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(71) Demandeurs/Applicants:
GUERRA, ERIC RAUL, US;
GUERRA, XOCHITL BRAHMS, US;
GUERRA, MAYRA PAULINA, US

(72) Inventeurs/Inventors:
GUERRA, ERIC RAUL, US;
GUERRA, XOCHITL BRAHMS, US;
GUERRA, MAYRA PAULINA, US

(74) Agent: HICKS INTELLECTUAL PROPERTY LAW

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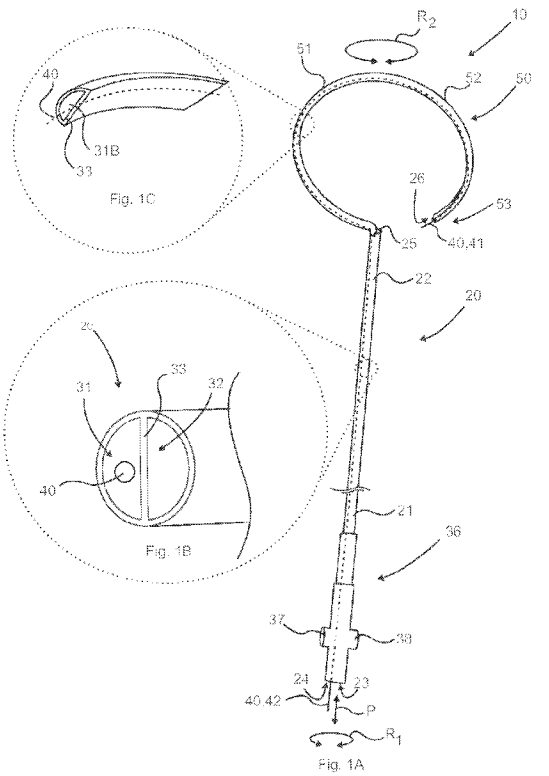
(54) Title: THROMBECTOMY CATHETER AND METHODS OF USE



(57) Abrégé/Abstract:
A thrombectomy catheter with a catheter or delivery sheath having a dual lumen extending therethrough, the catheter having a proximal segment and a distal segment and a linear section coupled therebetween, the distal segment configured as a loop, a port or aperture formed therein said dual lumen of said catheter, the port positioned proximate the distal segment, and a guidewire configured to longitudinally traverse therethrough one of the dual lumen of the catheter, an aspiration device connected thereto one of the dual lumen and configured to create a vacuum therein the catheter and the loop to extract a biomaterial.

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(72) Inventors; and
(71) Applicants: **GUERRA, Eric Raul** [US/US]; 2269 Horizons Drive, Ooltewah, Tennessee 37363 (US). **GUERRA, Xochitl Brahms** [US/US]; 2269 Horizons Drive, Ooltewah, Tennessee 37363 (US). **GUERRA, Mayra Paulina** [US/US]; 2269 Horizons Drive, Ooltewah, Tennessee 37363 (US).

(74) Agent: **GRELL, Mathew L.**; 2796 Soulier Street, Pittsburgh, Pennsylvania 15227 (US).

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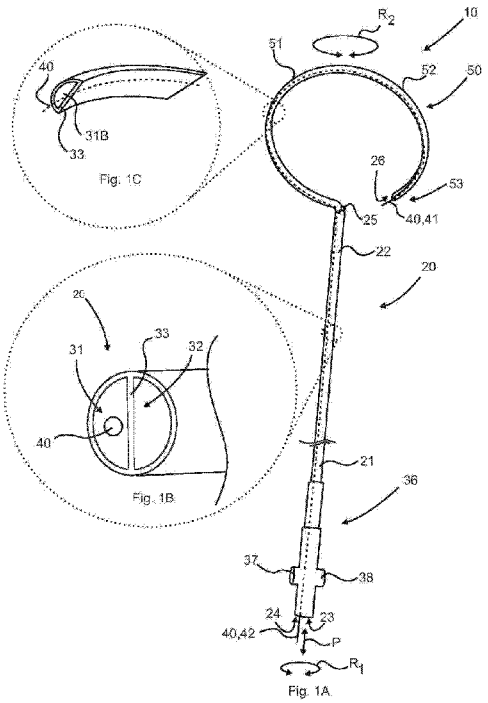
(54) **Title:** THROMBECTOMY CATHETER AND METHODS OF USE

(57) **Abstract:** A thrombectomy catheter with a catheter or delivery sheath having a dual lumen extending therethrough, the catheter having a proximal segment and a distal segment and a linear section coupled therebetween, the distal segment configured as a loop, a port or aperture formed therein said dual lumen of said catheter, the port positioned proximate the distal segment, and a guidewire configured to longitudinally traverse therethrough one of the dual lumen of the catheter, an aspiration device connected thereto one of the dual lumen and configured to create a vacuum therein the catheter and the loop to extract a biomaterial.



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THROMBECTOMY CATHETER AND METHODS OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

To the full extent permitted by law, the present United States Continuation-in-Part Patent Application hereby claims priority to and the full benefit of, U.S. Patent Application No. 15/964,593, filed April 27, 2018, which is entitled "Thrombectomy Catheter and Methods of Use," which claims priority to U.S. Provisional Application No. 62/598,436, filed December 13, 2017, which is entitled "X-tractor Thrombectomy Catheter and Methods of Use," which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

The disclosure relates generally to medical catheter devices and more specifically it relates to medical catheter devices with a deployable instrument to remove thrombi (blood clots).

BACKGROUND

A catheter is a medical device or apparatus made from medical grade materials serving a broad range of functions, such as insertion into the body to treat diseases or perform a surgical procedure. Moreover, catheters are often of an elongated form having manipulator means at its distal end and utilized for surgical manipulation of matter in a confined or inaccessible space within a human body or animal. For example, catheters may be utilized to perform suturing, cutting with a knife or scissor action, or by capture and retrieval devices through a small arthroscopic, endoscopic incision, percutaneous, or body aperture.

Furthermore, angioplasty, atherectomy, and deployment of stents and stent-grafts, procedures to treat vascular disease, often dislodge material or plaque from the vessel walls, which may result in the formation of clots or the release of emboli, which enter the bloodstream, and may be large enough to occlude smaller downstream vessels and potentially blocking blood flow to tissue. The result may pose a serious threat to the health or life of a patient if the blockage occurs in critical tissue, such as the heart, lungs, or brain.

One previous approach includes a catheter device having a cannula with an axial bore wherein a remote actuator means on a proximate end activates a sliding elastically deformable loop to extend past the confines of the deployment opening on the distal end thereof to deploy the elastically deformable loop and barrier member attached thereto and attains its deployed configuration. One disadvantage of this approach is that the elastically deformable loop may over expand or linearly expand causing a tear in tissue or a vessel in the deployment area. Another disadvantage of this approach is that the elastically deformable

loop may slice or puncture the biopsy, clot, or impaling the vessel wall when the sliding elastically deformable loop is expanded and/or retracted back into the deployment opening. Moreover, such elastically deformable loop is generally incapable of preventing material from escaping from the filter (barrier member) during the process of collapsing and retraction.

Another previous approach includes a catheter device having self-expanding vascular device, such as a support hoop expandable to an articulation region for supporting a sac or mesh filter for filtering or removing matter and capturing emboli from within a vascular system. One disadvantage of this approach is that the mesh filter may degrade flow through the vessel and may result in damage to the downstream cells and tissue normally fed by the blocked vessel. Consequently, it may be difficult or impossible to use such devices in small diameter vessels.

Therefore, it is readily apparent that there is a recognizable unmet need for a thrombectomy catheter and methods of use thereof that functions to deploy, scoop, collect, and remove material, plaque, clots, and emboli from the vessel walls without causing a tear in tissue or a vessel, slice or puncture the biopsy, clot, or impale the vessel wall. Also, to prevent material from escaping from the filter (barrier member) during the process of collapsing and retraction, not degrade flow through the vessel and may result in damage to the downstream cells and tissue normally fed by the blocked vessel, and enable operation in small diameter vessels.

SUMMARY

Briefly described, in example embodiment, the present apparatus overcomes the above-mentioned disadvantage, and meets the recognized need for a thrombectomy catheter and methods of use, by providing a catheter or delivery sheath having a dual lumen (passageway) extending therethrough, the catheter having a proximal segment and a distal segment and a linear section coupled therebetween, the distal segment configured as a loop (pigtail) or rim, a port or aperture formed therein said dual lumen of said catheter, the port positioned proximate the distal segment, and a guidewire configured to longitudinally traverse therethrough one of the dual lumen of the catheter, said guidewire configured with a mesh strainer (basket/net) configured to longitudinally traverse therethrough the other of the dual lumen of the catheter and exit therethrough said port and follow said loop to form retractable mesh strainer and, thus, functions to deploy, scoop, collect, and remove material, plaque, clots, and emboli from the vessel interior without causing a tear in tissue or a vessel, slice or puncture the biopsy, clot, or impale the vessel wall, to prevent material from escaping

from the filter (barrier member) during the process of collapsing and retraction, not degrade flow through the vessel and may result in damage to the downstream cells and tissue normally fed by the blocked vessel, and enable operation in small diameter vessels.

According to its major aspects and broadly stated, the thrombectomy catheter and methods of use, includes a catheter or delivery sheath having a dual lumen extending therethrough, the catheter having a proximal segment and a distal segment and a linear section coupled therebetween, the distal segment configured as a loop, a port or aperture formed therein said dual lumen of said catheter, the port positioned proximate the distal segment, and a guidewire configured to longitudinally traverse therethrough one of the dual lumen of the catheter, said guidewire having a first end affixed to a mesh strainer, the mesh strainer configured to longitudinally traverse therethrough the other of the dual lumen of the catheter and exit therethrough said port and follow said loop to form retractable mesh strainer.

In an exemplary embodiment of the remotely operated surgical device includes a flexible positioning instrument having an elongated catheter with a dual lumen bore therein extending from a first catheter end to a second catheter end, the dual lumen bore having a first lumen and a second lumen, and a pigtail attached thereto the second catheter end, the first lumen extends therethrough the elongated catheter and the pigtail, the second lumen extends therethrough the elongated catheter, a guidewire extendable therethrough the first lumen of the elongated catheter and the pigtail, and extendable therefrom the pigtail, the guidewire configured to angle the pigtail, and a retraction instrument configured having a proximal member and a distal member coupled to the proximal member, the distal member having a deformable rim and a barrier membrane affixed thereto the deformable rim and extendable therethrough the second lumen of the elongated catheter.

In a further exemplary embodiment of the method for removing a biomaterial from a patient's vessel including the steps of providing a remotely operated surgical device having a flexible positioning instrument, the flexible positioning instrument having an elongated catheter with a dual lumen bore therein extending from a first catheter end to a second catheter end, the dual lumen bore having a first lumen and a second lumen, and a pigtail attached thereto the second catheter end, the first lumen extends therethrough the elongated catheter and the pigtail, the second lumen extends therethrough the elongated catheter, a guidewire extendable therethrough the first lumen of the elongated catheter and the pigtail, and a retraction instrument configured having a proximal member and a distal member coupled to the proximal member, the distal member having a deformable rim and a barrier

membrane affixed thereto the deformable rim and extendable therethrough the second lumen of the elongated catheter, maneuvering the operated surgical device therethrough the patient's vessel, positioning the pigtail proximate the biomaterial, deploying the deformable rim and the barrier membrane therefrom the second lumen, rotating the deformable rim and the barrier membrane proximate the biomaterial, collecting the biomaterial therein the barrier membrane, retracting the deformable rim, the barrier membrane, and the biomaterial therethrough the second lumen.

