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(71) Applicant: CERETRIVE LTD. [IL/IL]; 17 Tchelet St., M.P. Misgav, 2017400 Misgav Business Park (IL).

(72) Inventors: MUSTAFA, Maysa; Geulim 37, 3091844 Zichron Yaakov (IL). VASYLEVYTSKY, Maxim; Efroni 12, 4424619 Kefar-Sava (IL). BELSON, Amir; Hareches 20, 5653820 Savion (IL). ALFIA, Aviram; Baz 67 a, App. 2, 2170765 Karmiel (IL).

(74) Agent: KOTLIZKY, Guy; At: Patentick - IP Portfolio Management, P/O/Box 151, 3780700 Beit Hananya (IL).

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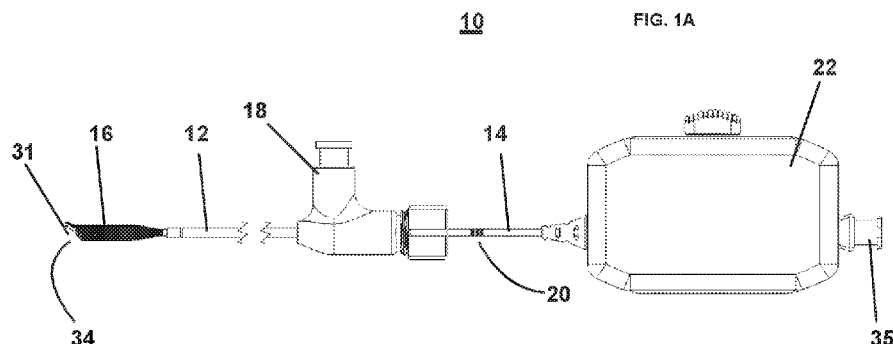
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(54) Title: RETRIEVAL SYSTEM AND METHOD



(57) Abstract: A catheter system including an inner tube movable within an outer tube and a funnel-shaped sleeve attached to the inner tube and configured for transitioning between a collapsed state when sequestered within the outer tube and an expanded state when advanced out of the outer tube.



RETRIEVAL SYSTEM AND METHOD

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BACKGROUND

The present invention relates to a system for retrieving material or objects from a biological vessel and to a method of using same. Embodiments of the present invention relate to a catheter having a funnel-like trap that is highly effective in trapping and retrieving brain emboli/thrombi.

Interventional procedures that are used to treat vascular pathologies not easily accessed by surgical procedures continue to increase in volume in recent years.

Such interventional procedures are particularly advantageous when used to treat pathologies that are located in small and remote vessels such as those within the brain.

Brain embolism is a vascular pathology that is caused when material, typically a blood clot, migrates and blocks a blood vessel that supplies brain tissue.

One conventional technique for retrieving a brain embolus involves the use of a retrieval catheter having a funnel-like trap that is used to capture and retrieve the embolus.

Although such retrieval devices are effective in retrieving small clots, retrieval of large clots can lead to clot fragmentation and release of potentially harmful clot particles into the blood stream.

Thus, there is still room for improvement in clot retrieval systems and in particular in the clot engagement and retraction capabilities of such systems.

SUMMARY

According to one aspect of the present invention there is provided a catheter system for retrieving material from a biological vessel comprising: an inner tube movable within an outer tube; a funnel-shaped sleeve attached to the inner tube and being configured for transitioning between a collapsed state when sequestered within the outer tube and an expanded state when advanced out of the outer tube; and a mechanism or indicator for enabling a user to advance a portion of the sleeve of a predetermined length out of the outer tube.

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According to embodiments of the present invention the mechanism is a trigger for triggering advancement of the portion.

According to embodiments of the present invention the indicator includes marking for indicating advancement of the portion.

5 According to embodiments of the present invention the sleeve is a braided sleeve.

According to embodiments of the present invention the braided sleeve decreases in length when expanded.

10 According to embodiments of the present invention the braided sleeve includes a cover.

According to embodiments of the present invention the cover is fabricated from polyurethane, TPU, PTFE or Silicone.

According to embodiments of the present invention the catheter system further comprises a conduit for applying suction within the braided sleeve.

15 According to embodiments of the present invention the catheter system further comprises a vacuum source in communication with the conduit.

According to embodiments of the present invention the portion of the sleeve of the predetermined length forms a cone when advanced out of the outer tube.

20 According to embodiments of the present invention a distal opening of the sleeve includes a closure mechanism.

According to embodiments of the present invention the closure mechanism includes a pull wire.

According to embodiments of the present invention the pull wire cinches closed the distal opening.

25 According to embodiments of the present invention the pull wire is arranged so as to enable separation of the material from a wall of the funnel-shaped sleeve includes.

According to embodiments of the present invention a distal end of the sleeve is beveled such that an opening of the sleeve forms a tilted oval when expanded.

30 According to embodiments of the present invention the funnel-shaped sleeve includes a radiopaque marker band.

According to embodiments of the present invention the braided sleeve includes wire loops at a distal end.

According to embodiments of the present invention the cover includes a hydrophobic coating.

According to embodiments of the present invention the catheter system further comprises a conduit for injecting a dye.

5 According to embodiments of the present invention the catheter system further comprises at least one sensor for identifying presence of the material within the funnel-shaped sleeve.

According to embodiments of the present invention a first sensor of the at least one sensor is positioned at a proximal region of the funnel-shaped sleeve.

10 According to embodiments of the present invention a second sensor of the at least one sensor is positioned at a distal region of the funnel-shaped sleeve.

According to embodiments of the present invention the catheter system further comprises a plurality of flexible arms positioned within the funnel-like sleeve and being attached thereto.

15 According to embodiments of the present invention the funnel-like sleeve has an hourglass-like shape when fully deployed.

According to another aspect of the present invention there is provided a method of retrieving material from a biological vessel comprising: partially advancing a funnel-shaped sleeve out of a tube of a catheter positioned in the biological vessel so as to form
20 a cone of a predetermined length within the biological vessel; suctioning the material in the biological vessel into the cone; and further advancing the funnel-shaped sleeve out of the tube and applying the suction to thereby trap the material within the funnel-shaped sleeve.

According to embodiments of the present invention suctioning is effected while
25 advancing the catheter in a direction of the material.

According to embodiments of the present invention the method further comprises closing a distal end of the funnel-shaped sleeve.

According to embodiments of the present invention the catheter is advanced through the biological vessel following partial deployment.

30 According to another aspect of the present invention there is provided a catheter system for retrieving material from a biological vessel comprising: an inner tube movable within an outer tube; a funnel-shaped sleeve attached to the inner tube and being configured for transitioning between a collapsed state when sequestered within

the outer tube and an expanded state when advanced out of the outer tube; and a plurality of flexible arms positioned within the funnel-like sleeve and being attached thereto, the plurality of flexible arms are configured capable of allowing material to enter the funnel-like sleeve while preventing the material from releasing out of the
5 funnel-like sleeve.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those
10 described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

15 BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative
20 discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the
25 invention may be embodied in practice.

In the drawings:

FIGs. 1A-F illustrate embodiments of the present catheter system including shovel-like funnels (Figure 1A, D-F), a standard funnel (Figure 1B), a trigger-release handle (Figures 1A-B) and a handle with markings (Figure 1C).

30 FIGs. 2A-C illustrate a two stage deployment of the shovel-funnel catheter configuration.

FIGs. 2D-E illustrate a shovel configuration in greater detail showing the leaflets formed from wire loops.

FIGs. 3A-C illustrate a two stage deployment of the standard-funnel catheter configuration.

FIGs. 4A-C illustrate clot capture using a shovel-funnel catheter configuration.

FIGs. 4D-F illustrate clot capture using a shovel-funnel catheter configuration
5 having flexible arms.

FIGs. 5A-C illustrate clot capture using the standard-funnel catheter configuration.

FIGs. 6A-B illustrate the trigger handle (Figure 6A) and markings (Figure 6B) used for partial deployment of a shovel or standard funnel.

10 FIGs. 7A-C are fluorographic images of clot capture in a pig model using the present catheter system fitted with a standard funnel.

FIGs. 8A-B are fluorographic images of clot capture in a pig model using the present catheter system fitted with a shovel funnel.

FIG. 8C is an image of the clot material retrieved by the procedure shown in
15 Figures 8A-B.

DETAILED DESCRIPTION

The present invention is of a catheter system and method that can be used to
20 retrieve material/objects such as emboli from a biological vessel such as a blood vessel.

The principles and operation of the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details set forth in
25 the following description or exemplified by the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Mechanical thrombectomy devices that utilize traps for retrieving clot material
30 are well known in the art. Such traps can include a closable distal opening for maintaining the retrieved clot within the sleeve while minimizing release of clot or fragments from the trap when it is pulled out of the vasculature.

In a previously-filed patent application (WO2019064306), the present inventors disclosed a unique trap-closure mechanism that substantially enhances whole clot retrieval. While reducing the present invention to practice, the present inventors set out to improve clot-trapping capabilities especially in cases of large clots.

5 Thus, according to one aspect of the present invention there is provided a catheter system for retrieval of material or object from a biological vessel.

As used herein, the term "material" refers to a biological material such as that characterizing a thrombus/embolus while the term "object" refers to an implant such as a stent, stent-graft and the like.

Any biological vessel can be accessed and treated using the present system, examples include vessels of the circulatory system (e.g., arteries, veins, lymph vessels), vessels of the urinary tract (e.g., urethra, ureters) and vessels of the lymphatic system.

The system of the present invention includes a funnel-like sleeve configured for transitioning between collapsed and expanded states. When in the expanded state the funnel-like sleeve is shaped as a funnel that tapers in diameter from the distal to the proximal end. The funnel includes a lumen that is accessible via a distal opening that can be circular in shape and perpendicular to the longitudinal axis of the catheter (also referred to herein as a "standard configuration") or oval in shape and tilted/angled with respect to the longitudinal axis of the catheter also referred to herein as a "shovel configuration").

