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(71) Applicant *(for all designated States except US)*: **BIO-SEAL TECH INC.** [US/US]; Top 19796, 141 Lanza Avenue 29N, Garfield, NJ 07026 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BEN DAVID, Shlomo** [IL/IL]; 19 Yehuda Hanasi Street, 69206 Tel Aviv (IL). **MAGENY, Yohanan** [IL/IL]; Moshav Ilanya, 15255 Lower Galilee (IL).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.O. Box 4060, 61040 Tel Aviv (IL).

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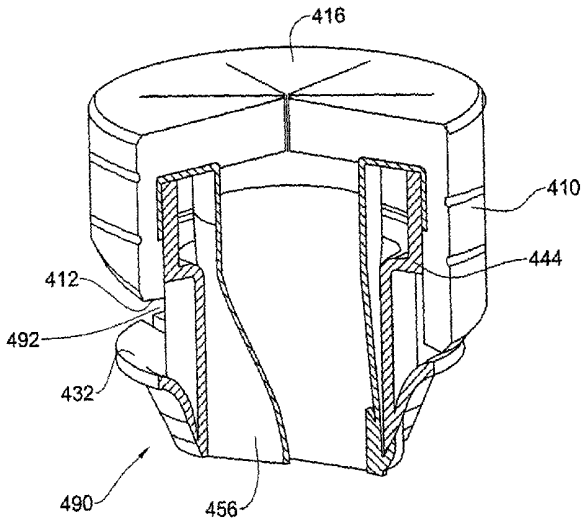
(54) Title: DEVICE AND METHOD FOR SEALING A PUNCTURE IN A BLOOD VESSEL



(57) Abstract: A sealing device for sealing a puncture in a blood vessel, the device being slidable over a guide tube and comprising a tubular housing (28), a resilient sealing member formed (36) with a sealing portion (30) spontaneously sealable upon deployment of the device into an operative state, an engaging portion (38) for bearing against an external surface of the blood vessel and an anchoring assembly (42) for engaging an internal surface of the blood vessel. The anchoring assembly (42) comprises anchor members which are displaceable between a constricted position in which they blend with the tubular housing, and an operative position in which the anchors are laterally deployed to engage the internal surface of the blood vessel.

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DEVICE AND METHOD FOR SEALING A PUNCTURE IN A BLOOD VESSEL

FIELD OF THE INVENTION

The present invention is generally in the field of homeostatic devices and in particular it is directed to a sealing device for sealing a puncture (incision) in a blood vessel of a patient during or after a medical procedure. The invention is also concerned with a deploying member and a method for deploying the sealing device into the aperture's site.

BACKGROUND OF THE INVENTION

During several surgical procedures, for example in treatment of vascular diseases, it is common practice to invade a blood vessel and introduce a treating or diagnostic device, e.g. balloons or various types of stents to operate on walls of the arteries, plaque removing devices, observation and flow diagnostic instruments, etc.

During such procedures, a blood vessel is punctured so as to allow introduction of the instrument through the artery and then maneuver it to the required site of operation. This is carried out in practice by introducing a guide tube often referred to as an *"introducer sheath"*, a "*guide sheath*" or a "*guide tube*", through which the instrument can then be easily maneuvered to the site of interest.

A problem occurs once the procedure is complete and the guide tube has then to be removed, when the percutaneous puncture bleeds. Bleeding may result in hematoma or in severe cases to malfunction of critical organs and even death. Such bleeding is stopped, by a most common method, by simply applying pressure on to the puncture site by a medically trained person for a sufficiently long period of time

until homeostasis takes place to spontaneously seal the puncture and stop the bleeding.

In cases of puncturing the femoral arteries, the required time may be as long as about 45 minutes or more and in some cases re-bleeding occurs if the patient is not in rest.

A variety of methods and devices have been suggested for replacing the traditional method disclosed above, some of which involve introducing chemical compounds which act as homeostasis catalysts or as adhering agents, whilst others aim at introducing various forms of plugging members into the puncture. The following is a list of prior art patents disclosing devices and methods for sealing punctured blood vessels: U.S. 4,705,040 4,890,612, 4,929,246, 5,108,420, 5,342,393, 5,350,399, 5,391,183, 5,613,974, 5,810,884, 5,861,003, 5,957,952, 5,984,950, 6,007,563 and WO 98/31287.

It is an object of the present invention to provide novel and inventive devices for sealing a puncture or an incision formed in a blood vessel or in other body organs, as well as an associated deploying member for deploying the sealing member into a sealing position within the puncture. A further object of the invention is to provide a method utilizing the sealing member and the associated deploying assembly.

SUMMARY OF THE INVENTION

The present invention calls for a sealing device and an associated deploying assembly, as well as a method for sealing a puncture or an incision formed in a body organ, typically but not limited, in a blood vessel.

By one feature of the present invention, the sealing device is introduced into the puncture over a guide tube (guide *sheath*) used for carrying out a medical procedure e.g. angioplasty, in which a probe is introduced into a blood vessel through the guide tube. The sealing member of the present invention is received within a deploying member used for displacing the sealing member into the

puncture site and then deploying it into its operative-sealing position, in which it is anchored within the puncture and seals the puncture/incision. The sealing device is fitted with anchoring means to ensure suitable anchorage within the puncture and is useful for a variety of guide tubes on the one hand and for a variety of wall thicknesses of the blood vessel at the puncture site, on the other hand.

In accordance with an embodiment of the invention there is provided a sealing device for sealing a puncture in a blood vessel, the device being slidingly receivable over a guide tube and comprising a tubular, resilient sealing member formed with a sealing portion spontaneously sealable upon deployment of the device into an activated state, an engaging portion for bearing against an external surface of the blood vessel and a plurality of anchors fitted at their fore end with fasteners for engaging an internal surface of the blood vessel t; said anchors being displaceable between a constricted position in which they blend with the tubular sealing member, and an operative position in which the fasteners are laterally deployed to engage the internal surface of the blood vessel.

In accordance with one particular embodiment, the anchors are fitted at their rear end with a manipulating bit engageable by a corresponding member of the deploying assembly.

In accordance with another embodiment, the sealing device comprises a plurality of anchors fitted at their fore end with a fastener which at the operative position spontaneously deforms into a laterally projecting position for engaging the internal surface of the blood vessel. For such spontaneous displacement the fasteners are pre-strained and retained at their constricted position by a suitable arresting arrangement (by a suitable sleeve member or a guide tube, prior to deploying) preventing them from spontaneous displacing into the operative position. In accordance with this embodiment, the fasteners are rearwardly facing thus adapted for engaging an internal surface of the blood vessel.

The present invention also suggests a unique application of a sealing device fitted with means for grabbing tissue of a blood vessel (or any other organ being

sealed) surrounding the puncture (i.e. lip or edges of the puncture) and applying force in direction so as to adjoin edges of the puncture, thus reducing the section area of the puncture and speeding the sealing process.

In accordance with a particular embodiment of that application, the fasteners are fitted with spikes facing rearwards for engaging tissue of the blood vessel, wherein at the deployed state the anchors are biased radially inwardly, for constricting the size of the puncture in the blood vessel.

According to another embodiment of that application, there are provided several spears axially displaceable with respect to the resilient sealing member, said spears having a fore end fitted for grabbingly engaging the external tissue surface of the blood vessel at locations peripheral to the puncture. At least said fore end being displaceable radially inwardly so as to decrease the imaginary delimited circle defined by the spears.

The radial inward force applied to the anchors and to the spears disclosed above is delivered by deformation of the resilient sealing member which deforms in a manner in which it constricts its diameter adjacent its fore end, applying inwardly directed radial force on the anchors and spears.

In accordance with still another embodiment of the invention, the engaging portion of the sealing member is truncated such that when it is engaged with the blood vessel, the sealing member bears at an inclination over the blood vessel. Accordingly, the fasteners are axially graded, giving rise to an imaginary path extending between edges thereof, said path conforming with the truncated edge of the sealing member.

The sealing device of the present invention is deployable into its operative position by a deploying assembly comprising a tubular housing, a tubular controller received within the housing and a tubular pusher member received within the controller, coaxially received within one another; said pusher adapted for manipulating the sealing member into its activated position.

By manipulating the controller and pusher of the deploying assembly, the sealing member is displaced into the puncture site. The pushing member is fitted with activating surfaces which are fitted with gliding surfaces inclined so as to engage with the manipulating bits at their constricted position and where rotation of the pusher member entails sliding displacement of the manipulating bits about said activating surfaces thereby deploying the anchors into their operative position.

According to one particular embodiment the pusher member also activates the tissue grabbing means into engagement with tissue of the blood vessel surrounding the puncture.

However, in accordance with the embodiment in which the fasteners are spontaneously laterally displaceable, the pushing member of the deploying assembly does not interfere with deployment of the fasteners into engagement with the internal surface of the blood vessel.

The present invention calls also for a method for sealing a puncture in a blood vessel, the method comprising the following steps:

(a) Obtaining a sealing assembly comprising a sealing member fitted within an associated deploying assembly, with a sleeve extending through the sealing assembly, said sleeve defining a through-going path;

(b) Introducing a medical guide tube through the path;

(c) Removing the sleeve;

(d) Carrying out a medical procedure through the guide tube:

(e) Slidingly displacing the sealing assembly over the guide tube until a fore end of the deploying assembly engages the blood vessel;

(f) Expelling the sealing assembly from the deploying assembly and introducing anchor fastener members of the sealing assembly into the blood vessel through the puncture;

(g) Deploying anchor fastener members into an operative position in which they are laterally expanded and engage the internal surface of the blood vessel;

(h) Disengaging the sealing assembly from the deploying assembly and withdrawing the guide tube, allowing a resilient sealing member formed in the sealing member to spontaneously seal.

According to a particular embodiment, at step (d) the guide tube is inserted into the blood vessel at an angle corresponding with a truncation angle of an engaging portion formed at the sealing member, for bearing against an external surface of the blood vessel.

Furthermore, at least step (e) is radio-monitored, whereby at least a fore end of the housing is made of or fitted with a radio-opaque material.

According to a modification of the invention, after the device has been deployed into the puncture site, tissue grabbing means are engaged with the tissue surrounding the puncture and upon applying thereto an inwardly directed radial force, the puncture size is decreased. The tissue grabbing means are either internal spikes e.g. formed on the fasteners and adapted for engaging an internal wall surface of the blood vessel, or spear-like members for engaging external wall surface of the blood vessel, or a combination of both means.

According to another particular embodiment, where the fasteners are fitted with rearwardly facing spikes, after step (e) axial force is applied to the sealing member in a rearward direction, thereby having the spikes engage tissue of the blood vessel.

In accordance with a different embodiment of the present invention, there is provided a sealing device for sealing a puncture in a blood vessel, the device is adapted for sliding over a guide tube and comprises a cylindrical body member having a distal end and a proximal end; an axially resilient member extending at said distal end, for bearing against external surface of the blood vessel adjacent boundaries of the puncture; and an anchoring assembly at said proximal end for

engaging internal wall surface of the blood vessel; said anchoring assembly comprises at least one flexible anchoring member having a constricted position for insertion into the puncture and a laterally expanded, anchoring position; and a sealing member spontaneously sealable upon withdrawal of the guide tube.

The cylindrical body may be formed with a complete enveloping wall (i.e. a tubular member) or, in accordance with a modification of the invention, may be a cylindrical cage formed with an apertured wall or a framework, or a plurality of support struts.

The axially resilient member ensures that the anchoring assembly projects only a required minimum into the blood vessel so as to minimize blood flow disturbances.

Said at least one flexible anchoring member is spontaneously deployable into its anchoring position for engagement with an inside surface of the blood vessel, adjacent boundaries of the puncture. The arrangement is such that during introducing the sealing device into the puncture location, the at least one anchoring members are in their constricted position and upon penetration through the puncture into the blood vessel, the at least one anchoring member deform into the anchoring position, bearing against the inside surface of the blood vessel.

The anchoring assembly comprises at least one anchoring member anchored to the body adjacent the proximal end of the housing with a free end thereof facing the distal end of the housing, said anchoring members are resilient members formed so as to normally project laterally into their anchoring. The anchoring members may be integrally formed with the housing or fixedly attached thereto. According to one application the anchoring members are in the form of a plurality of flexible leaf-like members which may be formed in a variety of different forms e.g. pointed or rounded edges, etc. According to another application the anchoring assembly may be in the form of a resilient skirt-like member, possibly formed with one or more axial slots for increasing flexibility of the one or more anchoring member. The sealing member, according to one particular design, is a membrane made of

resilient material formed with a central aperture which is normally biased into a sealed position. The aperture may be punctured or a recessed, allowing introduction of a guide tube through the aperture. Typically but not necessary, the sealing member extends at or adjacent the proximal end of the housing of the sealing device.

According to a different design, the sealing member is a resilient sleeve-like member received in the housing with a circumferential portion sealingly secured at a proximal end, and flattened adjoining lips at the distal end, whereby fluid flow through the sleeve, in a direction from the distal end towards the proximal end, is not admitted. Even more so, fluid pressure on outside walls of the sleeve cause the lips to tighten against one another. According to an embodiment thereof, side edges of the lips are secured to the housing adjacent the distal end. The sealing member is designed to admit introduction of the guide tube there through.

The axially resilient member is formed, by one embodiment with an oblique fore end. It is thus advantageous that where more than one anchoring member is provided that they extend at a corresponding inclination as that of the fore end of the axially resilient member, i.e. such that a circumferential gap between said fore end and the anchoring members is uniform. One possible way to render the resilient member axial deformity is by designing it as a bellows-type device.

By still a further application of the invention there is provided a deploying assembly for introducing the sealing device into the puncture vicinity and for deploying it into the operative, sealing position. The assembly comprises a rigid elongate retractor having a tube-embracing portion slidable over the guide tube and extending between a fore end and a rear end with an expanding member fitted at the rear end for radially expanding or constricting the tube-embracing portion. The retractor device is used for penetrating through tissue layers and retraction thereof. The deploying assembly further comprises a pusher sleeve slidable over the guide tube and within the retractor, with a fore end thereof engageable with the proximal end of the sealing device so as to propel it through the retractor and into the

puncture of the blood vessel. The fore end of the pusher sleeve and of the retractor may be radio opaque for monitoring its progress of the deploying procedure.

According to an embodiment of the device, the tube-embracing portion is formed with one or more axial openings to allow introducing or removal of the guide tube there through. According to one particular design, the tube-embracing portion is formed of two or more shell-like portions readily displaceable.

In some instances it is desirable to provide an obturator for inserting through the guide tube during the sealing process. The obturator serves to rigidify the guide tube and prevent it from accidental collapse, and where the obturator is provided with a plurality of radio-opaque markings, it also facilitates monitoring the deployment process of the sealing device.

A method utilizing the above different embodiment and the deploying member comprises the steps of:

(a) Obtaining a sealing assembly comprising a sealing member and an associated deploying assembly;

(b) Introducing a medical guide tube through a path within the sealing device;

(c) Carrying out a medical procedure through the guide tube;

(d) ounting a retractor of the deploying member over an exposed portion of the guide tube;

(e) slidingly displacing the retractor over the guide tube into through tissue layers until a fore end of the retractor engages the blood vessel;

(f) expanding the retractor and slidingly displacing the sealing device over the guide tube and through retractor, into the vicinity of the puncture of the blood vessel;

(i) deploying the sealing device into its operative state within the puncture wherein the resilient member is depreseed against external surface of the blood vessel and the anchoring members spontaneously

deploy to their operative position in which they are laterally expanded and engage the internal surface of the blood vessel;

(j) withdrawing the deploying member and the guide tube, allowing a resilient sealing member of the sealing member to spontaneously seal.

Where the deploying assembly comprises a pusher member, displacement of the sealing device into the vicinity of the puncture (step (f)), will be carried out by said pusher member.

BRIEF DESCRIPTION OF THE DRAWINGS

For better understanding the invention and to see how it may be carried out in practice, reference will now be made to the accompanying drawings, illustrating in a non-limiting manner, some embodiments of the present invention, in which:

Fig. 1 is an isometric view of a deploying assembly fitted with a sealing member (not seen) in accordance with the present invention, the deploying assembly being at its initial state;

Fig. 2 is a sectional view of the device seen in Fig. 1, visualizing also the sealing member;

Fig. 3A is a partially sectioned side elevation of the sealing device in accordance with the present invention, in a constricted, non-operative position;

Fig. 3B is a top view of Fig. 3A, illustrating a rear end of the sealing device;

Fig. 3C is a bottom isometric view of the device seen in Fig. 3A;

Fig. 4A is a top isometric view of the sealing member, with the anchors removed;

Fig. 4B is an isometric view of an anchor of the sealing device of the in accordance with an embodiment of the present invention;

Figs. 5A, 5B and **5C** correspond with Figs. 3A, 3B and 3C, respectively, in the operative state of the sealing device;

Fig. 6 is an isometric view of the housing of the deploying assembly in accordance with the present invention;

Fig. 7 is an isometric view of a controller of the deploying assembly in accordance with the present invention;

Fig. 8A is an isometric view of a pusher of the deploying assembly in accordance with the present invention;

Fig. 8B is a front elevation of the fore end of the pusher member seen in Fig. 8A;

Fig. 9 is an isometric view of a sleeve of the deploying device in accordance with the present invention;

Figs. 10A-10E represent four consecutive steps of deploying a sealing device in accordance with the present invention, using a deploying assembly of the invention;

Fig. 11A is a top isometric view of a sealing device in accordance with another embodiment of the invention, the device in its non-operative state;

Fig. 11B is a bottom isometric view of the device seen in Fig. 11A;

Fig. 11C is a planar view of a fore (bottom) end of the device of Fig. 11A;

Fig. 11D is a planar view of a rear end of the device of Fig. 11A;

Fig. 11E is an isometric view of a spear received within the sealing device of Figs. 11A-11D;

Fig. 12 is an isometric view of a modification of a pusher member used with a sealing device according to the second embodiment illustrated in Figs. 11A-11E;

Fig. 13A is a side elevation of the sealing device seen in Figs. 11A-11D, in the operative state of the device;

Figs. 13B-13D correspond with Figs. 11B-11D, respectively, in the operative state of the device;

Fig. 14 is an exploded isometric view of a sealing device in accordance with a different embodiment of the invention;

Fig. 15A is an isometric view from below illustrating the sealing device of Fig. 14 with the anchors in the constricted position;

Fig. 15B is an isometric view from below illustrating the device of Fig. 14 in a first deployment position in which the anchoring means are deployed into the blood vessel for engagement with the internal surface of the blood vessel;

Fig. 15C is an isometric view from below illustrating the sealing device of Fig. 14 in an operative position in which the anchors dispositioned radially inwardly;

Figs. 16A-16C are side views corresponding with Figs. 15A-15C, respectively;

Fig. 17 is a isometric view illustrating the sealing device of Fig. 14, with the anchors in their constricted position, the tubular sealing envelope removed;

Fig. 18 is an isometric view from above of a sealing device in accordance with a different embodiment of the present invention;

Fig. 19 is a partially sectioned isometric view of the sealing device seen in Fig. 18;

Fig. 20 is a partially sectioned isometric view illustrating the sealing device of Figs. 18 and 19 mounted on a guide tube;

Fig 21 is a partially sectioned isometric view of an embodiment of the sealing device seen in Figs. 18 and 19;

Fig. 22 is an isometric view from below visualizing the sealing member of the embodiment of Fig. 21;

Fig. 23 is a partially sectioned isometric view illustrating a sealing device similar to the previous embodiment with the sealing member being superimposed of the embodiment illustrated in Figs. 19 and 21;

Fig. 24 is a partially sectioned isometric view illustrating the sealing device of Fig. 22 mounted on a guide tube;

Fig. 25 is still another embodiment of a sealing device in accordance with the invention, wherein:

Fig. 25A is a top isometric view of the sealing device in it's sealing position;

Fig. 25B is bottom isometric view of the sealing device in it's sealing position (or free position); and

Fig. 25C is a top isometric view of the sealing device mounted on a guide tube in a position in which the device is deployed into the vicinity of a puncture;

Fig. 26A is bottom isometric view of a sealing device according to still a different embodiment, anchoring members thereof being at their retracted position;

Fig 26B is the same as Fig. 26A, the anchoring members illustrated in their expanded position;

Fig. 27 is an exploded isometric view of a deploying assembly for facilitating deployment of a sealing device in accordance with the present invention; and

Figs. 28A-28F are consecutive steps illustrating the deployment of a sealing device in accordance with the present invention with the use of the deploying device of Fig. 27 after carrying out a surgical procedure.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Turning first to Figs. 1 and 2, there is illustrated an assemblage **18** of a sealing device generally designated **20** (Fig. 2) and a deploying assembly generally designated **22**.

Further reference will be made to Figs. 3 and 4 for exemplifying the sealing device **20**. The sealing assembly **20** consists of a sealing member **28** having a generally tubular section formed of a resilient material, e.g. silicon rubber. The sealing member **28** is fitted with a sealing portion **30** which is a diaphragm formed with a plurality of vein-like slots **34**. These slots may have different shapes, e.g. plain radial slots, etc. The diaphragm **30** is normally biased to acquire an essentially sealed state. However, any other type of sealing arrangement is possible instead of diaphragm **30**.

An intermediate portion **29** of the sealing member **28** is significantly resilient and is axially collapsible upon applying thereto some axial force.

The sealing device **28** has a rear end **36** and a fore end **38** which is a truncated engaging portion adapted for bearing against the external surface of the blood vessel (not shown) and this arrangement is intended for conforming with an insertion angle of typically between about 30° to 45° which the angle at which a medical procedure of inserting an angioplast stent or other procedure is taking place, as known *per se*.

It is to be appreciated that the sealing member 20 may be formed as a unitary item or may be assembled out of several components. For example, the sealing member may be molded out of several different components, each having different resiliency, etc. Alternatively, the sealing member may be a formed by means of a resilient member received within a housing imparting it regions of varying resiliency as may be required.

The sealing member **20** is fitted with three anchors **40** (Fig. 4B) each formed with a fastener **42** for engaging with an internal surface of the blood vessel. Each fastener **42** is formed at its end with a spike **44**, the purpose of which will become apparent hereinafter. At a rear end of the anchor **40** there is formed a manipulating bit **46**.

Sealing member **28** is formed, in the particular example, with three bores **50** extending at an essentially radially direction (Fig. 3A) from the rear end **36** of the sealing member **28** at a slight inclination inwards. The bores **50** extend only a limited portion of the sealing member **28** and then opens into a common cavity marked **52** of the sealing member **28**. A stem portion **56** of anchors **40** is received within bore **50** with the manipulating bits **46** extending above rear end **36** of sealing member **28** and fasteners **42** extending in a graded manner, giving rise to an imaginary path which is essentially parallel to the engaging edge portion **38**. This arrangement ensures that when the sealing member **20** is in its activated position

engaged within a puncture of a blood vessel, it extends at an oblique angle with essentially similar pressure applied by the three fasteners **42**.

