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(54) Title: VENTRICULAR FUNCTION ASSISTING DEVICES AND METHODS OF USE THEREOF

(57) Abstract: The present invention provides devices and methods for assisting in the ventricular function of a treated heart, and tools for delivering and attaching elements of said devices to the wall of the heart. In general the devices of the invention are designed to assist in the ventricular function of the heart by utilizing elastic, and/or magnetic, elements designed to apply radially and/or tangentially directed forces over the wall of the heart, and/or alter the pressure conditions inside ventricle(s) of the heart. Embodiments of the invention may utilize restrictive elements which may optionally be attached over the heart during the implantation procedure, or at a later time, by changing the mode of operation of an implanted device of the invention.



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VENTRICULAR FUNCTION ASSISTING DEVICES AND METHODS OF USE
THEREOF

Field of the Invention

The present invention relates to methods and devices for improving ventricular function of the heart. More particularly, the invention relates to means for treating systolic and/or diastolic heart dysfunctions.

Background of the Invention

Heart failure (HF) is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. The cardinal manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and peripheral edema. Heart failure is most commonly associated with impaired left ventricle (LV) systolic function.

The term diastolic heart failure (DHF) generally refers to the clinical syndrome of heart failure associated with preserved left ventricular ejection fraction, in the absence of major valvular disease.

Primary diastolic dysfunction is typically observed in patients with hypertension and hypertrophic or restrictive cardiomyopathy, but can also occur in a variety of other clinical disorders and has a particularly high prevalence in the elderly population. Aging is associated with 'physiologic' diastolic dysfunction due to the increase in LV muscle mass and changes in passive elastic properties of the myocardium,

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hence, the concern of an increase in the incidence of diastolic dysfunction as the aging of the western world population progresses.

There is thus a need for, and it would be highly advantageous to have an in-vivo method and device for improving diastolic function of the heart, while minimally disturbing systolic function of the heart. Moreover, there is a need for such a method and device which is biocompatible and is specially configured for compact and long-term reliable use in humans.

Various in-vivo methods and devices for improving diastolic function of the heart are described in International patent applications Nos. PCT/IL02/00547 (WO 03/007778), PCT/IL05/01014 (WO 06/033107), PCT/IL04/00986 (WO 05/041745), and PCT/IL04/00072 (WO 04/066805), of the same assignee hereof, the descriptions of which is incorporated herein by reference. The aforementioned international patent applications describe elastic means used for improving diastolic function of the right or left ventricle of the heart by pushing and/or pulling, an inner and/or outer wall region of the ventricle during the cardiac cycle while minimally disturbing the heart function. The present invention provides modifications, improvements, and new methods and devices, for improving the diastolic function of the heart.

Summary of invention

The present invention provides devices and methods for assisting in the ventricular function of a treated heart, and tools for delivering and attaching elements of said devices to the wall of the heart. In general the devices of the invention are designed to assist in the ventricular function of the

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heart by utilizing elastic, and/or magnetic, elements designed to apply radially and/or tangentially directed forces over the wall of the heart, and/or alter the pressure conditions inside ventricle(s) of the heart .

Embodiments of the invention further utilize restrictive elements which may optionally be attached over the heart during the implantation procedure, or at a later time, by changing the mode of operation of an implanted device of the invention.

In one aspect the present invention is directed to an apparatus capable of selectively assisting diastolic dysfunctions and/or systolic dysfunctions by means of elastic or magnetic elements attached to the wall of the heart and configured to apply radially and/or tangentially directed forces thereover. Said apparatus further comprises restrictive elements adapted to encircle a perimeter (circumference) of the heart and capable of being changed between an engaging state and a non-engaging state, where in said engaging state they restrict heart expansions during the diastolic phase and in said non-engaging state the diastolic phase is not affected by them.