When collapsed, the funnel-like sleeve is a narrow cylinder having a small lumen (large enough for threading of a guidewire and/or microcatheter). The funnel-like sleeve can be self-expanding in which case, at least a portion of which will self-expand to a final diameter that is limited by a diameter of the vessel (and up to a diameter limited by the braid structure and the extent of deployment from the catheter sheath).

According to one embodiment of the present invention, the funnel-like sleeve can be fabricated from metallic (e.g. stainless steel or NITINOL) or polymeric (e.g., PTFE) wires that are braided in alternating helical and counter-helical directions. The braid can be covered (completely or partially) with a polymer such as TPU or polyurethane to allow application of a vacuum to an internal volume of the funnel-like sleeve.

The diameter of the wire can be between 0.02-0.25 mm while the braid angle between wires can range between 60-140 degrees. The funnel-like sleeve can be

fabricated using a mandrel of suitable size by wrapping wires in an alternating helical pattern. For example, a single wire can be looped and the tails of the loop can be wrapped in a helical pattern around the mandrel so as to form a crisscrossing pattern in every wire (1x1 pattern) or crisscrossing pattern every 2 wires (2x1 pattern) along the length of the mandrel. Several wires (12-64) can be used to form the braided structure. The structure of a braid with the same pattern with a small diameter (Figure 1G) have advantages with some configurations since it increases funnel radial force and thus prevents collapse under suction. An example of such braiding is provided in WO2019064306. The funnel-like sleeve can include wire loops at a distal end thereof (surrounding the opening of an expanded funnel-like sleeve). The wire loops form leaflets that provide axial support and decrease braid compression when the funnel-like sleeve contacts the clot (thereby minimizing an accordion effect that can occur when a braided structure is pushed against a clot). The wire loops also form a soft tip that minimizes vessel trauma during deployment. During suction, these wire leaflets collapse around and envelope the clot without causing collapse of the braid structure.

The parameters and dimensions of the catheter and funnel-like sleeve depend on use and type of vessel. When used in ischemic stroke applications in an intra-cranial artery, the target artery size could vary between 2.5-4.5 mm. The funnel-like sleeve diameter should be at least slightly larger than the vessel diameter to arrest blood flow, and would therefore range between 2-7 mm. The length of the funnel-like sleeve can be long enough to support receiving long clots within the lumen, but short enough to allow deployment of the funnel-like sleeve by pushing it out of the catheter outer tube or by pulling in of a sheath.

The present system also includes a catheter for delivering the funnel-like sleeve into the vessel. According to one embodiment of the present invention, the funnel-like sleeve can be attached to a distal end of the catheter inner tube (shaft) and covered by a removable sheath (outer tube) when in the collapsed configuration. Removal (pulling in proximal direction) of the sheath can deploy the funnel-like sleeve.

In another embodiment of the present invention the funnel-like sleeve is trapped in a collapsed state in a lumen of the outer tube of the catheter and is pushed out for deployment via an inner tube that is attached to the proximal end of the funnel-like sleeve.

The present catheter system can also include a source of suction (e.g., syringe, pump) that can apply a suctioning force to the lumen (internal volume) of the funnel-like sleeve via a dedicated conduit that fluidly connects the source of suction to the lumen of the funnel-like sleeve. The inner tube of the catheter can double as the fluid conduit.

Experiments conducted by the present inventors revealed that the distal opening of a fully extended funnel-like sleeve can at times be blocked by large thrombi when suction is applied to the lumen of the funnel-like sleeve. Such blockage can lead to collapse of the funnel-like sleeve upon suction.

The present inventors have discovered that partial deployment of the funnel-like sleeve such that a cone 2-8 mm in length extends out of the catheter or is uncovered by the sheath substantially enhances the ability of the system to collect thrombus material without blockage or collapse. As such, the present inventors have devised an approach wherein a conical portion of the funnel-like sleeve is first deployed (at the thrombus or deployed and advanced to the thrombus) and the thrombus is engaged and suctioned into this portion and then the rest of the funnel-like sleeve is gradually deployed while maintaining suction to completely engulf and trap the thrombus.

With this approach, the present system aspirates the thrombus and increases the volume of the funnel as it engulfs the thrombus.

To enable such functionality, the catheter system includes a mechanism or an indicator to allow partial deployment of the funnel-like sleeve. The mechanism can include a trigger for precise deployment of a portion of the funnel-like sleeve or an indicator having markings that enable a user to deploy a portion of the funnel-like sleeve of a specific length.

Referring now to the drawings, Figures 1A-D illustrate the catheter system of the present invention which is referred to hereinafter as system 10.

System 10 includes a catheter shaft that includes an outer tube 12 surrounding an inner tube 14. Inner tube 14 is attached to a funnel-like sleeve 16 (shown deployed in Figures 1A-C) that is used to trap (within lumen) and retrieve a material or object from a biological vessel (e.g., artery). Funnel-like sleeve 16 includes a distal opening 34 and a lumen 33 and can be one of two types, a shovel-like funnel-like sleeve 16 (Figures 1A, 1C, 1D) or a standard funnel-like sleeve 16 (Figure 1B).

Inner tube 14 can be an elongated hollow tube selected of a length, diameter and flexibility suitable for the intended treatment location. Different anatomical locations will require Inner tube 14 of different stiffness and axial flexibility. Inner tube 14 having variable stiffness and axial flexibility along the shaft length is well known in the art and
5 can be braided or coiled with an internal coating of a low friction material as PTFE, a metal braiding or coil over the internal layer, and an external polymer layer (jacket) such as PEBAX or polyamide composites with various durometer ratings. Such tubes are commonly used for delivery into tortuous vasculature or intra-cranial vasculature.

Outer tube 12 can be an elongated hollow tube capable of sliding over inner tube
10 14. The length of Inner tube 14 can be shorter than the length of inner tube 14 and to enable pulling back of outer tube 12 for partial and full deployment of funnel-like sleeve 16.

Outer tube 12 is selected of a length, diameter and flexibility suitable for the intended treatment location. Requiring high distal flexibility and trackability
15 performances, achieved by selecting soft material jacket and metal coil design. Outer tube 12 can be of different stiffness and axial flexibility and proximal stiffness and pushability for delivery in tortuous anatomy. A tube having variable stiffness and axial flexibility along its length is well known in the art. Such a tube can be braided or coiled with an internal polymer layer having low friction layer (e.g., PTFE), a metal braiding
20 and coil in different sections over the internal layer, and an external polymer layer (jacket) such as PEBAX, polyurethane or polyamide composites with various durometer ratings.

The outer diameter of inner tube 14 can be 0.5-4 mm (e.g., 1.5 mm), while the inner diameter of inner tube 14 (can function as the aspiration conduit) can be 0.3-3.5
25 mm. A wire lumen (for closure) can be separate from the inner lumen and can be .03-0.3 mm in diameter (can be positioned in the wall of inner tube 14). The length of inner tube 14 can range anywhere between 50-150 cm and is selected according to the target vessel and location treated.

The outer diameter of outer tube 12 can be 1-6 mm, while the inner diameter of
30 outer tube 12 (accommodates inner tube 14) can be 0.8-5.5 mm. The length of outer tube 12 can range anywhere between 45-145 cm and is selected according to the target vessel and location treated.

Funnel-like sleeve 16 can be 5-80 mm in length with a diameter tapering from 1-20 mm (distal) to 0.3-18 (Proximal) when fully deployed and 10-160 mm when sequestered within outer tube 12. Funnel-like sleeve 16 (standard or shovel) can alternatively have an hourglass shape when deployed (Figure 1D). The hourglass shape is advantageous the differences in diameter at the two regions of funnel-like sleeve 16 (marked as R1 and R2, proximal, distal respectively) cause a pressure differential between the funnel sections (distal proximal) due to the Bernoulli Principle and thus aid in advancing the material toward the proximal region (R1) of the funnel. Another advantage is that the proximal region (R1) can trap and hold a thrombus and prevent its release due to its smaller diameter (Figure 1F)(collapses onto the material).

The hourglass shape of funnel-like sleeve 16 shape (Figure 1G) is advantageous in that a narrowing region (e.g., transition from R2 to R1) will have an increase in PPI (Pitch Per Inch), which increases funnel rigidity thus prevents collapse under suction.

Deployment of funnel-like sleeve 16 can be effected by pulling back (proximally) outer tube 12 using handle 18 that is attached to outer tube 12 (Figure 1A) or by pushing out (distally) inner tube 14 against handle 18. Markings 20 can be used to determine the length of funnel-like sleeve 16 that is deployed. Such markings can be used for partial deployment of funnel-like sleeve 16 to form a cone-like shape (Figures 2B, 3B) of a predetermined length.

Figure 6B illustrates in greater detail a handle 18 that can be moved along with outer tube 12 to partially deploy and then fully deploy funnel-like sleeve 16. Handle 18 include a button 19 for releasing/locking movement of outer tube 12 with respect to inner tube 14. Markings 20 on inner tube 14 indicate partial (one or more stages) and full deployment of funnel-like sleeve 16.

System 10 can also include an actuator 22 for closing funnel-like sleeve 16 following entrapment of, for example, a thrombus. Such an actuator can include a mechanism for pulling a wire spanning from actuator 22 through inner tube 14 and to a distal opening 34 of funnel-like sleeve 16. Such a wire, when pulled, can cinch closed funnel-like sleeve 16.

The pull wire extends from the proximal end through the inner catheter (e.g., side wall conduit) through the lumen of funnel-like sleeve (in a helical pattern) and attaches to some or all of the wire loops forming distal end 31.

Closure can be via cinching (e.g., purse string) or via deflection (in the shovel configuration) by pulling the extended portions of the distal end (shovel tip) towards the base of the shovel. Alternatively, the shovel tip can be angled downward 10-30 degrees to disconnect the thrombus from the vessel wall by pulling the closure wire and lifting
5 it thereby changing the height of the shovel.