The arrangement is such that a stem portion of each of the anchors **40** is rotatably received within bores **50** between an inoperative position in which the fasteners **42** are constricted and do not extend from the tubular structure of sealing member **28**, and an operative position in which the fasteners are laterally expanded for engagement with internal surfaces of the blood vessel, in the position shown in Figs. 5A to 5C. However, it is to be noted that the stem portion **56** of anchors **40** extend through a common space **52** within the sealing member **20**.

The manner in which the fasteners are shifted into their laterally expanded position will be explained hereinafter with reference to the deploying assembly.

As seen in Fig. 2, the sealing device **20** is received within a fore end of the deploying assembly **22.**

The deploying assembly comprises a housing **70** (Fig. 6) which is a tubular member formed with an open rear end **72** and an open front end **74**. A front portion of housing **70** narrows towards the front end of the housing and is axially slotted at **76**, rendering said front portion resilient whereupon the sealing device **20** may be expelled therethrough as will become apparent hereinafter. Housing **70** is further formed with a plurality of axial slots **78** (three in the present case) extending axially with a lateral expansion **80** at a fore end of the slot. As can further be seen in Fig. 2, a rear end portion of housing **70** is formed with an internal thread **84** which is adapted for thread engaging with a corresponding thread formed on a connector member **90** (Fig. 7) rotatably engaged within housing **70**, whereby rotation of connector **90** yields axial displacement within housing **70**.

According to a preferred embodiment of the invention, at least a fore end **77** of the housing **70** is made of or fitted with a radio-opaque portion.

Turning now also to Fig. 7, the controller **90** is illustrated, said connector having a tubular shape snugly receivable within housing **70** and formed with a thread **92** (see also Figs. 1 and 2) engageable within thread grooves **84**. In the

particular example the threading is a three-start thread formed with a high pitch. The controller **90** is formed with three openings **96** corresponding with slots **78** and extensions **80** thereof. Controller **90** is fitted at its rear end with a grip portion **100**.

A pusher member **110** (Fig. 8A) is received within controller **90** and is adapted for axial displacement therewithin. Pusher **110** is formed with a ribbed gripping end **112** and three lateral bulges **116** equi-angularly disposed and adapted for projecting through apertures **96** in controller **90** and recesses **78** in housing **70**. The arrangement is such that bulges **116** ensures that the pusher **110** is restricted only to axial displacement with respect to the housing **70** which axial displacement is restricted to the length of recess **78**. However, when bulges **116** reach portion **80** of recess **78**, the pusher member may be rotated to a limited extent, as represented by arrow **120** in Fig. 10D.

Turning now also to Fig. 8B, a fore end of the pusher **110** is illustrated in which three recesses **124** are formed giving rise to a wall **126** cut at a slant serving as a gliding surface. Recesses **124** are sized to accommodate the manipulating tip **46** of anchors **40** whilst surfaces **126** are engageable with said manipulating bits.

At an initial state of the assemblage **18** (Fig. 8B) the recesses **124** of pusher **110** accommodate the manipulating bits **46** in a manner exemplified by one bit only in Fig. 8B illustrated in a solid line. However, upon rotation of the pusher **110** in the direction of arrow **120** (Fig. 8C) thereby imparting axial rotation of anchors **40** within the sealing member **28**.

Turning now back to Figs. 1 and 2, and with further reference to Fig. 9, a tubular sleeve **130** is inserted into the assemblage **18** through a fore end thereof, via opening **74** of the housing. The inner diameter of sleeve **130** is adapted to accommodate a guide tube (also referred to as *"sheath"*) used for carrying out the medical procedure, e.g. during angioplasty.

A fore end of sleeve **130** is fitted with an annular rim **132** for restricting its insertion into the housing and to constitute a gripping member.

In order to avoid mishandling of the device, directing arrows (not shown) are provided on the various components of the deploying assembly, indicating the direction of correct handling. At this stage pusher **110** remains fixed and does not displace with respect to housing **70**.

Further attention is now directed also to Figs. 10A-10E. The assemblage **18** seen in Fig. 2 is mounted on a guide tube (sheath) **150** seen in Fig. 10B and then the sleeve **130** is removed by pulling it at the rim **132**. Removing the sleeve **130** causes the sealing device **20** to slidingly engage the guide tube **150**. In Fig. 10A, the assemblage **18** is illustrated after having removed the sleeve **130**. At this stage, the assemblage **18** is slidingly received over the sheath **150** and the medical procedure, e.g. an angioplasty, takes place by introducing the guide tube **150** into blood vein **152** (Fig. 10B). Typically, the guide tube **150** is introduced into the blood vein at an angle of between about 30 and 45°, depending on the particular medical procedure.

At a next step, after completing the medical procedure, whilst the guide tube **150** is still within blood vessel **152**, the physician pushes the sealing assemblage **18** through tissue layers (skin, muscle, etc.) towards the blood vessel **152** by gripping the housing **70** and sliding it along the guide tube **152**. This procedure takes place under radiography whereby the radio-opaque portion **77** is visible so that the physician may determine when the fore end of the housing **70** reaches the blood vessel **152**.

Then, whilst gripping the housing the controller **90** is rotated by gripping it at grip **100** in a direction of arrow **158** in Fig. 10C until fully received within housing **70**, thus entailing its axial displacement forwardly within the housing **70**. This results in expelling the sealing device forward within the housing **70** giving rise to expanding of the fore end **76** of the housing **70**, as seen in Fig. 10C.

After expanding of the fore end of housing **70** took place, pusher **110** is axially displaced forwardly (Fig. 10D) whereby bulges **116** move within grooves **78** to their forward most position. This maneuver exposes the sealing device **20** as can

be seen in Fig. 10D. Upon forward expelling of sealing device **20** the oblique engaging portion **38** of sealing member **28** comes to bear against the external surface of blood vessel **152** whereby further displacement of the device into the blood vessel entails shrinkage of the resilient sealing member **28**, in particular at the resilient portion **29**, resulting in displacement of the lower portion of the shanks **56** and fasteners **42** of anchors **40** within the blood vessel.

In order to anchor the sealing assembly within the puncture of the blood vessel, the pusher **110** is rotated in the direction of arrow **120** in Fig. 10E, allowing bulges **116** to radially displace within the broadened opening **80**.

By this rotation, the anchors **40** are axially rotated into the position seen in Figs. 5A-5C whereby the fasteners are laterally expanded for engaging internal wall surface of the blood vessel at peripheral portions of the puncture formed in the blood vessel.

The physician then applies light force in an outward direction ensuring that spikes **44** engage within the tissue of the blood vessel whereby the device is properly anchored and secured within the puncture of the blood vessel. At a final stage the guide tube **150** is withdrawn allowing the diaphragm **30** to spontaneously close, thereby sealing the sealing device preventing blood flow through. It then remains only to further remove the deploying assembly **22**, thereby completing the medical procedure and the puncture in the blood vessel is sealed.

The arrangement is such that the shrinkage of the sealing member **28**, in particular at the intermediate portion **29** entails inward radial deflection of the anchors **40**, thereby applying some inward radial force urging a constriction of the size of the puncture in the blood vessel for more rapid spontaneous healing thereof.

Further attention will now be made to another embodiment of the invention, making reference to Figs. 11 through 13, illustrating a modified sealing assembly **220** which in Figs. 11A through 11D is in the non-operative position and in Figs. 13A through 13D is at an operative position.

The sealing assembly **220** comprises a sealing member **228** which is essentially similar to sealing member **28** in the embodiment of the previous drawings, with the only exception being that it comprises a plurality of bores (three in the present example), thus, elements which are similar to elements disclosed in connection with the previous embodiment will be designated with corresponding reference numbers shifted by two hundred.

The bores are not visualized in the figures and they axially extend only through a rear portion of sealing member **228**. The bores extend from a rear end **36** into a common central cavity **252** (Figs. 11B, 11C and 13A-13C) of the sealing member **228**.

Received within the bores are three spears **229** (Fig. 11E), each having a rear head portion **231** of greater diameter than the bores of the sealing member, thus preventing the spears **229** from unintentional disengagement from the bores. A fore end **233** of each of the spears **229** is pointed such that the edges of the three spears define together an imaginary circular path. A rear stem portion of the spears **229** axially extends through the bore of the sealing member and a fore stem portion of the spear extends in the common space and is radially displaceable inwardly, upon deformation of the sealing member **228**.

The sealing device **20** is also fitted with three anchors **240**, similar to anchors **40** in the previous embodiment with the only difference residing in that the fasteners **242** lack a rearwardly facing spike **44** and are rather essentially flat though being arranged in a grading pattern, as in the previous embodiment.

The associated pusher member **310** (Fig. 12) for interacting with the sealing device **220** of the present embodiment, is principally similar to pusher **110** of the previous embodiment with an exception that it is formed with three axial recesses **313** each extending from a recess **324**. The longitudinal recess accommodates the rear heads **231** of the spears **229** when the pusher member **310** is in its forward position, thus preventing the spears **229** from engaging with tissue.

Operation of the sealing member disclosed hereinabove in connection with the second embodiment is principally similar to that which has been explained and illustrated in connection with the previous embodiment, but with the following exception. After introducing the sealing device **220** into the vicinity of the puncture in the blood vessel and manipulating the deploying member as disclosed with reference to the first embodiment, the fasteners **242** radially expand as in Figs. 13A-13D (similar to the arrangement of corresponding Figs. 5A-5C) apart from the spikes. Instead, fore end **232** of spears **229** grabbingly engages into external wall surface of the blood vessel and upon axial deformation of the resilient sealing member **228**, the fore ends of the spears are forced in a radially-inward direction, thus adjoining the lips of the puncture at the blood vessel and restricting the puncture's size.

It will be appreciated that the fasteners may also be pointed with spikes, as in the first embodiment, for the same purpose.

Herein the description, reference was made to three spikes and three spears. It is to be appreciated that this is an example only and any other suitable number of tissue-grabbing means may be used.

Further attention is now directed to Figs. 14 to 17 illustrating a sealing device in accordance with another embodiment of the invention generally designated **300**. For the sake of clarity, those components which are similar to components of sealing device **20** illustrated in connection with the embodiments seen in Figs. 3 and 4 are given same reference numerals shifted by **300**.

The sealing device **300** comprises a sealing member **328** formed at a rear end thereof with a sealing portion **330** in the form of a diaphragm fitted with a plurality of vein-like slots **334** which as normally biased into a sealed position though allowing introducing therethrough of a sheath, as explained hereinbefore.

The sealing member **328** has a tubular shape with an intermediate resilient portion **329** with four bores **350** axially extending from rear end **336**, through a rear portion of the side walls and into the central, common space **352** (Figs. 15A-15C).

The structure of sealing member **328** is made of a resilient material such as silicone rubber which may be easily deformed and which assumes its original shape as soon as depressing force is removed.

Attached onto rear edge **336** there is a retaining ring **349** made of an essentially rigid material and formed with four recesses **353** corresponding with apertures **350** on rear edge **336** of the sealing member **328**.

A fore end **338** is truncated as explained in connection with a sealing device **28** in the previous embodiment, and is fitted with a anchor retention ring **355** made of an essentially rigid material, the purpose of which will become apparent hereinafter. Retention ring **355** is formed with a plurality of bores **357** for improving the connection with the sealing member **328** during the molding process. Retention ring **355** may be made of a radio or pack material.

Four anchors **340** are provided, each fitted at a rear end thereof with an expanded head **346**, larger than apertures **353** in ring **349**. Each anchor **340** is formed at its fore end with two fasteners **342** which in the present embodiment are of different lengths. The fasteners **342** are illustrated in Fig. 14 in their constrained position in which they extend essentially parallel to stem portion **356** and assume an arced shape corresponding with the radii of the sealing member **328** so as to blend with it in the constricted position as will be explained hereinafter with reference to Fig. 15A. However, the fasteners **342** are normally biased to displace in a lateral direction as illustrated in Figs. 15B, 15C and corresponding Figs. 16B and 16C. This arrangement is obtained for example by pre-straining the fore end of the anchors.

Preferably all components are made of a biodegradable or bio-absorbable material.

Turning now to Figs. 15A and 16A, the sealing member **300** is illustrated in the constricted position in which the stems **356** of anchors **340** coaxially extend along the sealing member **328** and when a guide sheath (not shown) extends through the sealing member **300** it depresses the stem portions **356** and the

fasteners **342** into the resilient sealing member **328**, as illustrated in Fig. 15A, whereby the sealing device **300** is slidable over the sheath. This is the position in which the sealing member is retained within the deploying assembly (similar to that disclosed in connection with the previous embodiment, whereby a medical procedure is carried out without interference of the sealing device **300**.

Assembly of the sealing device over the guide tube (sheath) is similar with that disclosed in connection with the previous embodiment. After completing the medical procedure, whilst the guide tube is still within the blood vessel, the physician pushes the sealing assemblage through tissue layers (skin, muscle, etc.) towards the blood vessel, sliding it along the guide tube. This procedure takes place under a geography whereby the radio or pack portion (typically retention ring **355**) is visible, so that the physician may determine when the fore end of the sealing device **300** reaches the external face of the blood vessel.

Then, similar to the description in connection with Fig. 10C above, whilst gripping the housing of the deploying member, control **90** is rotated, resulting in expelling of sealing device **300** in a forward direction, giving rise to expansion of the fore end **76** of housing **70** (Fig. 10C).

After expansion of the fore end, pusher **110** is axially displaced forwardly (Fig. 10D) exposing the sealing device **300** until the oblique fore end **338** bears against the external surface of the blood vessel such that further axial displacement of the sealing device **300** entailed axial shrinkage of the resilient sealing member **328** (as in the position of Figs. 15B and 16B), in particular along the resilient portion **329**, until a position in which anchors **342** disengage from the retention ring **355** and laterally project within the blood vessel, engaging with inner surface of the blood vessel, at peripheral portions of the puncture formed in the blood vessel.

Preferably all components are made of a biodegradable or bio-absorbable material

As in the previous embodiment, the physician then applies a light force in an axial outward direction, first to ensure that the fasteners **342** are indeed engaged with the tissue of the blood vessel, whereby the device is properly anchored and secured within the puncture of the blood vessel. Then, the guide tube is withdrawn, allowing the sealing diaphragm **320** to spontaneously close, thereby sealing the sealing device and preventing blood flow therethrough.

Upon removal of the guide tube and the deploying assembly, an inward radial force is applied by the walls of the sealing member **328**, applying an inward radial force over the stem portion **356** of anchors **340**, entailing their radially inward displacement as in the position of Figs. 15C and 16C urging constriction of the size of the puncture in the blood vessel for faster healing and spontaneous sealing of the puncture.

It will be appreciated that the particular construction of the fore end of pusher **110** (namely recesses **124** and gliding surfaces **126**) are unnecessary, nor is the arrangement of rotation of the pusher **110** within the controller **90**. In the present embodiment there is merely required axial displacement of the components.

Turning now to a further embodiment illustrated in Figs. 18 and 19, there is a sealing device generally designated **400** comprising a tubular body **402** having a distal end **404** and a proximal end **406**, with a axially deformable head member **410** axially resilient and for that purpose it is typically made of silicon rubber and may be formed as a bellows, so as to be axially deformable at integral fold lines **411**. Optionally, the head member may be provided with an axially biasing spring member embedded within the device so as to increase resiliency of the device (not shown). The head member has an oblique distal end **412** which, as explained in connection with previous embodiments, is suited for inclined engagement with a blood vessel. A proximal end of the member **410** serves as a sealing member **416** formed with a plurality of radially extending slits **418**. This arrangement makes it possible to introduce through the sealing device a guide tube **420** (Fig. 20) whilst

upon removal of the guide tube **420** the sealing member **416** spontaneously seals as in the position of Figs. 18 and 19.

It is to be appreciated that rather than radial slits **418** there may be provided merely a through-going aperture and owing to significant resilience of the sealing member **416** it is possible to introduce a guide tube there through while maintaining the feature of spontaneous sealing thereof.

The sealing device **400** is formed at its distal end with an anchoring assembly **426** which in the present embodiment is a ring-like member formed with several axial slits **428** giving rise to formation of flexible anchoring members **432** which in the non-biased position have a free end thereof laterally projecting as in Figs. 18 to 19. The anchoring member blends with the distal end **404** of the housing **402** which slightly taper so as to facilitate penetration of the sealing device into the puncture at the blood vessel.

Arrangement is such that the distal end **412** of member **410** is adapted for bearing against external surface of the blood vessel adjacent boundaries of the puncture whilst the resilient anchor members **432** bear against inside boundary surfaces of the punctured vessel whereby resilience of the member **410** and of the anchoring members **432** ensure tight sealing of the apertures boundaries which are maintained clamped between the peripheral surface of distal end **412** and the anchoring members **432**.

Whilst in the disclosed embodiments the housing **402** is a complete enveloping wall (i.e. a tubular member) it is appreciated that it may rather be in the form of a cylindrical caged formed out of a cylindrical framework or may be an apertured tubular member. Furthermore, the housing may be somewhat tapering such that a fore end thereof is narrower then its rear end. The gap **401** formed between member **410** and anchoring member **426** is in fact a clamping zone sized so as to clampingly accommodate a wall thickness of the punctured vessel. It is thus desired that some axial biasing means be provided and this is obtained by either or both axial flexibility of member **410** and the elasticity of anchoring

member **432**. The contour of anchoring members **432** is such as to facilitate easy insertion through the apertures perimeter and spontaneous expansion of the anchoring members to the anchoring position, presenting withdrawal of the device.

The housing **402** has at its rear (distal) end a widened portion indicated in Fig. 19 as **413** for receiving flaps of the sealing membrane **416** at the open position when a guide tube extends there through, as in fig. 19.

The embodiment of Figs. 21 and 22 illustrates a sealing device generally designated **440** which is principally similar to the previous embodiment except that the sealing arrangement is different and is devoid of the axially deformable head member. Instead, housing **442** comprises a laterally projecting portion **444** with an annular bottom surface **446** bearing against the external surface of the vessel adjacent the boundaries of the puncture constituting a gap **448** between said surface **446** and the three edges **450** of anchoring members **432**.

The sealing mechanism in accordance with the present embodiment, generally designated **452** comprises a sleeve-like member **456** which at the proximal end comprises a skirt portion **458** attached to the housing **442** and sealingly secured thereto and at the distal end comprises two flattened lip members **460**, spanning across the diameter of the housing. The sleeve **456** is made of a flexible material which permits introduction therethrough of a guide tube **480** (see Fig. 24) and the sleeve spontaneously gains the position of Figs. 21 and 22 in which the lip **460** sealingly engage one another, preventing flow through the sealing device **440**.

As further noted, best in Fig. 22, the sleeve member **456** is secured at the distal end **404** of the housing by means of attachments **464** extending below the anchoring member **426** thus preventing collapsing of the sleeve member **456** upon withdrawal of the guide tube **480** (Fig. 24). Furthermore, two hollow pockets **468** are formed at both sides of the sleeve **456**, whereby upon withdrawal of the guide tube **480**, when the sealing device is in its operative position within a puncture in a

blood vessel, blood enters these pockets and applies pressure on the lips **460**, tightening their engagement thus increasing sealing of the sealing device.

With further reference to Fig. 23, there is illustrated a sealing device **490** which is a combination of sealing devices **400** (Figs. 18-20) and **440** (Figs. 21 and 22). Accordingly, like elements have been given like reference numbers as in the previous embodiments. The sealing device **490** comprises a head member **410** which is axially resilient and comprises a sealing portion **416**. A sealing gap **492** is formed between an oblique bottom surface of head member **410** and an upper free end of anchoring members **432**. In addition to sealing member **416** there is provided a sealing sleeve **456** clampingly secured between a portion of housing **444** and the head member **410**, the operation of said sleeve member being as explained hereinabove in connection with the embodiment of Figs. 21 and 22.

Fig. 24 illustrates the sealing device **490** of Fig. 23 with a guide tube **480** extending therethrough. At this position the medical procedure is carried out through the lumen of guide tube **480** whilst upon withdrawal of the guide tube **480**, the sealing device spontaneously seals, first upon engagement of lips **460** of sleeve **456** and then, sealing of the sealing member **416** upon removal of the guide tube **480** from head member **410**.

Whilst in the disclosed embodiments the housing **402** is a complete enveloping wall (i.e. a tubular member) it is appreciated that it may rather be in the form of a cylindrical caged formed out of a cylindrical framework or may be an apertured tubular member.

The sealing device **493** of Fig. 25 differs from the sealing device **400** in Fig. 18 only in its anchoring assembly **494** constructed by forming a plurality of apertures **495** (Figs. 25A and 25B) in the tubular housing **496** and imparting the cut-outs elasticity thereby forming anchoring members **497** which are normally outward projecting as in the figure. As in the previous embodiment, the formed, distal end **498** is slanted so as to facilitate easy insertion of the sealing device into the puncture's vicinity. In operation, the anchoring members **497** will bear against

an inner wall surface of the blood vessel at peripheries of the puncture formed therein. In the figures the tips of the cut-outs are rounded, however they may also be pointed, etc (not shown). The sealing device 494 in Fig. 25C is illustrated mounted on a guide tube **499**.

The sealing assembly in the embodiment of Figs. 25 is similar as in Fig. 18 and comprises a body member **410** formed with a sealing assembly **416**. However, other sealing arrangements are possible as well or in combination, e.g. the arrangement as in Figs. 21 and 22.

The embodiment of Fig. 25 has an advantage when used in conjunction with a sealing assembly as illustrated in connection with the embodiment of Figs. 21 and 22, whereas blood may flow through apertures **495** formed in housing **496** thus applying pressure on the sealing sleeve (not shown in Figs. 25) to tighten the sealing effect.

It will be appreciated by a skilled person that the anchoring assembly may, rather than be integrally formed with the housing, may be fixedly attached thereto, e.g. by adhering, welding, etc.

Further attention is now directed to Figs. 26A and 26B illustrating still another embodiment of a sealing device in accordance with the present invention generally designated **500** which being compared to the previous embodiments differ mainly in the different anchoring assembly generally designated **502** as well as in the construction of the tumor member **504**.

In the embodiment of Figs. 26, the head member **508** is identical with corresponding head member **410** in the embodiment of Fig. 25, and is integrally formed with a sealing portion (not shown). The anchoring assembly **502** comprises several anchor units each supported by a study **510** formed at its proximal end with two anchors **512** which are resilient members formed so as to normally laterally project as in Fig. 26B although may be easily deformed into the position of Fig. 26A, e.g. while being pushed through an aperture in a blood vessel whereby

the walls of the blood vessel cause the anchor members **512** to deform into position of Fig. 26A.