According to one preferred embodiment of the invention the ventricular function assisting apparatus comprises anchoring means capable of being attached to the wall of the heart, elastic elements capable of being attached to said anchoring means, at least two restrictive elements adapted to encircle a perimeter of the heart, said restrictive elements capable of being changed between a engaging state and a non-engaging state over the heart, and elongated flexible elements capable of being attached between said restrictive elements via their extremities while being movably engaged in said anchoring

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means along portions of their lengths, wherein said ventricular function assisting device is capable of being selectively changed between two modes of operation by changing the state of said restrictive means between their non-engaging and engaging states over the heart.

The ventricular function assisting device of the invention is preferably attached over the heart by placing at least two restrictive elements more or less horizontally around the heart, attaching the anchoring means to wall region(s) of the heart located between the restrictive elements, attaching the elastic elements to said anchoring means such that they can be elastically deformed and store potential energy in them during the systolic phase and release said stored energy during the diastolic phase, thereby applying radially outward and tangentially directed forces over said wall regions, and attaching the extremities of said elongated flexible elements between said restrictive elements such that at least some of them are movably engaged in said anchoring means.

The elastic elements are generally made in a "v" like shape having torsion loop(s) at its apex and two arms attached by one of their ends to said torsion loops, where each of said side arms comprising attachment components at their other end. Preferably, the elastic elements are made from an elastic wire coiled into a "V" like shape such that torsion loop(s) are formed at its apex with two side arms, wherein the end portions of said side arms are curved to form the attachment components. According to one specific embodiment the attachment components are made in a "G"-like shape. In an alternative embodiment the attachment components are made in a "U"-like shape .

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The anchoring means are preferably made from a turned wire having a bottom and top portions, wherein said bottom portion is formed in a helical shape adapted to be screwed into a soft tissue and its top portion comprises one or more retaining parts configured to receive the attachment components provided in the elastic elements, wherein some, or all, of the retaining parts are further adapted to movably hold a portion of the elongated flexible elements. In a preferred embodiment of the invention the retaining parts are made from a curved wire configured to receive and hold the attachment components of the elastic elements while allowing non-interlocking passage of the elongated flexible elements through it. Most preferably, the retaining part is formed in a shape of a vertical ring being in a plane substantially vertical to the plane of the helical turns of the bottom portion of the anchoring means. The top portion of the anchoring means may be implemented by a flanged rod having circumferential gaps formed between its flanges used as retaining parts suitable to receive and hold the attachment components of the elastic elements. The top portions of the anchoring means may further comprise a dome-like cover for preventing tissue injuries .

The restrictive elements are preferably made from a rigid, or semi-rigid, circular stripe having a fastening mechanism capable of changing its circumference from a non-engaging state into its engaging state by reducing its circumference. The fastening mechanism may be implemented by a fastening screw (e.g., as a gear clamp). Alternatively, the fastening mechanism may be implemented by a spring and a removable support bar attached over a gap formed in the restrictive element configured such that its circumference may be reduced by removing said removable support bar.

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According to one embodiment the restrictive elements have a wavy configuration or implemented by tension springs. Advantageously, the flexible elongated elements may be attached to the restrictive elements by means of pulling, or pushing, springs.

In another specific embodiment the flexible elongated elements are attached at one end to a restrictive element while their other end is attached together by a connecting component near the apex of the heart.

Advantageously, the elastic elements are attached to anchoring means placed over the left ventricle of the heart, such that when the restrictive elements of the ventricular function assisting device are in their non-engaging state the apparatus substantially assists in diastolic heart dysfunction, and whenever said restrictive elements are changed into their engaging state the apparatus substantially assists in both diastolic and systolic heart dysfunctions.

In another aspect the present invention is directed to a kit comprising the elements of ventricular function assisting device of the invention and tools capable of delivering and attaching the anchoring means to the heart, and tools capable of delivering and attaching the elastic elements to said anchoring means, wherein said tools are capable of delivering and attaching said elements and means via a minimally invasive procedure.