Figure 1B illustrates a handle 23 that includes a trigger 26 and mechanism for triggering partial deployment of funnel-like sleeve 16 (to the state shown in Figures 2B, 3B). The mechanism pulls back outer tube 12 a measured distance upon actuation of trigger 26. Alternatively, trigger 26 can be a slider that is movable to an indent or
10 marking. A slider configuration of handle 23 is shown in greater detail in Figure 6A showing. Trigger 26 is a slider button that can be moved proximally-distally along housing 27. Such movement pulls outer tube 12 proximally to partially and then fully uncover and deploy funnel-like sleeve 16. Indents in housing 27 stop the slider button at preset positions corresponding to a first partial deployment (cone-like shape), second
15 and optionally third partial deployments and full deployment.

System 10 can also include a source of suction attached to inner tube 14 through port 35. Such a source of suction can be a syringe 28 (Figure 1C) or a pump that applies a suctioning pressure of -2 to -12 psi.

Figures 2A-C and 3A-C illustrate deployment of a shovel-like (Figures 2A-C) or standard (Figures 3A-C) funnel-like sleeve 16 out of outer tube 12. As is mentioned
20 hereinabove, funnel-like sleeve 16 is deployed in steps wherein in a first step it is partially deployed to form a cone-like shape. Such deployment can be effected by pulling in outer tube 12 or pushing out inner tube 14 as is describe hereinabove.

In the shovel configuration, partial deployment (e.g., of a tip portion) can be used
25 to facilitate navigation through torturous vessels.

The shovel configuration of funnel-like sleeve 16 is shown in greater detail in Figures 2D-E.

In the embodiments shown in these Figures, funnel-like sleeve 16 is braided (and optionally covered) and includes distal end wire loops 17 that form leaflets that extend
30 distally to lengthen distal end 31 by 1-3 mm around 25%-75% of the circumference of funnel-like sleeve 16. The resulting distal end 31 is beveled at an angle (B) that can be 30-80 degrees.

Wire loops 17 can also be angled (A) outward (splayed out, Figure 2D) at 120--170 degrees (around most or all of the circumference) such that distal end 31 of the funnel-like sleeve 16 defining opening 34 has a diameter larger than that of the lumen of funnel-like sleeve 16 (15-60% larger). This enhances the ability of distal end 31
5 leaflets to engulf the thrombus and creates a seal between distal end 31 of funnel-like sleeve 16 and the vessel wall. This results in a higher aspiration force, smoother clot entrance into funnel-like sleeve 16 and reduces the chance of artery and funnel-like sleeve collapse.

Figures 4A-C and 5A-C illustrate the stepwise capture of a thrombus 30 lodged
10 in a blood vessel 32.

In a first step (Figures 4A, 5A), system 10 is positioned at a distance from, or adjacent to, the thrombus 30 using standard over the wire, percutaneous access, techniques (with the wire positioned through inner tube 14). Funnel-like sleeve 16 is then partially deployed using trigger 26 or markings 20 and distal opening 34 of Funnel-
15 like sleeve 16 is advanced and positioned against thrombus 30 (Figures 4B, 5B). Suction is then applied through inner tube 14 to partially internalize/engage thrombus 30. Slow and small volume of blood is drawn in the syringe, indicating thrombus engagement.

Funnel-like sleeve 16 is then extended out while maintaining suction to thereby completely internalize thrombus 30. Once completely internalized, distal opening 34 of
20 funnel-like sleeve 16 is closed (e.g., with a pull wire). System 10 can then be retrieved along with thrombus 30 out of the body.

Figures 4D-F illustrate capture using a standard funnel-like sleeve 16 having a capture/closure mechanism that includes flexible arms 21 at a distal portion of funnel-like sleeve 16. Arms 21 are attached to the braid material of funnel-like sleeve 16 (or
25 are formed therewith) and project distally at an angle of 16 - 25°degrees away from a centerline of funnel-like sleeve 16. When material (thrombus) advances towards the opening of funnel-like sleeve 16 (Figure 4D), it pushes arms 21 outward (Figure 4E) thus allowing the material to move into funnel-like sleeve 16. In that respect, arms 21 function as a flexible trap door. Once the material is within the proximal portion of
30 funnel-like sleeve, any movement towards the distal end pushes arms 21 to effectively block the distal opening and prevent material release (Figure 4F).

Funnel-like sleeve 16 and outer tube 12 and/or inner tube 14 can include radiopaque markers 41 (Figure 2F) to indicate funnel opening under fluoroscopy, and

the distance of distal end 31 from the thrombus or occlusion site. Radiopaque markers 41 can be, for example, 3-6 gold dots that are positioned on the braid wires near or at distal end 31 around the circumference. The distance between imaged radiopaque markers can be used to indicate the extent of opening of funnel-like sleeve 16 in the vessel.

Funnel-like sleeve 16 can also include sensors or sensor arrays 43 (at proximal and distal ends) for detecting the presence of material within the lumen. Sensors 43 can be impedance sensors such as those described in US20190159684.

Base (proximal) sensor 43 can be used to determine when suction can be halted as material reaches the tapered base portion of funnel-like sleeve 16. Tip (distal) sensors 43 can be used to determine if material is at the opening of funnel-like sleeve 16 and possibly interfering with closure.

System 10 can also include a macerator 24 (Figures 9A-B) for macerating trapped thrombi. Macerator 24 can be introduced into funnel-like sleeve 16 through inner tube 14 (Figure 9A) and can include a deployable cutter 25 that can include a 1 or more arcuate blades that when rotated macerate the thrombus material and allow subsequent collection thereof through inner tube 14.

As used herein the term “about” refers to $\pm 10\%$.

Additional objects, advantages, and novel features of the present invention will become apparent to one ordinarily skilled in the art upon examination of the following examples, which are not intended to be limiting.

EXAMPLES

Reference is now made to the following example, which together with the above descriptions, illustrate the invention in a non-limiting fashion.

Animal Trials

A trial was conducted on a 60 Kg female pig using a prototype of the present system having a standard or shovel funnel. The clot was produced from pig autologous blood to create a whole blood thrombus, the thrombus was injected to the target site using a 6Fr sheath and an angiogram was performed to verify vessel occlusion. A

femoral access site was used to navigate the system over-the-wire and microcatheter to the occluded site in the vessel with the funnel collapsed within the catheter sheath (outer tube). The funnel tip with radiopaque markers and a marker band on the outer catheter tip were visible under fluoroscopy (Figure 7A) during navigation.

5 The catheter distal end was positioned a few millimeters from the clot and the microcatheter and guide wire were removed. The funnel was advanced to the distal edge of the outer tube and the outer tube was pulled back 2-3 mm partially deploying the funnel to form a cone (Figure 7B). Suction was applied and the outer tube was pulled while the inner tube attached to the funnel was pushed forward to fully deploy the funnel
10 (Figure 7C). The distal opening of the funnel was closed using a pull wire and retracted into the outer tube. The system was then removed along with the clot trapped within the funnel.

A second trial was conducted on a 60 Kg female pig using a prototype of the present system having a shovel-like funnel. A femoral access site was used to navigate
15 the system over-the-wire and microcatheter to the occluded site in the vessel with the funnel collapsed within the catheter sheath (outer tube).

The catheter distal end was positioned a few millimeters from the clot (indicated by the contrast border of the angiograph) and the microcatheter and guide wire were removed (Figure 8A). The funnel was advanced to the distal edge of the outer tube and
20 the outer tube was pulled back 2-3 mm partially deploying the funnel to form a cone (Figure 8B). Suction was applied and the outer tube was pulled while the inner tube attached to the funnel was pushed forward to fully deploy the funnel (Figure 8C). The distal opening of the funnel was closed using a pull wire and retracted into the outer tube. The system was then removed along with the clot trapped within the funnel.

25 It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided
30 separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations

will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the
5 specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

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WHAT IS CLAIMED IS:

1. A catheter system for retrieving material from a biological vessel comprising:

- (a) an inner tube movable within an outer tube;
- (b) a funnel-shaped sleeve attached to said inner tube and being configured
5 for transitioning between a collapsed state when sequestered within said outer tube and an expanded state when advanced out of said outer tube; and
- (c) a mechanism or indicator for enabling a user to advance a portion of said sleeve of a predetermined length out of said outer tube.

10 2. The catheter system of claim 1, wherein said mechanism is a trigger for triggering advancement of said portion.

3. The catheter system of claim 1, wherein said indicator includes marking
for indicating advancement of said portion.

15 4. The catheter system of claim 1, wherein said sleeve is a braided sleeve.

5. The catheter system of claim 4, wherein said braided sleeve decreases
in length when expanded.

20 6. The catheter system of claim 4, wherein said braided sleeve includes a cover.

7. The catheter system of claim 6, wherein said cover is fabricated from
25 polyurethane, TPU, PTFE or Silicone.

8. The catheter system of claim 6, further comprising a conduit for
applying suction within said braided sleeve.

30 9. The catheter system of claim 8, further comprising a vacuum source in communication with said conduit.

10. The catheter system of claim 1, wherein said portion of said sleeve of said predetermined length forms a cone when advanced out of said outer tube.

5 11. The catheter system of claim 1, wherein a distal opening of said sleeve includes a closure mechanism.

12. The catheter system of claim 11, wherein said closure mechanism includes a pull wire.

10

13. The catheter system of claim 12, wherein said pull wire cinches closed said distal opening.

14. The catheter system of claim 12, wherein said pull wire is arranged so as to enable separation of said material from a wall of said funnel-shaped sleeve includes.

15

15. The catheter system of claim 1, wherein a distal end of said sleeve is beveled such that an opening of said sleeve forms a tilted oval when expanded.

20

16. The catheter system of claim 1, wherein said funnel-shaped sleeve includes a radiopaque marker band.

17. The catheter system of claim 4, wherein said braided sleeve includes wire loops at a distal end.

25

18. The catheter system of claim 6, wherein said cover includes a hydrophobic coating.

19. The catheter system of claim 1, further comprising a conduit for injecting a dye.

30

20. The catheter system of claim 1, further comprising at least one sensor for identifying presence of said material within said funnel-shaped sleeve.