For assisting in the penetration through the aperture in the blood vessel, the distal tip of the anchors designated as **516** is tapered and blends with a corresponding tapering end **518** of housing **504**.

The housing **504** rather than being a tubular member as in the previous embodiment is a cage-like member constructed of a plurality of support studs **522** bearing at their distal end the ring **518**. The density of stud **522** determines the rigidity of the structure.

Further noticed in the embodiment of Figs. 26A and 26B, the gap **530** between the fore end **532** of head member **508** and the distal end **536** of the anchoring members **512** remains constant in spite of the inclination of the fore end **532** of head member **508** since the studs **510** of the anchoring assembly are of corresponding length thereby assuring that when the sealing device **500** is introduced into site at an angle (which is typical procedure in carrying out the medical procedures concerned) the sealing of the puncture is most effective.

Fig. 27 illustrates a deploying assembly in accordance with another embodiment of the present invention generally designated **600** comprising a retractor unit **604** and a pusher unit **608**. Retractor unit **604** comprises two shell members **612**, facing each other giving rise to a confined space therebetween **614** sized for slidingly receiving a guide tube as will become apparent hereinafter with reference to Figs. 28. The shell members **612** are articulated to one another by a coiled spring actuator **618** fixed to the shell members at flanges **620**.

The arrangement is such that depressing the actuating member **618** in the direction of arrows **624** entails retraction of shell members **612** in the direction of arrows **628**.

The pusher unit **608** is similar in construction to the retractor unit **604** as it comprises two shell-like members **630** sized for sliding over a guide tube (as will become apparent hereinafter with reference to Figs. 28) and within the cavity **614**

of the retractor unit **604**. Shell members **630** are retractable from one another by opening the biasing support ring **634** in the direction of arrows **638** so as to enable mounting of the pusher unit **608** on a guide tube.

At least the fore end **640** of pusher unit **608** and possibly also the fore end **642** of retractor unit **604** are radio opaque so as to enable monitoring the deploying procedure by known radiology means.

With further reference being made now to Figs. 28A to 28F, a method for deploying a sealing device in accordance with the present invention, using a deploying assembly **600** as illustrated in connection with Fig. 27, will now be described, using the same reference numerals as in Fig. 27, whereby the sealing device is designated **650** which device may be any of the aforementioned devices as described and as claimed in accordance with the present invention.

In Fig. 28A, there is illustrated a guide tube **656** which prior to beginning with a medical procedure is fitted at its rear end with the sealing device **650**, the latter having no interference whatsoever with the medical procedure taking place through the guide tube **656** which is introduced through different tissue layers **658** into the blood vessel **660** through a puncture formed therein.

As the medical procedure ends, an obturator **655** is introduced into the guide tube **656** for stiffening same and preventing its accidental collapse. According to one embodiment, the obturator is marked with a plurality of radio-opaque marks **557** for facilitating monitoring the deploying process. Then, the deploying assembly is mounted, first mounting the retractor unit **604**. For that purpose, the shell members **612** are separated from one another by depressing the actuator ring **618** expanding the distance between the shell members **612** enabling mounting of same on the guide tube **656**, as in Fig. 28B at a location between sealing device **650** and the organ's tissue **658**.

Retractor unit **604** is then pushed over the guide tube into the tissue layers **658** until its fore end **642** reaches the blood vessel **660**, monitoring the progress of the radio opaque fore end **642** under conventional radiology means.

Once the retractor unit **604** reached its position, the actuating ring **618** is again depressed (in the direction of arrows **624** in Fig. 27) overcoming the natural sealing force of the tissue layers **658**, until a position in which the gap **614** between shell members **612** is sufficient, at least at a rear end thereof to allow introducing of the sealing member **650** as in the position of Fig. 28C.

Once the sealing device **650** is pushed forwards into the position of Fig. 28C (this may be carried out merely by using one's hands) the pusher unit **608** is mounted at the rear portion of the guide tube **656** as in the position of Fig. 28D. By pushing the pusher unit **608** in the direction of arrow **666** in Fig. 28E, the sealing device **650** is propelled forward over the guide tube **656** and between the shell members **612** of the retractor **604**. As the proximal leading end of the sealing device **650** penetrates through the puncture of the blood vessel **660** its anchoring assembly will deform into a retracted position and will spontaneously snap into its anchoring position as explained hereinabove in connection with the sealing devices. Monitoring the distance through which the sealing device is propelled may be carried out either by monitoring the radio opaque front end **640** of the pusher member **608** (see Fig. 27) or by providing the outer surface of shell members **630** of the pusher member **608** with visible indications marked **669** in Fig. 27.

After completing the sealing procedure the pusher unit **608** is withdrawn and removed (position of Fig. 28F) and then the retractor unit **604** may be removed from the puncture site merely by sliding it backwards in the direction of arrow **670** in Fig. 28F.Furthermore, a skilled person will appreciate that in fact, the tissue tends to act in a manner to reduce the size of the puncture, i.e. applies force in a direction to spontaneously reduce the sectional area thereof (as the direction of the force applied on the tissue-grabbing members) and thus assist in the sealing process.

Whilst some embodiments have been described and illustrated with reference to some drawings, the artisan will appreciate that many variations are

possible which do not depart from the general scope of the invention, *mutatis, mutandis*.

CLAIMS:

1. A sealing device for a puncture in a blood vessel, the device being slidingly receivable over a guide tube and comprising a tubular, resilient sealing member formed with a sealing portion spontaneously sealable upon deployment of the device into an activated state, an engaging portion for bearing against an external surface of the blood vessel and a plurality of anchors fitted at their fore end with fasteners for engaging a corresponding internal surface of the blood vessel and at a rear end with a manipulating bit; said anchors being displaceable between a constricted position in which they blend with the tubular sealing member, and an operative position in which the fasteners are laterally expanded and engage the internal surface of the blood vessel.

2. A sealing device according to claim 1, further comprising a plurality of tissue-grabbing members adapted for engaging with tissue portion surrounding the puncture, and an arrangement for applying to said tissue-grabbing members an inwardly directed radial force.

3. A sealing device according to Claim 2, wherein the fasteners are fitted with spikes facing rearwards, for engaging tissue of the blood vessel.

4. A sealing device according to Claim 3, wherein at the deployed state the anchors are biased radially inwardly, for constricting the size of the puncture in the blood vessel.

5. A sealing device according to Claim 1, wherein the engaging portion of the sealing member is truncated, whereby upon engaging with the blood vessel the sealing member bears at an inclination thereover.

6. A sealing device according to Claim 5, wherein the fasteners are axially graded, giving rise to an imaginary path extending between edges thereof, said path conforming with the truncated edge of the sealing member.

7. A sealing device according to Claim 1, wherein each anchor comprises a stem portion axially extending along the sealing member, said stem being formed at its rear end with the manipulating bit and at its fore end with the fastener.

8. A sealing device according to Claim 7, wherein a first portion of the stem extends through side walls of the sealing member and a second portion of the stem extends within a common cavity of the sealing member.

9. A sealing device according to Claim 8, wherein the sealing member is formed with a plurality of bores extending only a portion of the length of the sealing member and rotationally receiving the first portion of each stem.

10. A sealing device according to Claim 7, wherein at an operative position of the device the sealing member applies radial force on the stems of the anchors, urging the fasteners radially inwardly for constricting the size of the puncture formed at the blood vessel.

11. A sealing device according to Claim 1, wherein the anchors are formed at their aft end with a manipulating bit temporarily engageable by a deploying member for displacing into the operative position.

12. A sealing device according to Claim 2, wherein the sealing member is fitted with a plurality of spear members for grabbing external wall surface of the blood vessel around the puncture and constricting the size of the puncture by applying thereto force in a radially-inward direction.

13. A sealing device according to Claim 12, wherein the spear members have a rear head projecting from a rear end of the sealing member, a rear stem portion axially extending through a bore of the sealing member, a fore stem portion extending through a common cavity of the sealing member and pointed tissue engaging fore ends.

14. A sealing device according to Claim 1, deployable into its operative position by a deploying assembly comprising a tubular housing, a tubular controller received within the housing and a tubular pusher member received within the controller,

coaxially received within one another; said pusher adapted for manipulating the sealing member into its activated position.

15. A sealing device according to Claim 14, wherein the pusher member has restricted axial displacement with respect to the housing.

16. A sealing device according to Claim 14, wherein the pusher member has restricted rotational displacement with respect to the housing.

17. A sealing device according to Claim 14, wherein at least a fore end of the housing is radio-opaque material.

18. A sealing device according to Claim 14, wherein a fore end of the housing converges to a lesser diameter, said fore end being radially expandable to admit deployment therethrough of the sealing device.

19. A sealing device according to Claim 14, wherein a sleeve is fitted into the pusher via the fore end of the housing, said sleeve extending also through the sealing device and retaining it in its constricted position.

20. A sealing device according to Claim 15, wherein the pusher member is formed with at least one lateral projection exiting through a corresponding slot formed in the controller and a corresponding slot formed in the housing, thereby restricting the axial displacement of the pusher within the housing.

21. A sealing device according to Claim 20, wherein the at least one slot formed in the controller and in the housing are formed at their front ends with a lateral extension allowing for rotation of the pusher member about its longitudinal axis.

22. A sealing device according to Claim 14, wherein the controller is axially displaceable within the housing, whereby axially displacement thereof entails intrusion of the sealing member through the fore end of the housing.

23. A sealing device according to Claim 14, wherein a fore end of the pusher member is formed with activating surfaces adapted for engagement with the manipulating bits of the anchors and deploying the anchors into the operative position.

24. A sealing device according to Claim 23, wherein the activating surfaces are gliding surfaces inclined so as to engage with the manipulating bits at their constricted position and where rotation of the pusher member entails sliding displacement of the manipulating bits about said activating surfaces thereby deploying the anchors into their operative position.

25. A sealing device according to Claim 1, wherein the tubular sealing member is biased to axially shrink.

26. A sealing device according to Claim 1, wherein the sealing portion is a diaphragm with a normally closed flow path formed by a plurality of slots, intrinsically biased into close the flow path.

27. A sealing device according to Claim 1, wherein at least a component of the sealing member is made of a biodegradable or bio-absorbable material.

28. A sealing device according to Claim 1, wherein the fasteners are biased for spontaneous lateral deformation wherein they are retained at their constricted position by an annular portion of the sealing member.

29. A sealing device according to Claim 28, wherein a retaining member is fitted at a fore end of the sealing member for retaining the fasteners of the anchors at their constricted position.

30. A sealing device according to Claim 28, wherein a rear end of the sealing member is fitted with a counter portion made of a hard material wherein a rear engaging end of the anchors bears against the counter member.

31. A sealing device according to Claim 28, wherein at the constricted position the fasteners are parallel to a stem portion of the anchor and extend at an arced layout for blending with the circular pattern of the sealing member.

32. A deploying assembly for deploying a sealing device according to Claim 1, comprising a tubular housing, a tubular controller received within the housing and a tubular pusher member received within the controller, coaxially received within one another; said pusher adapted for engagement with the manipulating bits of the sealing device and manipulating the sealing member into its activated position.

33. A deploying assembly for deploying a sealing device according to Claim 28, comprising a tubular housing, a tubular controller coaxially received within the housing and a tubular pusher member coaxially received within the controller, said pusher adapted for engagement with a rear end of the sealing device and for manipulating it into its activated position.

34. A method for sealing a puncture in a blood vessel, the method comprising the following steps:

(i) Obtaining a sealing assembly comprising a sealing member fitted within an associated deploying assembly, with a sleeve extending through the sealing assembly, said sleeve defining a through-going path;

(ii) Introducing a medical guide tube through the path;

(iii) Removing the sleeve;

(iv) Carrying out a medical procedure through the guide tube:

(v) Slidingly displacing the sealing assembly over the guide tube until a fore end of the deploying assembly engages the blood vessel;

(vi) Expelling the sealing assembly from the deploying assembly and introducing anchor fastener members of the sealing assembly into the blood vessel through the puncture;

(vii) Deploying anchor fastener members into an operative position in which they are laterally expanded and engage the internal surface of the blood vessel;

(viii) Disengaging the sealing assembly from the deploying assembly and withdrawing the guide tube, allowing a resilient sealing member formed in the sealing member to spontaneously seal.

35. A method according to Claim 34, wherein at step (**d**) the guide tube is inserted into the blood vessel at an angle corresponding with a truncation angle of an engaging portion formed at the sealing member, for bearing against an external surface of the blood vessel.

36. A method according to Claim 34, wherein at least step (**e**) is radio–monitored, whereby at least a fore end of the housing is radio-opaque material.

37. A method according to Claim 34, wherein the anchors are biased radially inwardly, for constricting the size of the puncture in the blood vessel.

38. A method according to Claim 34, wherein the fasteners of the fitted with rearwardly facing spikes whereby after step (**e**) axial force is applied to the sealing member in a rearward direction, thereby having the spikes engage tissue of the blood vessel.

39. A method according to Claim 34, wherein the deploying assembly comprises a tubular housing, a tubular controller received within the housing and a tubular pusher member received within the controller, coaxially received within one another; said pusher adapted for manipulating the sealing member into its activated position; wherein step (**f**) is carried out by the following steps:

(i) Axially displacing the controller within the housing in a forward direction;

(ii) Axially displacing the pusher within the controller.

40. A method according to Claim 39, wherein the controller and housing are thread-engaged whereby step (**a**) is carried out by rotating the controller within the housing.

41. A method according to Claim 39, wherein a fore end of the pusher member is formed with activating surfaces adapted for engagement with corresponding manipulating bits formed at rear ends of the anchors, whereby deploying the anchors into the operative position of step (**g**) is carried out by rotating the pusher within the housing.

42. A method according to Claim 34, which after step (**f**) spear members are engaged with an external surface of the blood vessel surrounding the puncture and by applying inwardly directed radial force, the lips of the punctured blood vessel are adjoined, thereby decreasing the size of the puncture.

43. A sealing device for sealing a puncture in a blood vessel, the device is adapted for sliding over a guide tube and comprises a body member having a distal end and a proximal end; an axially resilient member extending at said distal end, with a fore end for bearing against an external surface of the blood vessel adjacent boundaries of the puncture; and an anchoring assembly at said proximal end for engaging internal wall surface of the blood vessel, said anchoring assembly comprises at least one flexible anchoring member having a constricted position for insertion into the puncture and a laterally expanded, anchoring position; and a spontaneously sealable sealing member.

44. A sealing device according to Claim 43, wherein the body member is a complete enveloping wall having a cylindrical shape.

45. A sealing device according to Claim 43, wherein the body member comprises a plurality of apertures.

46. A sealing device according to Claim 43, wherein the body member is a cylindrical framework.

47. A sealing device according to Claim 43, wherein the at least one flexible anchoring member is spontaneously deployable into its anchoring position for engagement with an inside surface of the blood vessel, adjacent boundaries of the puncture.

48. A sealing device according to Claim 47, wherein the anchoring assembly comprises at least one anchoring member attached to the body member adjacent the proximal end ,with a free end thereof facing the distal end of the body member, said anchoring members being elastic members normally extending in the laterally projecting position.

49. A sealing device according to Claim 48, wherein the anchoring members are integrally formed with the body member or fixedly attached thereto.

50. A sealing device according to Claim 43, wherein the sealing member is a membrane made of resilient material formed with a central aperture normally sealed, said aperture being a puncture through the membrane or a plurality of slits.

51. A sealing device according to Claim 43, wherein the sealing member is a resilient sleeve-like member received in the body member with a circumferential portion sealingly secured at a proximal end thereof, and flattened adjoining lips at the distal end, whereby fluid flow through the sleeve, in a direction from the distal end towards the proximal end, is not admitted.

52. A sealing device according to Claim 43, wherein the resilient member has an oblique fore end for bearing against the external surface of the blood vessel adjacent boundaries of the puncture.

53. A sealing device according to claim 52, wherein the anchoring members extend at a corresponding inclination as that of the fore end of the resilient member, whereby a circumferential gap between the fore end and the anchoring members is uniform.

54. A sealing device according to claim 43, wherein the anchoring assembly comprises a partitioned skirt-like portion secured at a distal end thereof to said body member and where a proximal end thereof faces the distal end of the body member.

55. A sealing device according to claim 43, wherein the anchoring assembly comprises a plurality of anchors fitted at proximal ends of axially extending studs.

56. A sealing devices according to claim 55, wherein the studs form the body member.

57. A sealing device according to claim 43, wherein the anchoring members are leaf-like members cut out from the body member where they remain attached to the body member at the proximal end.

58. A deploying assembly for introducing the sealing device according to claim 43 into the puncture vicinity, the assembly comprising a retractor unit and a pusher member, said retractor unit comprising a rigid elongate tube-embracing portion slidable over the guide tube and extending between a fore end and a rear end with an expanding member fitted at the rear end thereof for readily expanding or constricting the tube-embracing portion; said pusher member being slidable over the guide tube and within the retractor unit, with a fore end thereof engageable with

the proximal end of the sealing device so as to propel it through the retractor and into the puncture of the blood vessel.

59. A deploying assembly according to claim 58, wherein the fore end of the pusher sleeve and of the retractor are radio opaque for monitoring progress of the deploying procedure.

60. A deploying assembly according to claim 58, wherein the retractor unit and the pusher member are formed with one or more axial openings to allow introducing or removal of the guide tube there through.

61. A deploying assembly according to claim 60, wherein the retractor unit and the pusher member are each formed with at least a pair of shell-like members supported at their rear end by an elastic clamp for radial displacement of said shell-like members with respect to one another; so as to facilitate mounting the retractor unit and the pusher member on the guide tube and fir expanding the retractor unit for tissue retraction..

62. A method utilizing the above different embodiment and the deploying member comprises the steps of:

(i) Obtaining a sealing assembly comprising a sealing member and an associated deploying assembly;

(ii) Introducing a medical guide tube through a path within the sealing device;

(iii) Carrying out a medical procedure through the guide tube;

(iv) Mounting a retractor of the deploying member over an exposed portion of the guide tube;

(v) Slidingly displacing the retractor over the guide tube into through tissue layers until a fore end of the retractor engages the blood vessel;

(vi) Expanding the retractor and slidingly displacing the sealing device over the guide tube and through

retractor, into the vicinity of the puncture of the blood vessel;

(vii) Deploying the sealing device into its operative state within the puncture wherein the resilient member is depressed against external surface of the blood vessel and the anchoring members spontaneously deploy to their operative position in which they are laterally expanded and engage the internal surface of the blood vessel;

(viii) Withdrawing the deploying member and the guide tube, allowing a resilient sealing member of the sealing member to spontaneously seal.

63. A method according to claim 62, wherein after step (c) an obturator is introduced into the guide tube for rigidifying the guide tube.

64. A method according to claim 63, wherein the obturator is formed with a radio-opaque scale to thereby facilitate monitoring the deployment process of the sealing device.

FIG. 1

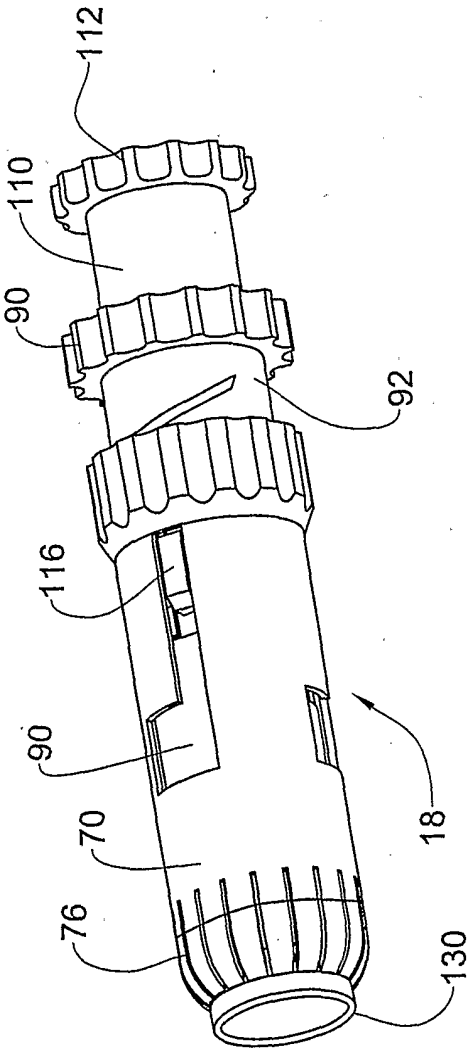
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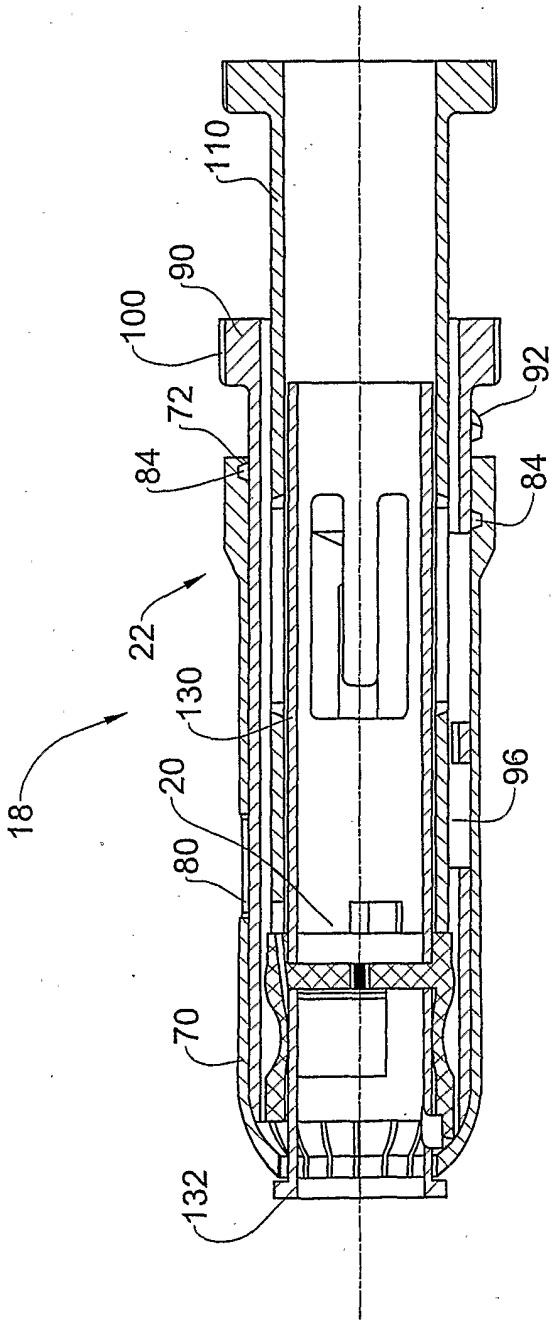
FIG. 2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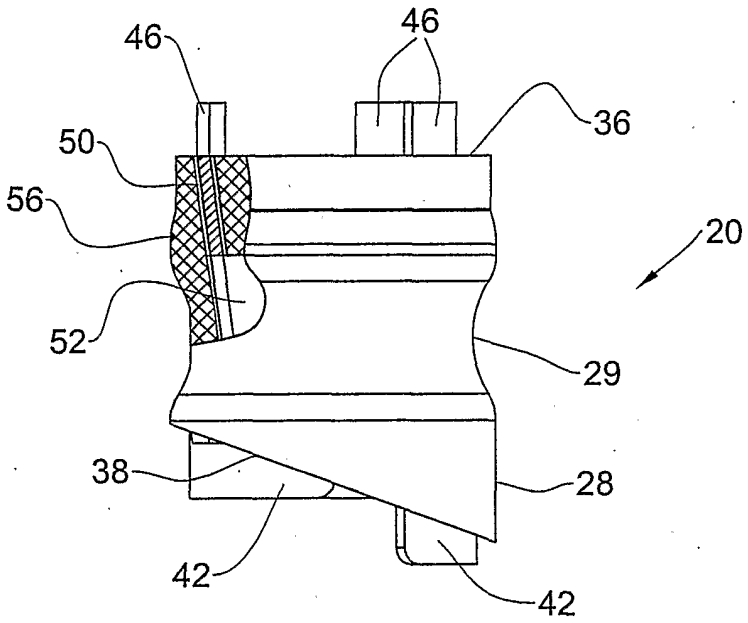

