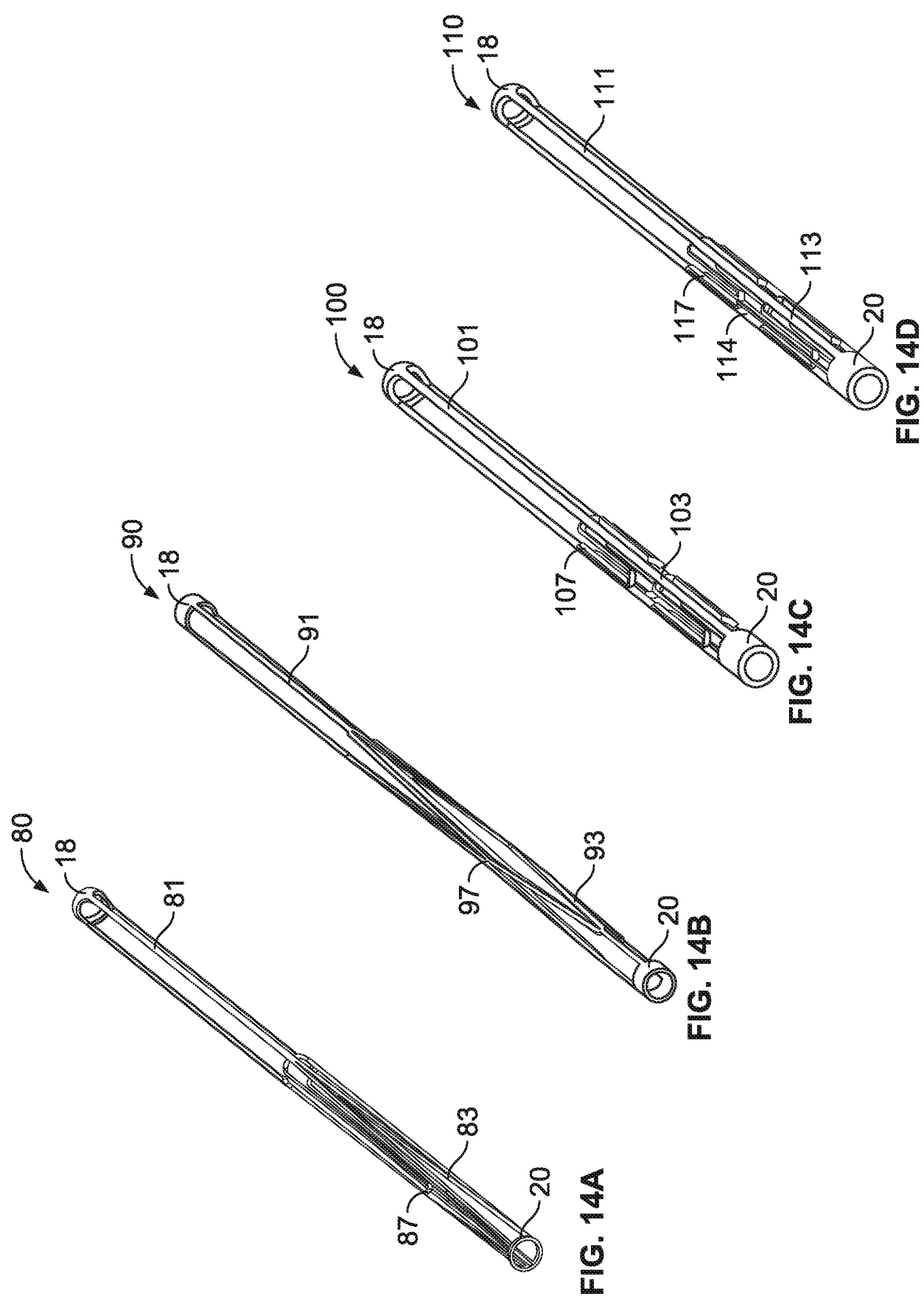
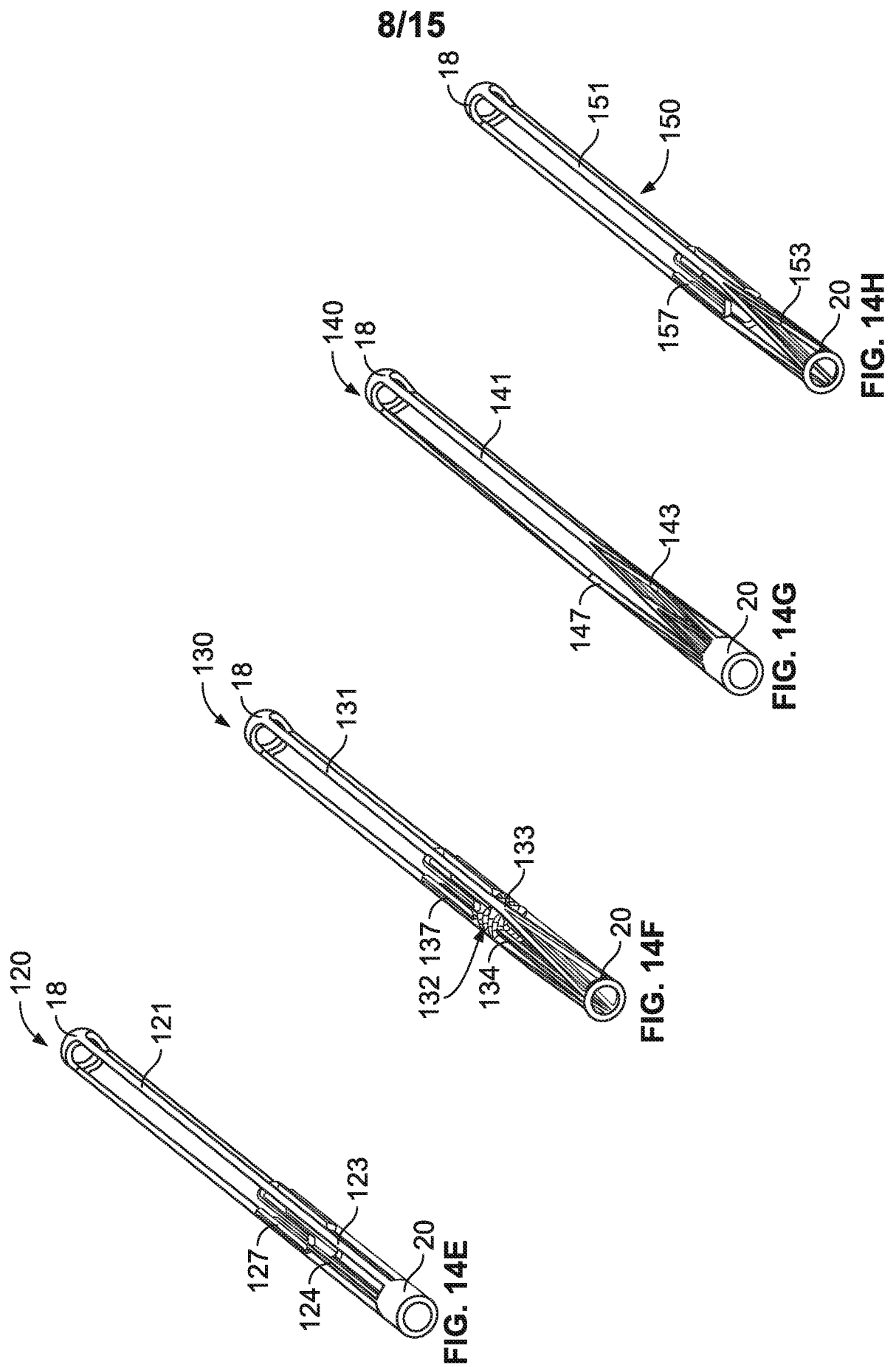