21. The catheter system of claim 20, wherein a first sensor of said at least one sensor is positioned at a proximal region of said funnel-shaped sleeve.

22. The catheter system of claim 21, wherein a second sensor of said at least one sensor is positioned at a distal region of said funnel-shaped sleeve.

23. The catheter system of claim 1, further comprising a plurality of flexible arms positioned within said funnel-like sleeve and being attached thereto.

24. The catheter system of claim 1, wherein said funnel-like sleeve has an hourglass-like shape when fully deployed.

25. A method of retrieving material from a biological vessel comprising:
(a) partially advancing a funnel-shaped sleeve out of a tube of a catheter positioned in the biological vessel so as to form a cone of a predetermined length within the biological vessel;
(b) suctioning the material in the biological vessel into said cone; and
(c) further advancing said funnel-shaped sleeve out of said tube and applying said suction to thereby trap the material within said funnel-shaped sleeve.

26. The method of claim 25, wherein (b) is effected while advancing said catheter in a direction of the material.

27. The method of claim 25, further comprising:
(d) closing a distal end of said funnel-shaped sleeve.

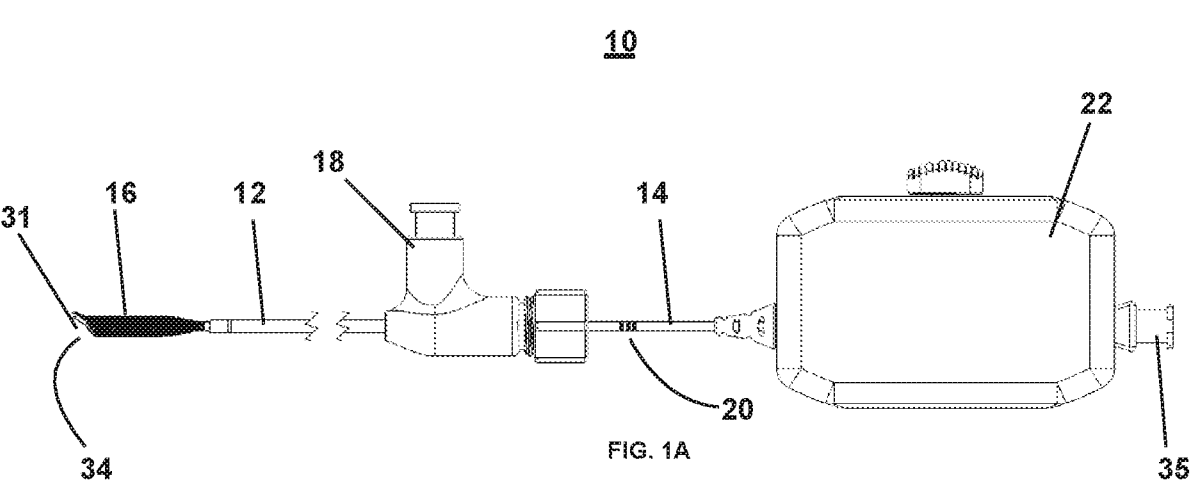
28. The method of claim 25, wherein said catheter is advanced through the biological vessel following (a) and prior to (b).

29. A catheter system for retrieving material from a biological vessel comprising:

- (a) an inner tube movable within an outer tube;
- (b) a funnel-shaped sleeve attached to said inner tube and being configured
5 for transitioning between a collapsed state when sequestered within said outer tube and
an expanded state when advanced out of said outer tube; and
- (c) a plurality of flexible arms positioned within said funnel-like sleeve and
being attached thereto, said plurality of flexible arms are configured capable of allowing
material to enter said funnel-like sleeve while preventing said material from releasing
10 out of said funnel-like sleeve.

30. The catheter system of claim 1, wherein a diameter of said funnel-like is smaller in a middle portion than a proximal or distal portions when fully deployed.

15 31. The catheter system of claim 1, further comprising a device for macerating thrombus material trapped inside said funnel-like sleeve.