Accordingly, a feature of the thrombectomy catheter and methods of use is its ability to spin the pigtail or distal segment configured as a loop multiple times proximate the undesirable material enabling it to scoop up clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris therein mesh blood strainer and extract them from a human blood vessel.

Another feature of the thrombectomy catheter and methods of use is its ability to provide a mesh strainer or basket porous so that blood cells may pass through freely while clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris are captured therein.

Still another feature of the thrombectomy catheter and methods of use is its ability to provide a dual lumen catheter where one lumen forms a passageway for the guidewire and the other lumen forms a passageway for the mesh strainer.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a remotely operable surgical device or guidewire.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a flexible a dual lumen catheter.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a flexible a dual lumen catheter having a flexible pigtail having a passageway for the guidewire and a deployment or exit port formed proximate or at the tip end.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a retractable mesh strainer that traverses therearound the distal segment configured as a loop to form a basket or net to scoop up clots, plaque, emboli, or other dislodge matter therein mesh strainer.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a catheter with a deployable mesh basket, net, mesh strainer to track around a loop, pigtail on the distal segment of the catheter.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device that overcomes disadvantages of previously known vascular filter nets and thrombectomy/embolectomy devices, and employs few components.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device that is capable of being contracted to a small delivery profile, thus permitting use of the device in small blood vessels.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device without the need for specialized delivery catheters.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device to provide a vascular device that reduces the risk of clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris escaping from the device when the device is retracted and removed.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device to percutaneously remove clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris from human blood vessel without performing surgery or without giving a clot buster.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device to capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris from human blood vessel just by spinning the pigtail, loop, or distal segment configured as a loop multiple times proximate the undesirable material.

Yet another feature of the thrombectomy catheter and methods of use is the ability to remove the net, basket, deployable mesh basket, or mesh strainer multiple times through the dual lumen catheter without losing position of the pigtail, loop, or distal segment configured as a loop adjacent to the working area.

Yet another feature of the thrombectomy catheter and methods of use is the ability to provide a vascular device with aspiration or suction via an aspiration device to collect and remove clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris from human blood vessel by suctioning undesirable material (aspiration thrombectomy) therein a distal end of a lumen proximate the undesirable material and drawing such down the lumen channel.

These and other features of the thrombectomy catheter and methods of use will become more apparent to one skilled in the art from the following Detailed Description of the Embodiments and Claims when read in light of the accompanying drawing Figures.

BRIEF DESCRIPTION OF THE DRAWINGS

The present thrombectomy catheter and methods of use will be better understood by reading the Detailed Description of the embodiments with reference to the accompanying drawing figures, in which like reference numerals denote similar structure and refer to like elements throughout, and in which:

FIG. 1A is a top perspective view of an exemplary embodiment of a thrombectomy catheter;

FIG. 1B is a perspective cross-sectional view of an exemplary embodiment of a dual lumen elongated catheter of the thrombectomy catheter of **FIG. 1A**;

FIG. 1C is a perspective cross-sectional view of an exemplary embodiment of a single lumen pigtail of the thrombectomy catheter of **FIG. 1A**;

FIG. 2 is a top perspective view of an exemplary embodiment of the thrombectomy catheter of **FIG. 1A,** shown with a guidewire passing therein a first lumen elongating the pigtail;

FIG. 3 is a top perspective view of an exemplary embodiment of vascular medical instrument;

FIG. 4A is a top perspective view of an exemplary embodiment of a thrombectomy catheter of **FIG. 1**, shown with a guidewire traversing therein first lumen, and retractable instrument traversing therein second lumen;

FIG. 4B is a perspective cross-sectional view of the elongated catheter of a thrombectomy catheter of **FIG. 1**, shown with a guidewire and a retractable instrument traversing therethrough;

FIG. 5A is a top perspective view of an exemplary thrombectomy catheter of **FIG. 1** with retractable instrument deployed therebetween pigtail;

FIG. 5B is a front perspective view of thrombectomy catheter of **FIG. 5A** with vascular medical instrument, shown netting undesirable material or debris for retrieval;

FIG. 6 is a top view of thrombectomy catheter of **FIG. 5A** passing through the heart and deployed in a vascular vessel of the lung with retractable instrument shown netting undesirable material or debris for retrieval;

FIG. 7 is a flow diagram of a method deploying, using, and retrieving thrombectomy catheter of **FIGs. 1-6** to remove undesirable material or debris from a vascular vessel;

FIG. 8 is a top perspective view of an exemplary embodiment of a thrombectomy catheter with aspiration device;

FIG. 9 is a top perspective view of an exemplary thrombectomy catheter of **FIG. 8** with undesirable material being drawn therein lumen distal end; and

FIG. 10 is a flow diagram of a method deploying, using, and retrieving thrombectomy catheter of **FIGs. 1-6** and **8-9** to remove undesirable material or debris from a vascular vessel via aspiration.

It is to be noted that the drawings presented are intended solely for the purpose of illustration and that they are, therefore, neither desired nor intended to limit the disclosure to any or all of the exact details of construction shown, except insofar as they may be deemed essential to the claimed invention.

DETAILED DESCRIPTION

In describing the exemplary embodiments of the present disclosure, as illustrated in **FIGS. 1A, 1B, 1C, 2, 3, 4A, 4B, 5A, 5B, 6 7, 8, 9,** and **10** specific terminology is employed for the sake of clarity. The present disclosure, however, is not intended to be limited to the specific terminology so selected, and it is to be understood that each specific element includes all technical equivalents that operate in a similar manner to accomplish similar functions. Embodiments of the claims may, however, be embodied in many different forms and should not be construed to be limited to the embodiments set forth herein. The examples set forth herein are non-limiting examples, and are merely examples among other possible examples.

Referring now to **FIGs. 1A, 1B, 1C**, by way of example, and not limitation, there is illustrated an example embodiment of a flexible surgical positioning instrument **10.** Surgical positioning instrument **10** may include a base section, such as hand grip **36,** having first rotation flap **37** and second rotation flap **38**, as coupled to a longitudinal linear member, cannula, housing, catheter, or sheath, such as elongated catheter **20** extending linearly therefrom hand grip **36**. Preferably, elongated catheter **20** may include two or dual axial bores therethrough or space created inside elongated catheter **20** and extending from first catheter end **21** to second catheter end **22.** Moreover**,** two or dual axial bores therethrough may include first lumen **31** and second lumen **32** separated by divider **33.**

Furthermore**,** second catheter end **22** of surgical positioning instrument **10** may be configured as a loop, open ended loop, or enclosure, such as pigtail **50** formed thereon or attached thereto second catheter end **22**. It is contemplated herein that pigtail **50** may be formed in a variety of sizes and configurations and include first pigtail section **51** and second pigtail section **52** with first pigtail section **51** affixed thereto second catheter end **22** of elongated catheter **20** and second pigtail section **52** forming an enclosure that loops around

back to a position proximate second catheter end **22**. It is contemplated herein that elongated catheter **20** and pigtail **50** may preferably be configured or constructed of plastic, polymeric material includes polytetrafluorethylene, polyurethane, polyethylene, Teflon, and the like as such materials offers a variety of forms, shapes, ease of manufacture, and flexibility; however, other suitable materials may be utilized provided such material has sufficient strength, flexibility, and/or durability as would meet the purpose described herein. The material of elongated catheter **20,** second lumen **32** pigtail **50,** second lumen or medical instrument exit aperture **25** may be reinforced with fibers, rings, or longitudinal ribs, for example, to enable it to withstand the forces exerted on it by retractable instrument **60** while it is constrained within second lumen **32** and deformed by elongated catheter **20.**

First lumen **31** may extend therethrough hand grip **36**, elongated catheter **20,** and pigtail **50,** beginning with an entrance hole, such as first lumen or guidewire entrance aperture **24** and exit therefrom pigtail **50** proximate pigtail end **53** through an exit or deployment hole opening to the environment, such as first lumen or guidewire exit aperture **26.**

Second lumen **32** may extend therethrough hand grip **36** and elongated catheter **20** beginning with an entrance hole, such as first instrument aperture **23** and exit therefrom elongated catheter **20** proximate second catheter end **22** through an exit or deployment hole, such as second instrument aperture **25** proximate second catheter end **22.**

Referring now to **FIGs. 2**, by way of example, and not limitation, there is illustrated an example embodiment of guidewire **40** for deployment and retraction use therein first lumen **31** of elongated catheter **20** and pigtail lumen **31B** of pigtail **50.** Guidewire **40** may include first guidewire end **41** and second guidewire end **42.** In use, a path or vessel guiding device, such as guidewire **40** may be extended therethrough first lumen **31** of elongated catheter **20** and pigtail lumen **31B** of pigtail **50** beginning with an entrance hole, such as first lumen entrance aperture **24** and exiting therefrom pigtail **50** proximate pig tail end **53** through an exit or deployment hole opening to the environment, such as first lumen exit aperture **26** to a position beyond or extend and extendable therefrom pigtail **50** to assist or guide second catheter end **22** and pigtail **50** therethrough a blood vessel **V**, turn, fork or other vascular maneuverability. First guidewire end **41** extends through the deployment opening, such as guide wire aperture **26** and is remotely controlled from second guidewire end **42.** Moreover, as guidewire **40** passes therethrough pigtail **50,** pigtail **50** may angled or straighten (as shown in **FIG. 2**) or angle, such as pigtail angle **A** (from approximately 0-270 degrees relative to perpendicular thereto elongated catheter **20,** 9 o'clock counterclockwise to 12 o'clock),

depending on the flexibility or rigidity of first guidewire end **41** passing therethrough. Furthermore, first rotation **R1** of elongated catheter **20** causes or results in similar rotation, such as rotation **R2** of pigtail **50.** Both pigtail angle **A** and rotation **R2** enable a variety of positions of first guidewire end **41** to assist or guide or position guidewire **40,** pigtail **50,** and second catheter end **22** therethrough a blood vessel **V**, turn, fork or other vascular maneuverability. Still furthermore, movement of or moving guidewire **40,** such as push/pull **P1** of second guidewire end **42** causes first guidewire end **41** to move in and out therefrom guide wire aperture **26** to assist or guide or position guidewire **40,** pigtail **50,** and second catheter end **22** therethrough a blood vessel, turn, fork or other vascular **V** maneuverability.

Alternatively, first lumen **31** and pigtail lumen **31B** may be utilized as an access for additional laparoscopic or endoscopic devices, and/or fluid access or withdrawal, lighting, video, and like medical instruments **40A**. Such an endoscope can also provide surgical implements such as lasers, scalpels, irrigation and aspiration means, visualization means, and the like **40A**. The specific configuration and dimensions of first lumen **31** and pigtail lumen **31B** will vary with the intended use of surgical positioning instrument **10**, and whether access for additional medical instruments **40A** is provided. In general the axial bore of first lumen **31** may have an internal diameter of 6-12 F (French=1/3 mm), however other diameters are contemplated herein to accommodate a working channel of an endoscope.