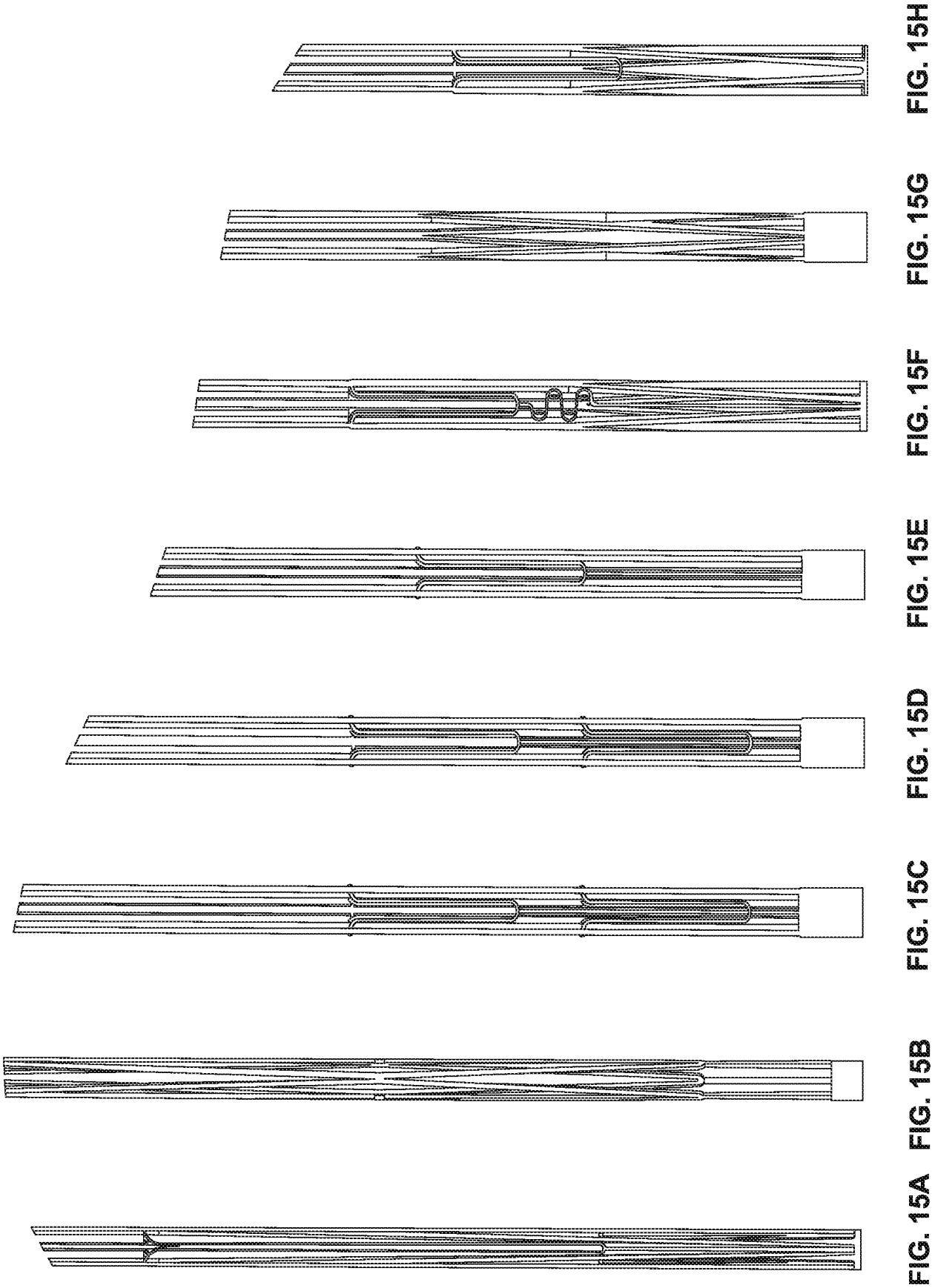