According to one embodiment the kit comprises fastening means capable of holding the top portion of the anchoring means, and a screwing tool comprising: a proximal handle having a rotatable wheel disposed in its; a hollow shaft attached to said handle, said hollow shaft comprises a rotatable rod

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mechanically linked to said rotatable wheel; a hinged head attached at the distal end of said hollow shaft in which there is a rotatable holder capable of receiving and holding said fastening means in it, wherein said rotatable rod and said rotatable holder are mechanically linked such rotations of said wheel are delivered thereby to said rotatable holder. The hinged head may further comprise foldable locator capable of indicating the distance between adjacent anchoring means place on the wall of the heart.

Additionally or alternatively, the kit may comprise a delivery tool having an elongated stack capable of holding a plurality of anchoring means, said elongated stack comprising a pushing spring adapted to advance the anchoring means distally toward a distal opening wherein there is a screwing head mechanically linked to an electrical motor and capable of holding the distal-most anchoring means in said stack and move it out of said stack via said distal opening. Advantageously, the delivery tool may further comprise optical guiding means mounted on opposing sides in a distal section thereof which are adapted to emit a light beam capable of designating a new location for placing a new anchoring means.

The kit may further comprise a delivery tool suitable for delivering and attaching the elastic elements, comprising a proximal handle having a slider element movably placed therein and capable of being moved between a proximal and distal states, a slidable hollow shaft comprising mechanically linked to said slider element, and an elongated rod fixedly attached to said proximal handle and passing inside said handle and said slidable hollow shaft, wherein said elongated rod comprises a retaining part adapted to receive and hold the torsion loop(s) of an elastic element when said slider element in its proximal state, such that the arms of said elastic

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elements are capable of being folded into said slidable hollow shaft by changing the state of said slider element into its distal state.

In another aspect the present invention is directed to a ventricular function assisting device utilizing a plunger mechanism designed to increase the volume of the left ventricle of the heart during diastolic phase and reduce its volume during the systolic phase.

According to one preferred embodiment the ventricular function assisting device comprises a cylindrical housing having a front section having a front opening capable of being sealably attached to a first opening formed in a ventricle of the heart, and a rear section to which there is attached a conduit capable of communicating between said rear section and said ventricle via a second opening formed therein to which said conduit is capable of being sealably attached, wherein each of said sections comprises a slidable plunger movably disposed thereinside, said plungers are mechanically linked by a connecting rod, and wherein the cross-sectional area of the plunger in the rear section is greater than the cross-sectional area of the plunger in the front section, and wherein said plungers are mechanically linked to an elastic element (e.g., spring) mounted inside said ventricular function assisting device and adapted to push, or pull said plungers thereinside.

According to another preferred embodiment the ventricular function assisting device comprises a cylindrical housing a slidable plunger slidably disposed thereinside, said slidable plunger is made from a magnetic or ferromagnetic material, a front and rear coils wound on, or in, the wall of said cylindrical housing, and a front opening, or passage, capable

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of being attached to an opening formed in a ventricle of the heart and communicating between said cylindrical housing and said ventricle, wherein said coils are capable of being electrically connected to a controllable current source configured to activate said coils, or one of them, to apply magnetic forces for sliding said slidable plunger rearwardly during the diastole, and to apply magnetic forces for sliding said slidable plunger forwardly during the systole.

Brief Description of the Drawings

The present invention is illustrated by way of example in the accompanying drawings, in which similar references consistently indicate similar elements and in which:

- Figs. 1A to 1X schematically illustrate various embodiments of ventricular function assisting devices configured for treating systolic and diastolic dysfunctions and tools suitable for attaching the same to the heart in a minimally invasive procedure, wherein Figs. 1A and 1B show a configuration of anchoring means and elastic elements having G-shaped attachments suitable for use in the ventricular function assisting device, Figs. 1C to 1F show embodiments of anchoring means having dual-level anchoring sites in their head sections and elastic elements having C-shaped attachments, Fig. 1G shows a perspective view of a tool for guiding in the positioning of the attachment means, Fig. 1H shows a perspective view of the attachment means used in Fig. 1B, Figs. 1I to 1N show various views and exemplify the use of a tool for attaching the attachment means of the invention to the wall of the heart, Figs. 1O to 1Q show another embodiment of a tool for attaching the attachment means to the wall of the heart in which the attachment