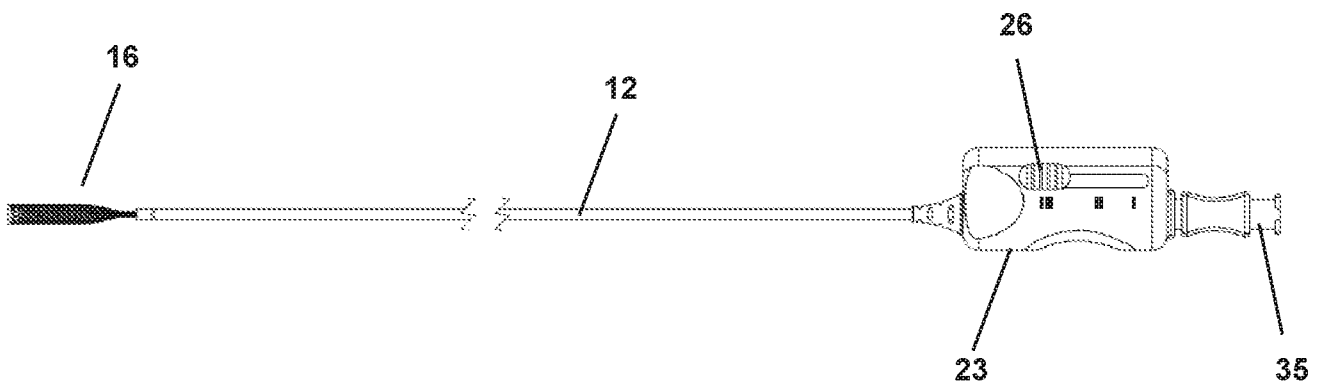


FIG. 1B

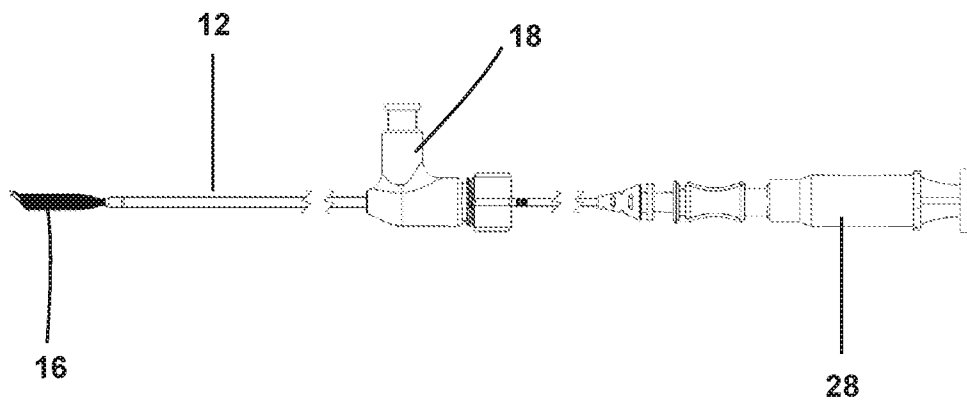


FIG. 1C

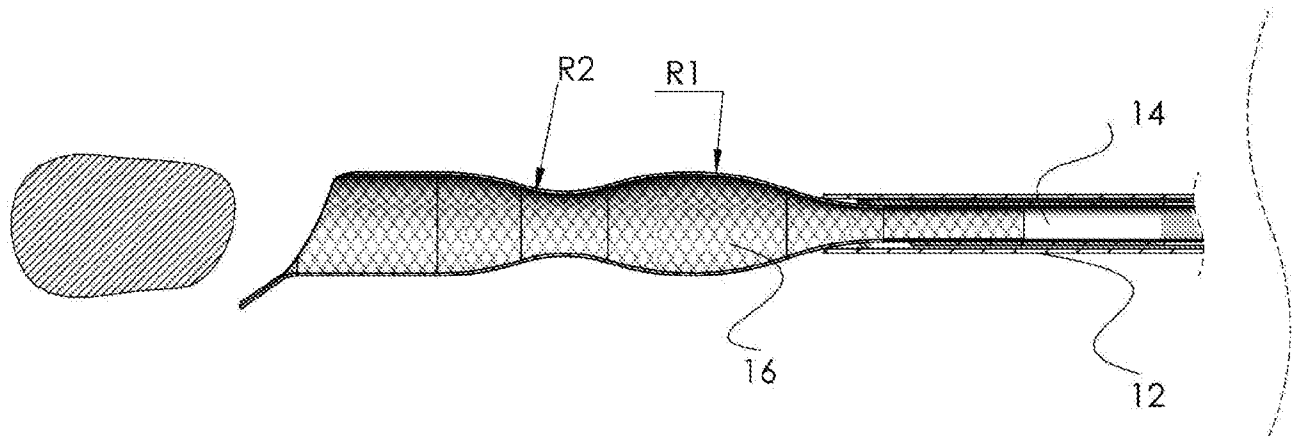


FIG. 1D

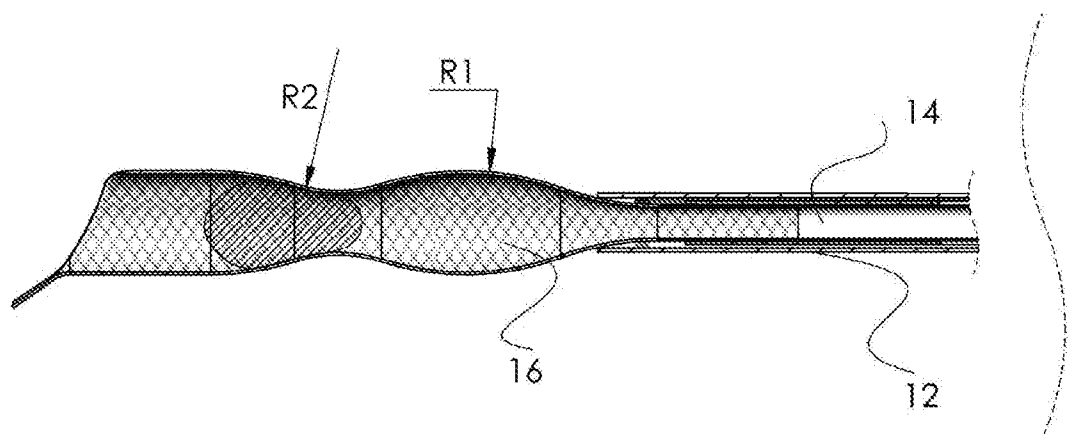


FIG. 1E

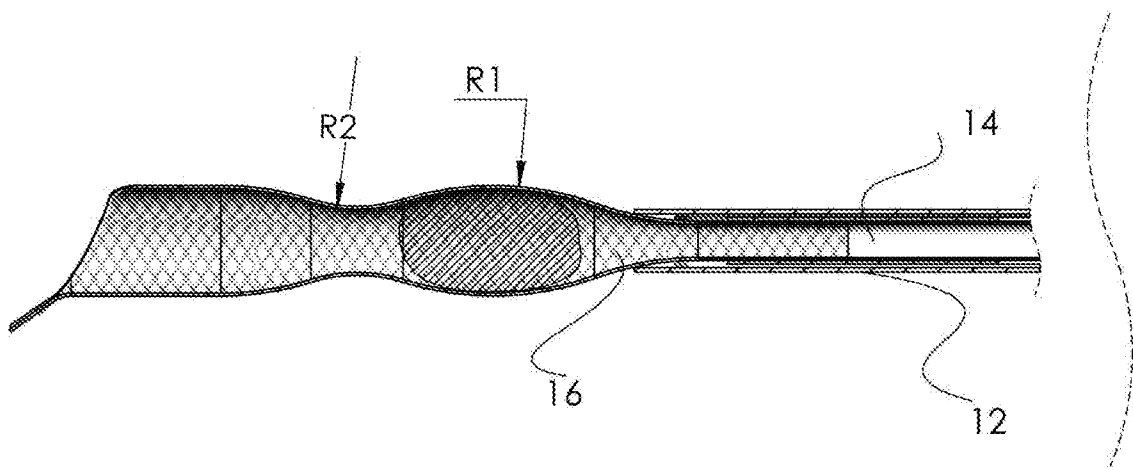


FIG. 1F

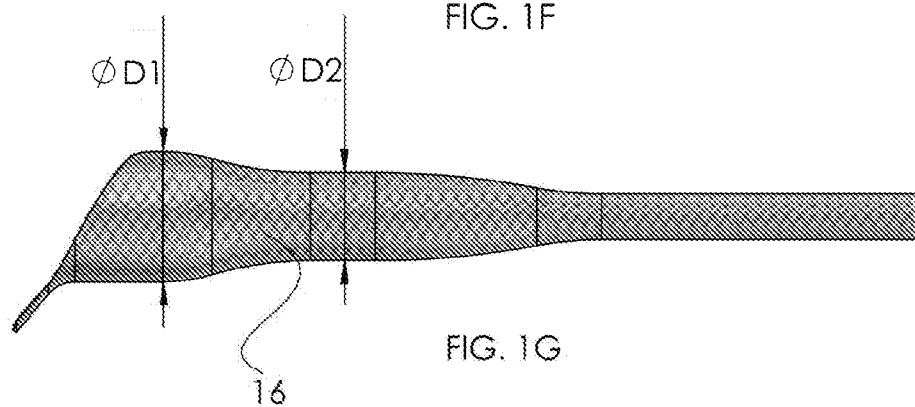
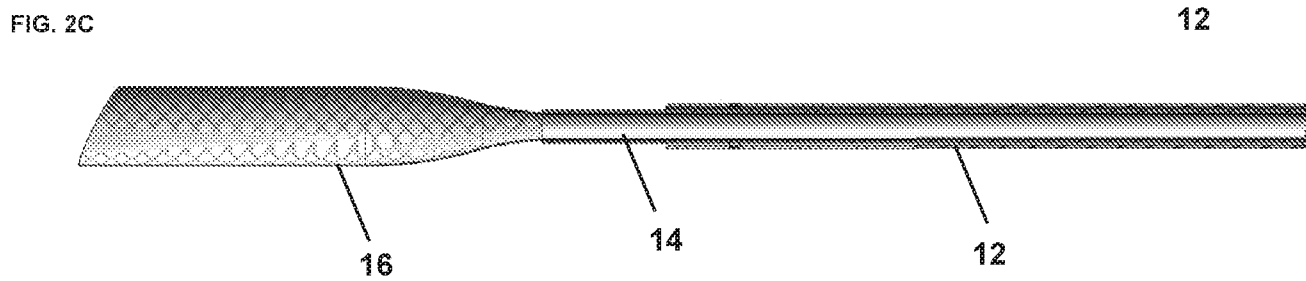
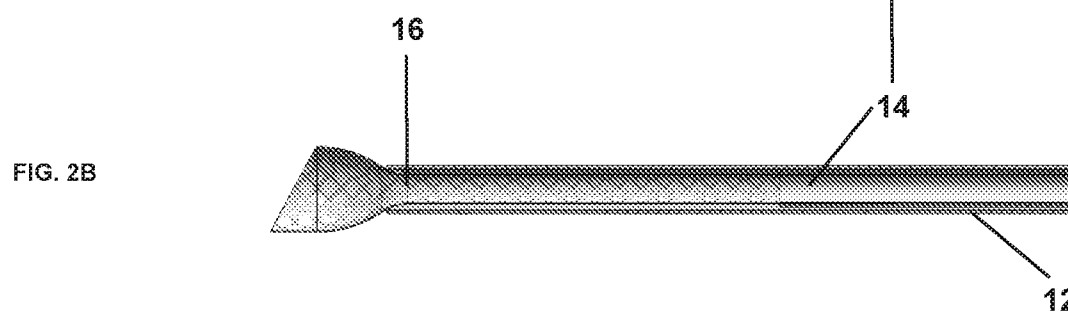
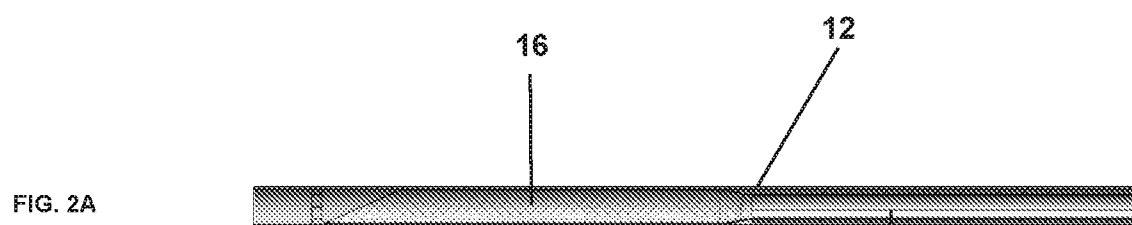