FIG. 13D

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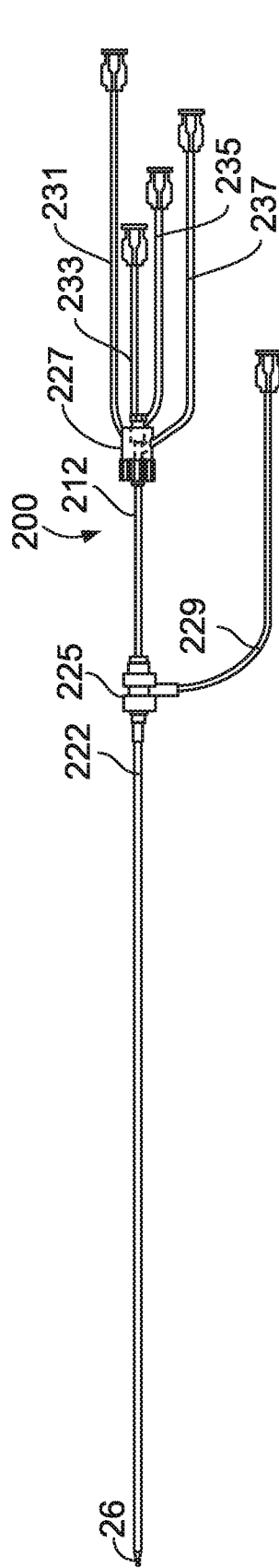