Referring now to **FIG. 3**, by way of example, and not limitation, there is illustrated an example embodiment of a retractable instrument **60**, for use with surgical positioning instrument **10.** Retractable instrument **60** may include a proximal or elongated member or operator, such as proximal member **64** having a first member end **65** and a second member end **66.** First member end **65** may be configured having a loop, enclosure, or basket, pigtail such as deformable rim **67** configured thereon and proximate second member end **66**. It is contemplated herein that deformable rim **67** may be configured in a variety of sizes and shapes preferably matching pigtail **50** in size and shape.

Moreover, deformable rim **67** may be configured of one or two components, such as first deformable section **61** and second deformable section **62** and may alternatively include one or more pivot joint **68** therebetween first deformable section **61** and second deformable section **62.** Deformable rim **67** is preferably made of a flexible, elastic, or shape memory material or alloy biocompatible material capable of flexing, bending, or collapsing to a configuration which may enter and exit first instrument aperture **23**, traverse axial bore of second lumen **32,** expanding to deployed net after passing therethrough second instrument

aperture **26,** and collapsing to re-enter second instrument aperture **26** to extract biomaterial therefrom a blood vessel or other vascular channel or conduit **V**.

It is further contemplated herein that deformable rim 67 may include one or more joints or hinges, such as pivot point **68** positioned therearound deformable rim 67 or between first deformable section **61** and second deformable section **62** to enable deformable rim 67**,** first deformable section **61,** and second deformable section **62** to linearly collapse or fold and traverse therethrough first instrument aperture **23**, axial bore of second lumen **32,** and second instrument aperture **25.** It is still further contemplated herein that deformable rim **67** may form an opening, such as rim inlet **69.**

When expanded**,** deformable rim **67** may have a diameter of from about 1 cm or less to about 3 cm but other sizes are contemplated herein. Moreover, a barrier membrane or other sifting or filtering membrane, such as mesh strainer **63** preferably runs, spans, or is affixed thereto deformable rim **67** loosely, forming a rounded open end capture net across rim inlet **69**. Mesh strainer **63** may be utilized to filter or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, or other undesirable material or debris from within human blood vessels **V**.

The specific configuration and dimensions of axial bore of second lumen **32** will vary with the use of surgical positioning instrument **10,** the parameters of retractable instrument **60,** such as insertion/retraction member **64** and sized to receive deformable rim **67** having first deformable section **61** and second deformable section **62** in a constrained configuration with mesh strainer **63** furled around first deformable section **61,** second deformable section **62,** and insertion/retraction member **64**. In general, the axial bore of second lumen **32** may have an axial bore or internal diameter of 6-12 F (French=1/3 mm) to accommodate retractable instrument **60** in a constrained configuration, however other diameters are contemplated herein**.**

Alternatively, second lumen **32** may be utilized as an access for additional laparoscopic or endoscopic devices, and/or fluid access or withdrawal, lighting, video, and like medical instruments **40A**. Such an endoscope can also provide surgical implements such as lasers, scalpels, irrigation and aspiration means, visualization means, and the like **40A**.

Referring again to **FIG. 1A**, the outer diameter of the catheter **20** may vary with the application, the size of first lumen **31** and second lumen **32,** the size of deformable rim **67** of retractable instrument **60** having first deformable section **61** and second deformable section **62,** whether access for additional laparoscopic or endoscopic devices, and/or fluid access or

withdrawal, lighting, video, and the like **40A,** and whether additional lumens are included in surgical positioning instrument **10**.

Referring now to **FIGs. 4A and 4B**, by way of example, and not limitation, there is illustrated an example embodiment of retractable instrument **60** for deployment and retraction use therein second lumen **32** of surgical positioning instrument **10.** Moreover, second guidewire end **42** may be pulled and as guidewire **40** retracts therethrough pigtail **50,** pigtail **50** may return to pigtail or loop configuration as shown in **FIGs. 1** and **4A.**

In use, deformable rim **67** of first member end **65** may be preferably collapsed and mesh strainer **63** may be furled or wrapped therearound deformable rim **67** and/or first member end **65** of retractable instrument **60.** Collapsed deformable rim **67** and furled mesh strainer **63** may be inserted therein first instrument aperture **23** of second lumen **32.** Collapsed deformable rim **67** and furled mesh strainer **63** may be disposed within, extended, and traverse therethrough second lumen **32** of elongated catheter **20** and exit or deploy therethrough or extendable therefrom**. Upon** deformable rim **67** and furled mesh strainer **63 exit thereof** second lumen **32**, deformable rim **67** expands to deployed deformable rim **67** with mesh strainer **63** unfurled to an expanded collection state positioned proximate pigtail **50**. When deployed first deformable section **61** and second deformable section **62** of deformable rim **67** expand back to a non-compressed position as shown in **FIG. 5** to create expanded deformable rim **67** having rim inlet **69** and mesh strainer **63,** where expanded deformable rim **67** preferably mates up with or may be positioned proximate or within pigtail **50,** as shown in **FIG. 5.**

Referring now to **FIG. 5A** and **5B**, by way of example, and not limitation, there is illustrated an example embodiment of retractable instrument **60** shown deployed therefrom second lumen **32** of surgical positioning instrument **103** In use, push/pull **P1** of second member end **66** may deploy or extend deformable rim **67** within pigtail **50** or past the confines of second instrument aperture **25** on the distal end thereof second catheter end **22** to deploy deformable rim **67** and mesh strainer **63** attached thereto and attains its deployed configuration**.** Rotation **R3** of second member end **66** causes or results in similar rotation, such as rotation **R4** of deformable rim **67** having rim inlet **69** and mesh strainer **63,** which in turn causes deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**. Moreover, rotation **R1** of elongated catheter **20** results in rotation **R2** of pigtail **50** which in turn results in rotation **R4** of deformable rim **67** having rim inlet **69** and mesh strainer **63** due

to abutting or contact therebetween pigtail **50** and deformable rim **67** (deformable rim **67** abuts pigtail **50**), which in turn causes deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**. Undesirable material or debris **M** may be removed from blood vessel **V** by extracting retractable instrument **60** and deformable rim **67** having rim inlet **69** and mesh strainer **63** containing undesirable material or debris **M** back therein second instrument aperture **25** collapsing deformable rim **67** and pulling retractable instrument **60** down second lumen **32** of surgical positioning instrument **10** and out first instrument aperture **23,** as shown in **FIGs. 4A** and **4B.** Push/pull **P1** of second member end **66** may retrieve deformable rim **67** by collapsing deformable rim **67** and mesh strainer **63** may be furled or wrapped therearound deformable rim **67** and/or first member end **65,** and retractable instrument **60** with undesirable material or debris **M** may be pulled therethrough second instrument aperture **25** and exit out first instrument aperture **23.**

It is contemplated herein that deformable rim **67** and pigtail **50** may be similar or matched in size and shape, such as circumference and/ or diameter, to enable abutting or contact therebetween pigtail **50** and deformable rim **67** (deformable rim **67** abuts pigtail **50**).

Referring now to **FIG. 6**, by way of example, and not limitation, there is illustrated an example embodiment of surgical device, the combination of retractable instrument **60** and surgical positioning instrument **10.** In use, surgical positioning instrument **10,** shown with pigtail **50** inserted into a patient and serpentinely deployed therethrough blood vessel **V,** heart **H,** lung **L,** and into lung blood vessel **V.** It is contemplated herein that surgical positioning instrument **10** may be deployed therein any fluid-carrying vessels where debris needs to be removed.

In use, push/pull **P1** of guidewire **40** may be extended therethrough pigtail **50,** causing pigtail **50** to straighten or elongate (as shown in **FIG. 2**) or angle, such as pigtail angle **A,** therein blood vessel **V** depending on the flexibility or rigidity of first guidewire end **41** passing therethrough. Furthermore, first rotation **R1** of elongated catheter **20** causes pigtail **50** to similarly rotate, rotation **R2** therein blood vessel **V.** Both pigtail angle **A** and rotation **R2** enable a variety of positions of first guidewire end **41** to assist or guide or position guidewire **40,** pigtail **50,** and second catheter end **22** therethrough or therein blood vessel **V**, heart **H**, lung **L** to serpentine, turn, maneuver a fork of or other vascular maneuverability to precisely maneuver and position pigtail **50** therein blood vessel **V**. The objective of surgical

positioning instrument **10** is to preferably position pigtail **50** in a specific location within a patient's vessel.

Push/pull **P1** of second member end **66** results in exit or deployment of deformable rim **67** having rim inlet **69** and mesh strainer **63** therethrough second instrument aperture **25** proximate a junction between second catheter end **22,** and expanding to deployed deformable rim **67** with mesh strainer **63** after passing therethrough second instrument aperture **25** to a position proximate pigtail **50** therein blood vessel **V**.

Moreover, rotation **R3** of second member end **66** results in rotation **R4** of deformable rim **67** within blood vessel **V** having rim inlet **69** and mesh strainer **63,** which in turn causes deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**.

Furthermore, rotation **R1** of elongated catheter **20** results in rotation **R2** of pigtail **50** within blood vessel **V** which in turn results in rotation **R4** of deformable rim **67** having rim inlet **69** and mesh strainer **63** due to abutting or contact therebetween pigtail **50** and deformable rim **67,** which in turn causes deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**.

Push/pull **P1** of second member end **66** results in collapsed deformable rim **67** having rim inlet **69** and mesh strainer **63** being retracted or entry therein second instrument aperture **25** and traversing therethrough second lumen **32** to first instrument aperture **23** to remove undesirable material or debris **M** captured therein mesh strainer **63** from blood vessel **V**. It is contemplated herein that such capture and retrieval of undesirable material or debris **M** may be accomplished multiple times with multiple passes, deployment, retract, and retrieval of retractable instrument **60** therethrough second lumen **32** of surgical positioning instrument **10.**

It is contemplated herein that second lumen **32** angioplasty, atherectomy, and deployment of stents and stent-grafts, procedures to treat vascular disease may be deployed therethrough second lumen **32.** Such instruments often dislodge material or plaque from the vessel walls of blood vessel **V,** which may result in the formation of clots or the release of emboli, biomaterial, such as undesirable material or debris **M**, which enter the bloodstream, and may be large enough to occlude smaller downstream vessels and potentially blocking blood flow to tissue. The result may pose a serious threat to the health or life of a patient if

the blockage occurs in critical tissue, such as the heart, lungs, or brain. Retractable instrument **60** may be utilized herein to traverse second lumen **32** to capture and remove undesirable material or debris **M** from blood vessel **V.**

It is further contemplated herein that pigtail **50** encircling of deformable rim **67** may protect blood vessel **V** when deformable rim **67** expands preventing contact therewith blood vessel **V** preventing a tear in tissue or a vessel in the deployment area.

It is still further contemplated herein that pigtail **50** encircling of deformable rim **67** may protect blood vessel **V** when deformable rim **67** expands or retracts preventing contact therewith blood vessel **V** preventing slice or puncture the biopsy, clot, or impaling the vessel wall of blood vessel **V**.