FIG. 1G



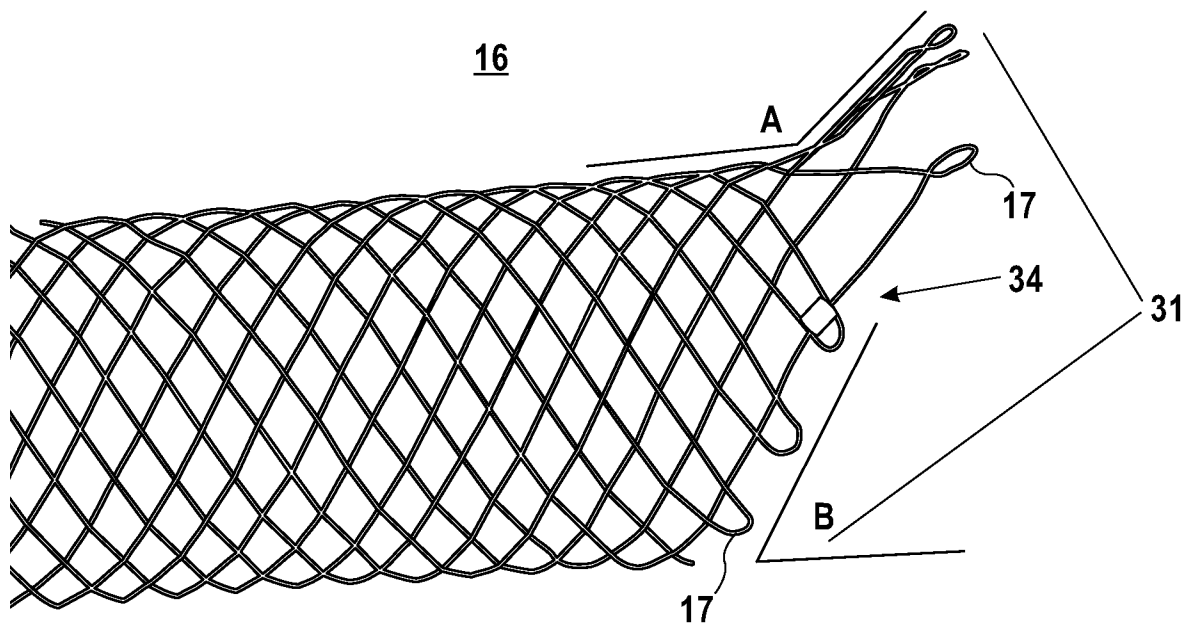


FIG. 2D

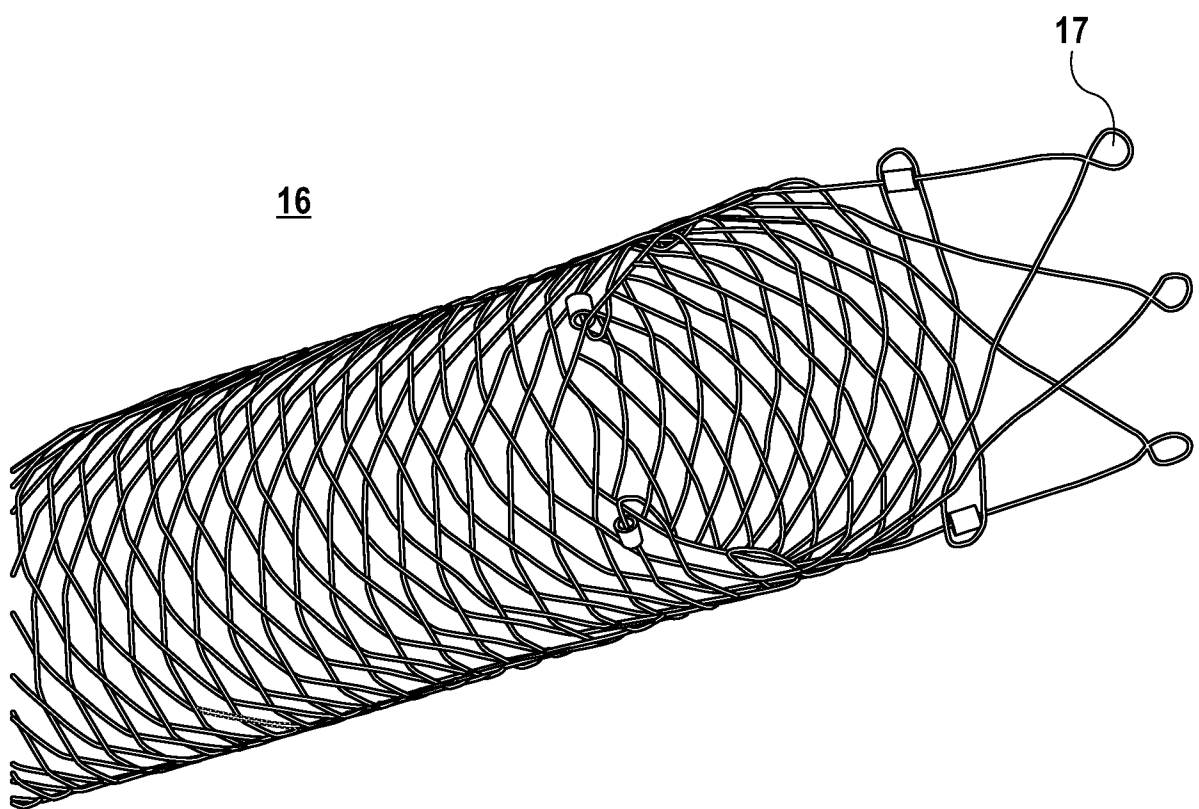


FIG. 2E

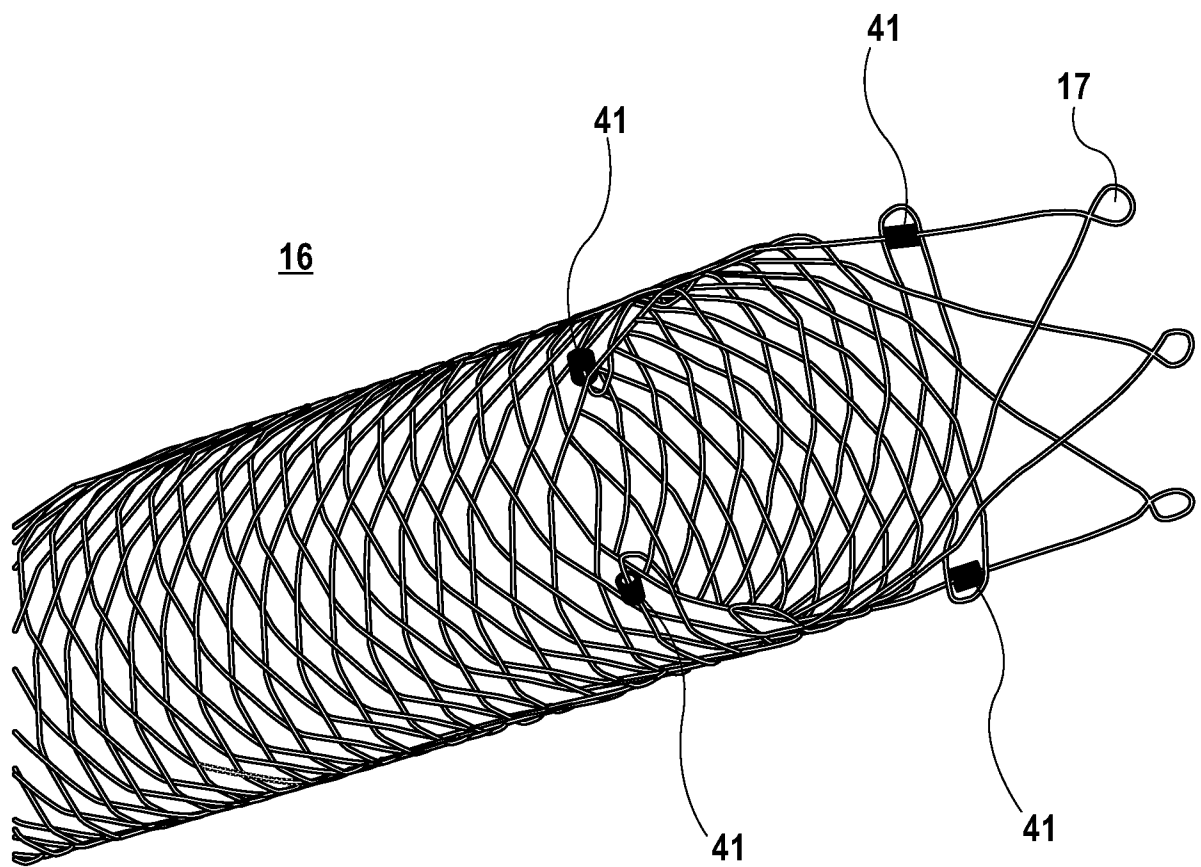


FIG. 2 F

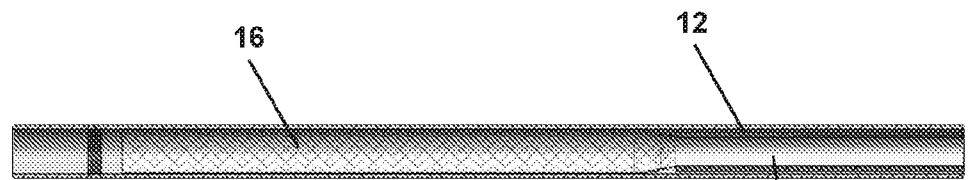


FIG. 3A

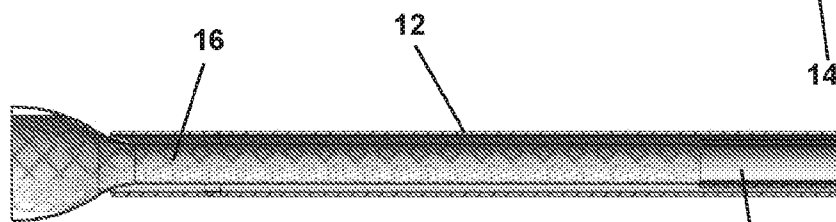


FIG. 3B

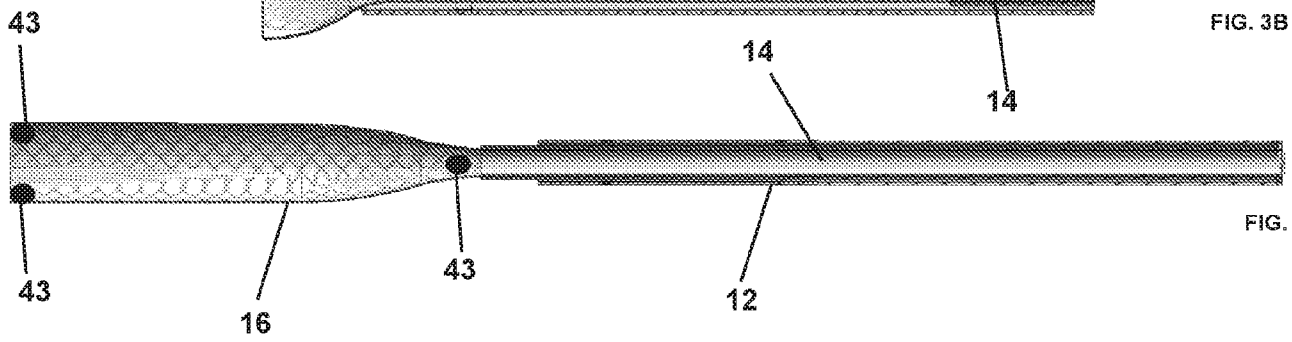