FIG. 3A

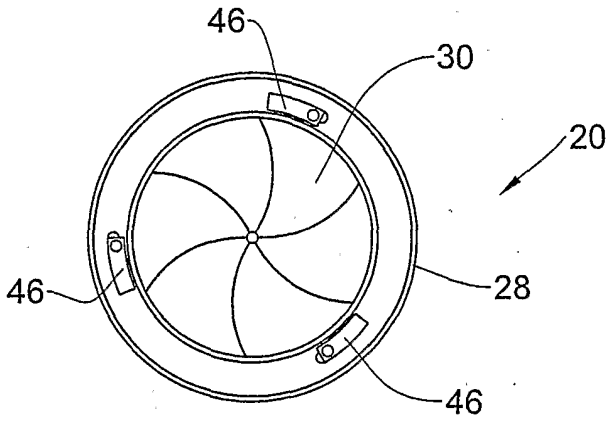

FIG. 3B

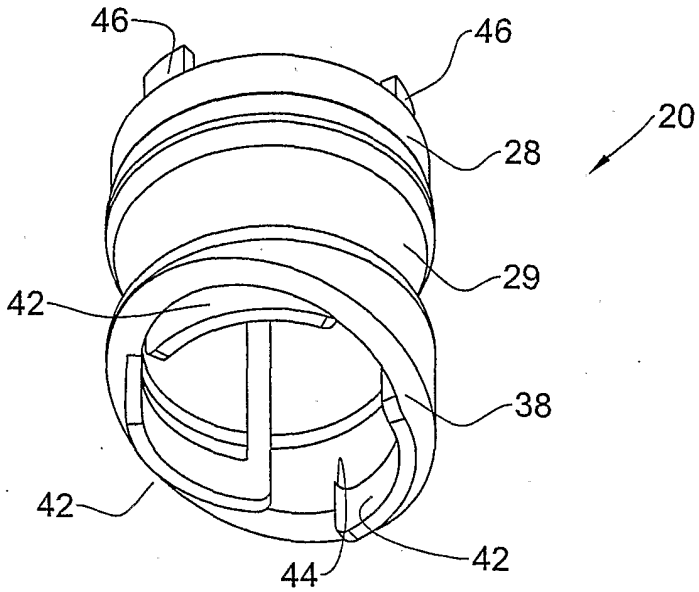

FIG. 3C

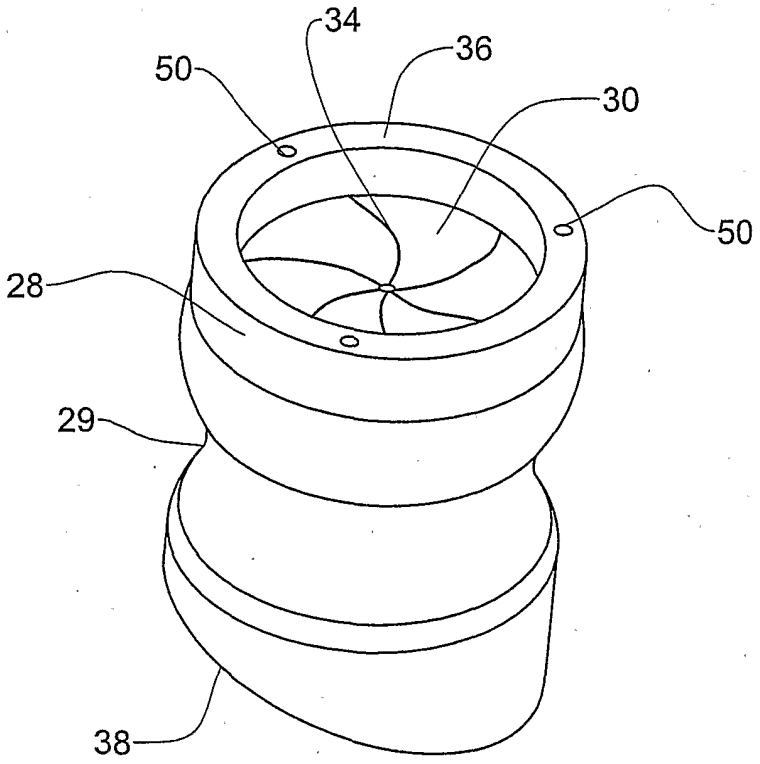

FIG. 4A

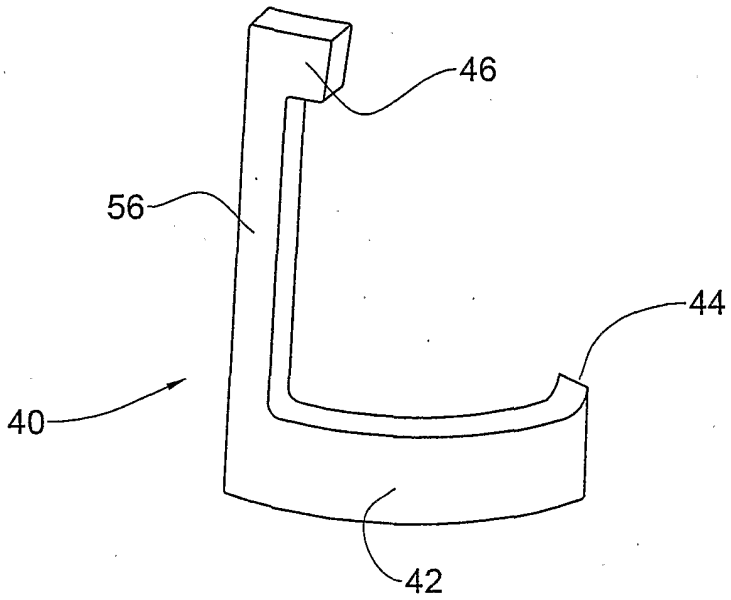

FIG. 4B

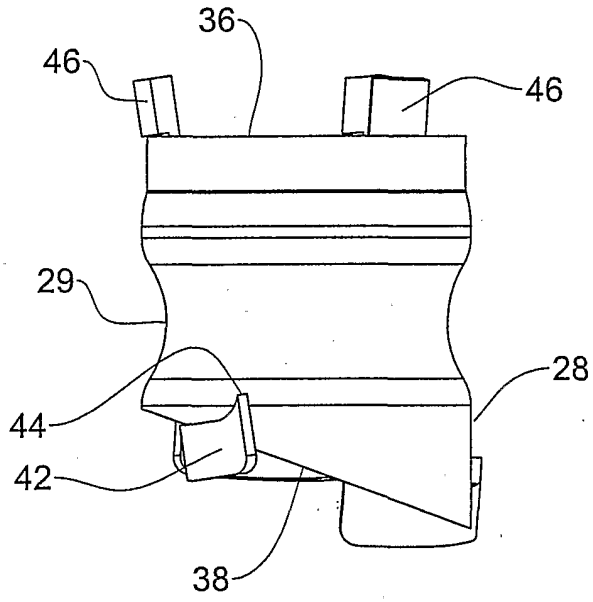

FIG. 5A

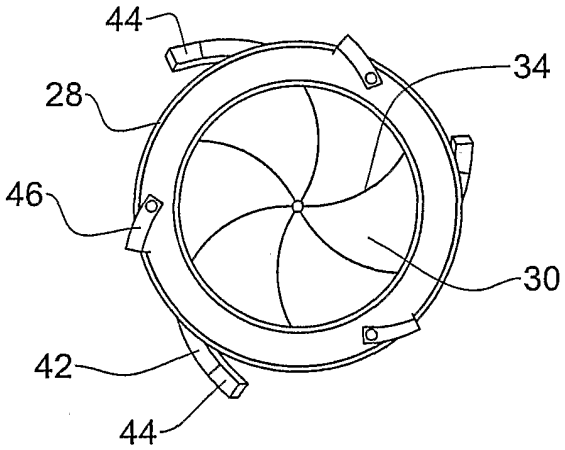

FIG. 5B

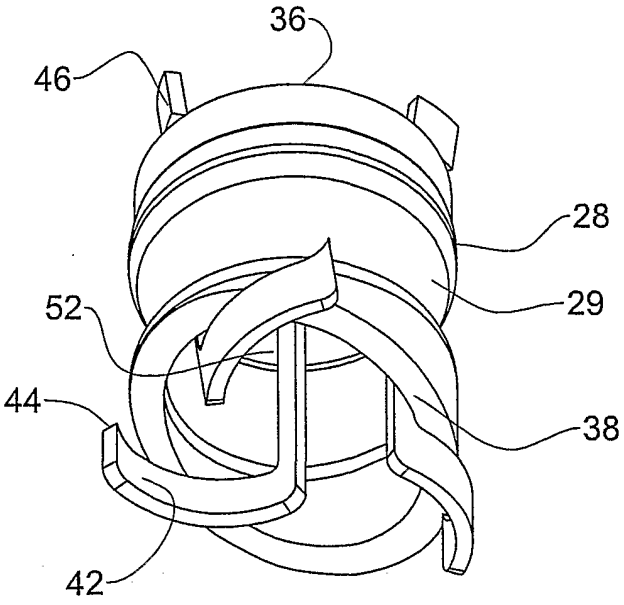

FIG. 5C

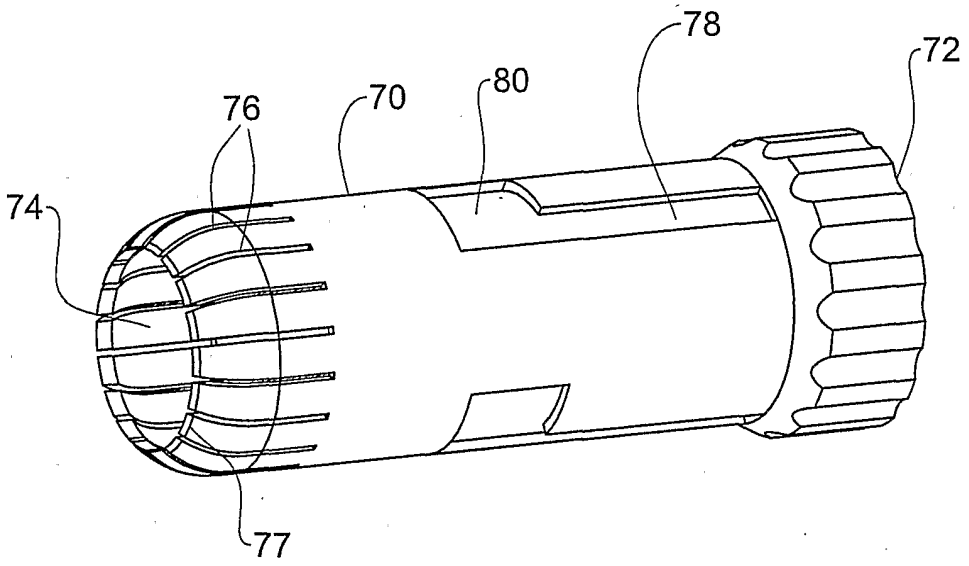

FIG. 6

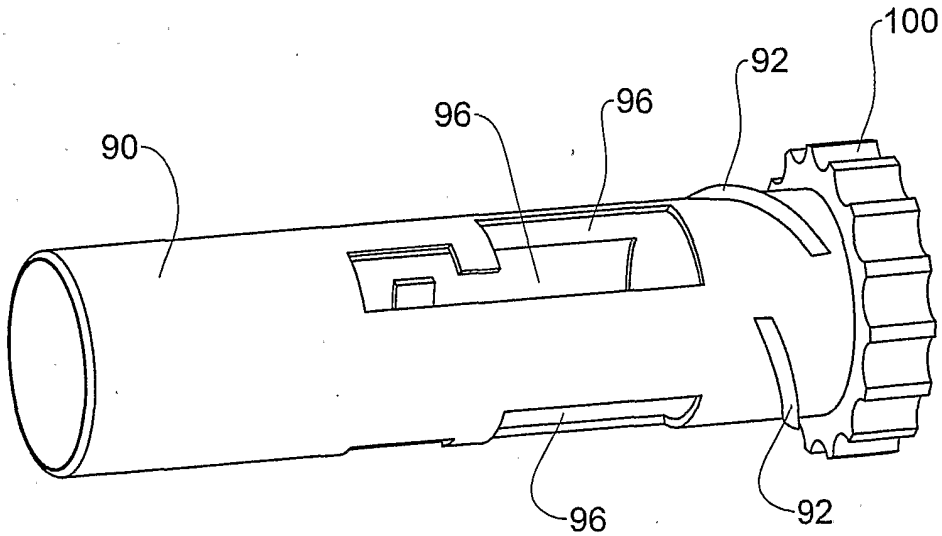

FIG. 7

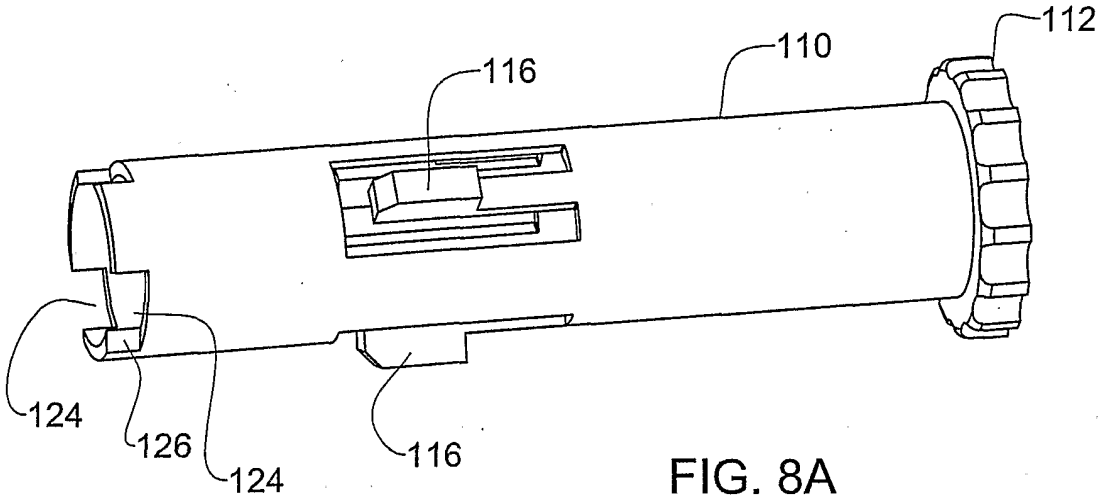

FIG. 8A

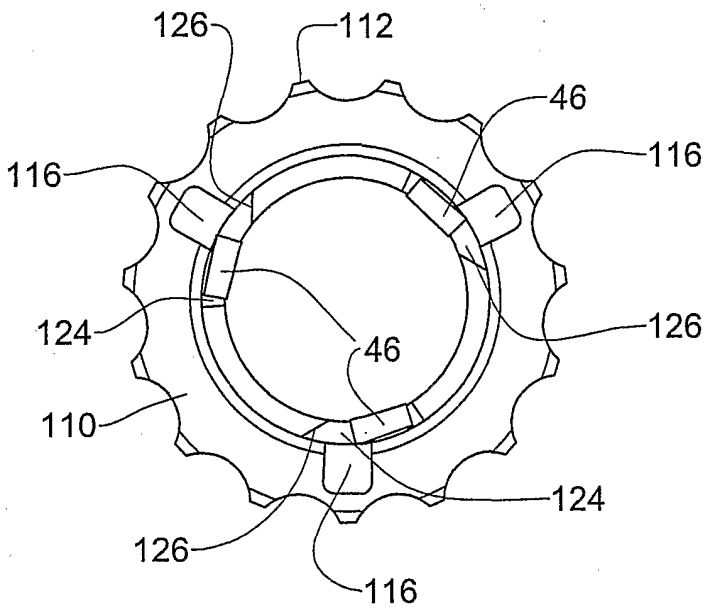

FIG. 8B

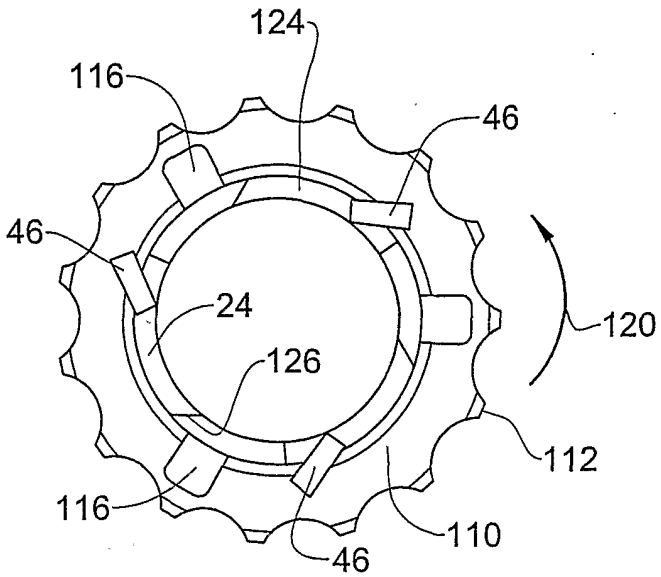

FIG. 8C

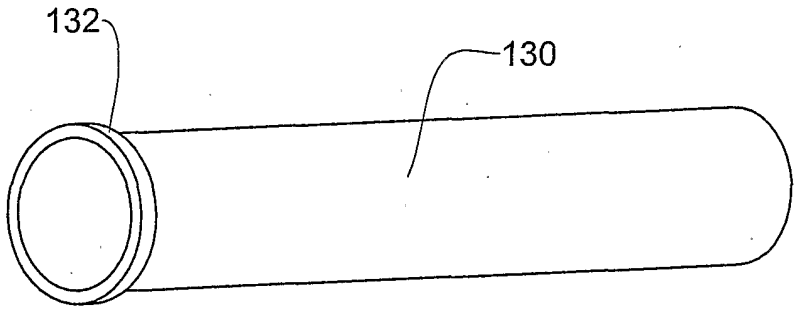

FIG. 9