It is yet further contemplated herein that second lumen **32** may be utilized for delivery of other medical instrument(s), such as a suture to conduct a biopsy or other medical instrument to meet the needs of the medical application being performed with surgical positioning instrument **10**.

It is yet further contemplated herein that second lumen **32** may be sized or configured adjustable to accommodate different diameter or sized medical instruments **60**.

Referring now to **FIG. 7**, there is illustrated a flow diagram **700** of utilizing surgical positioning instrument **10** and retractable instrument **60** to remove clots or the release of emboli, biomaterial, such as undesirable material or debris **M** from blood vessel **V.** In block or step **710,** providing surgical positioning instrument **10** having elongated member **20** with two or dual axial bores therethrough, such as first lumen **31** and second lumen **32,** and pigtail **50** on one end and integral retractable instrument **60** having deformable rim **67** and mesh strainer **63** as described above in **FIGS. 1-6** including (collapsing deformable rim **67** and wrapping mesh strainer **63** therearound first member end **65** and insertion therein first instrument aperture **23** of second lumen **32**) and (traversing first instrument aperture **23** (push/pull **P1** of second member end **66**) to second instrument aperture **25** of second lumen **32).**

In block or step **715,** manipulating or moving guidewire **40** (push/pull **P1** of guidewire **40** or rotate **R1** elongated member **20**) to alter the position of pigtail **50** for a path or vessel guiding device to maneuver or advance surgical positioning instrument **10** therethrough blood vessel **V**, turn, fork or other vascular maneuverability and positioning pigtail **50** proximate material or debris **M**.

In block or step **720,** deploying retractable instrument **60** via expanding deployed deformable rim **67** with mesh strainer **63** after passing therethrough second instrument

aperture **25** to a position proximate pigtail **50** (deploying deformable rim **67** and mesh strainer **63** therefrom second lumen 32). When deployed first deformable section **61** and second deformable section **62** of deformable rim **67** expands back to a non-compressed position.

In block or step **730,** rotating deformable rim **67** and mesh strainer **63** proximate material or debris **M** via rotating second member end **66** of retractable instrument **60,** rotation **R3,** results in rotation **R4** of deformable rim **67** having rim inlet **69** and mesh strainer **63,** which in turn causes expanded deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**.

In block or step **730,** rotating deformable rim **67** and mesh strainer **63** proximate material or debris **M** via rotating elongated catheter **20,** rotation **R1**, results in rotation **R2** of pigtail **50** which in turn results in rotation **R4** of deformable rim **67** having rim inlet **69** and mesh strainer **63** due to abutting or contact therebetween pigtail **50** and deformable rim **67,** which in turn causes deformable rim **67** having rim inlet **69** and mesh strainer **63** of retractable instrument **60** to scoop up or collect or capture clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V**.

In block or step **735,** collecting material or debris **M** therein mesh strainer **63** via scooping up or collecting or capturing clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** from blood vessel **V** therein mesh strainer **63**.

In block or step **740,** retracting deformable rim **67,** mesh strainer **63**, and material or debris **M** therethrough second instrument aperture **25** of second lumen **32** via collapsing deformable rim **67** by push/pull **P1** of second member end **66** to retrieve collapsing deformable rim **67** and mesh strainer **63** may be furled or wrapped therearound deformable rim **67** and/or first member end **65,** and retractable instrument **60** with undesirable material or debris **M** may be pulled therethrough or entry therein second instrument aperture **25** and exit out first instrument aperture **23.**

In block or step **745,** repeating steps **715-740.**

Referring now to **FIG. 8**, by way of example, and not limitation, there is illustrated an example embodiment of a flexible surgical positioning instrument **10.** Surgical positioning instrument **10** may include access hub or port, such as aspiration port **90** positioned

proximate hand grip **36** or first catheter end **21.** Aspiration port **90** may provide access, may be connected, in communication thereto first lumen **31** running the length thereof elongated catheter **20,** pigtail lumen **31B** of pigtail **50,** and thereto pigtail end **53.** Moreover, surgical positioning instrument **10** may include a side arm or conduit, such as aspiration tube **80** which may include a distal end, such as first tube end **81** and a proximate end, or second tube end **82**. Second tube end **82** may be affixed or removeably affixed thereto aspiration port **90.** Aspiration tube **80** may include three way stop cock valve **84** with cock bar **85.** Cock bar **85** may be rotated (rotational) between open position for passage therethrough and for suction, diversion position to divert debris **M to** threaded port and cap **83,** and closed position to seal second tube end **82**. Furthermore, surgical positioning instrument **10** may include a suction, vacuum or negative pressure device, such as aspiration device **70.** Aspiration device **70** may include a syringe having a housing or body such as syringe barrel **72,** plunger **71** positioned therein and drawn or moved, such as as movement **M** therein syringe barrel **72,** and adapter port **73** provides an exit or entrance thereto syringe barrel **72.** Aspiration device **70** or more specifically adapter port **73** may be connected, in communication, or removeably connected thereto first tube end **81** preferably to perform aspiration, vacuum, or suction **S** therethrough aspiration tube **80,** aspiration port **90,** lumen **31** of elongated catheter **20,** pigtail lumen **31B** of pigtail **50,** and therethrough pigtail end **53.**

Referring now to **FIG. 9**, by way of example, and not limitation, there is illustrated an example embodiment of pigtail **50** shown proximate clots, plaque, emboli, thrombi (blood clots), fatty deposit, biomaterial, or other undesirable material or debris **M** within blood vessel **V**. Moreover, aspiration or suction thereby aspiration device **70** preferably results in debris **M** being suctioned in or drawn or pulled (pulls/suctions) or collected or captured therein pigtail end **53**. Furthermore with continued aspiration or suction (aspiration thrombectomy) thereby aspiration device **70** debris **M** may be pulled or traverse pigtail lumen **31B** of pigtail **50,** lumen **31** of elongated catheter **20,** aspiration port **90,** and aspiration tube **80,** thereto aspiration device **70** whereby debris **M** has been removed therefrom blood vessel **V.**

It is contemplated herein that pigtail **50** may be in an extended configuration as shown in **FIG. 2** rather than in a curled configuration as shown in **FIGs. 5** during aspiration or suction (aspiration thrombectomy) of debris **M.**

Referring now to **FIG. 10**, there is illustrated a flow diagram **1000** of utilizing surgical positioning instrument **10** and retractable instrument **60** to remove clots or the release of emboli, biomaterial, such as undesirable material or debris **M** from blood vessel **V**

via aspiration or suction. In block or step **1010,** providing surgical positioning instrument **10** having elongated member **20** with two or dual axial bores therethrough, such as first lumen **31** and second lumen **32,** and pigtail **50** on one end and aspiration port **90,** aspiration tube **80,** and aspiration device **70** as described above in **FIGS. 8-9.**

In block or step **1015,** manipulating or moving first catheter end **21** to alter the position of pigtail **50** for a path or vessel guiding device to maneuver or advance surgical positioning instrument **10** therethrough blood vessel **V**, turn, fork or other vascular maneuverability and positioning pigtail **50** proximate material or debris **M,** block or step **1020**.

In block or step **1030,** operating aspiration device **70** (aspirating or suctioning) for collecting, capturing, debris **M** therein pigtail end **53**. Furthermore with continued aspiration or suction step **1040** (aspiration thrombectomy) thereby aspiration device **70** debris **M** may be pulled or traverse pigtail lumen **31B** of pigtail **50,** lumen **31** of elongated catheter **20,** aspiration port **90,** and aspiration tube **80,** thereto aspiration device **70** step **1050** whereby debris **M** has been removed therefrom blood vessel **V.**

The foregoing description and drawings comprise illustrative embodiments of the present disclosure. Having thus described exemplary embodiments, it should be noted by those ordinarily skilled in the art that the within disclosures are exemplary only, and that various other alternatives, adaptations, and modifications may be made within the scope of the present disclosure. Merely listing or numbering the steps of a method in a certain order does not constitute any limitation on the order of the steps of that method. Many modifications and other embodiments of the disclosure will come to mind to one ordinarily skilled in the art to which this disclosure pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Although specific terms may be employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation. Moreover, the present disclosure has been described in detail, it should be understood that various changes, substitutions and alterations can be made thereto without departing from the spirit and scope of the disclosure as defined by the appended claims. Accordingly, the present disclosure is not limited to the specific embodiments illustrated herein, but is limited only by the following claims.

WHAT IS CLAIMED IS:

1. A remotely operated surgical device, said surgical device comprising:

a flexible positioning instrument having an elongated catheter with a dual lumen bore therein extending from a first catheter end to a second catheter end, said dual lumen bore having a first lumen and a second lumen, and a pigtail attached thereto said second catheter end, said first lumen extends therethrough said elongated catheter and said pigtail, said second lumen extends therethrough said elongated catheter;

a guidewire extendable therethrough said first lumen of said elongated catheter and said pigtail, and extendable therefrom said pigtail, said guidewire configured to angle said pigtail; and

an aspiration device connected thereto said first lumen and configured to create a vacuum therein said first lumen of said elongated catheter and said pigtail.

2. The remotely operated surgical device of Claim 1, further comprising a guidewire entrance aperture positioned proximate said first catheter end and a guidewire exit aperture positioned proximate a pigtail end of said pigtail.

3. The remotely operated surgical device of Claim 1, wherein a rotation of said elongated catheter results in said rotation of said pigtail.

4. The remotely operated surgical device of Claim 1, further comprising a hand grip affixed thereto said first catheter end.

5. The remotely operated surgical device of Claim 3, wherein said pigtail disposed at a location within a patient's vessel.

6. The remotely operated surgical device of Claim 1, further comprising a first instrument aperture positioned proximate said first catheter end and a second instrument aperture positioned proximate said second catheter end.

7. The remotely operated surgical device of Claim 1, wherein said pigtail further comprises a pigtail lumen in communication with said first lumen.

8. The remotely operated surgical device of Claim 7, further comprising an aspiration port positioned proximate said proximate said first catheter end, said aspiration port in communication with said first lumen.

9. The remotely operated surgical device of Claim 8, further comprising an aspiration tube having a first tube end and a second tube end, said second tube end in communication with said aspiration port.

10. The remotely operated surgical device of Claim 9, further comprising an aspiration device in communication with said first tube end.

11. The remotely operated surgical device of Claim 10, wherein said aspiration device further comprises a syringe having a syringe barrel, a plunger positioned therein said syringe barrel, and adapter port exiting said syringe barrel.

12. The remotely operated surgical device of Claim 9, wherein said aspiration tube includes stop cock valve having a cock bar rotational between an open position, a diversion position, and a closed position.

13. The remotely operated surgical device of Claim 10, wherein a rotation of said first catheter end results in said rotation of a pigtail end adjacent a biomaterial therein.

14. The remotely operated surgical device of Claim 13, wherein an aspiration therein said aspiration device creates an aspiration in said aspiration tube, said aspiration port, said first lumen, and said pigtail lumen to collect said biomaterial therein.

15. The remotely operated surgical device of Claim 14, wherein further aspiration therein said aspiration device suctions said biomaterial through said pigtail lumen, said first lumen, said aspiration port, said aspiration tube, and into said aspiration device.