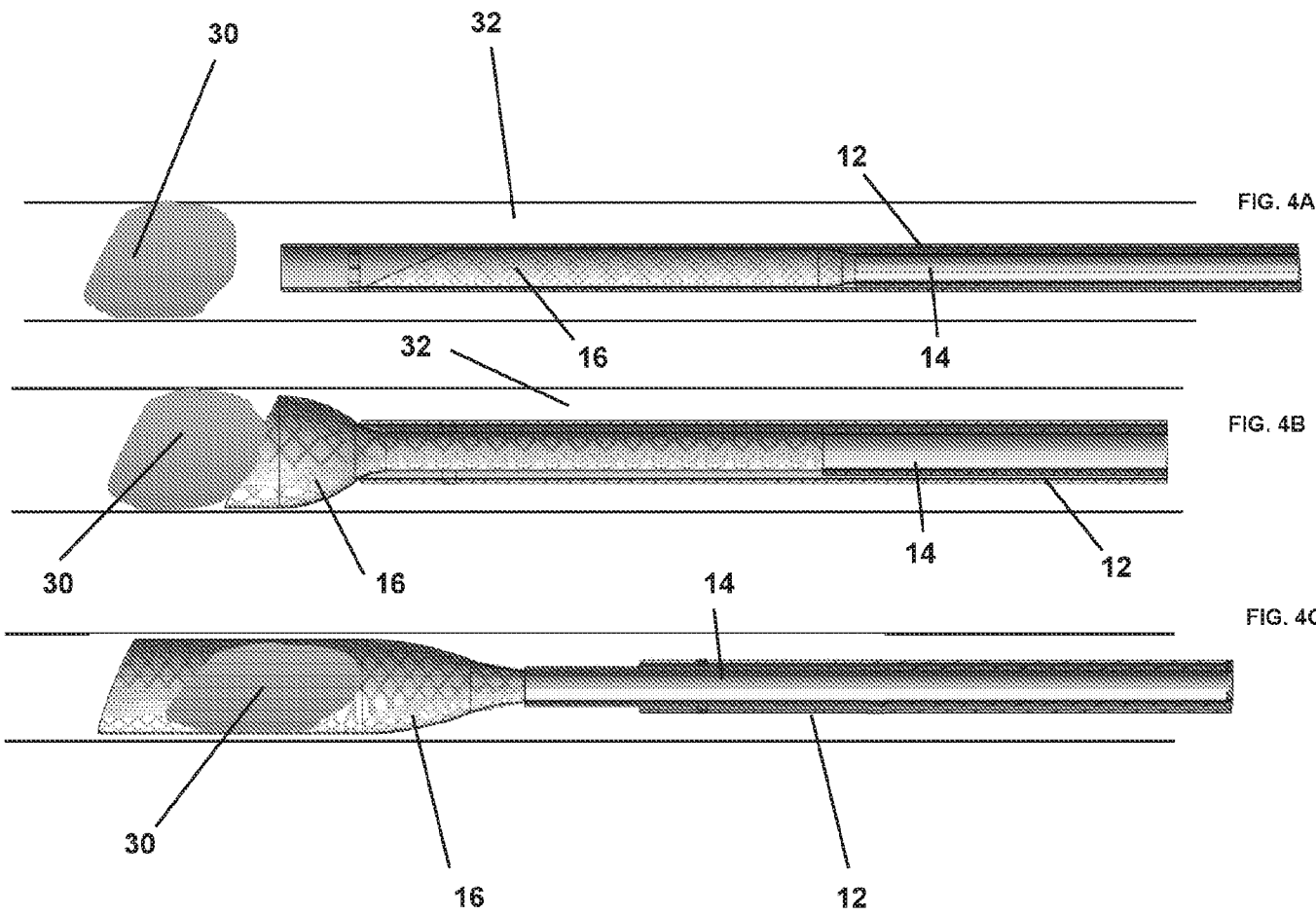
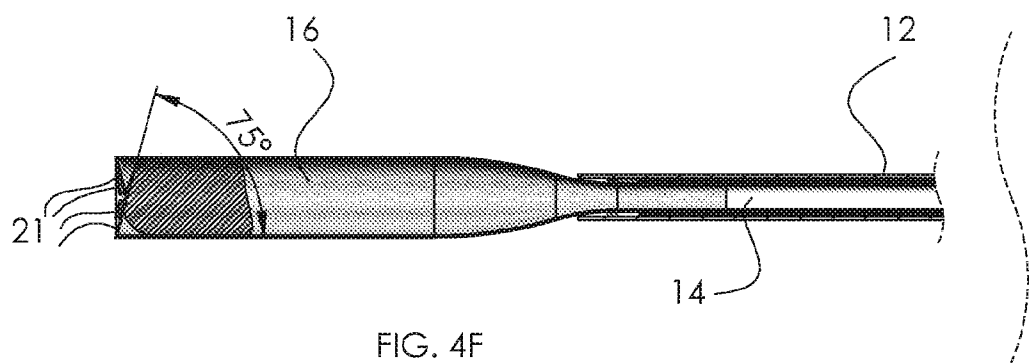
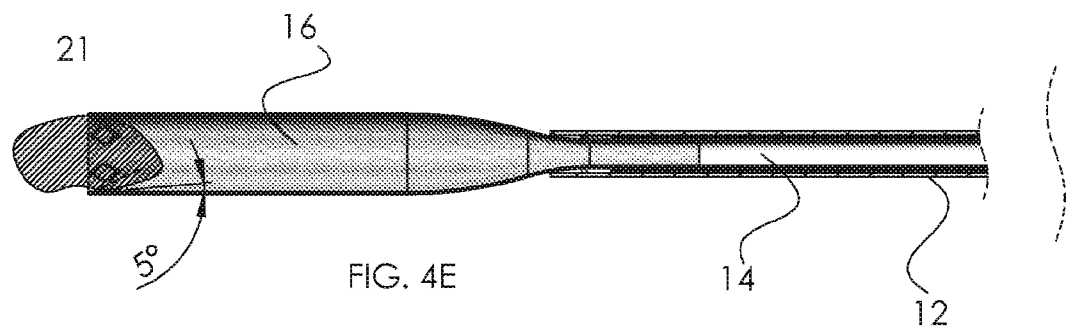
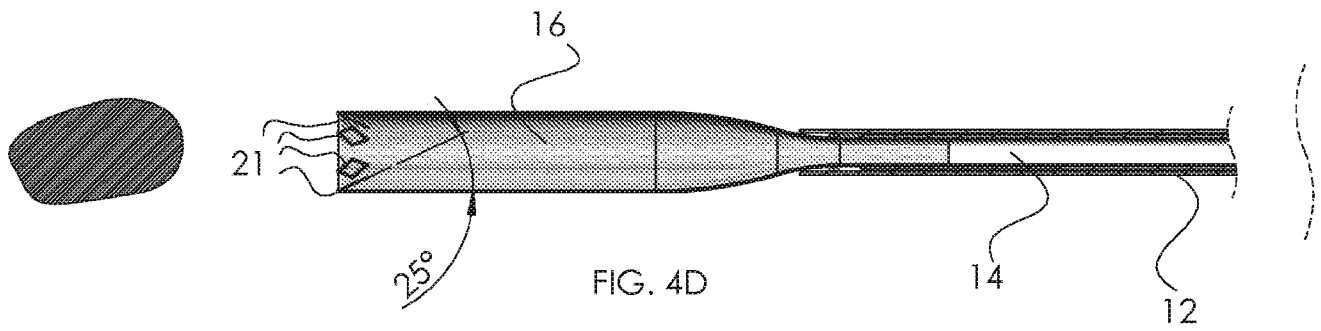
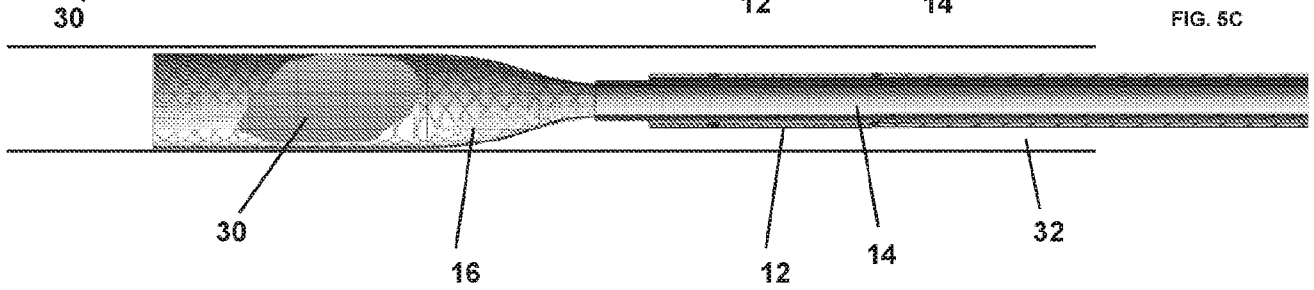
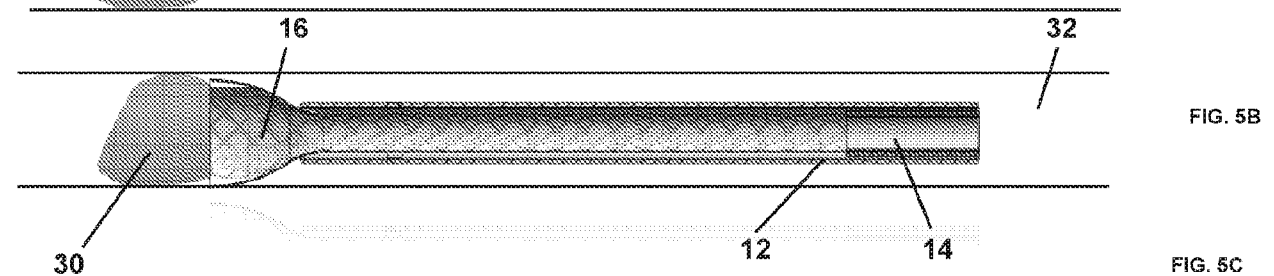
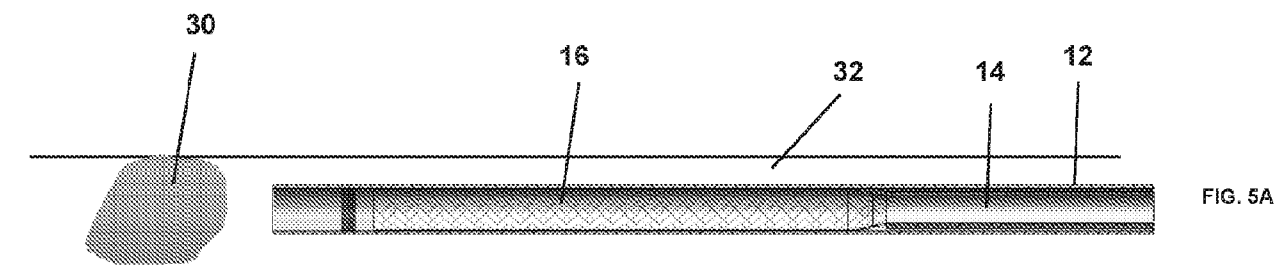
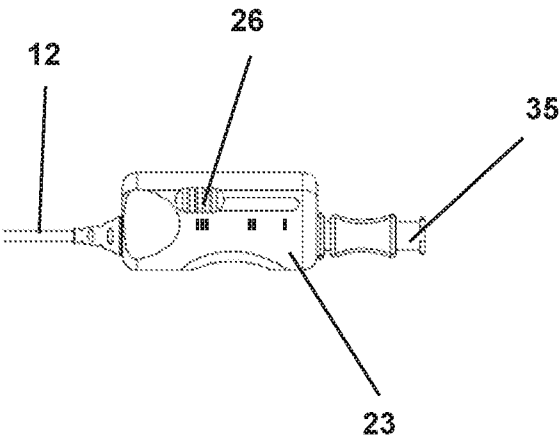