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means are maintained in an internal stack, Figs. 1R to 1T shows a tool for delivering and attaching the elastic elements, Fig. 1U shows a perspective view of the ventricular function assisting device of the invention having two operation modes, Fig. 1V shows the ventricular function assisting device shown in Fig. 1U when mounted on a heart, and Figs. 1W and 1X illustrate an exemplary implementation of a fastening mechanism (in an open and closed states, respectively) suitable for fastening the ventricular function assisting device over the heart;

- Figs. 2A and 2B schematically illustrate a ventricular function assisting device which employs elastic restrictive elements;
- Figs. 3A and 3B schematically illustrate ventricular function assisting devices for treating systolic and diastolic dysfunctions which employ an intermediate restrictive element;
- Figs. 4A to 4C schematically illustrate an implementation of the ventricular function assisting device which is configured to enclose the apex of the heart, wherein Fig. 4A is a perspective view, Fig. 4B schematically illustrates an exemplary fastening mechanism, and Fig. 4C is a side view;
- Figs. 5A and 5B schematically illustrate a device for treating systolic and diastolic dysfunctions which is based on a magnetic/electromagnetic mechanism;
- Figs. 6A and 6B schematically illustrate the structure and operation of a ventricular function assisting device of the invention based on a plunger mechanism;
- Figs. 7A and 7B respectively show a perspective view and a sectional view of specific implementations of the ventricular function assisting device illustrated in Figs. 6A and 6B.

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- Figs. 8A to 8E show sectional views of various implementations of ventricular function assisting devices of the invention based on plunger mechanisms, wherein Fig. 8A shows an embodiment employing an anterior spring, Fig. 8B shows an embodiment employing a posterior spring, Fig. 8C exemplifies attachment of an embodiment employing a posterior spring to the heart, Fig. 8D shows an embodiment employing a posterior spring placed in an isolating enclosure, and Fig. 8E exemplifies attachment of an embodiment employing an anterior spring to the heart;
- Figs. 9A and 9B schematically illustrate a ventricular function assisting device employing an electromagnetically driven plunger; and
- Figs. 10A and 10B schematically illustrate a method and apparatus for inserting treatment devices into the heart and for mounting the same on its inner wall.

It should be noted that the embodiments exemplified in the Figs. are not intended to be in scale and are in diagram form to facilitate ease of understanding and description.

Detailed Description of Preferred Embodiments

The present invention provides methods and devices for treating systolic and/or diastolic heart dysfunctions and delivery tools suitable for delivering and attaching elements to the wall of the heart in a minimally invasive procedure. In general, devices of the present invention are designed to assist the operation of the heart by aiding in volume enlargement of the left ventricle and by reducing the pressures therein during diastolic function, and aiding in

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the pumping of blood from the left ventricle during systolic function. Some embodiments of the invention are further configured to limit ventricular dilatation in the treatment of systolic dysfunctions, wherein the limiting of ventricular dilatation may be activated at a later time after installing the device on a patient's heart (also referred to herein as devices having two operation modes).

In one preferred embodiment of the invention the ventricular function assisting device is composed of elastic elements designed to be attached to the wall of the left ventricle, and of restrictive elements (e.g., rings or stripes) designed to be fastened over the heart of the patient. Figs. 1A to 1X illustrate various preferred embodiments of a ventricular function assisting devices comprising elastic (or resilient) elements (**43** or **54**) having "V"-like shape (e.g., torsion springs), and in some embodiment also restrictive elements, **41a** and **41b** (shown in figs 1U and 1V), and tools that may be used for assisting in the attachment of these elements.

In this preferred embodiment ventricular function assisting device (**40** shown in figure 1U and 1V) is designed to operate in two different modes. In the first mode of operation, device **40** is attached to the patient's heart such that elastic elements **43** attached over the left ventricle apply tangential and radial forces thereover during contractions and expansions thereof, while the restrictive elements, **41a** and **41b**, are in a non-operative state, namely, said restrictive elements **41 a** and **41b** are placed around the patient's heart (**10**) such they do not interfere with its expansions.