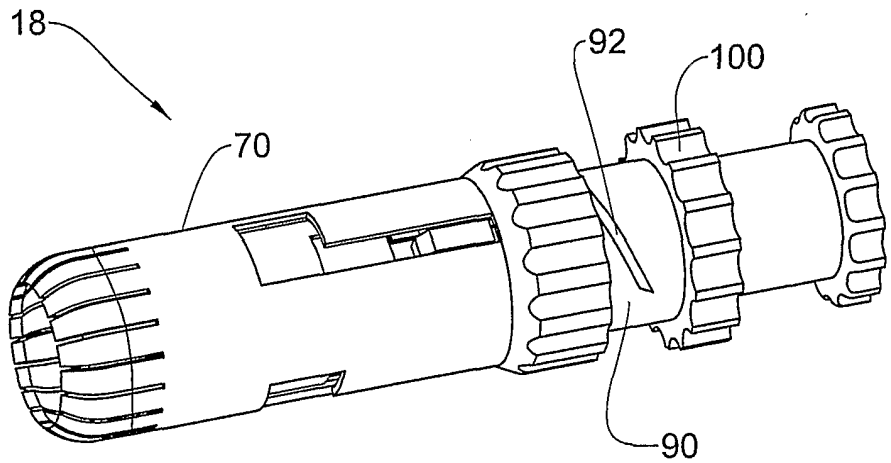

FIG. 10A

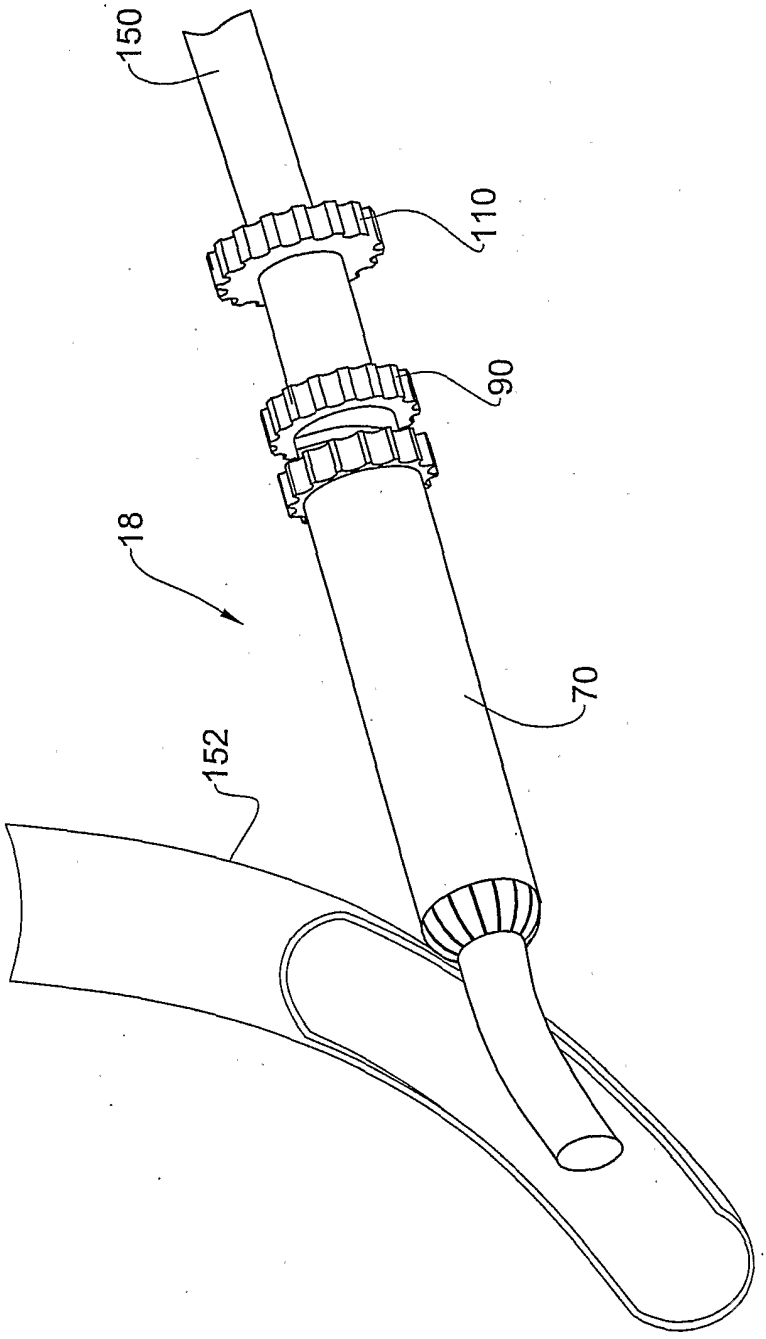

FIG. 10B

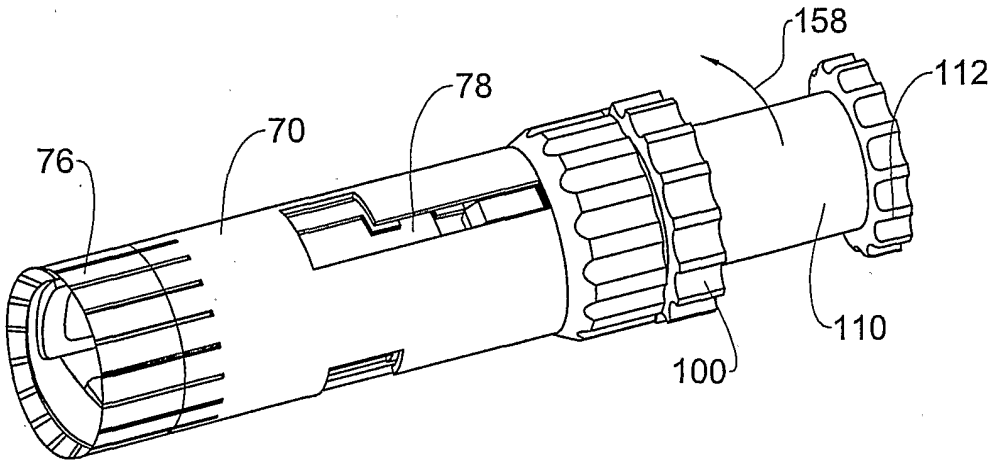

FIG. 10C

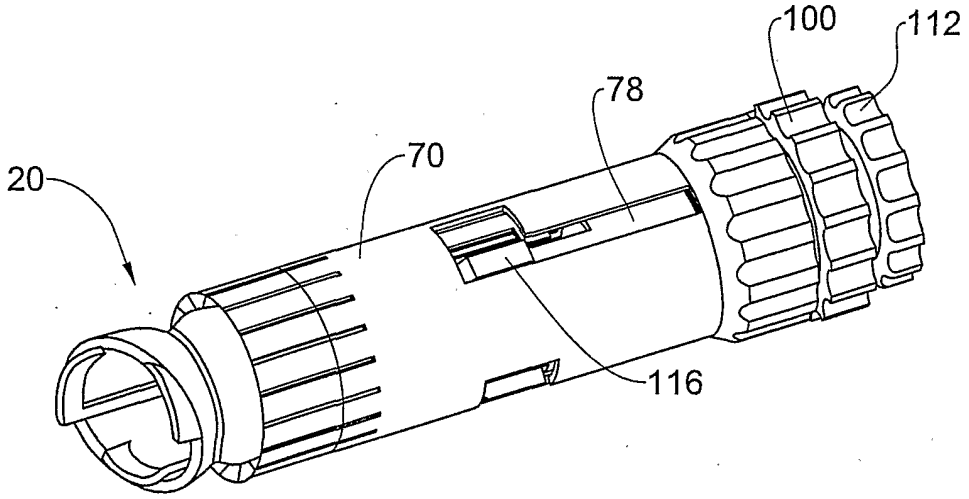

FIG. 10D

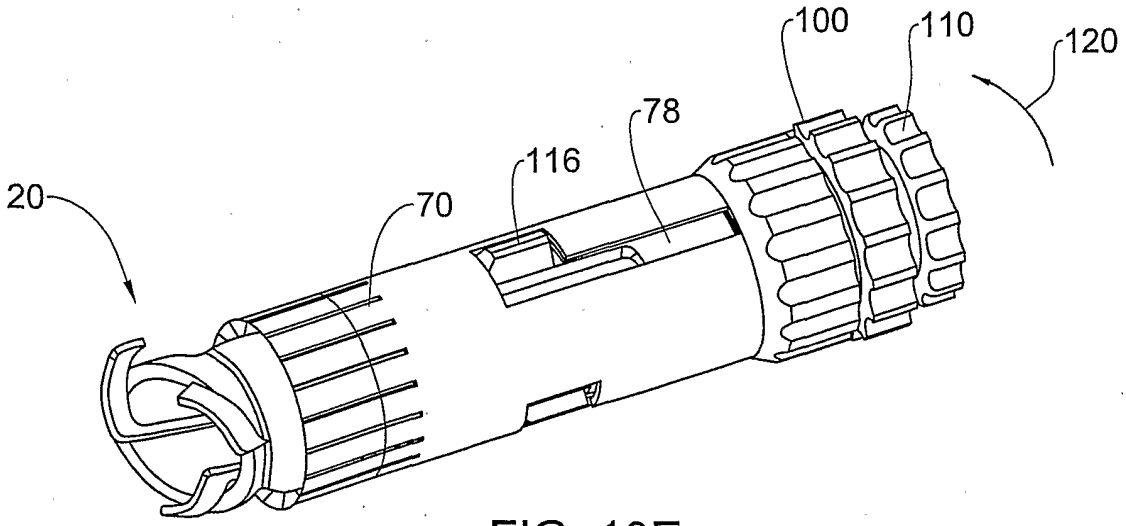

FIG. 10E

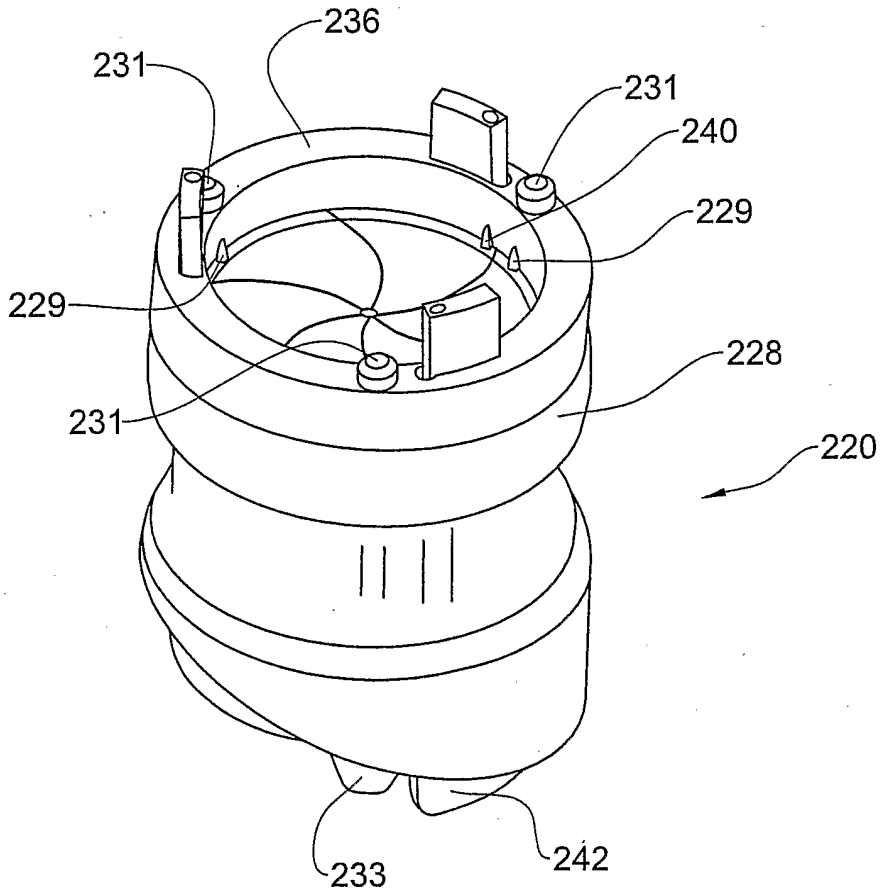

FIG. 11A

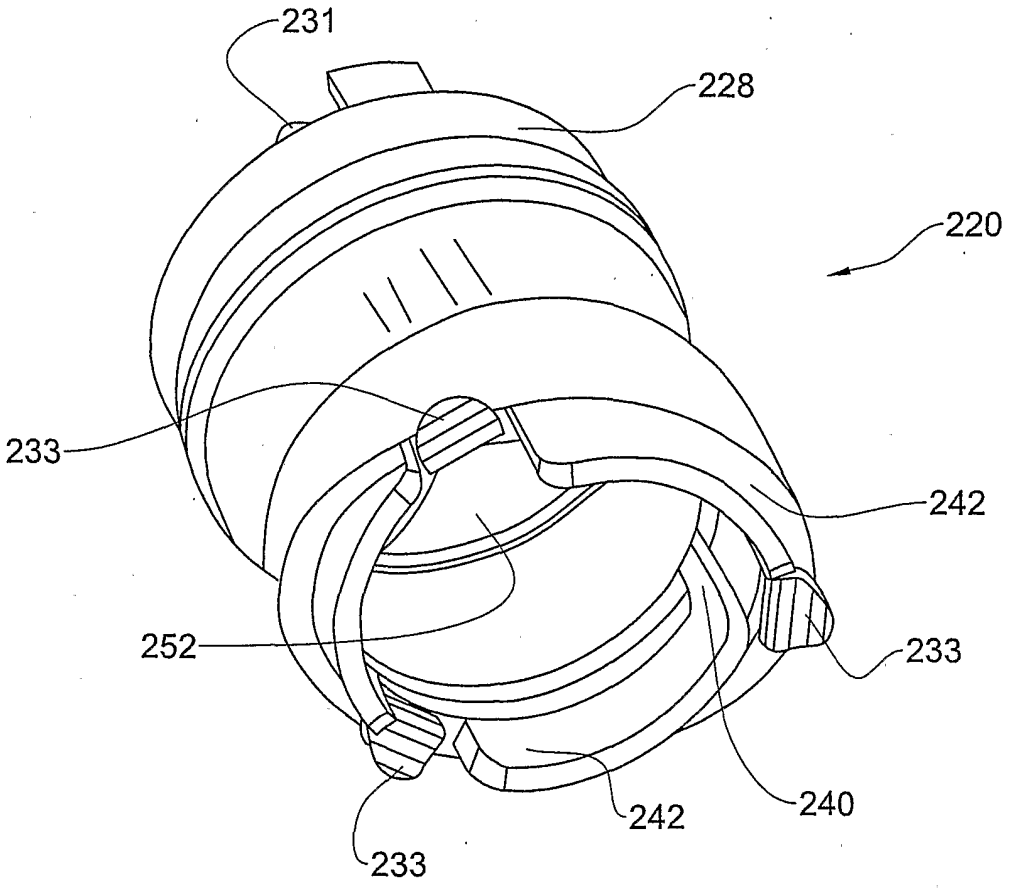

FIG. 11B

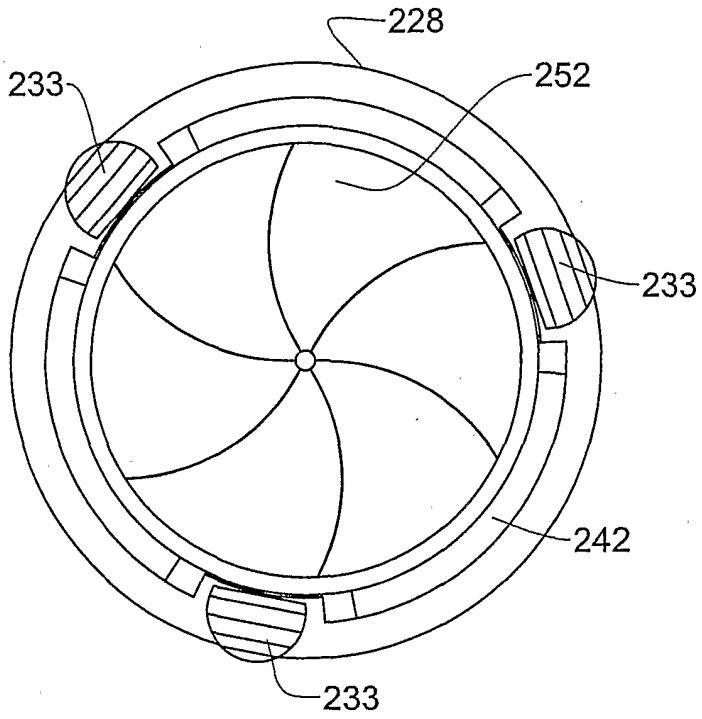

FIG. 11C

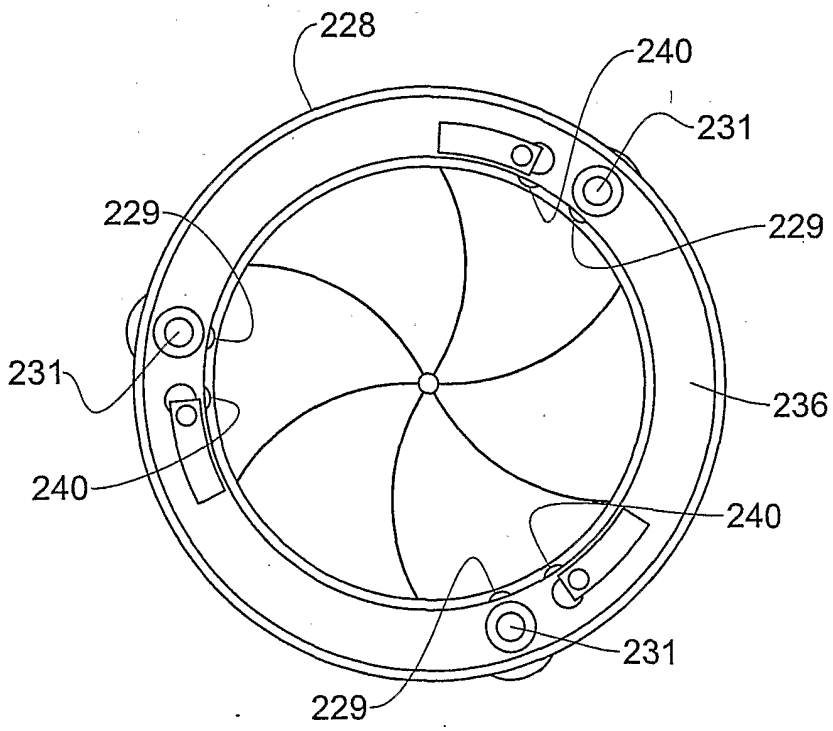

FIG. 11D

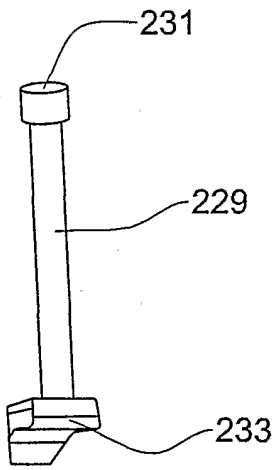

FIG. 11E

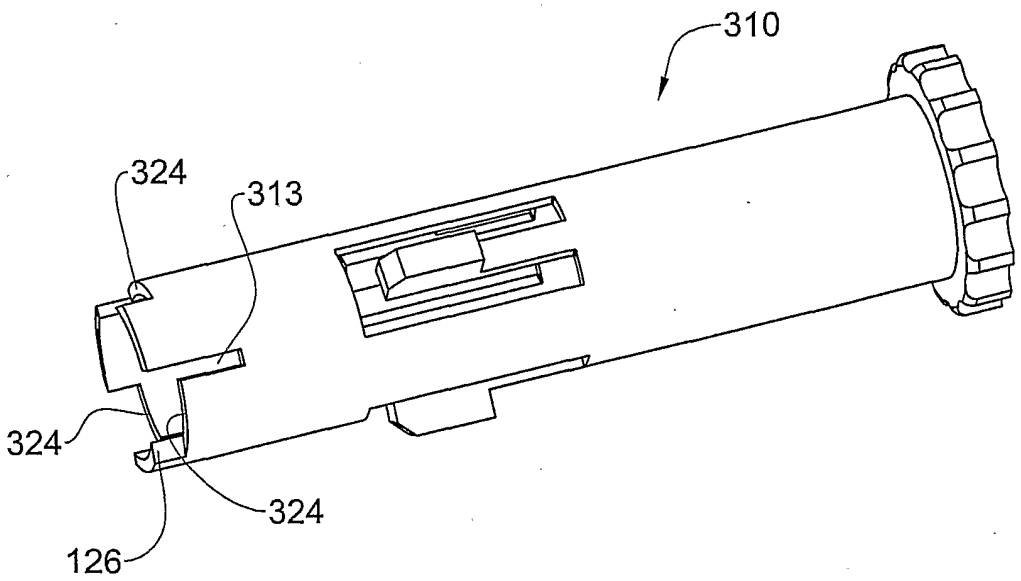

FIG. 12

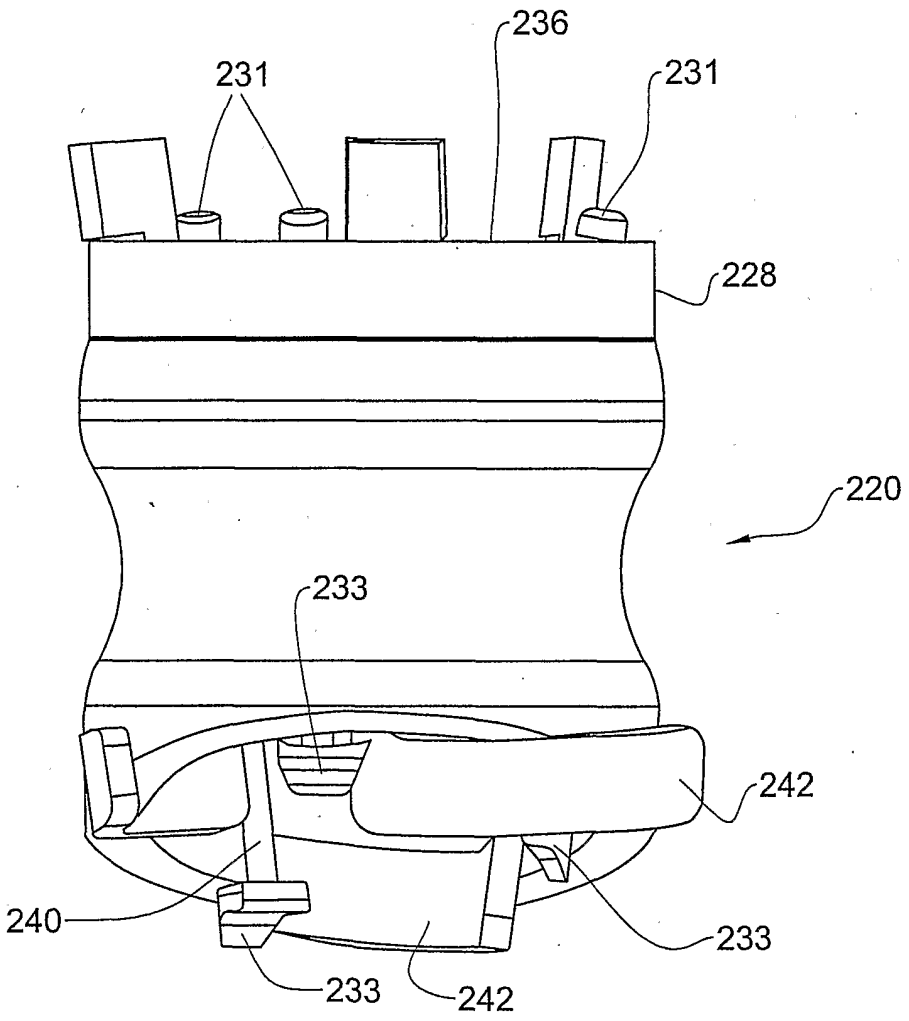

FIG. 13A

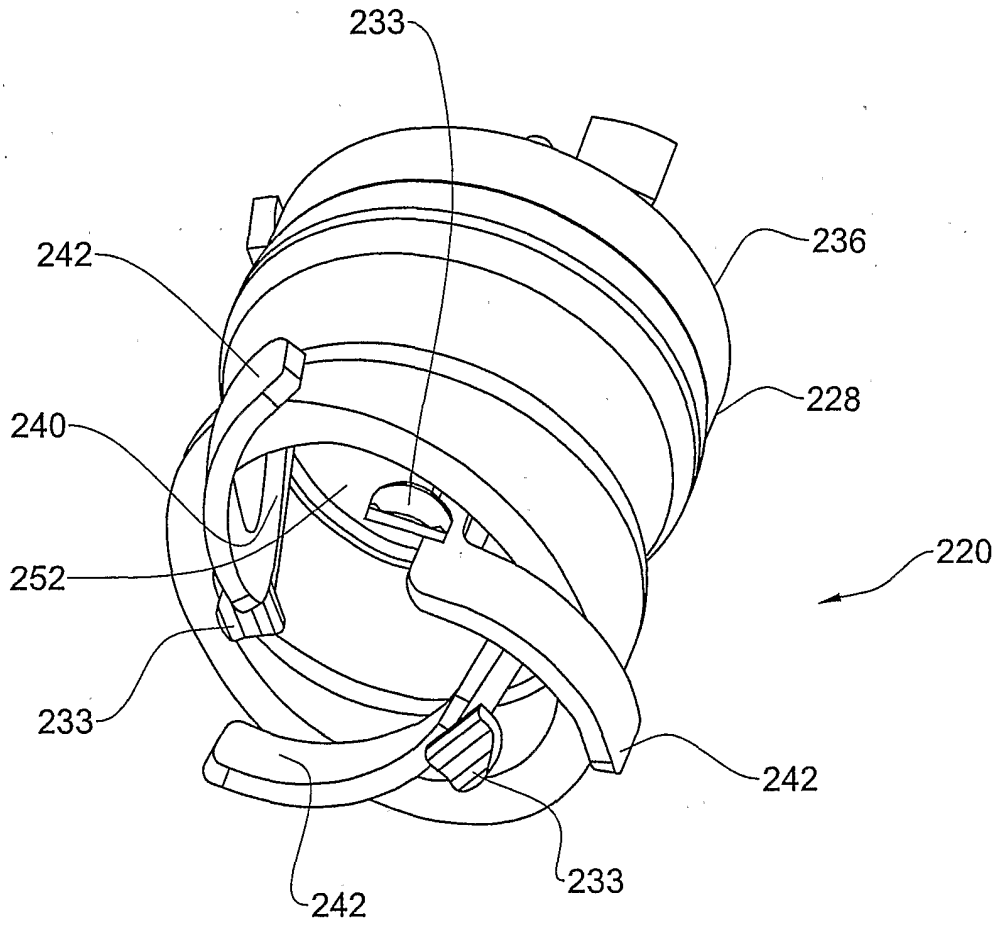

FIG. 13B