FIG. 16A

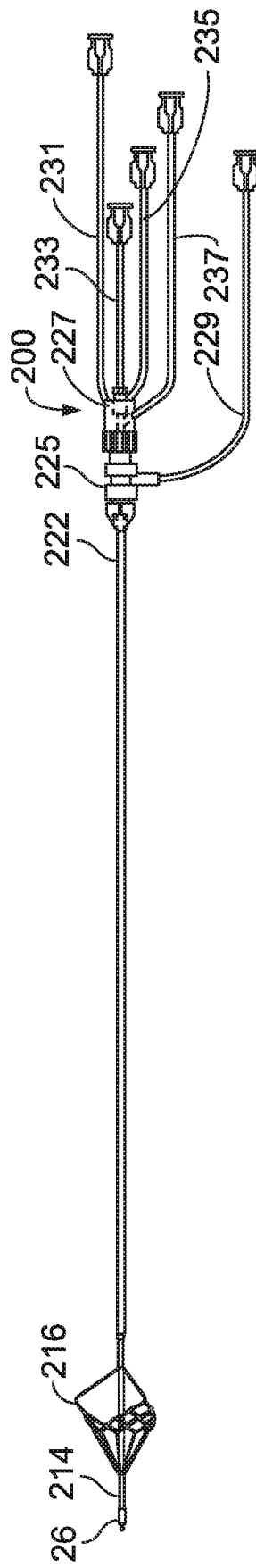


FIG. 16B

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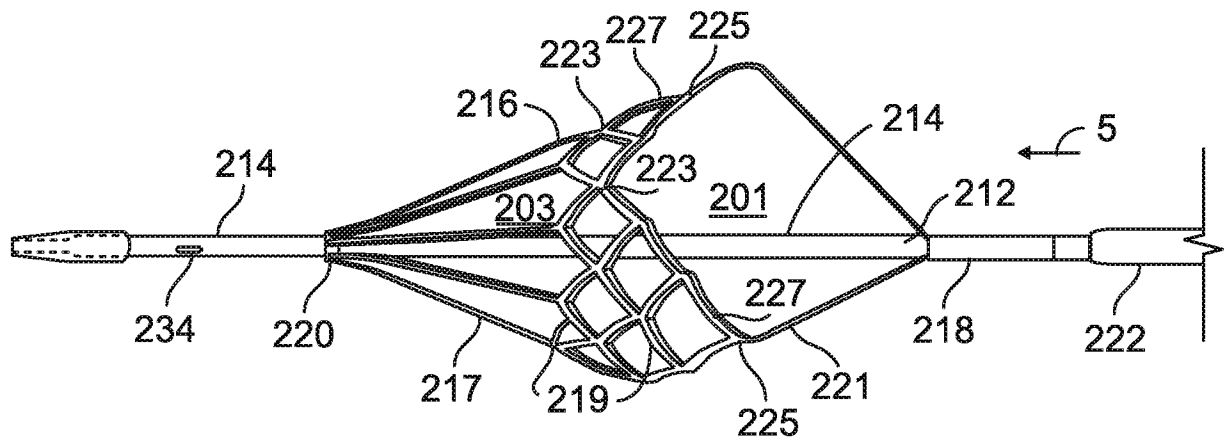