The first mode of operation of device **40** is mainly directed for treating diastolic dysfunctions. During the systole elastic elements **43** are compressed (the distance between their

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arms is reduced) as they store elastic potential energy. During diastole, the elastic potential energy stored in elastic elements **43** is released as they apply radial and tangential forces over their respective attachment elements **45**.

In the second mode of operation of device **40** the perimeter of restrictive elements **41** is diminished by means of a fastening mechanism **42** (**42a** in upper restrictive element **41a** and **42b** in lower restrictive element **41b**) such that said restrictive elements **41a** and **41b** and the patient's heart become engaged. The second mode of operation of device **40** is mainly directed for treating systolic dysfunctions. As will be explained hereinbelow the mode of operation of device **40** may be changed from the first mode to the second mode at a later time, after installing the device. This configuration is particularly desirable in patients initially suffering from diastolic dysfunctions and which develop systolic dysfunction ailments during later treatment stages.

Figs. 1A and 1B show a configuration of anchoring means **45** and elastic elements **43** suitable for use in the ventricular functions assisting device **40** (shown in Fig. 1U and 1V). Elastic element **43** is preferably a type of torsion spring made from an elastic wire formed in a "V"-like shape, having torsion loop(s) **30** at its apex and "G"-shaped anchoring loops **43a** at the end of its arms. Anchoring loops **43a** may have a spiral shape and they are preferably formed by bending the end sections of the arms towards spring loop(s) **30**, thereby forming knees **43k**, and thereafter bending said end sections away from said spring loop(s) **30** to form a spiral shape therewith. In this way an "S"-like shape (marked by dotted line **4** in Fig. 1A) is formed at the end of each arm, wherein

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the bottom portion of the "S"-like shape is further curved to form the "G"-shaped curved fasteners **43a**.

As best seen in Fig. 1A, elastic element **43** comprises a first arm **14a** which is relatively straight, and a second arm **14b** which is curved relative to the plain of the element. As shown in Fig. 1B, in the attachment of elastic elements **43** to attachment elements **45**, second arms **14b** of elastic elements **43** are curved such that the straight arm **14a** of the adjacent elastic element may be passed beneath the curved arm to engage the head section of the attachment element **45** while maintaining a gap **39** therebetween.

As best seen in Fig. 1H, anchoring means **45** comprise a head section **45a**, a neck section **45b** and an attachment section **45c**. Anchoring means **45** are preferably made from a curved wire, wherein the attachment section **45c** is curved in a helix (spring) shape ending in a sharp tip for facilitating threading thereof into the wall of the heart. Near the neck section **45b** of the anchoring means **45** the distances between the helix loops are reduced abruptly to form the neck section **45b**, which acts as a stopper to prevent excess threading of anchoring means **45**.

Anchoring means **45** may be used for delivering medicaments into the tissue into which it is threaded. In such implementation the attachment section **45b** of anchoring means **45** may be coated by one or more layers of therapeutic medicaments, or alternatively, the attachment section **45b** may be prepared to include an internal lumen, suitable for maintaining said medicaments thereinside, and release aperture communicating with said internal lumen, for releasing the medicaments into the tissue therethrough. These drug delivery implementations

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may be designed for providing delayed drug delivery to the tissue.

As exemplified in Fig. 1B, anchoring means **45** may be employed for delivering electrical signal to the heart tissue by connecting a pacemaker **85** thereto. Pacemaker **85** is a type of conventional pacemaker device which uses electrical impulses, typically delivered by electrodes contacting the heart muscles, to regulate heart beats. The primary purpose of pacemaker **85** is to maintain an adequate heart rate, either since the heart's natural pacemaker (the sinus node) is not functioning properly (i.e., slow heart beats), or if there is a block in the heart's electrical conduction system. In some cases it may be advantageous to combine with pacemaker **85** an implantable defibrillators, which is integrated into a single implantable device. Other possible implementations may include multiple electrodes for stimulating different locations over the heart muscle to improve synchronization of the lower chambers of the heart. As shown in Fig. 1B, the pacemaker **85** is electrically connected to loop **45a** of anchoring means **45** by means of electrical cable **85w**, wherein anchoring means **45** is implanted in the heart tissue and used as an electrical conductor for delivering the electric signals produced by pacemaker **85** to the heart tissue.