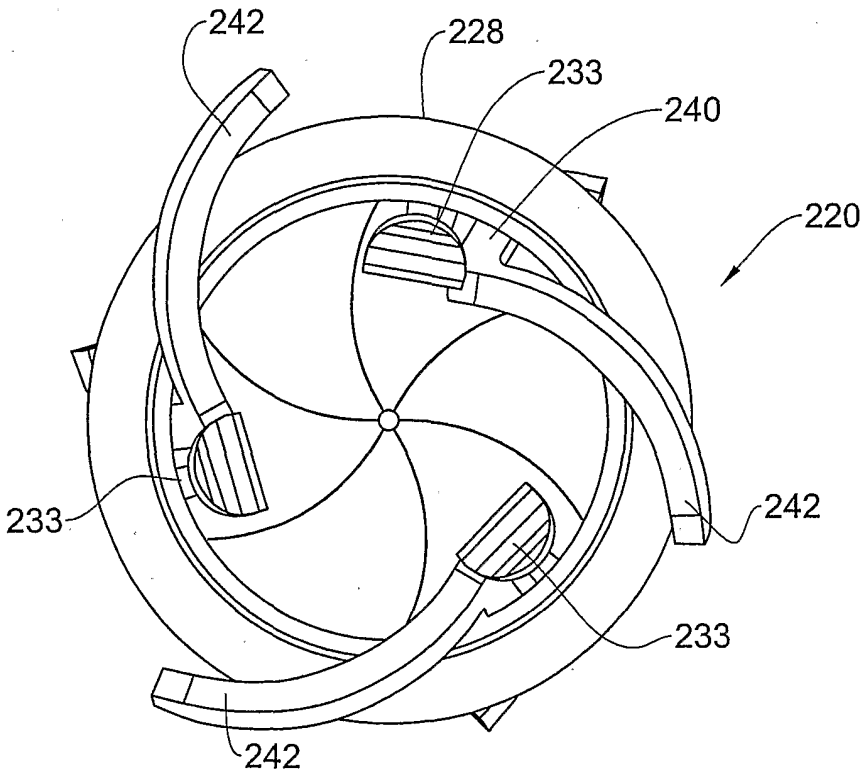

FIG. 13C

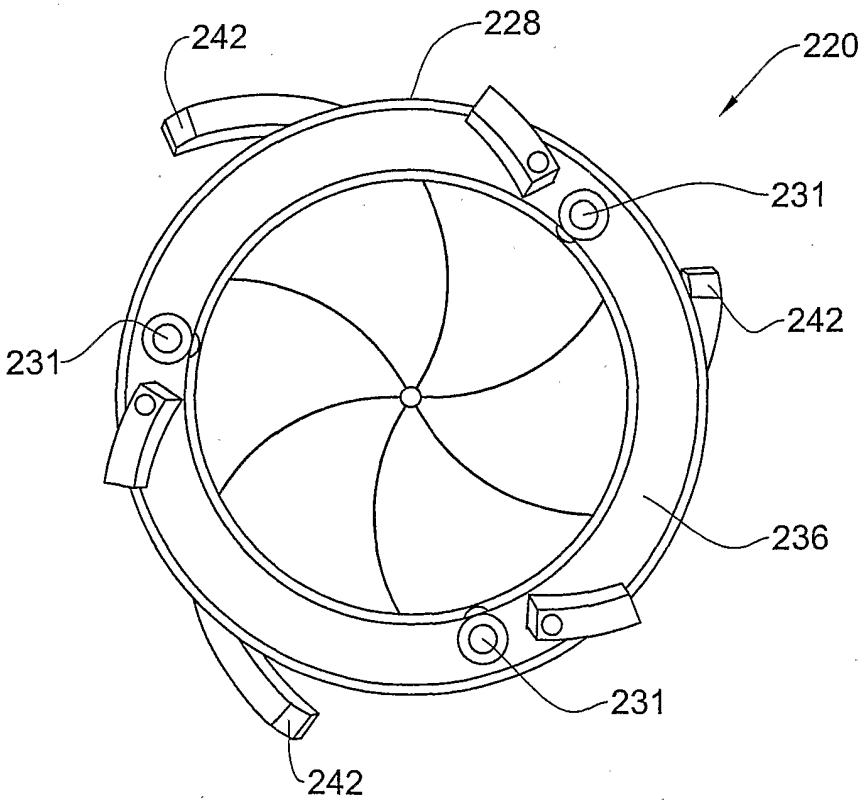

FIG. 13D

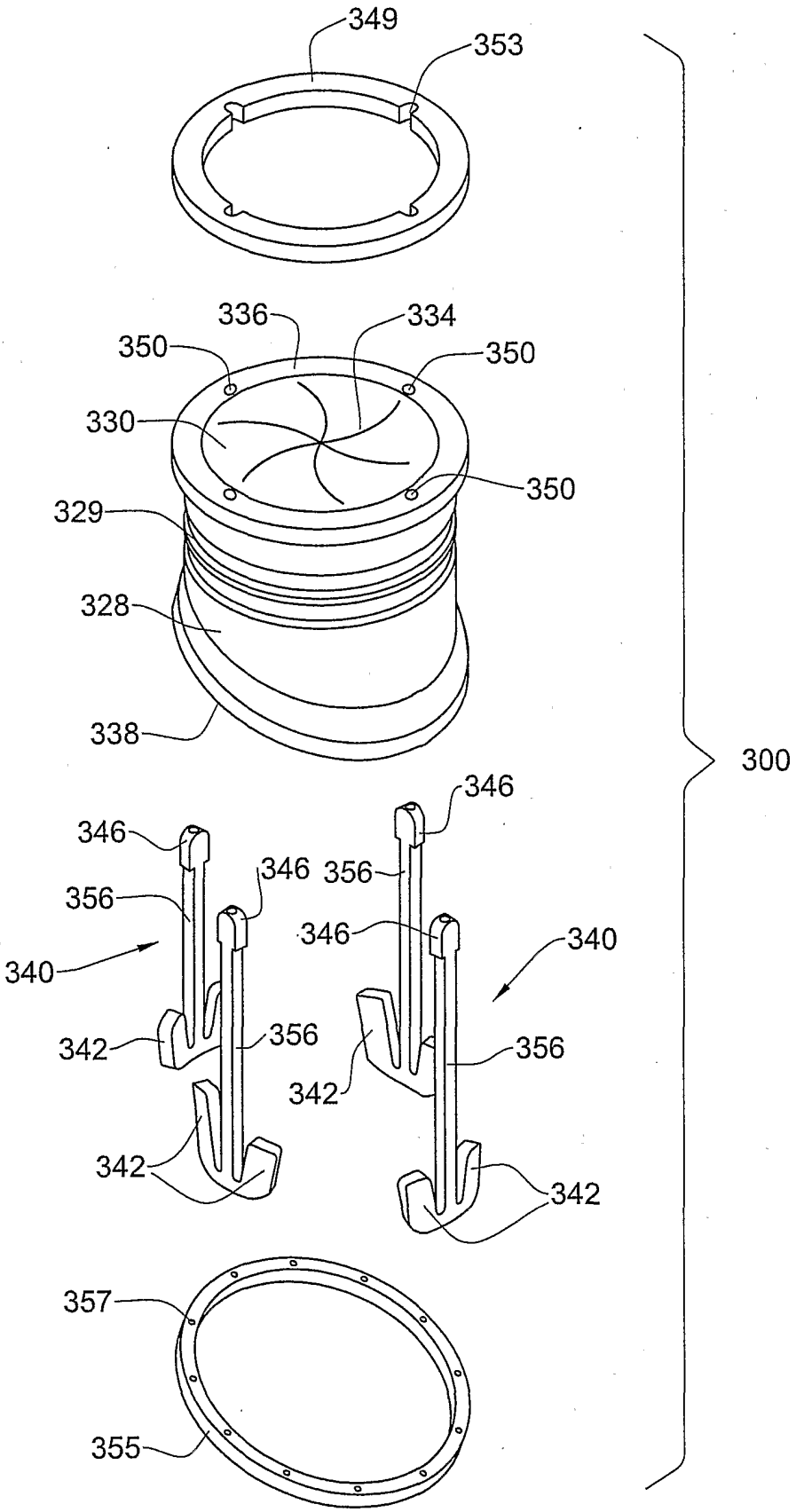
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FIG. 14

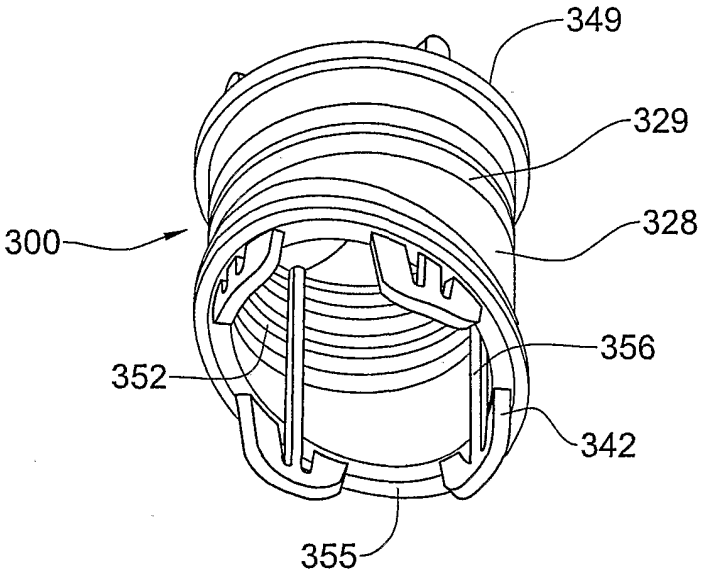

FIG. 15A

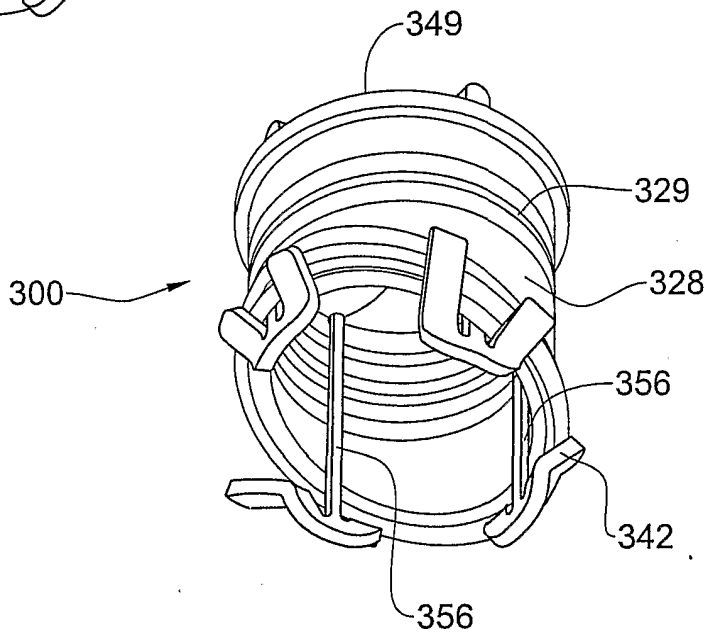

FIG. 15B

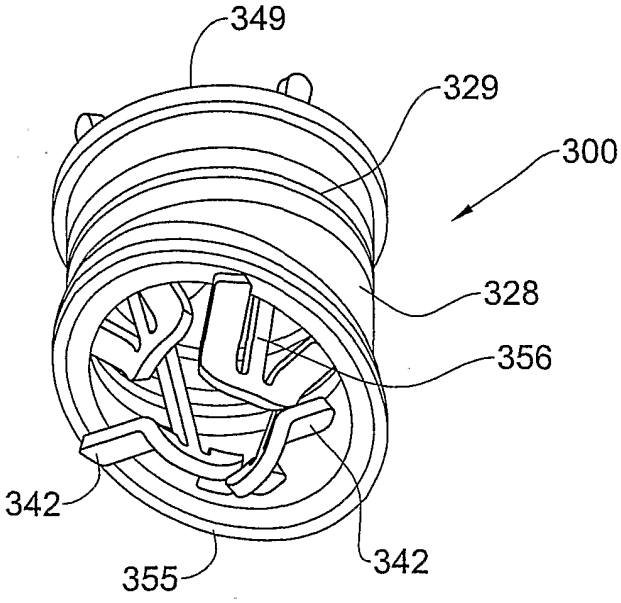

FIG. 15C

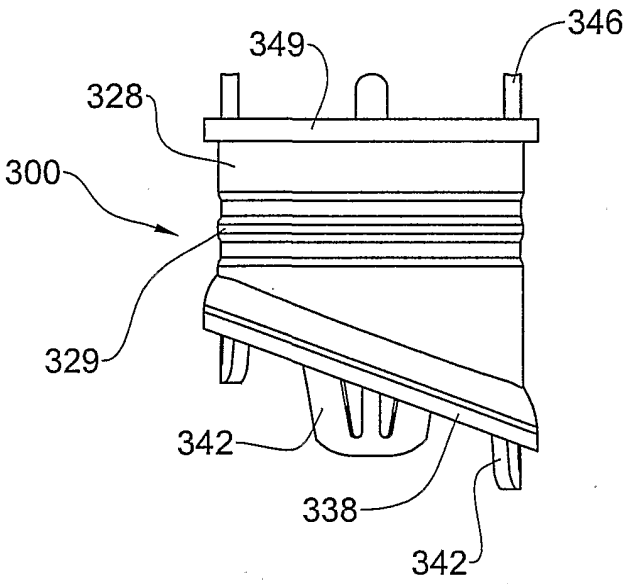

FIG. 16A

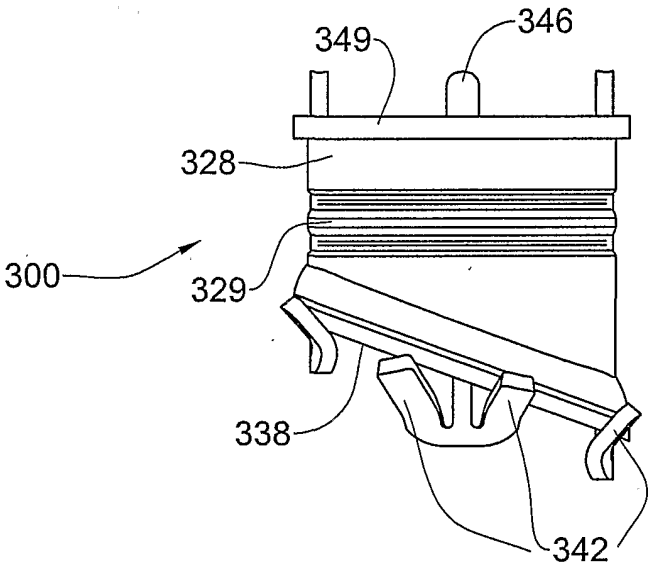

FIG. 16B

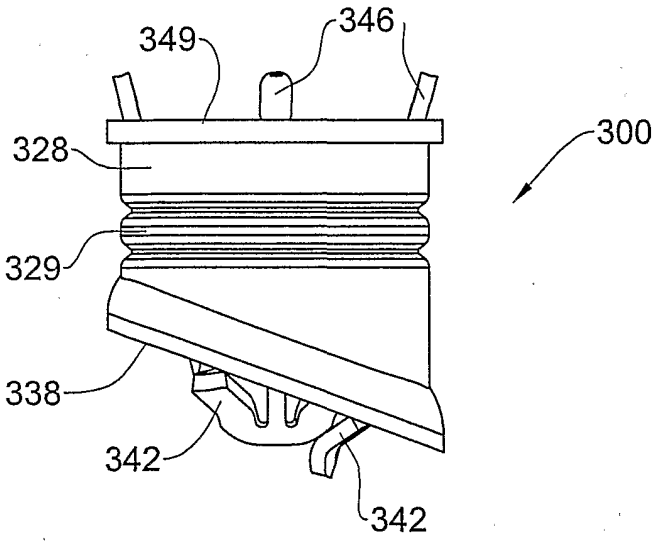

FIG. 16C

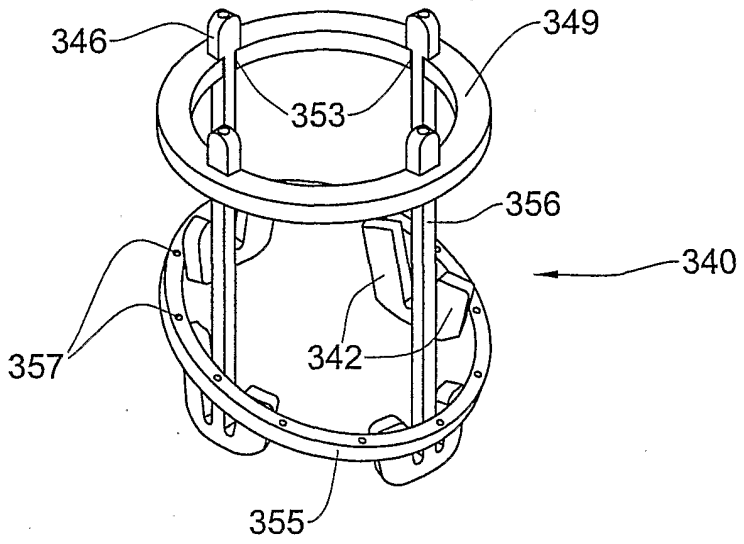

FIG. 17

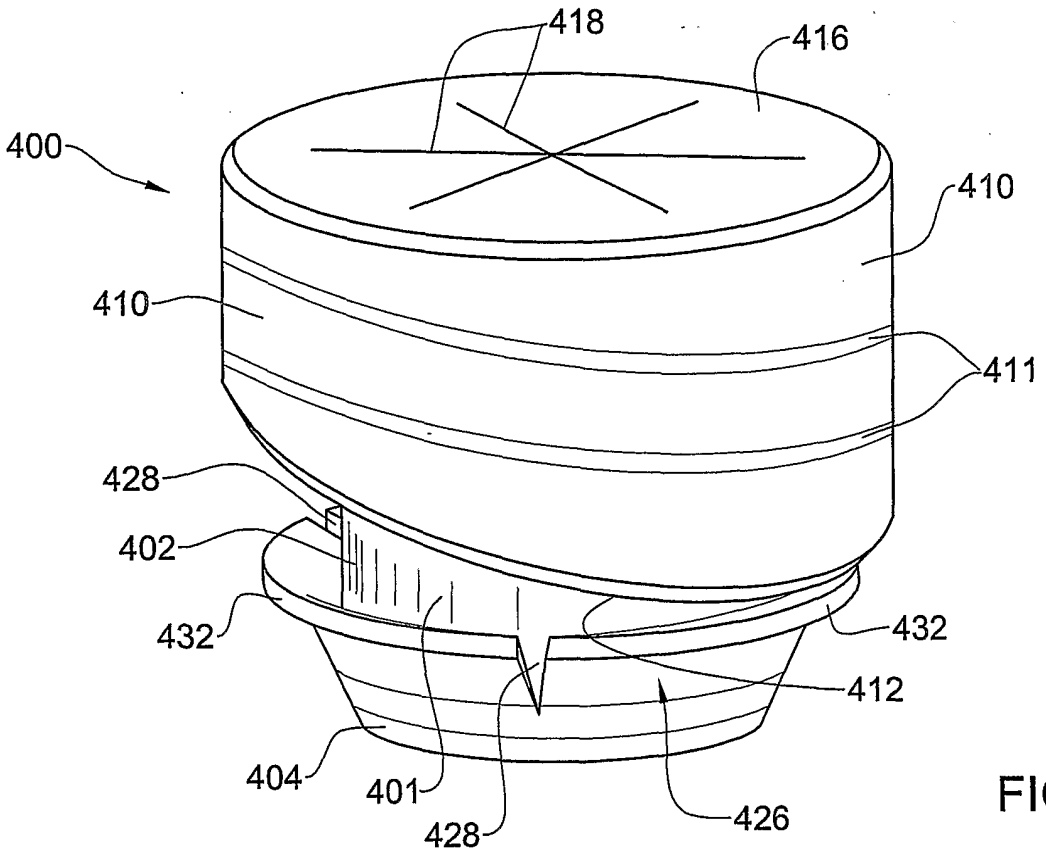
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FIG. 18