FIG. 17

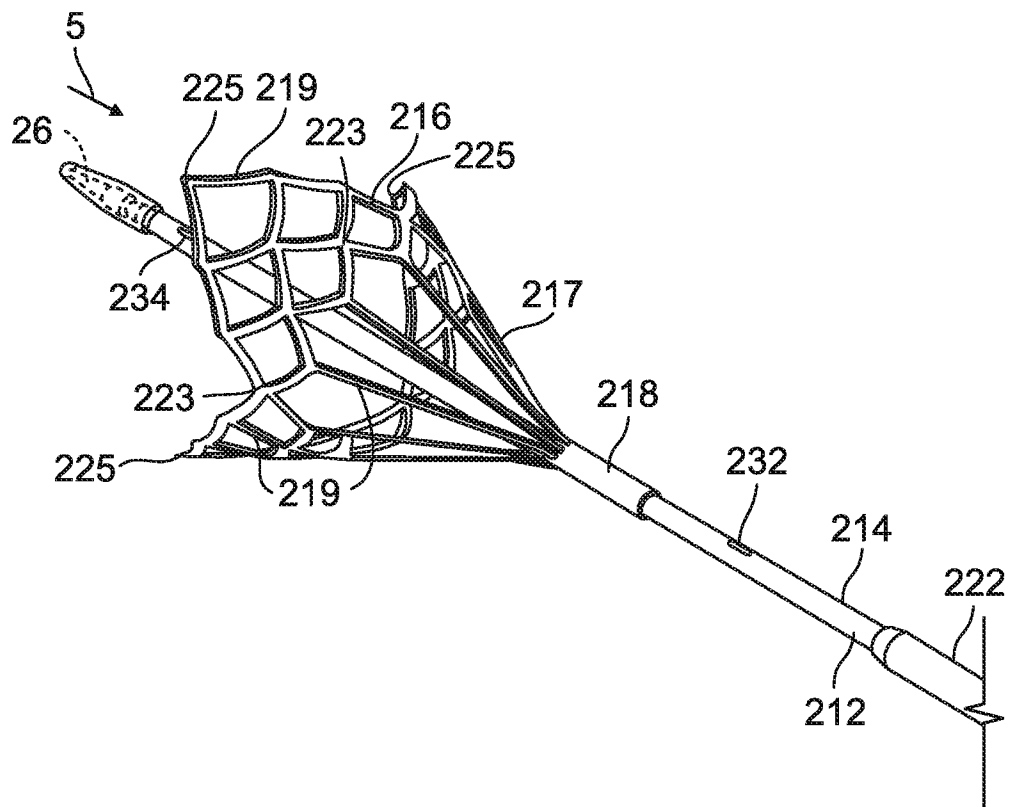


FIG. 18

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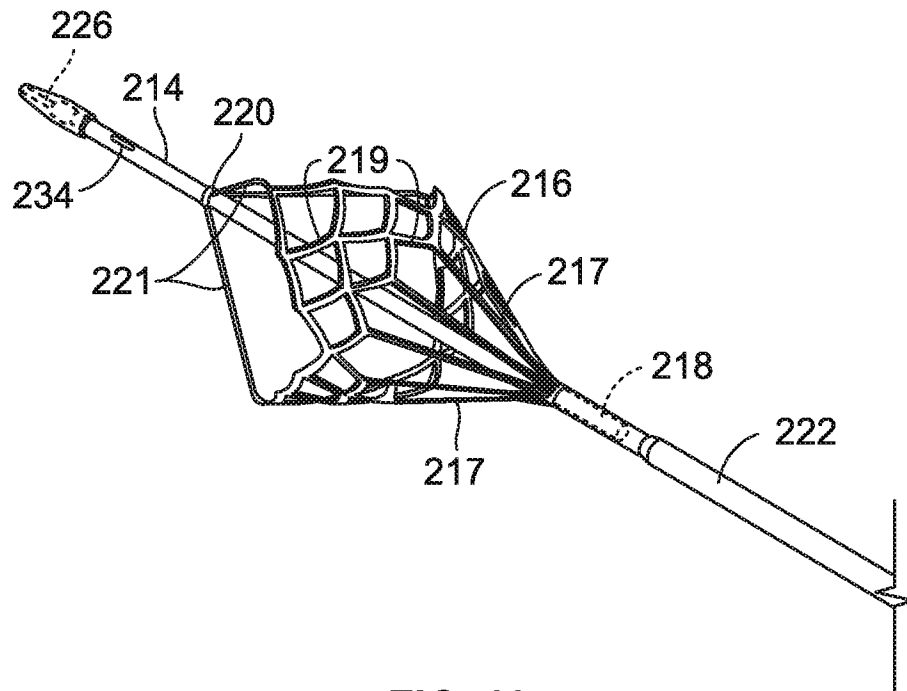