16. A method for removing a biomaterial from a patient's vessel comprising the steps of:

providing a remotely operated surgical device having a flexible positioning instrument, said flexible positioning instrument having an elongated catheter with a dual lumen bore therein extending from a first catheter end to a second catheter end, said dual lumen bore having a first lumen and a second lumen, and a pigtail attached thereto said second catheter end, said first lumen extends therethrough said elongated catheter and said pigtail, said second lumen extends therethrough said elongated catheter, a guidewire extendable therethrough said first lumen of said elongated catheter and said pigtail, and an aspiration device connected thereto said first lumen and configured to create a vacuum therein said first lumen of said elongated catheter and said pigtail;

maneuvering said operated surgical device therethrough the patient's vessel;

positioning said pigtail proximate the biomaterial;

aspirating said aspiration device; and

collecting the biomaterial therein said first lumen.

17. The method of Claim 16, further comprising the step of moving said guidewire therein said first lumen to straighten said pigtail to an angle.

18. The method of Claim 16, further comprising the step of rotating said first catheter end which rotates said pigtail proximate the biomaterial.

19. The method of Claim 16, further comprising the step of moving said guidewire therein said first lumen to abut said pigtail proximate the biomaterial.

20. The method of Claim 18, further comprising the step of rotating said first catheter end rotates said pigtail proximate the biomaterial.

21. The method of Claim 20, further comprising the step of further aspirating the biomaterial therethrough said first lumen to collect the biomaterial therein said aspiration device.