It should be understood that pacemaker **85** may be implanted together with ventricular function assisting device employing anchoring means **45**, or alternatively, it may be implanted later, if required. Pacemaker **85** is implanted in the patient's body in substantially the same way as in conventional pacemaker procedures, such that it may be placed under the chest or abdomen skin of the patient, but instead of using the conventional pacemaker electrodes the electrical signals it

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produces are delivered to the patient's heart through anchoring means **45**.

The head section **45a** is formed in a shape of a loop through which the "G"-shaped anchoring loops **43a** of the elastic elements **43** can be passed to engage the same therein. Head section **45a** may be formed in any suitable geometrical shape e.g., circular, elliptic, rectangular, however, in this preferred embodiment the head section **45a** is formed in a shape of a ring.

Anchoring means **45** (also shown in Fig. 1H) can be threaded into the wall of the heart by rotation. The attachment method of elastic elements **43** and anchoring means **45** is shown in Fig. 1B, wherein two elastic elements **43** are mounted by means of attachment elements **45**.

Elastic element **43** may be manufactured using conventional wire (e.g., having circular, elliptic, or rectangular/polygonal cross section) curving techniques, photo chemical etching techniques, laser cutting, or by an erosion process (e.g., using tin films) from a type of elastic metal or plastic, such as, but not limited to, Nitinol, stainless steel, silicon, or a suitable alloy, composite compound, or absorbable material (e.g., PLLA, PGA, or PLA), preferably from a Cobalt alloy, having a diameter (thickness) of about 0.45 mm. The length of the arms of elastic element **43** may generally be in the range of 20 to 30 mm, preferably about 23 mm, and the angle α therebetween is about $165\pm 5^\circ$. The diameter of torsion loop(s) **30** may generally be in the range of 3.5 mm (for elastic elements mounted at the extremities of the lined sequence) to 5.7 mm, and the diameter of the "G"-shaped anchoring loops **43a** is preferably about 2 ± 1 mm.

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Anchoring means **45** may be manufactured by using conventional spring manufacturing techniques, wire curving processes which may be followed by a suitable thermal treatment to set mechanical characteristics and relax curving tensions. Anchoring means **45** may be manufactured from a type of metal or plastic material, such as, but not limited to, Nitinol, stainless steel, silicon, or a suitable alloy, composite compound, or absorbable material (e.g., PLLA, PGA, or PLA), preferably from, a Cobalt alloy. Most preferably, anchoring means **45** are made from a turned wire having thickness of about 0.45 mm and made of a Cobalt alloy. The total length of anchoring means **45** may generally be in the range of 8 to 18 mm, preferably about 15 mm. The diameter of the helix loops in the attachment section **45c** may generally be in the range of 3 to 6 mm, preferably about 5 mm, the distance between consecutive loops thereof may generally be in the range of 1 to 3 mm, preferably about 2 mm, and the length of said attachment section may generally be in the range of 6 to 12 mm, preferably about 8 mm. The diameter of the neck section **45b** may generally be in the range of 2 to 6 mm, preferably about 5 mm, and its length may generally be in the range of 0.5 to 2 mm, preferably about 1.5 mm.

A product comprising elastic elements and anchoring means suitable for ventricular function assisting device **40** is sold under the ImCardia trademark of CorAssist cardiovascular Ltd., Israel.