FIG. 19

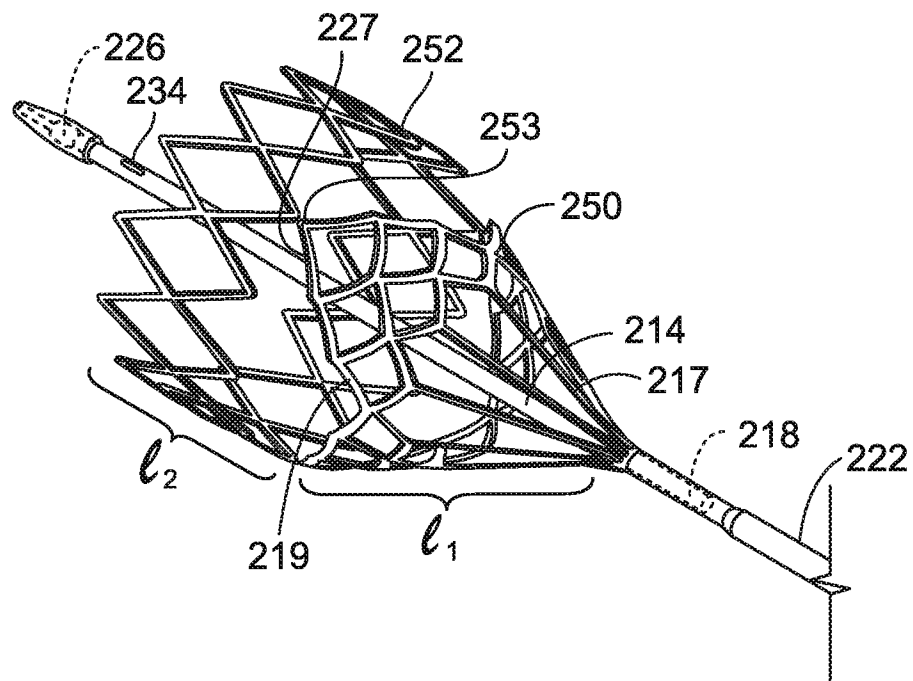


FIG. 20



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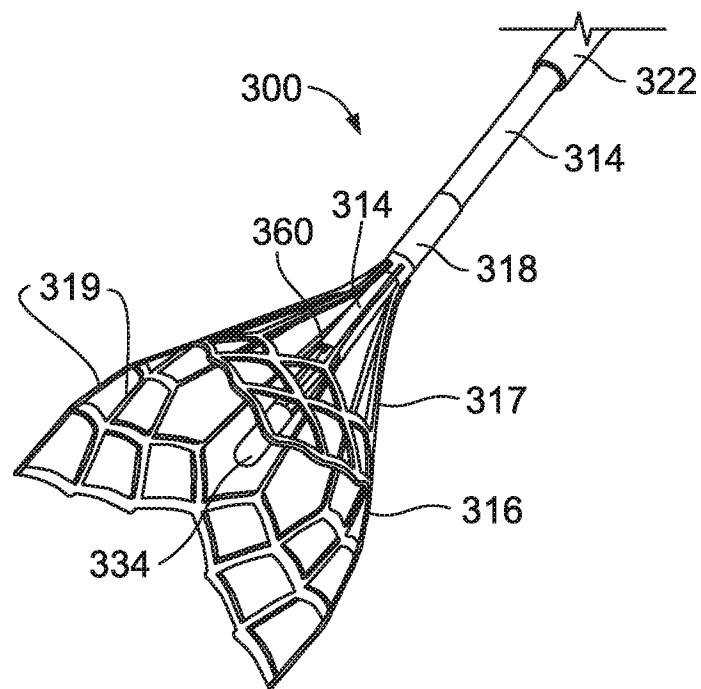