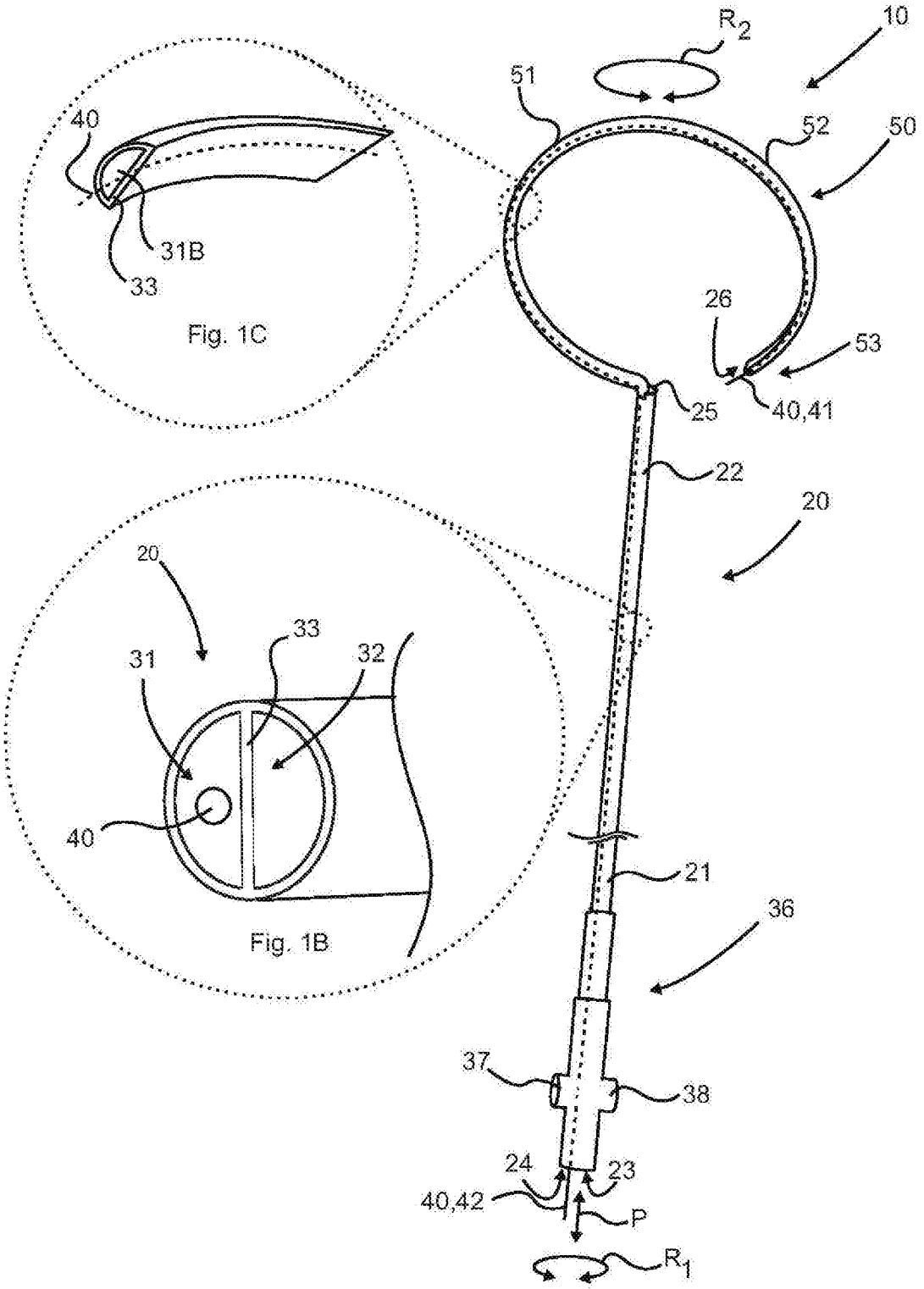

Fig. 1C

Fig. 1B

Fig. 1A

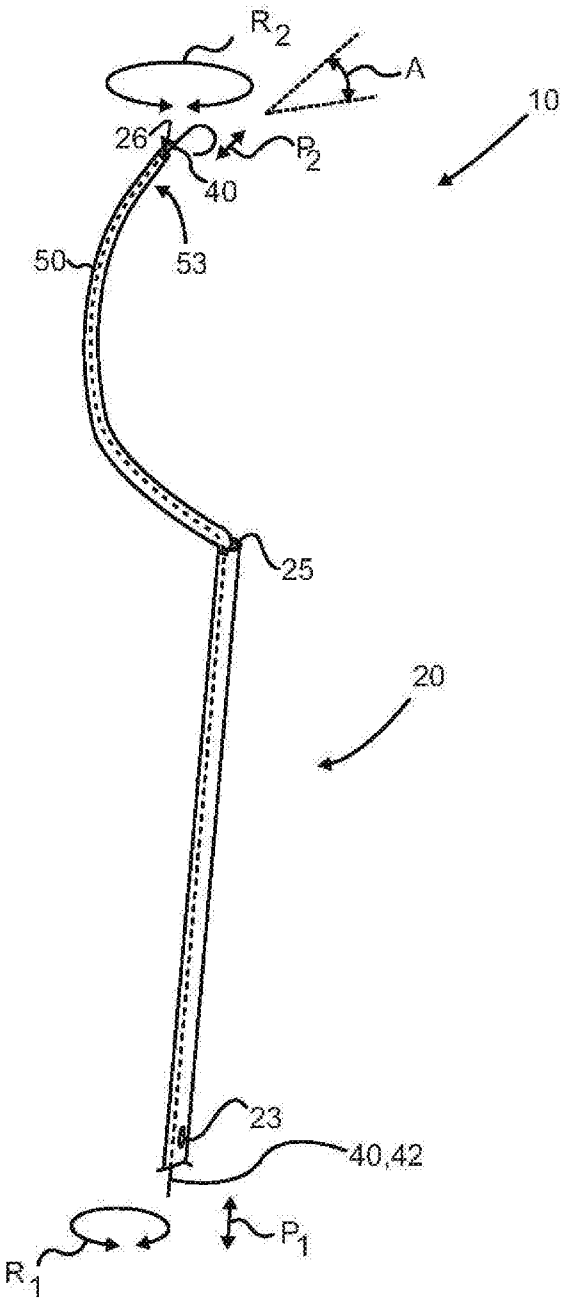

Fig. 2

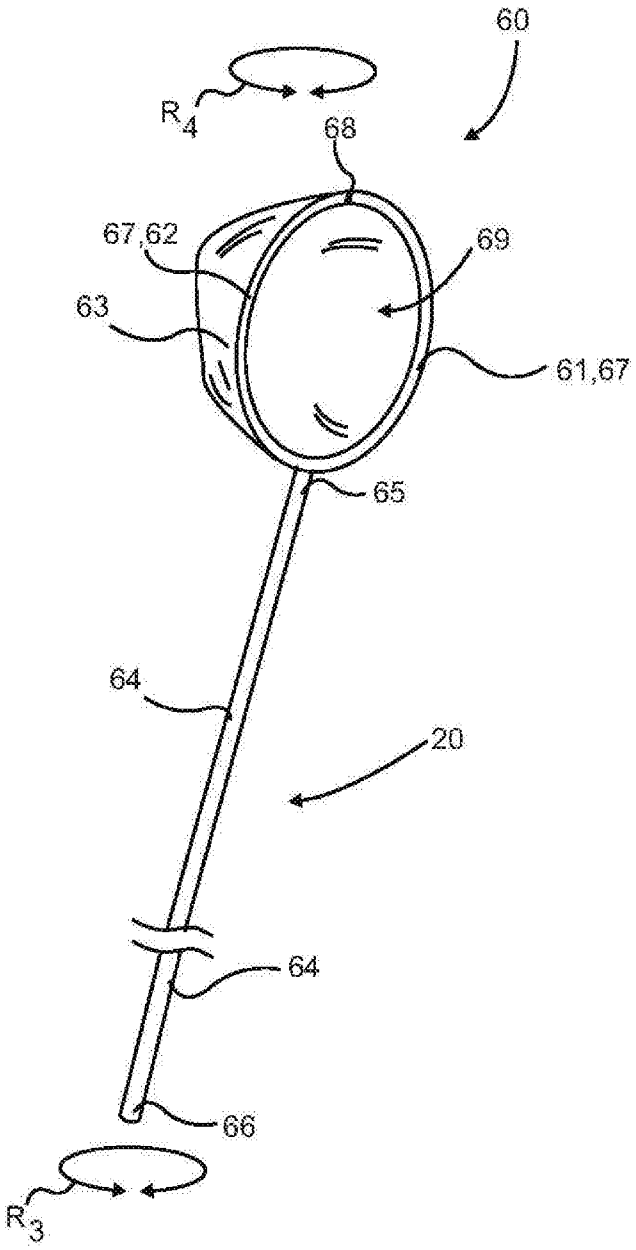

Fig. 3

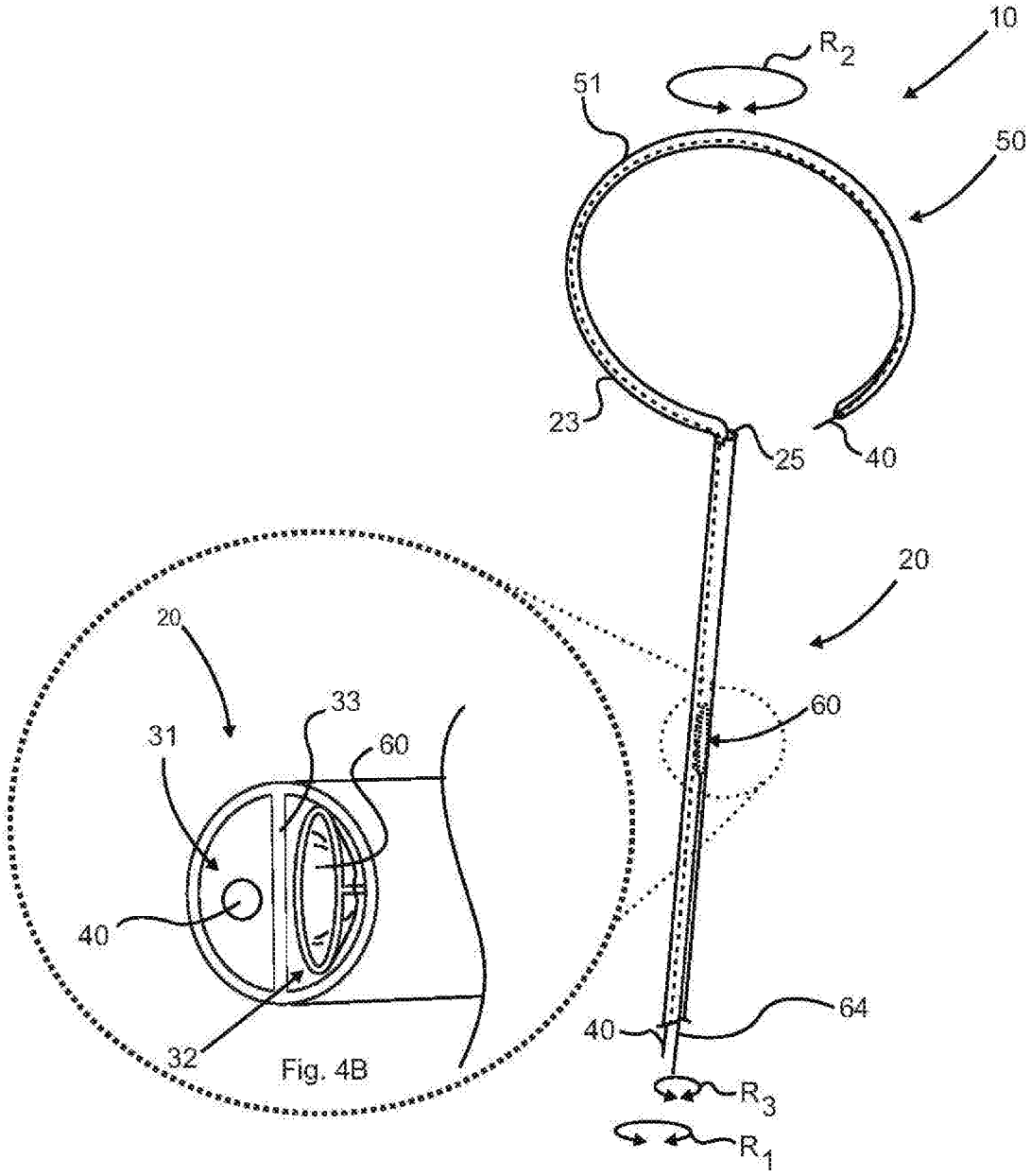

Fig. 4B

Fig. 4A

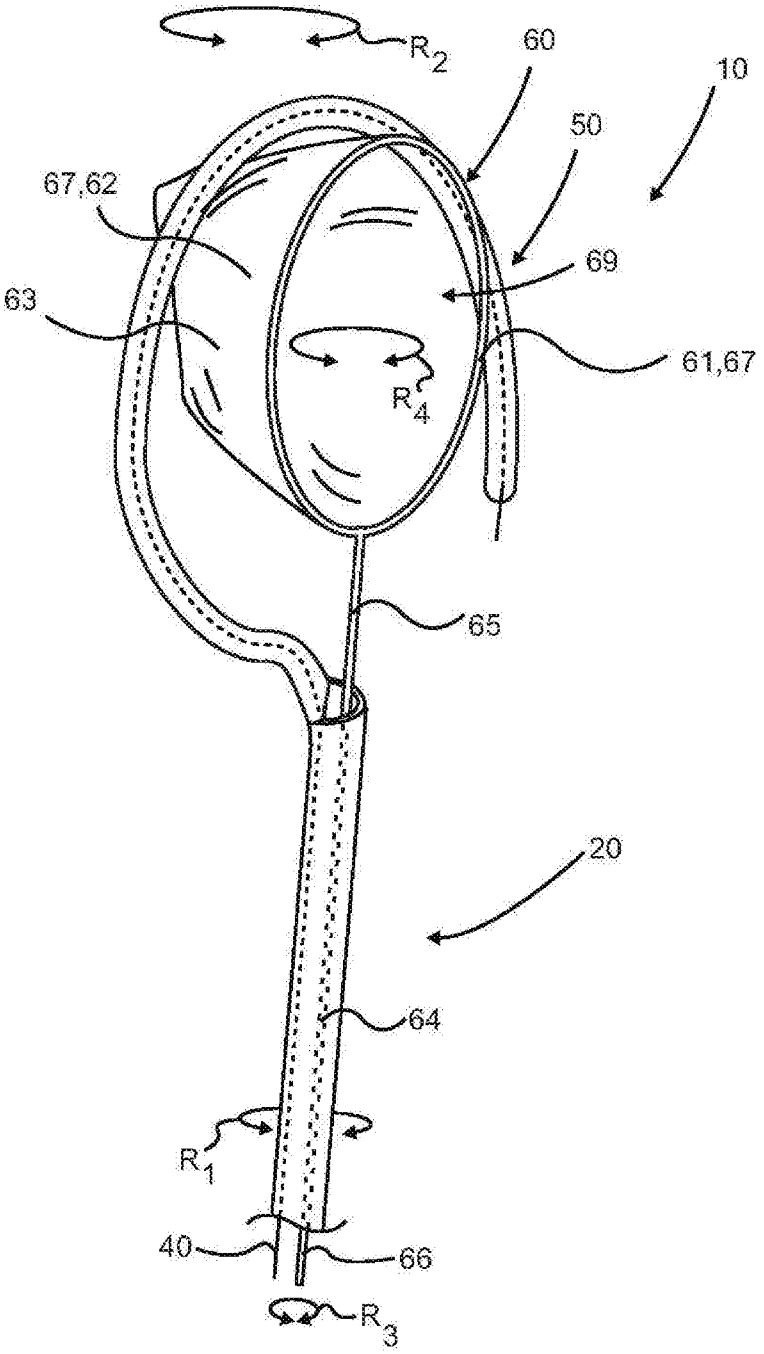

Fig. 5A

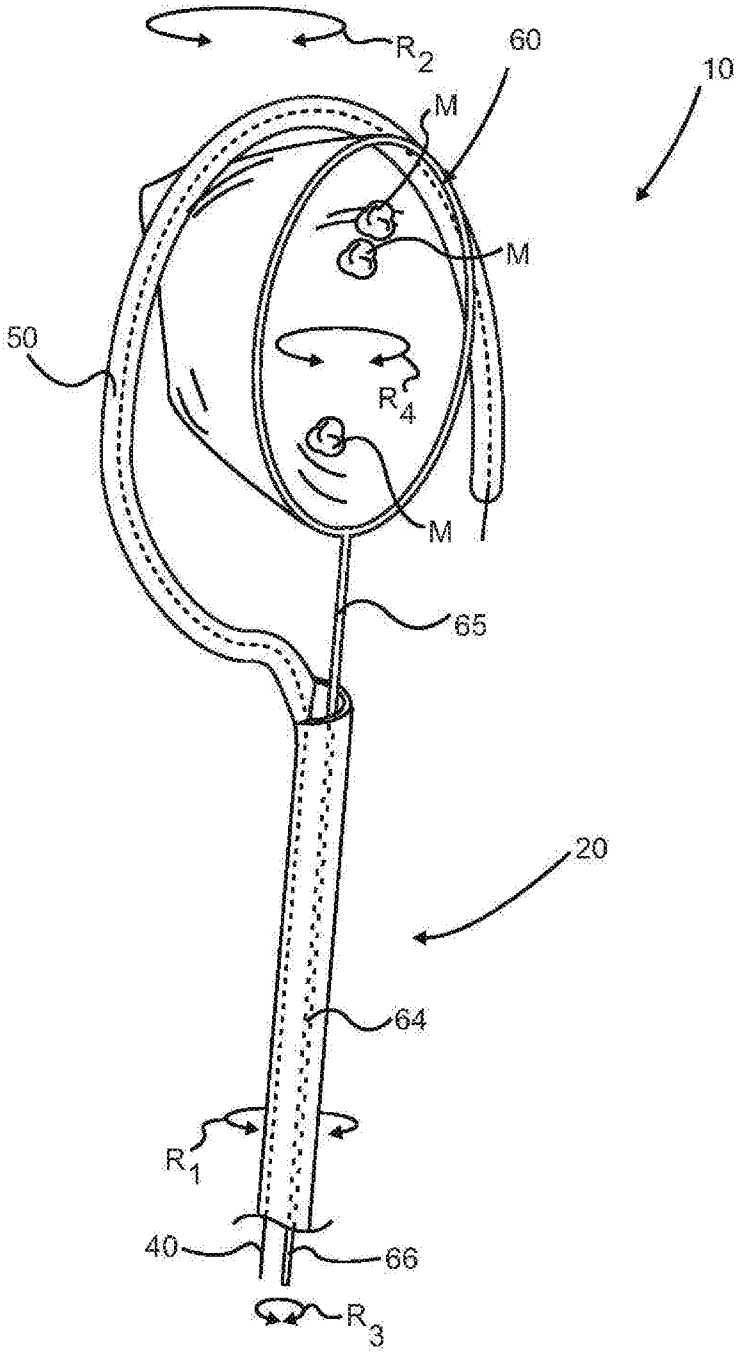

Fig. 5B

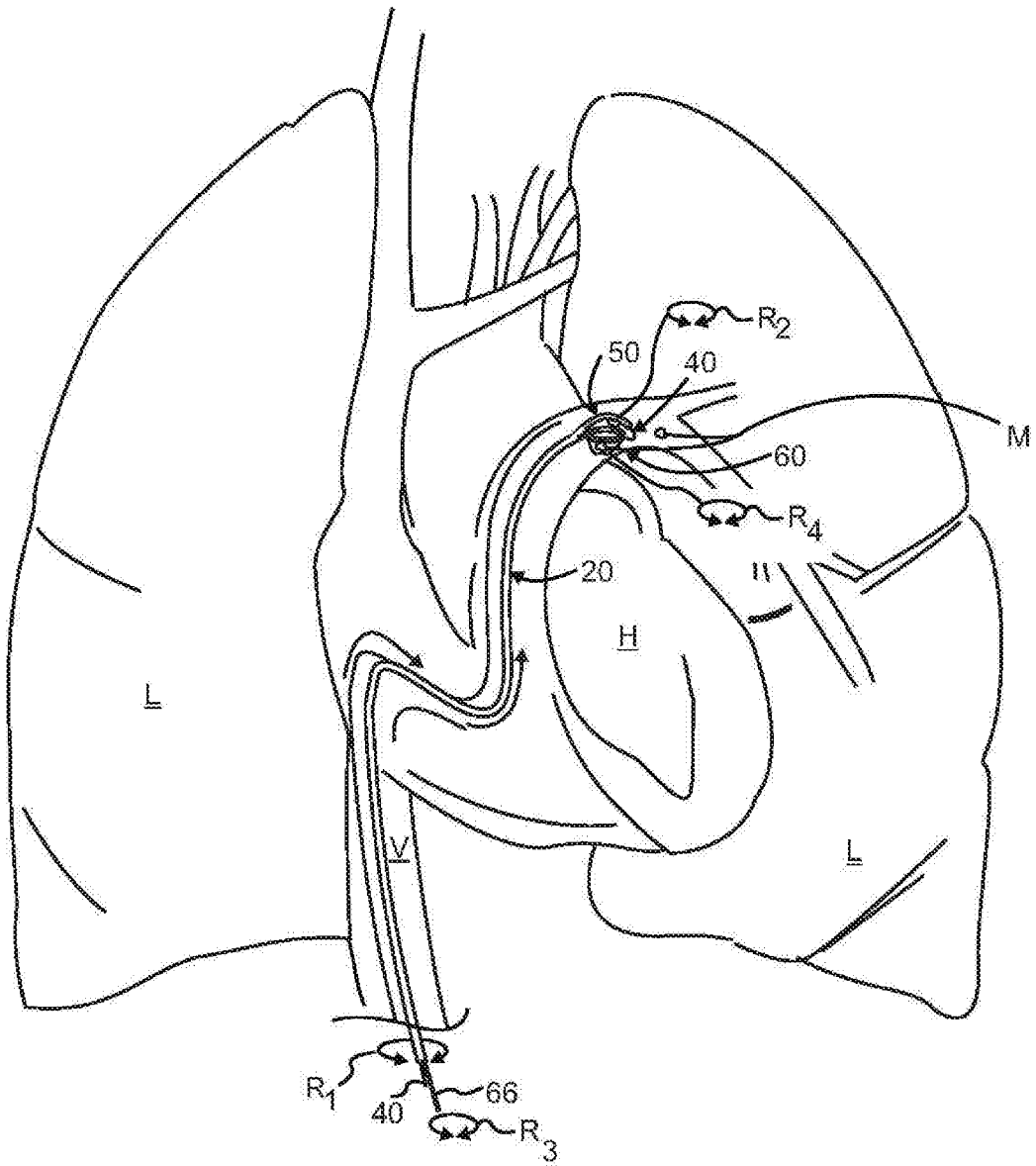

Fig. 6

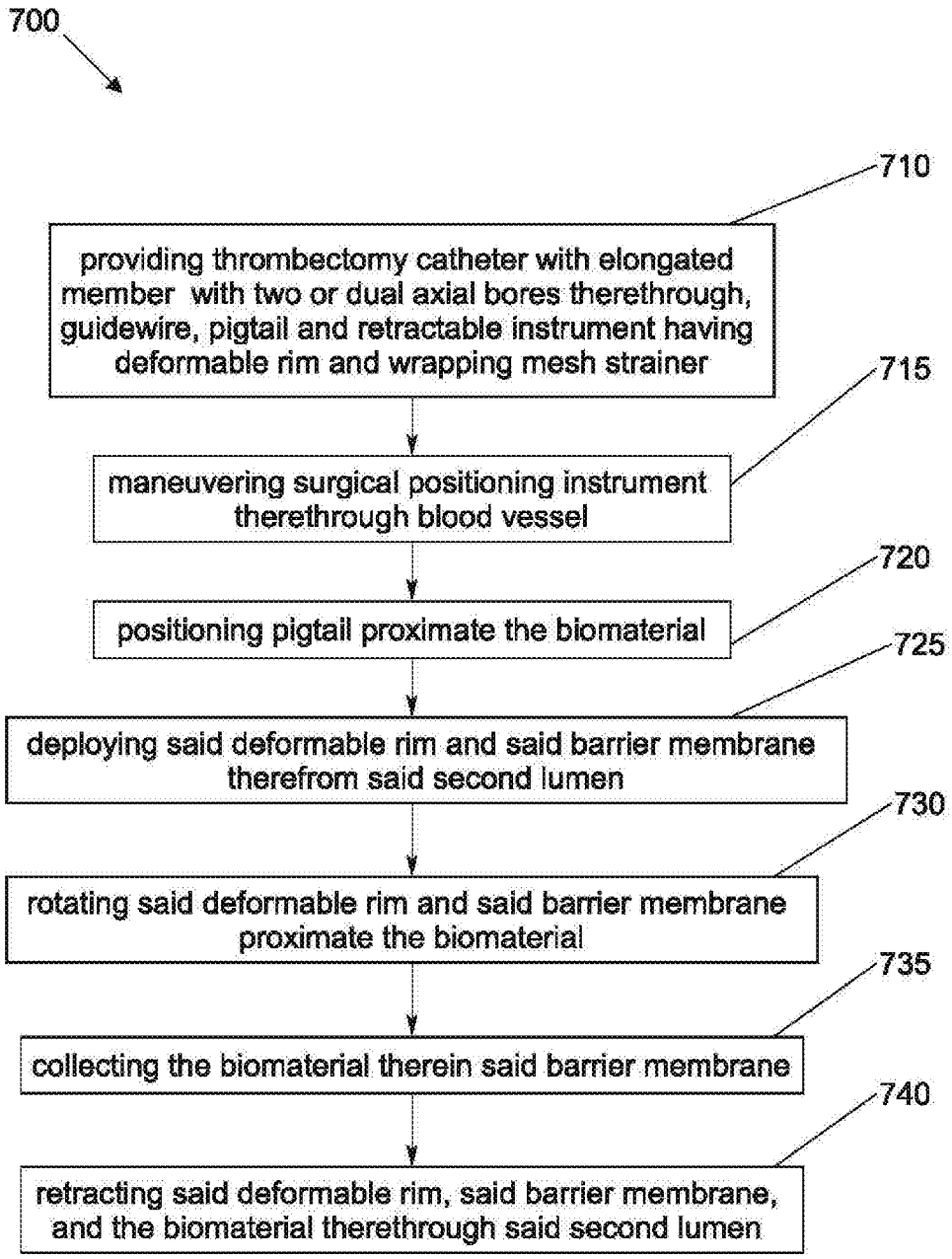
700
710
providing thrombectomy catheter with elongated member with two or dual axial bores therethrough, guidewire, pigtail and retractable instrument having deformable rim and wrapping mesh strainer
715