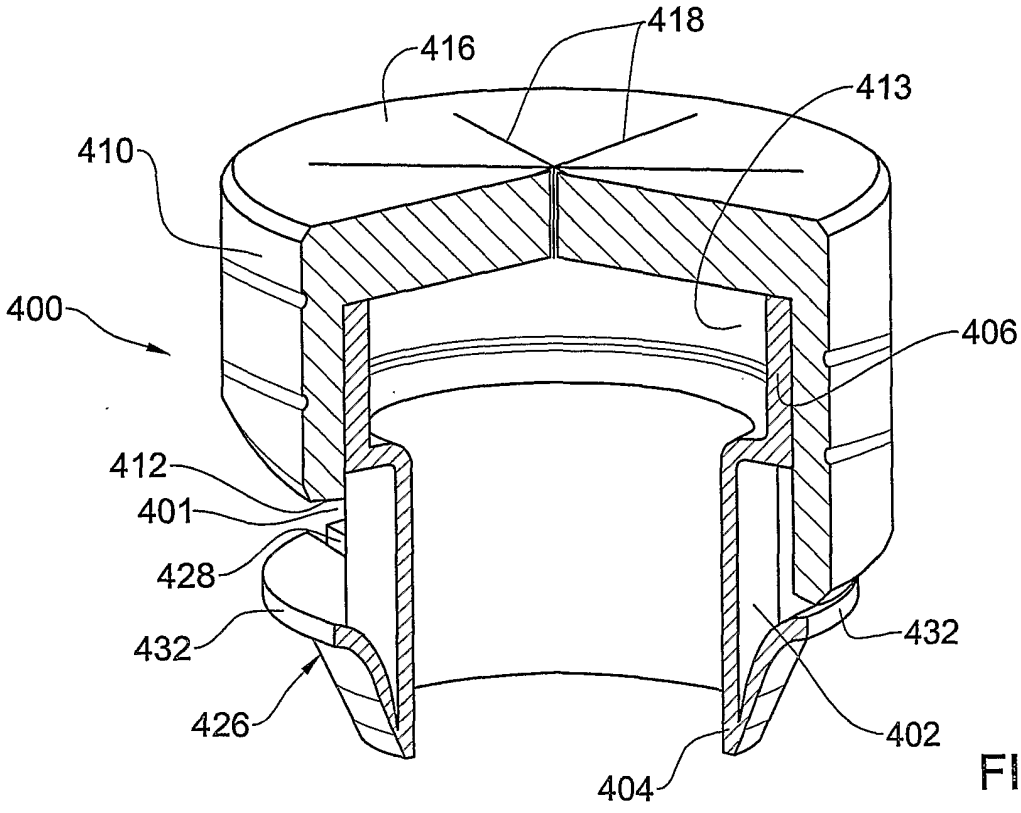
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FIG. 19

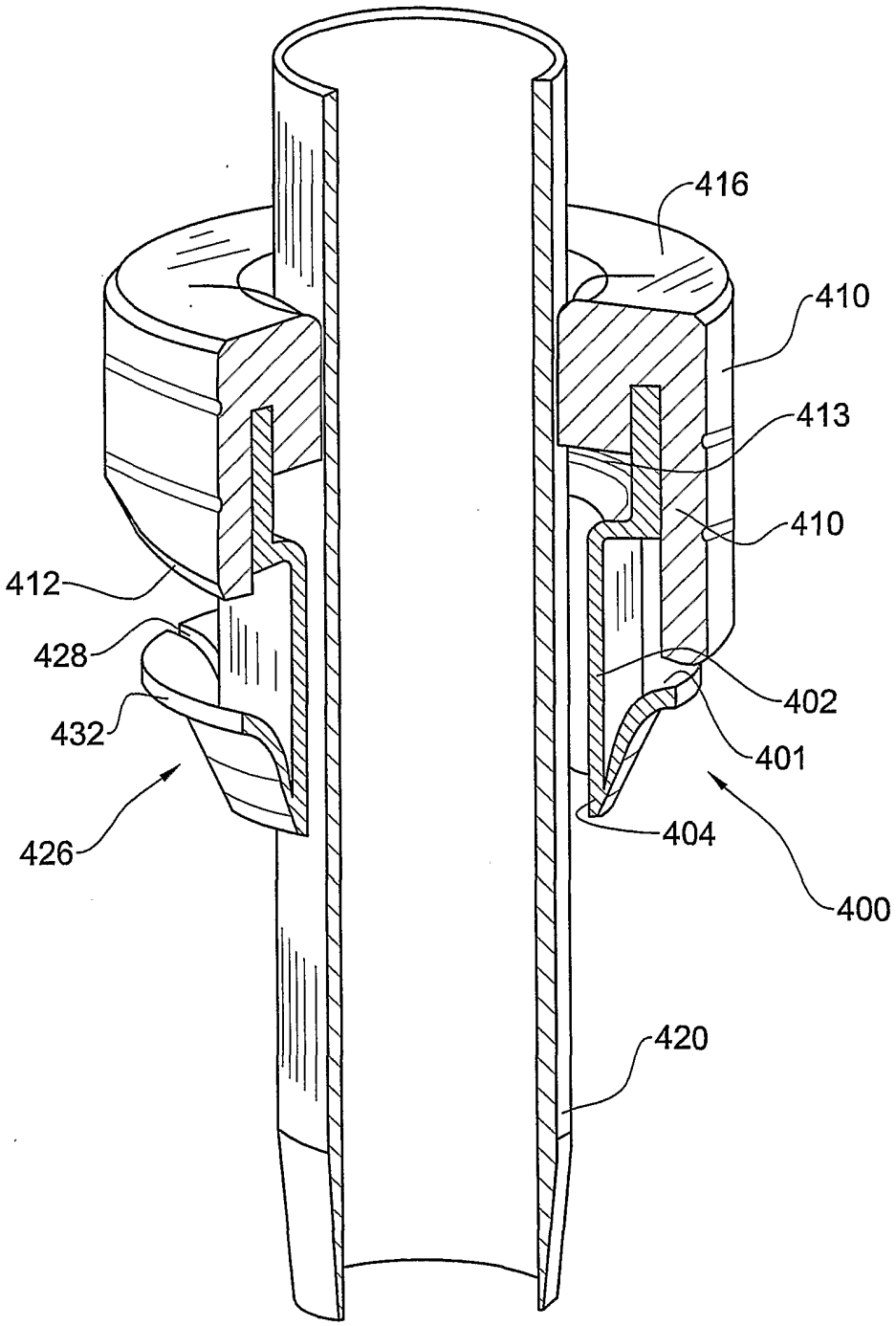

FIG. 20

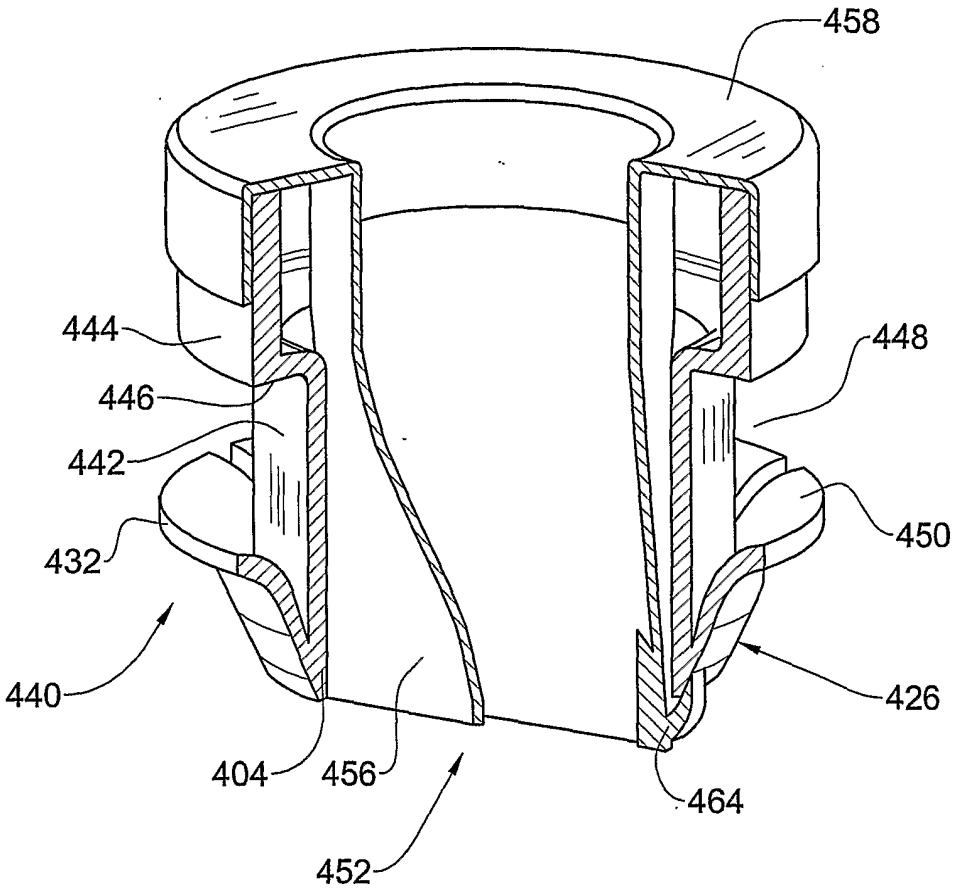
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FIG. 21

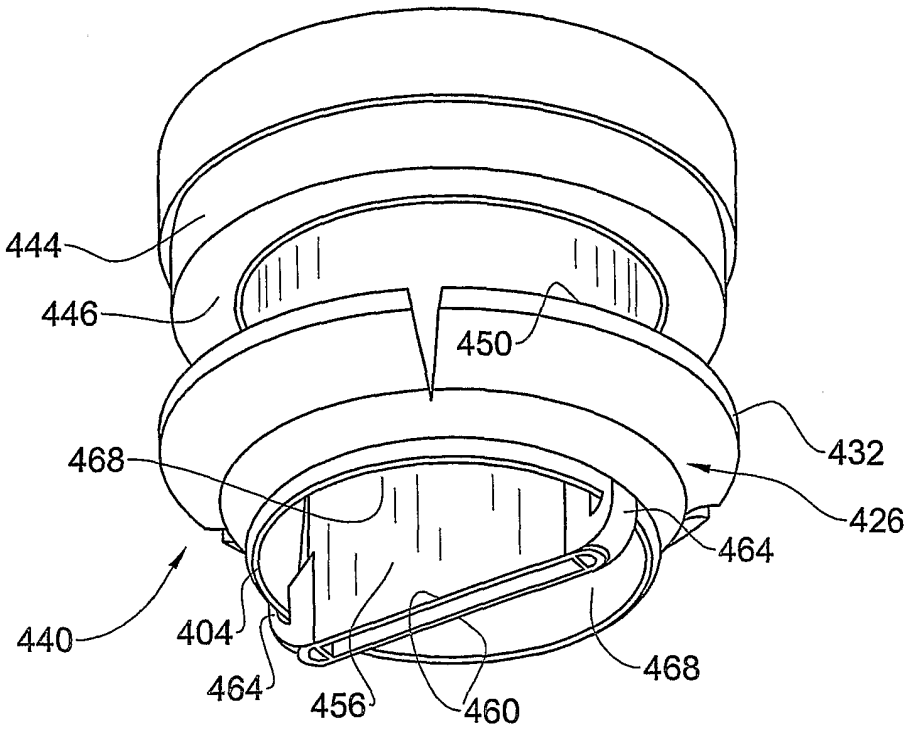
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FIG. 22