FIG. 21A

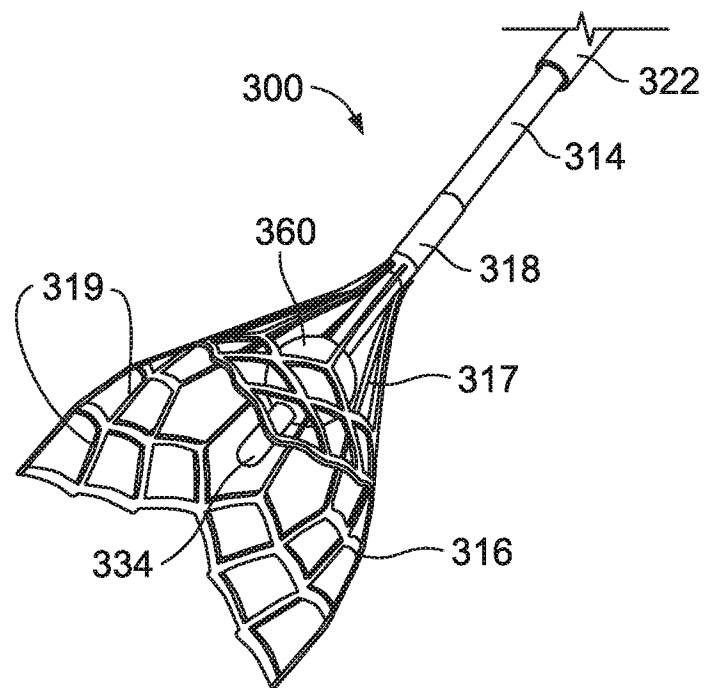


FIG. 21B

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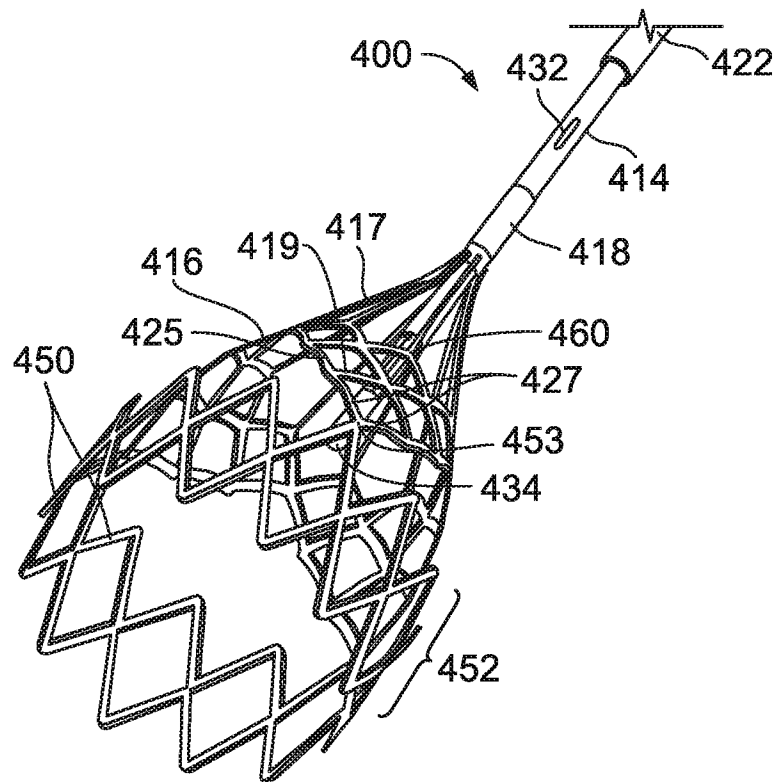