maneuvering surgical positioning instrument therethrough blood vessel
720
positioning pigtail proximate the biomaterial
725
deploying said deformable rim and said barrier membrane therefrom said second lumen
730
rotating said deformable rim and said barrier membrane proximate the biomaterial
735
collecting the biomaterial therein said barrier membrane
740
retracting said deformable rim, said barrier membrane, and the biomaterial therethrough said second lumen

FIG. 7

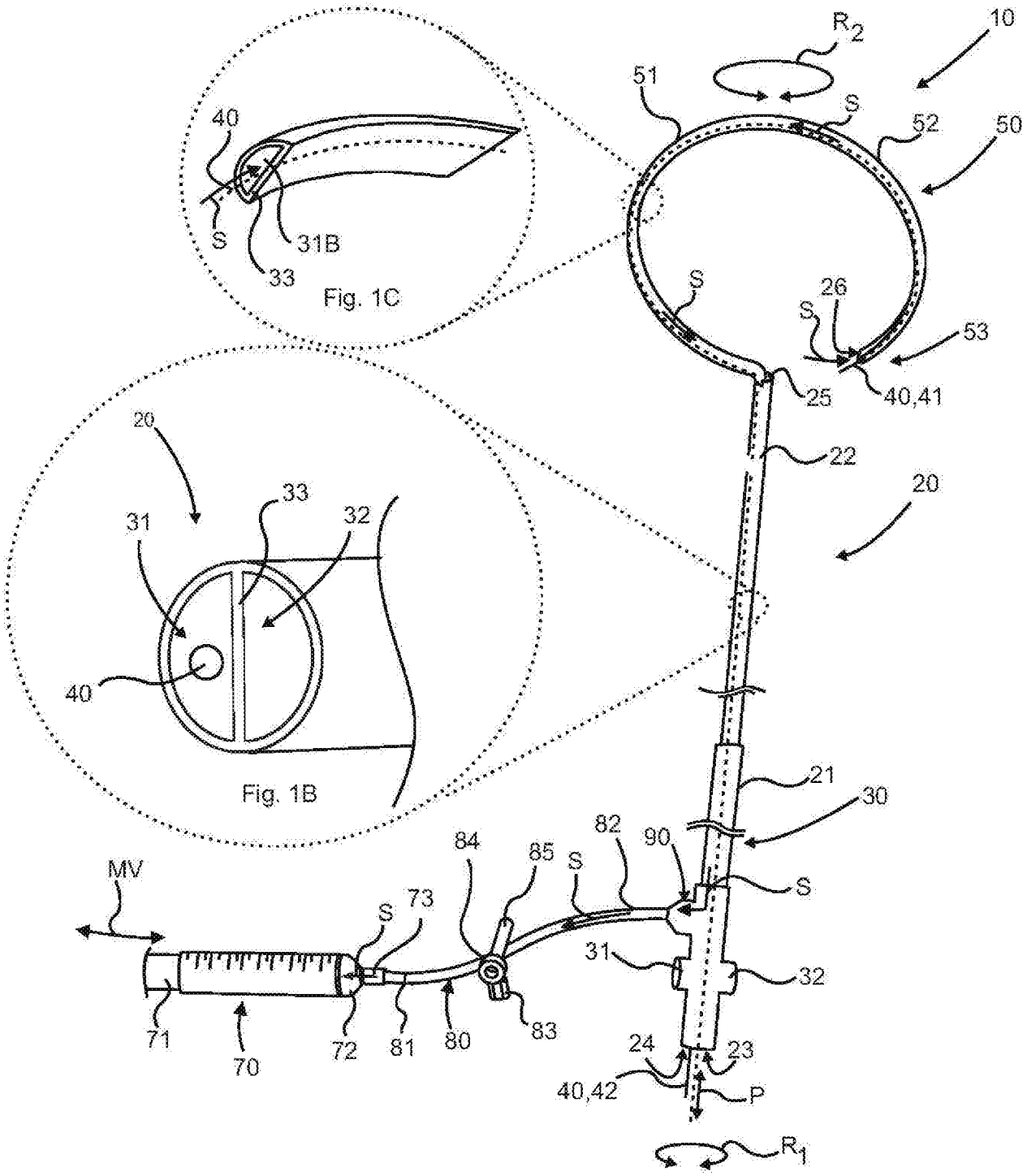
R2
10
51
S
52
50
40
S
31B
33
Fig. 1C
S
26
S
53
25
40,41
20
22
20
33
31
32
40
Fig. 1B
21
30
82
90
84
85
S
S
MV
S
73
31
32
71
70
72
81
80
83
24
23
40,42
P
R1