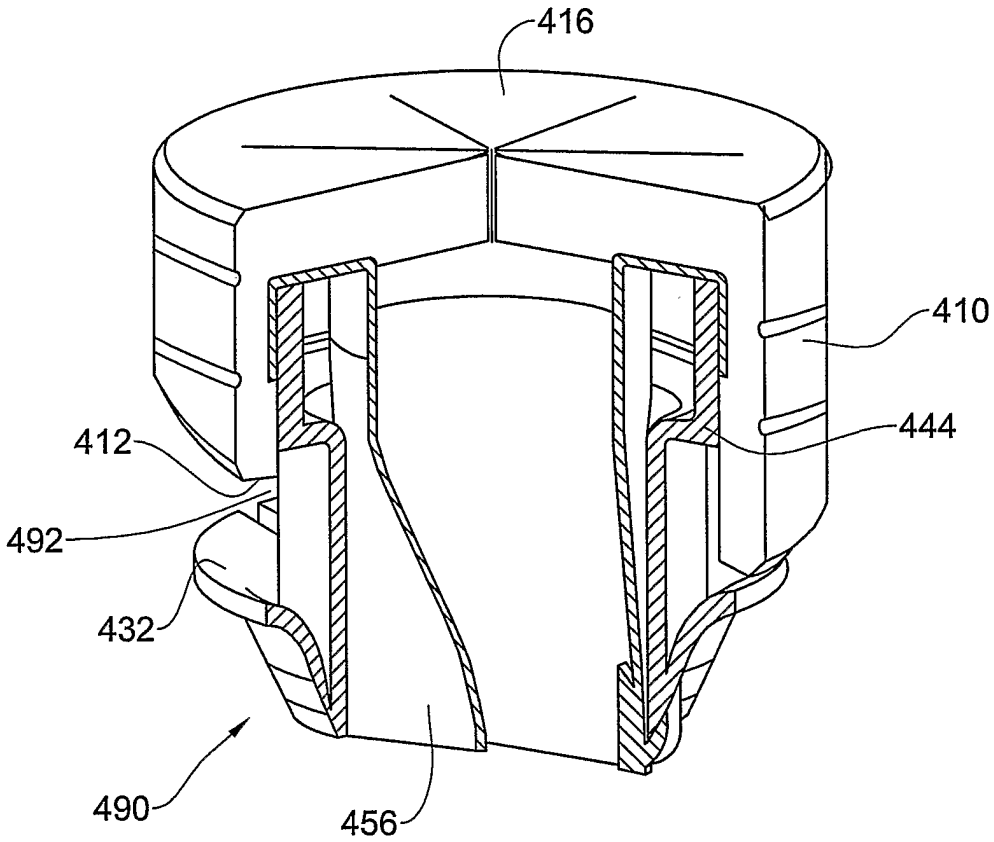

FIG. 23

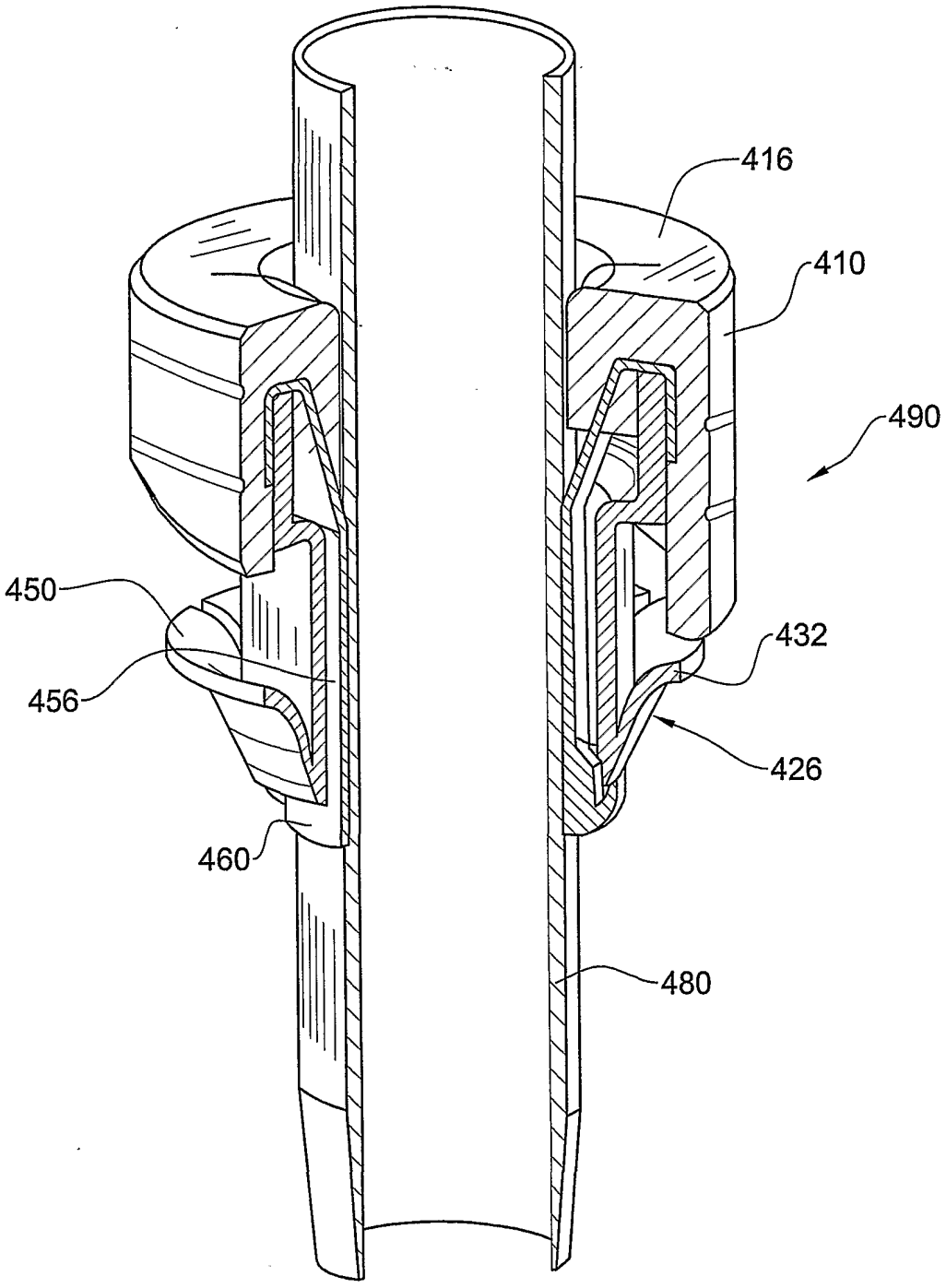

FIG. 24

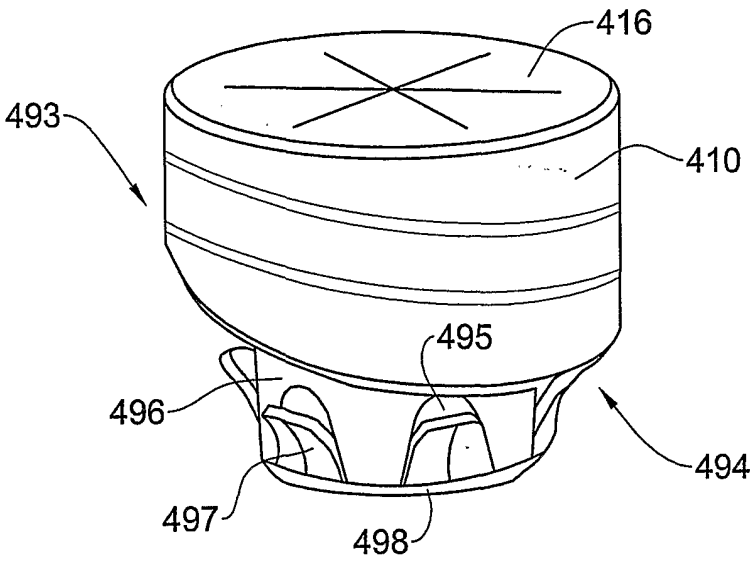

FIG. 25A

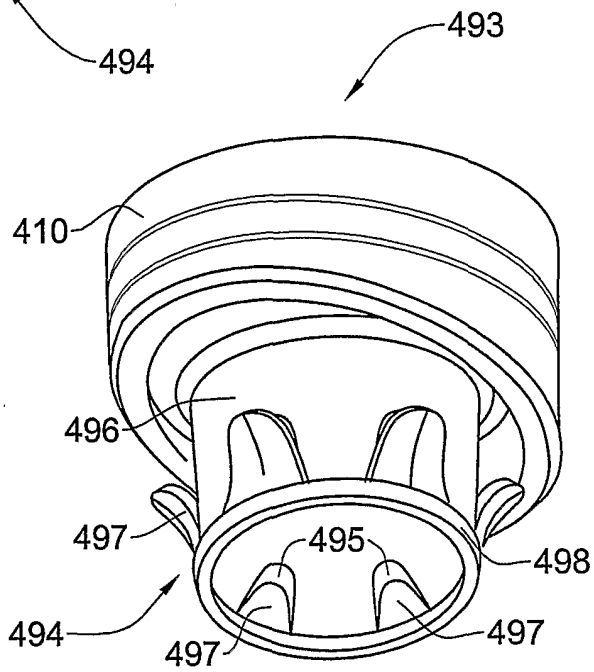

FIG. 25B

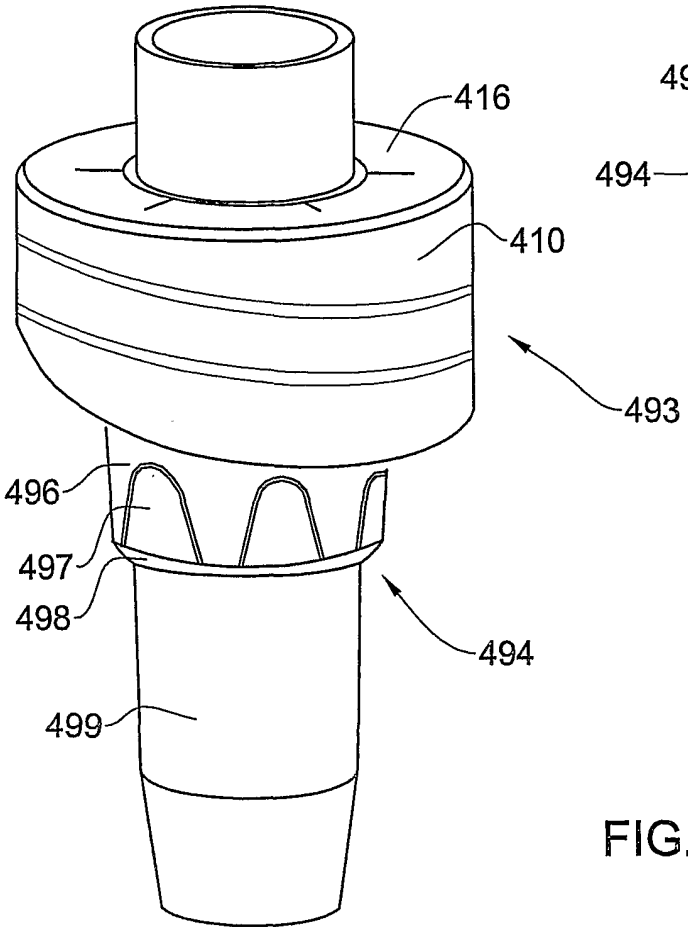

FIG. 25C

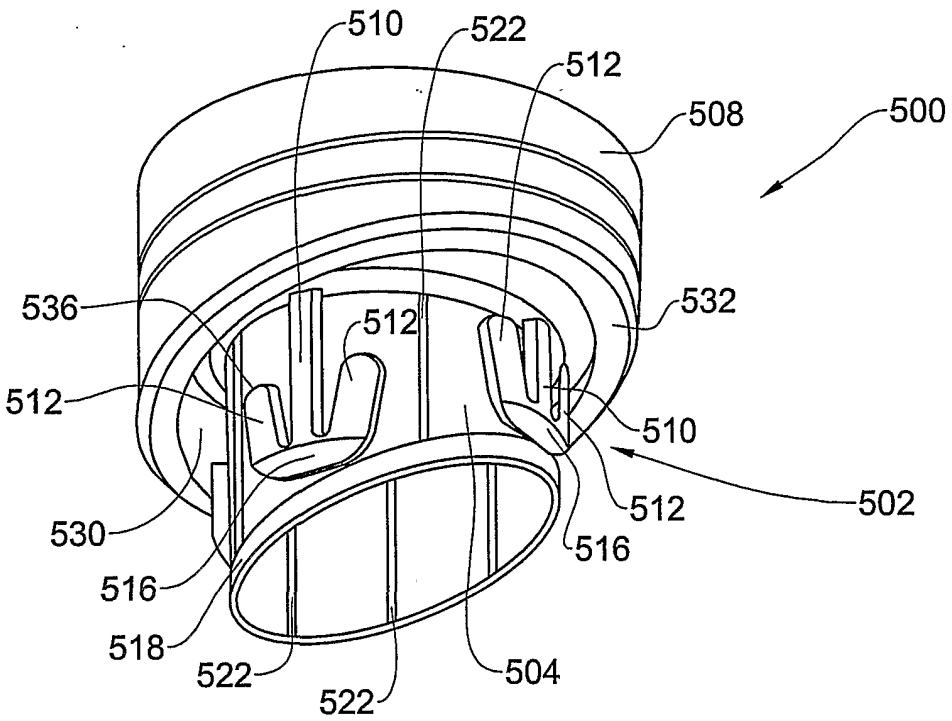

FIG. 26A

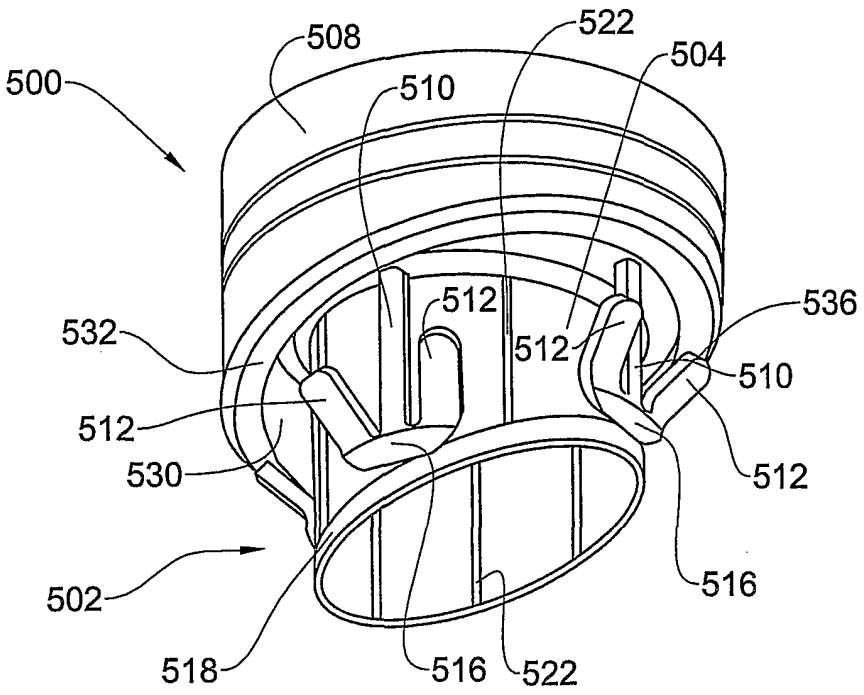

FIG. 26B

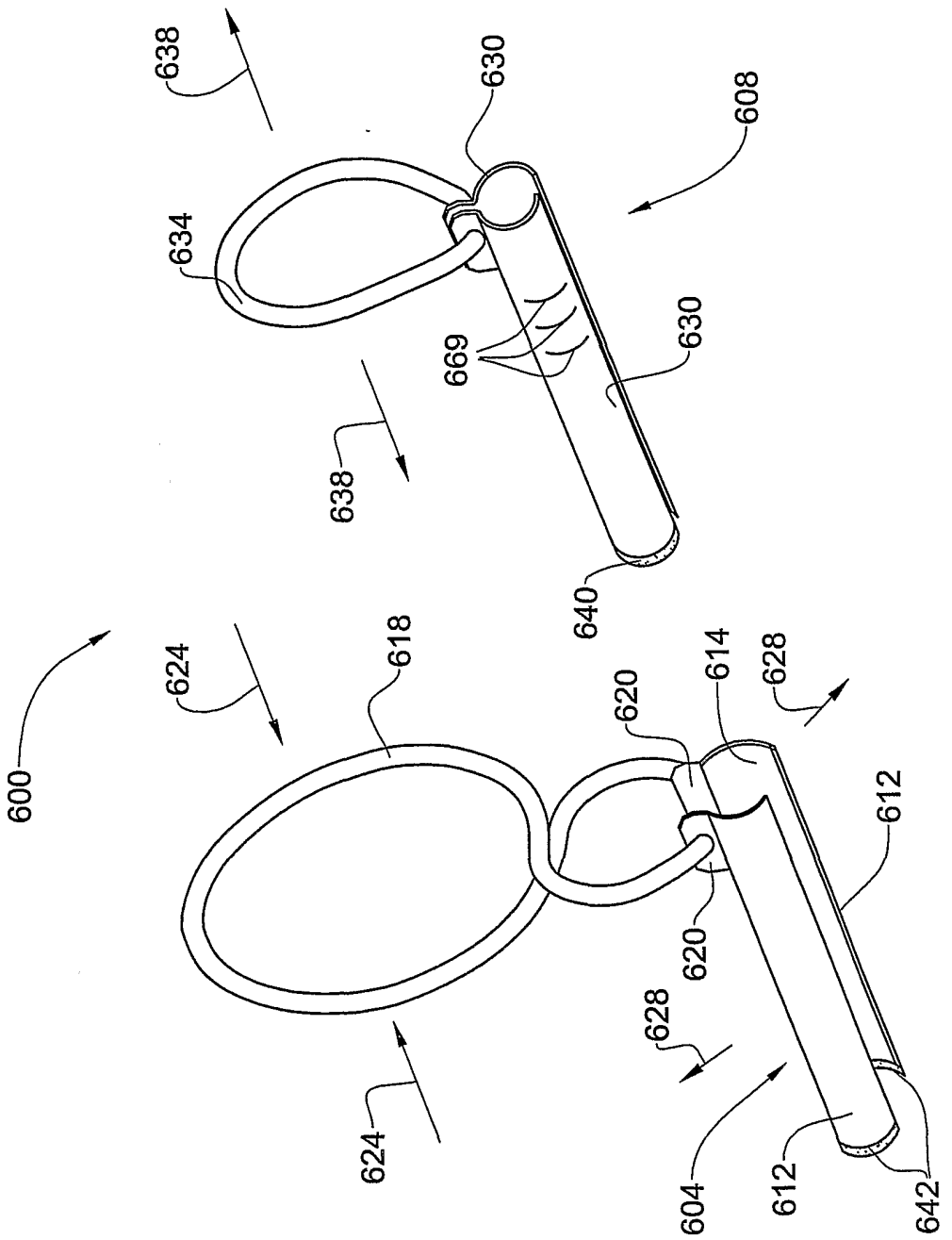
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FIG. 27

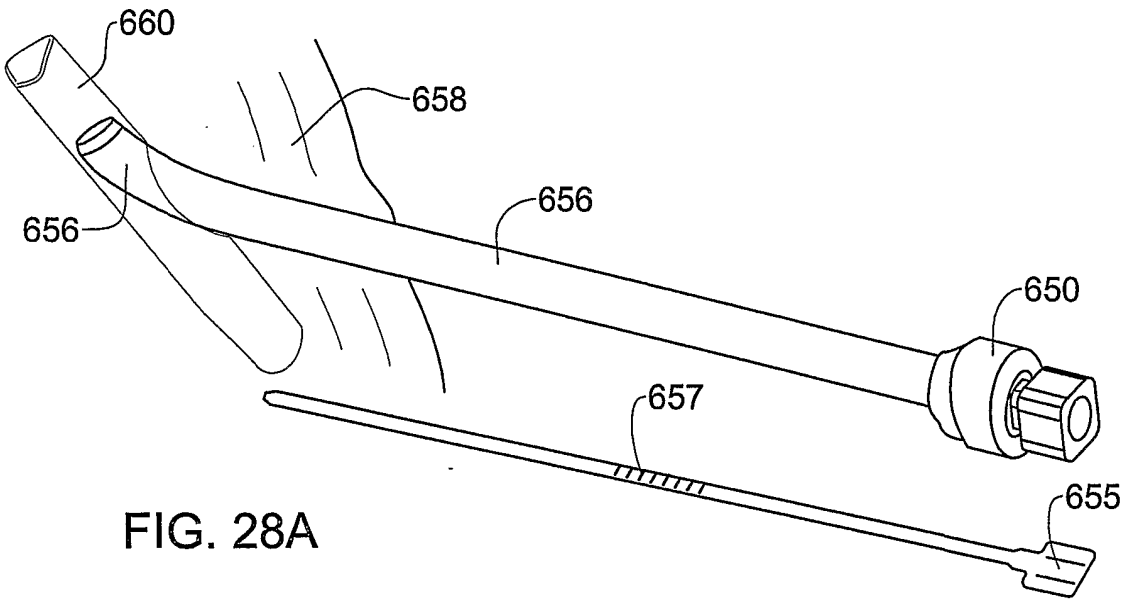

FIG. 28A

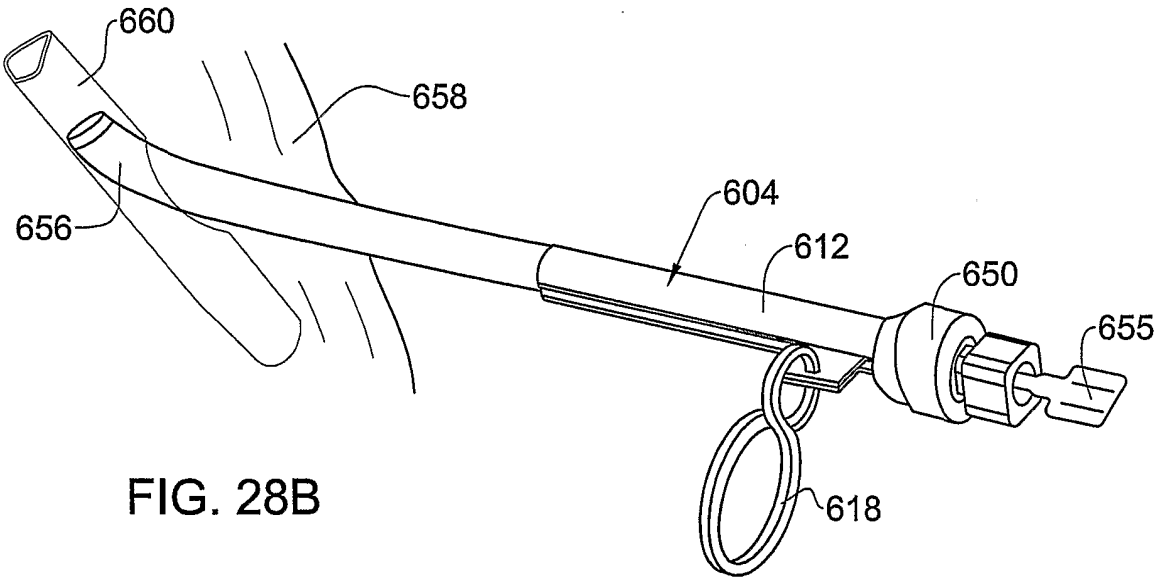

FIG. 28B

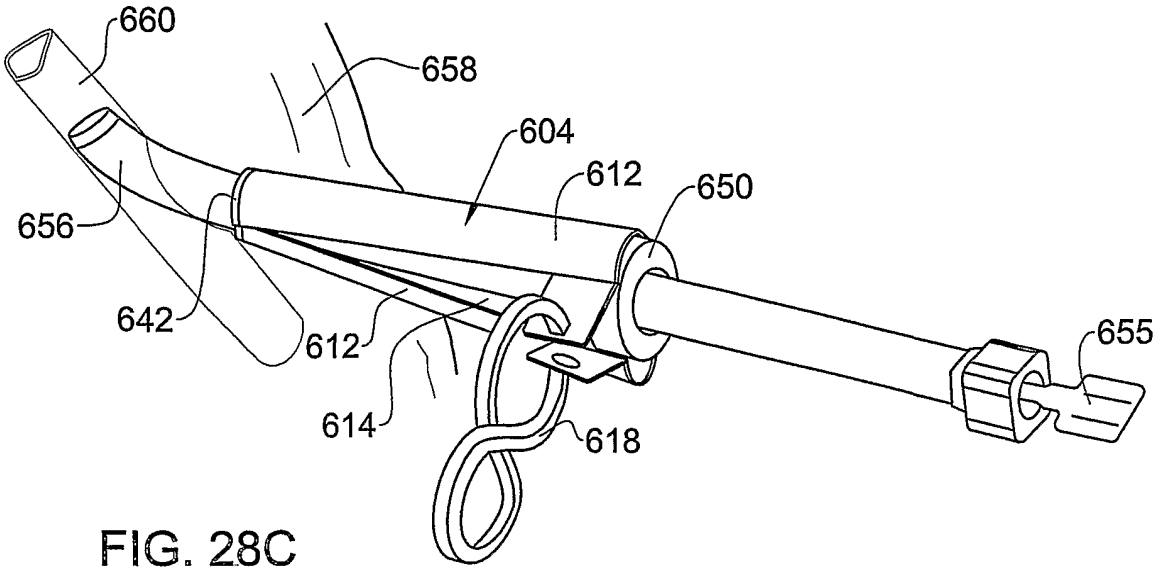

FIG. 28C

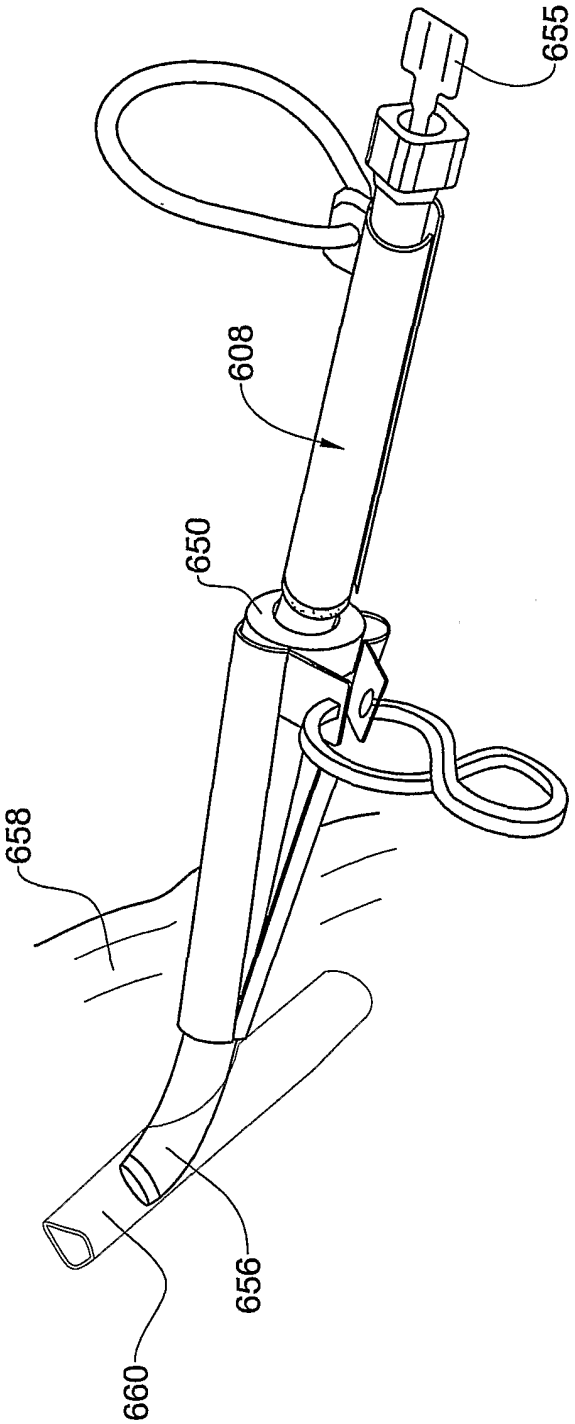

FIG. 28D

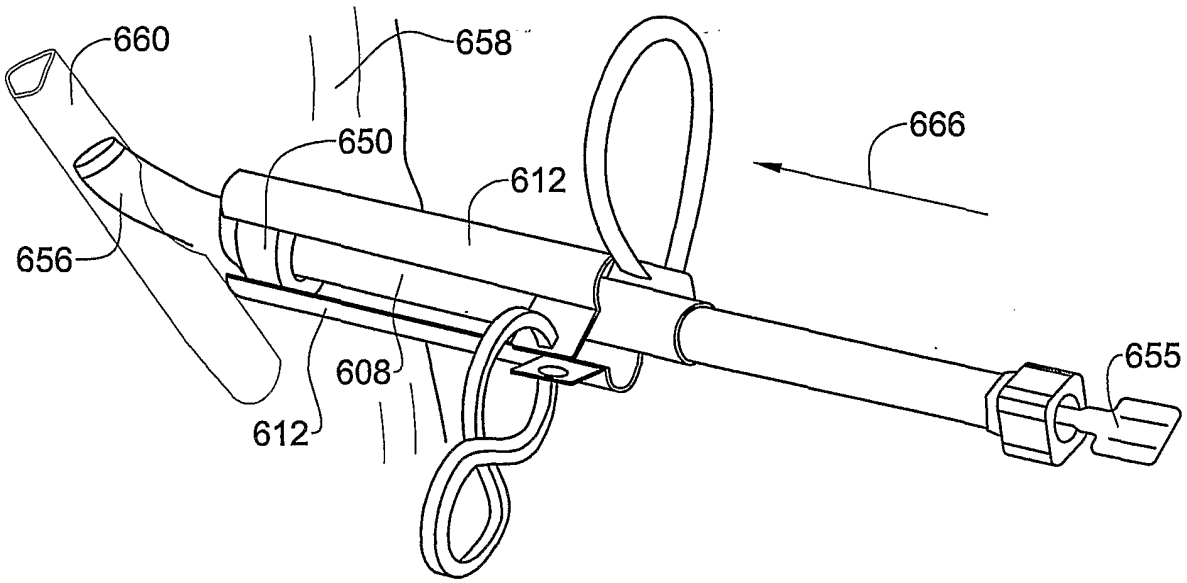

FIG. 28E

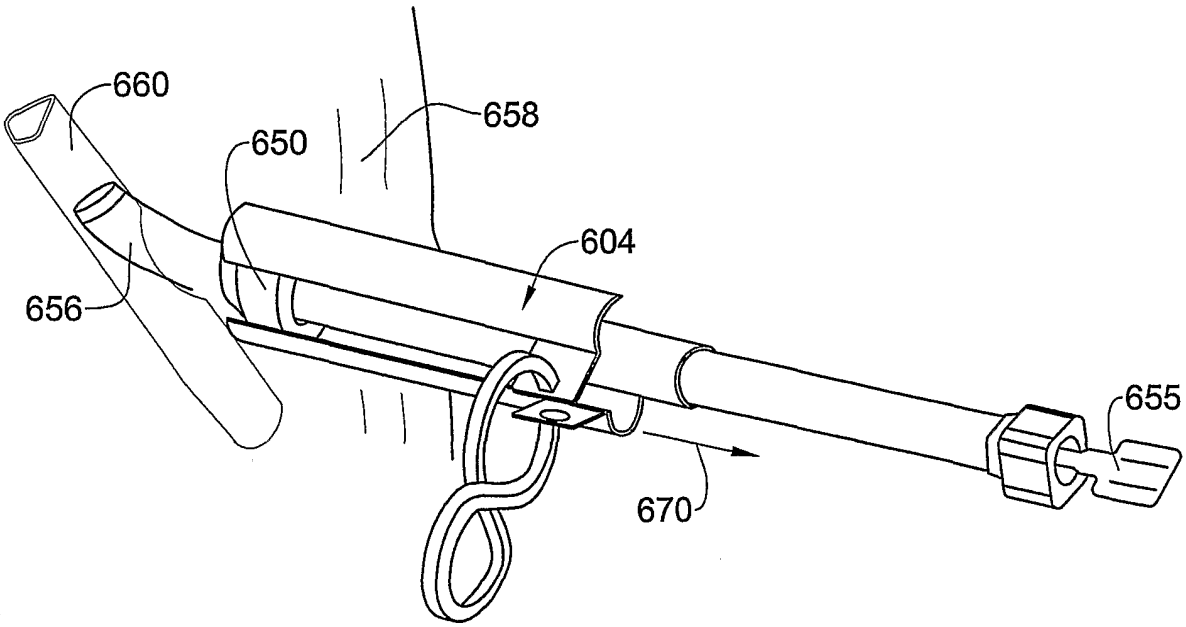

FIG. 28F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/00027

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61B17/34

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)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 542 428 A (DEXIDE INC) 19 May 1993 (1993-05-19) column 4, line 32 - line 35 column 5, line 32 - line 54 column 6, line 32 - line 49 figures 1,2,4,7	1,25,26, 28, 43-45, 47,50
X	US 5 512 053 A (PEARSON RONALD W ET AL) 30 April 1996 (1996-04-30) column 2, line 57 -column 4, line 25 figures 1,2	1,25,26, 28, 43-45, 47,50,51

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 March 2002	18/03/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Compos, F

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/00027

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 5 984 950 A (CRAGG ANDREW H ET AL) 16 November 1999 (1999-11-16) column 5, line 36 - line 37 column 5, line 57 - line 65 column 6, line 37 - line 42 column 7, line 15 - line 66 figures 3,5,7,9,10	1-3, 11-15, 22,23, 27,28, 32,33, 43,47
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A	WO 97 07741 A (YOON INBAE) 6 March 1997 (1997-03-06) page 11, line 5 -page 12, line 17 figures 6-9	1,43
A	US 5 330 501 A (YOUNG WAYNE P ET AL) 19 July 1994 (1994-07-19) column 5, line 28 -column 7, line 15 column 7, line 44 - line 63 figures 1,3,8	1,32,33, 43,58-61
X,P	WO 01 89398 A (MOUNT OLYMPUS DEVICES LLC) 29 November 2001 (2001-11-29) page 11, line 11 - line 16 page 17, line 1 - line 7 figures 5-7,31,32	1-3, 43-45, 47,50
A,P	US 6 197 042 B1 (ALDRICH WILLIAM N ET AL) 6 March 2001 (2001-03-06) column 2, line 1 - line 31 figure 1	

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