FIG. 22A

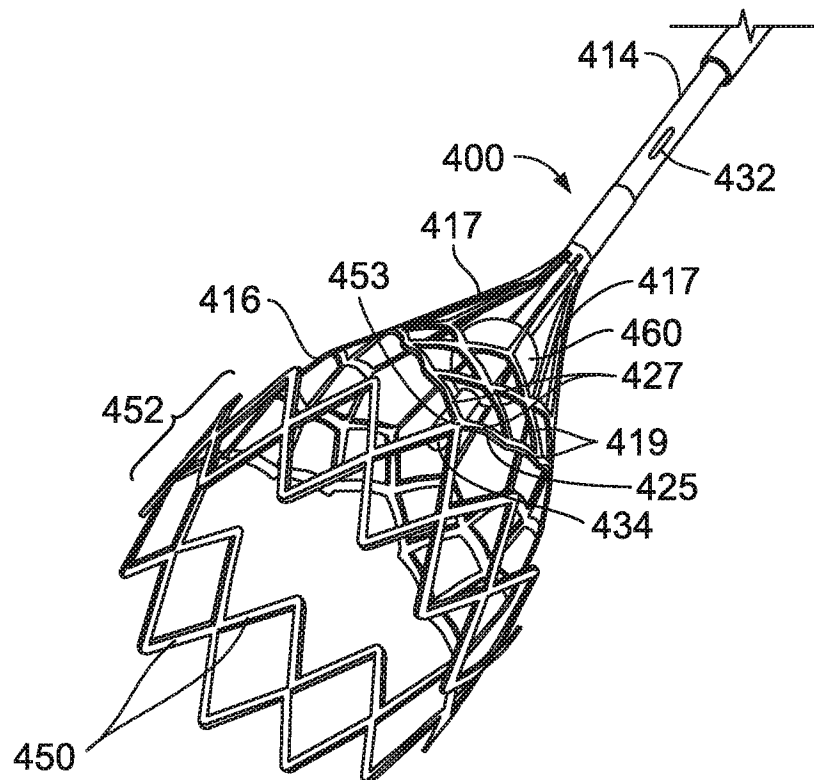


FIG. 22B

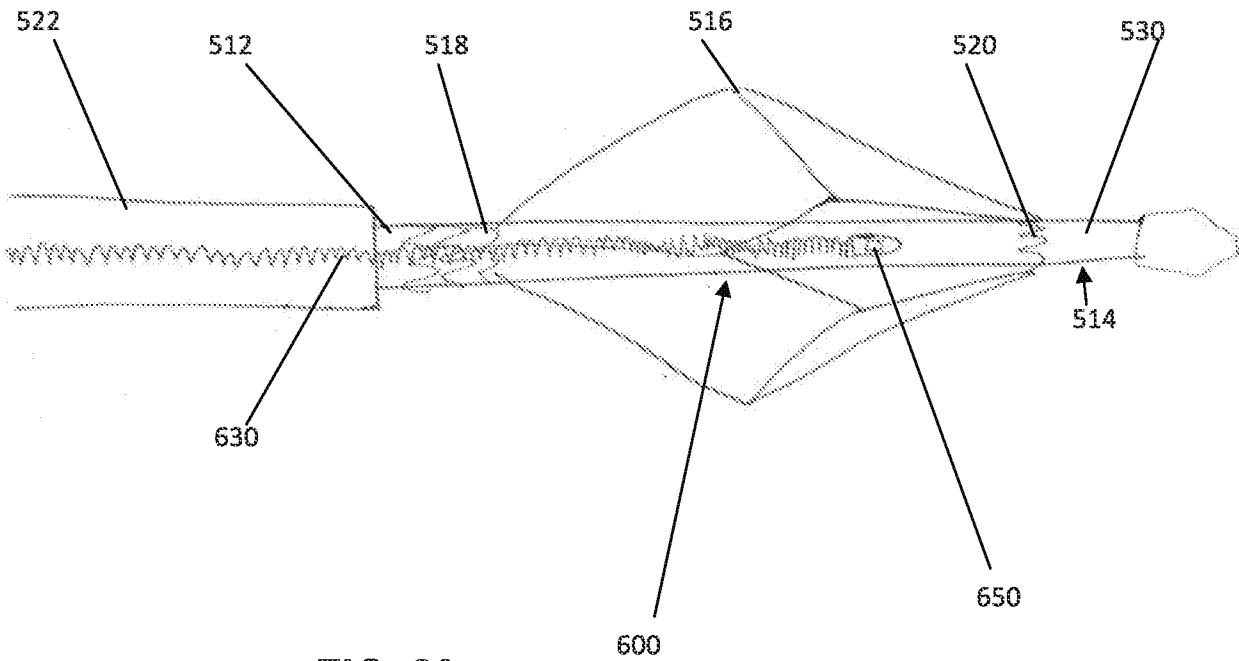


FIG. 23

## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2014/010505****A. CLASSIFICATION OF SUBJECT MATTER****A61M 25/16(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61M 25/16; A61M 5/165; A61B 17/22; A61F 2/01; A61B 5/0215; A61B 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) &amp; Keywords: IVC, inferior vena cava, embolic, filter, imaging, optical, monitor, ultrasound, probe

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010-0217304 A1 (ANGEL, L. F. et al.) 26 August 2010 See abstract; claims 1, 2, 19-20; paragraph [0050]; figures 6, 12.	9-20
A	WO 2012-003369 A2 (MUFFIN INCORPORATED) 5 January 2012 See abstract; claim 1; page 17, lines 17-27; figure 5.	9-20
A	US 2011-0098739 A1 (BATES, M. C.) 28 April 2011 See abstract; claims 26-27; paragraphs [0038]-[0041]; figure 2.	9-20
A	WO 2004-049932 A2 (SCIMED LIFE SYSTEMS, INC.) 17 June 2004 See abstract; claims 1-2; page 4, lines 12-17; figure 1.	9-20
A	US 6682543 B2 (BARBUT, D. R. et al.) 27 January 2004 See abstract; claim 1; column 14, line 61-column 15, line 29; figure 2.	9-20



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

24 April 2014 (24.04.2014)

Date of mailing of the international search report

**01 May 2014 (01.05.2014)**

Name and mailing address of the ISA/KR

International Application Division  
Korean Intellectual Property Office  
189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan City, 302-701,  
Republic of Korea

Facsimile No. +82-42-472-7140

Authorized officer

Han, Inho

Telephone No. +82-42-481-3362



# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2014/010505**

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-8  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 1-8 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2014/010505**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010-0217304 A1	26/08/2010	AU 2008-292832 A1 AU 2011-203980 A1 CA 2698109 A1 CA 2783378 A1 EP 2195047 A1 EP 2521577 A2 US 2009-0062840 A1 US 2013-197565 A1 US 8613753 B2 US 8668712 B2 WO 2009-029861 A1 WO 2011-085266 A2 WO 2011-085266 A3	05/03/2009 26/07/2012 05/03/2009 14/07/2011 16/06/2010 14/11/2012 05/03/2009 01/08/2013 24/12/2013 11/03/2014 05/03/2009 14/07/2011 22/12/2011
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US 6682543 B2	27/01/2004	AU 3888097 A CA 2261111 A1 EP 1645242 A2 EP 1645242 A3 US 2002-0123761 A1 US 5662671 A US 5895399 A US 5993469 A US 5997557 A US 6010522 A US 6309399 B1 WO 98-02084 A2 WO 98-02084 A3	09/02/1998 22/01/1998 12/04/2006 22/04/2009 05/09/2002 02/09/1997 20/04/1999 30/11/1999 07/12/1999 04/01/2000 30/10/2001 22/01/1998 10/12/1998