Fig. 8

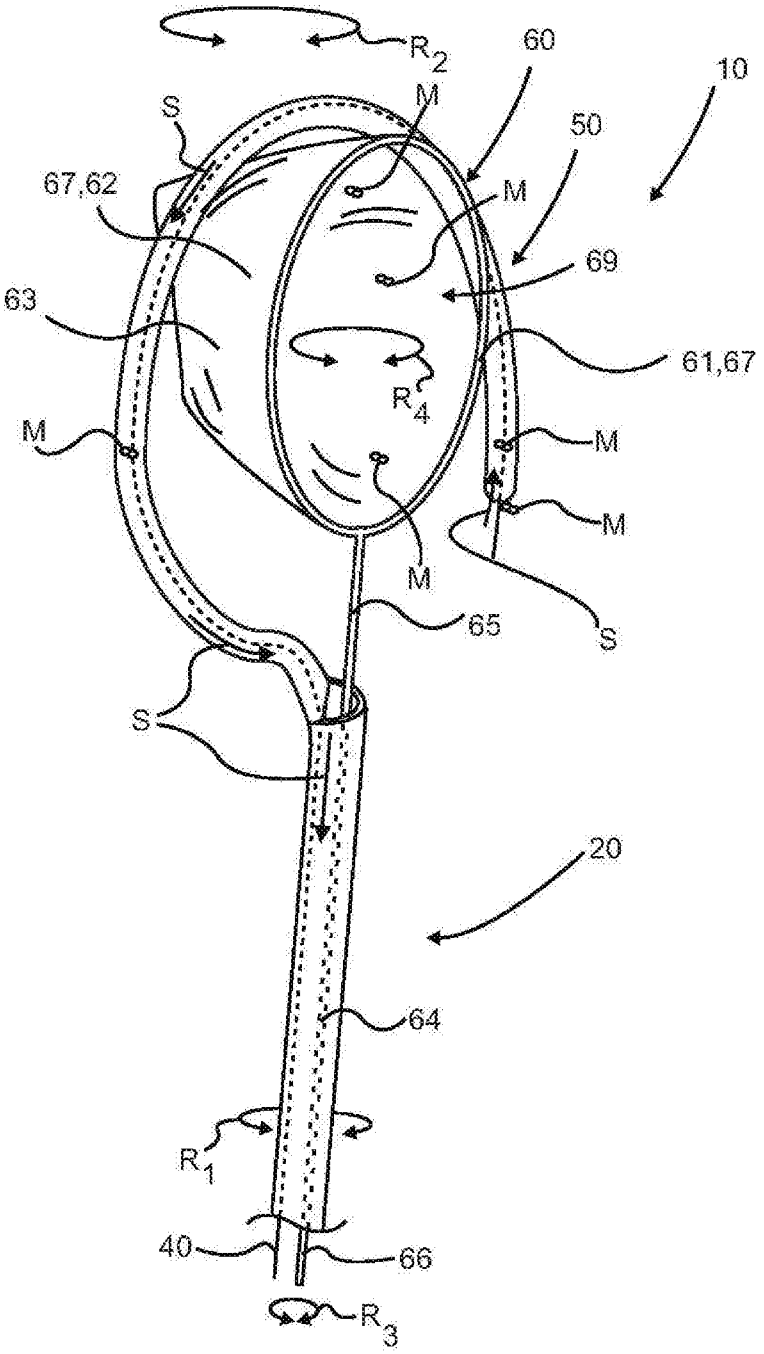

Fig. 9

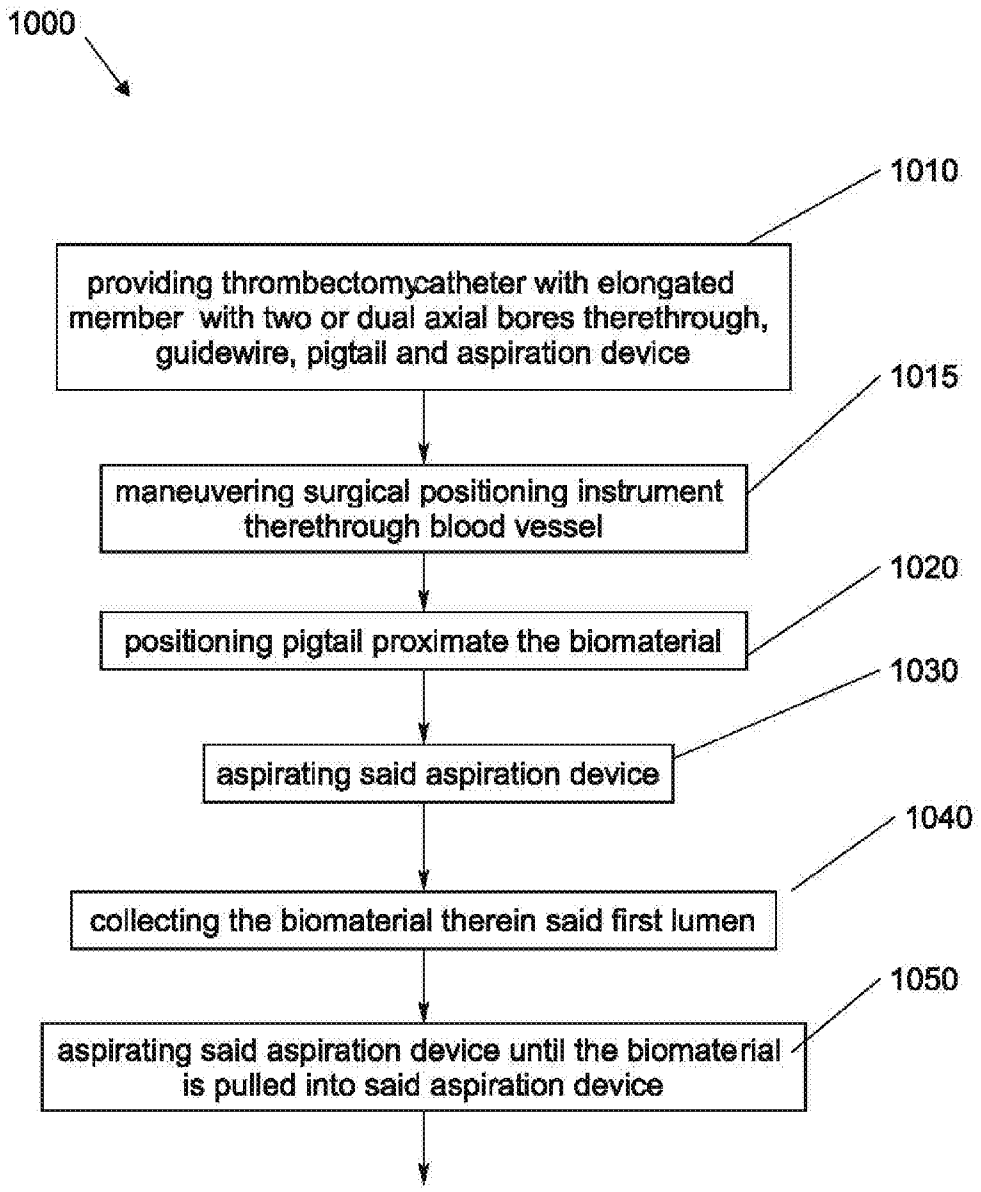
1000
1010
providing thrombectomycatheter with elongated member with two or dual axial bores therethrough, guidewire, pigtail and aspiration device
1015
maneuvering surgical positioning instrument therethrough blood vessel
1020
positioning pigtail proximate the biomaterial
1030
aspirating said aspiration device
1040
collecting the biomaterial therein said first lumen
1050
aspirating said aspiration device until the biomaterial is pulled into said aspiration device

FIG. 10

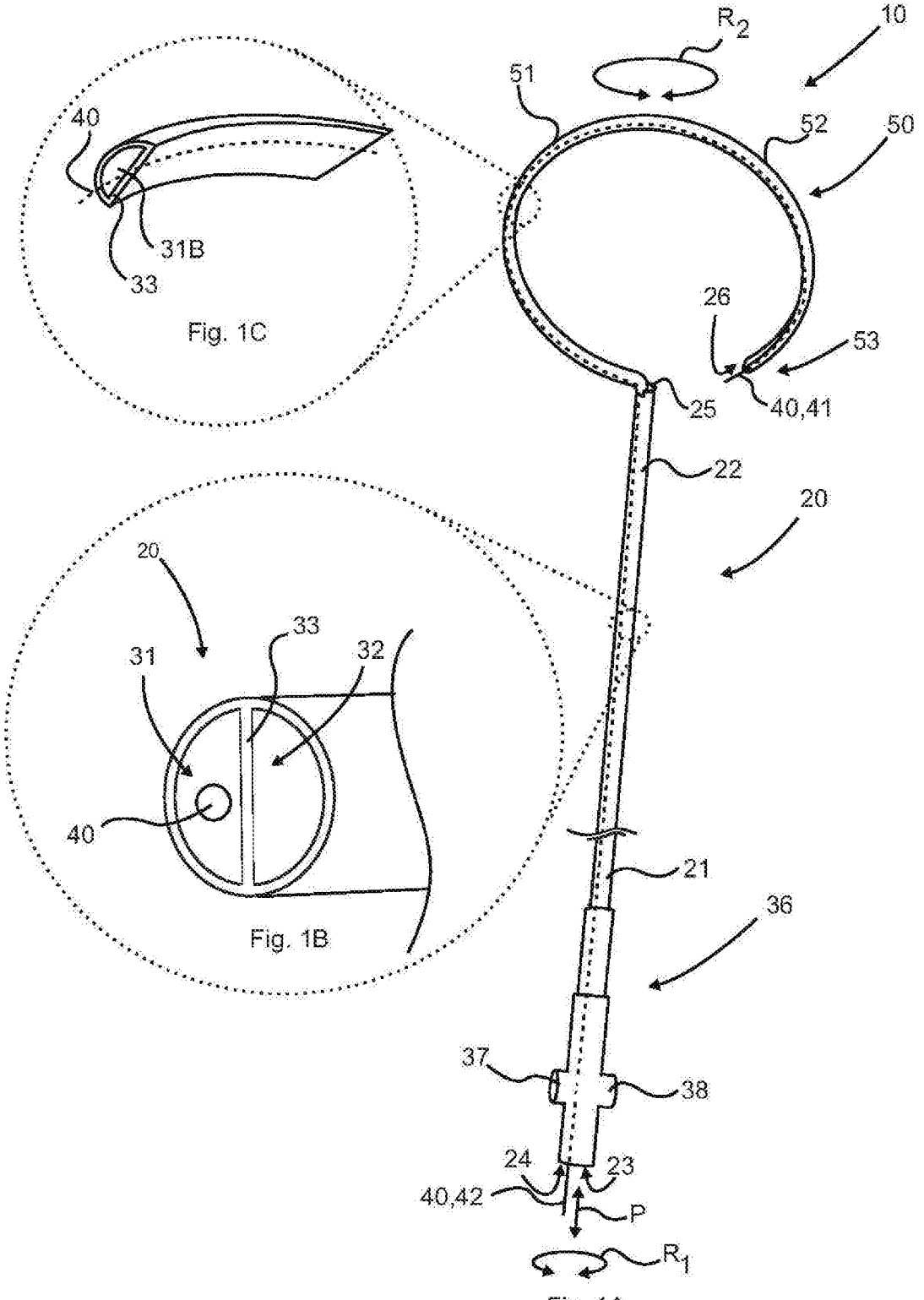

Fig. 1C

Fig. 1B

Fig. 1A