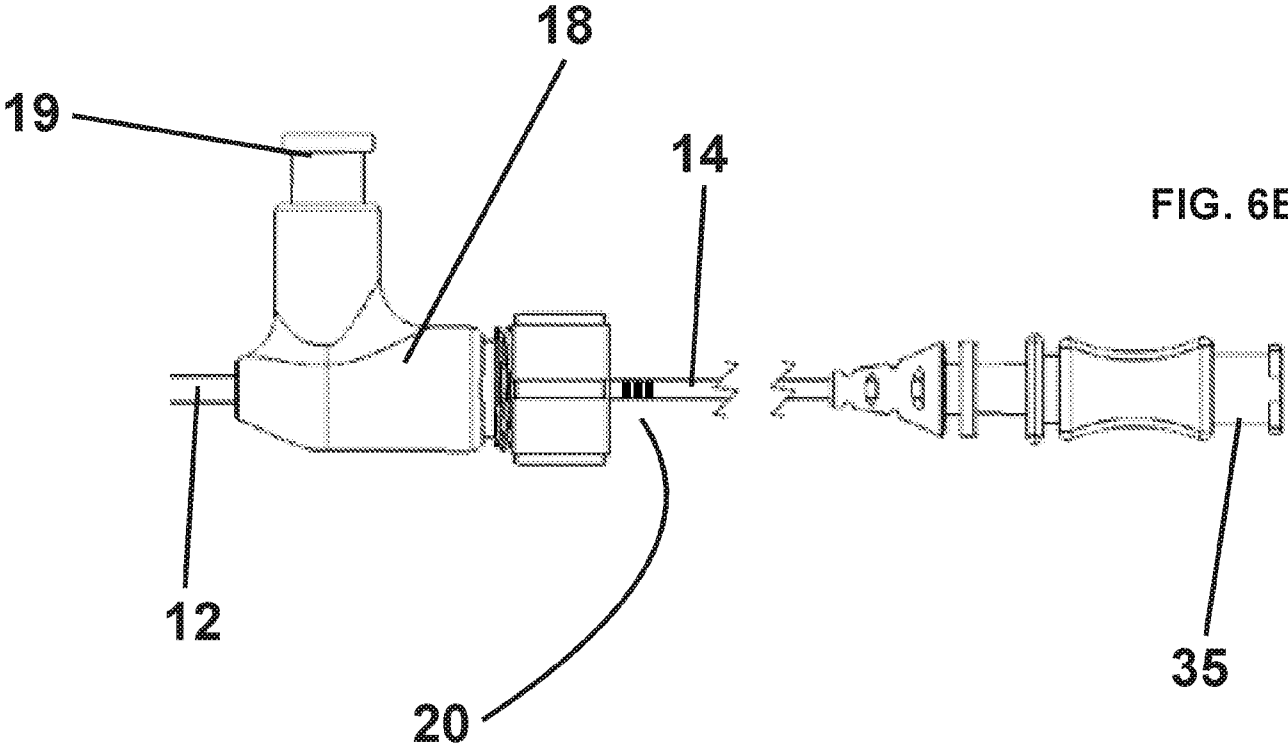
FIG. 3C











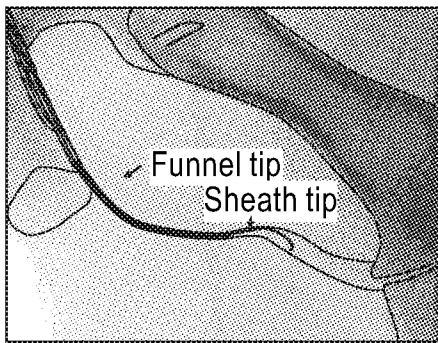


FIG. 7A

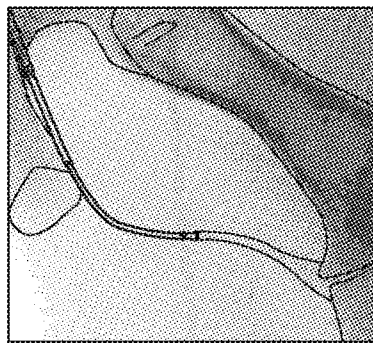


FIG. 7B

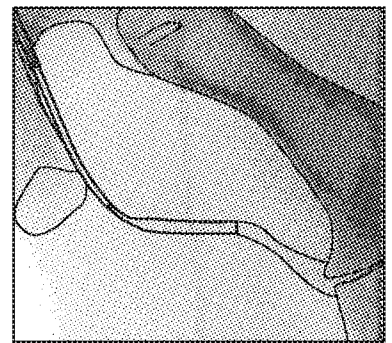


FIG. 7C

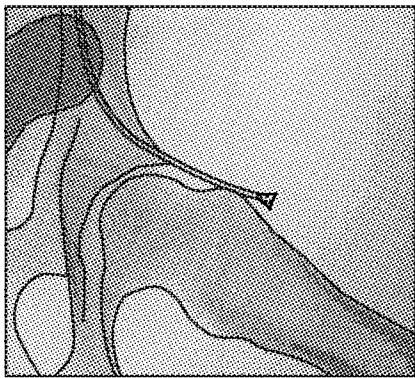


FIG. 8A

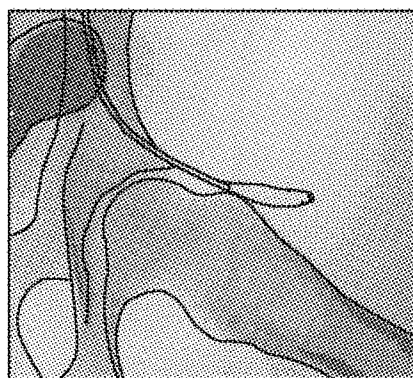


FIG. 8B

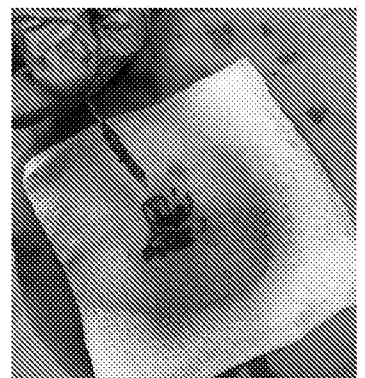


FIG. 8C

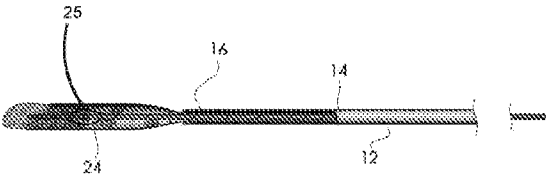


Fig. 9B

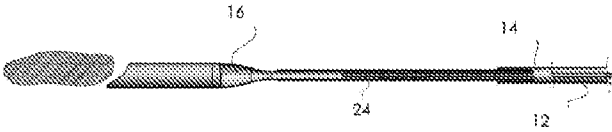


Fig. 9A

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2021/051461

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/00(2022.01)i; A61B 17/22(2022.01)i; A61B 17/221(2022.01)i; A61M 25/01(2022.01)i; A61M 25/06(2022.01)i; A61M 1/00(2022.01)i; A61M 25/09(2022.01)i

CPC:A61M 25/0074; A61B 17/22031; A61B 17/221; A61B 2017/2215; A61M 25/0175; A61M 25/0681; A61M 2025/0004; A61M 1/84; A61M 25/0076; A61M 25/091

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 25/00; A61B 17/22; A61B 17/221; A61M 25/01; A61M 25/06; A61M 1/00; A61M 25/09

CPC:A61M 25/0074; A61B 17/22031; A61B 17/221; A61B 2017/2215; A61M 25/0175; A61M 25/0681; A61M 2025/0004; A61M 1/84; A61M 25/0076; A61M 25/091

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

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

Databases consulted: Google Patents, Orbit, Similari (AI-based)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y X	WO 2020099386 A1 (ANACONDA BIOMED SL) 22 May 2020 (2020-05-22) Abstract; Figs. 5, 20; table 1; page 9 – lines 3-4, 8-9, 16, 21-22, page 11 – lines 17-20, page 14 – lines 22-24, page 17 – lines 1,28-29, page 19 – lines 7,21-22, page 45 – lines 16-21;	11-14 1-10,15-22,24
Y	WO 2019064306 A1 (CERETRIVE LTD) 04 April 2019 (2019-04-04) Abstract; Figs. 1A, 4A-B; page 8 – lines 13-15, page 15 – lines 15-18;	11-14,27
Y X	WO 2016113047 A1 (ANACONDA BIOMED SL) 21 July 2016 (2016-07-21) Abstract; Figs. 4, 8; page 11 – lines 11-18;	27 25,26,28
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P,X	US 2021154433 A1 (NEURAVI LTD) 27 May 2021 (2021-05-27) Abstract; Fig. 1	1,25



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
 “&” document member of the same patent family

Date of the actual completion of the international search

24 March 2022

Date of mailing of the international search report

24 March 2022

Name and mailing address of the ISA/IL

Israel Patent Office
Technology Park, Bldg.5, Malcha, Jerusalem, 9695101,
Israel
Israel

Telephone No. **972-73-3927190**

Email: **pctoffice@justice.gov.il**

Authorized officer

RINGEL Avigail

Telephone No.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/IL2021/051461

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