Another possible configuration of elastic elements and anchoring means is depicted in Figs. 1C to 1F. In this preferred embodiment the attachment section **53c** and the neck section **53b** of the anchoring means **53** are made from a curved wire, while its head section **53m** is made from a flanged rod comprising a flanged base **53g** adapted to firmly fit into the

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loops of neck section **53b**, a flanged top **53h**, and a middle flange **53f** therebetween. The gaps **53q** and **53r** respectively obtained in head section **53m** between flanged base **53g** and middle flange **53f**, and between flanged top **53h** and middle flange **53f**, are adapted to receive "C"-shaped graspers **54u** of elastic element **54**. Elastic element **54** is preferably a type of torsion spring made from an elastic wire formed in a "V"-like shape, having torsion loop(s) **54r** at its apex and "C"-shaped graspers **54u** at the end of its arms **54a**. The wire at the tips of "C"-shaped graspers **43a** is preferably shaped to form fastening loops **54q** adapted to provide firm attachment over the flanged rod **53m**. Flanged rod **53m** is preferably attached to neck section **53b** of anchoring means **53** by welding.

Fig. 1F demonstrates attachment of neighboring elastic elements **54** to a mutual anchoring means **69**. The attachment section **69c**, neck section **69b** and head section **69a**, of anchoring means **69** are preferably made from a single wire turned such that the shape of head section **69a** is similar to the shape of flanged rod (**53m**) in anchoring means **53**, by forming an expanded top **69h** and expanded middle **69f** such that corresponding gaps **69q** and **69r** are obtained suitable for receiving the graspers of the elastic element.

Fig. 1E illustrates one preferred embodiment of an anchoring means **55** having attachment section **55c** and neck section **55b** made from a curved wire, and a head section **55m** made from a flanged rod, as in anchoring means **53** (shown in Fig. 1D) described hereinabove, and further comprising domelike top **55z** screwed into the flanged top **55h** of anchoring means **55** for protecting and preventing tissue injury. In this example elastic elements **54'** are attached to anchoring means **55** by means of closed loops provided on its arms and which are fitted into the gaps formed in head section **55m**. Elastic

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elements **54'** and anchoring means **53** may be manufactured from similar materials, and by means of similar techniques, as in the respective means previously described hereinabove.

Fig. 1G shows a perspective view of a guiding tool **68** suitable for guiding the operator in the positioning of the anchoring means of the invention. Guiding tool **68** comprises an elongated handle **68r** and a locator portion **68y** attached to its distal end. Locator portion **68y** comprises two perpendicular arms used for designating the distance between adjacent anchoring means. In use, the arm having a curved end **68c** will typically be engaged in the attachment section of the anchoring means (e.g., **45c** of anchoring means **45**) while the arm comprising the vertical ending **68u** will be used to guide the operator in determining a location for a new anchoring means to be attached. Guiding tool **68** may be manufactured from stainless steel, nitinol, or from a biocompatible alloy, by extrusion or a metal working process, for example. The length of guiding tool **68** may generally be in the range of 180-200 mm, its diameter about 1 to 2 mm, and the width of locator portion **68y** may be about 30 to 70 mm.

Figs. 1H to 1O illustrate and demonstrate attachment of the anchoring means **45** depicted in Fig. 1H by means of a screwing tool **57**. With reference to Fig. 1J, screwing tool **57** comprises a proximal handle **57h** to which there is attached a hollow shaft **57s** having a hinged head **57d** connected thereto by hinge **57i**. Proximal handle **57h** comprises a rotatable wheel **57w** mounted in depressions **57e** provided in opposing sides of proximal handle **57h**. Screwing tool **57** may further comprise a foldable locator **57g** for aiding the operator in determining locations for screwing the anchoring means **45** over the heart wall. In Fig. 1J foldable locator **57g** is shown in its deployed state, if however it is not needed, it may be rotated about

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the hinges connecting it to hinged head **57d**, such that it is placed over and aligned with a side surface thereof.

With reference to Fig. 1L, illustrating a sectional view of screwing tool **57**, hinged head **57d** comprises a distal opening **57o** adapted to receive and hold a holding cup **56** in which anchoring means **45** is held by means of a fastening rod **58**. The base of holding cup **56** is firmly received in rotatable holder **57z** rotatably mounted inside hinged head **57d**, on its base. Hollow shaft **57s** comprises a rotatable rod **57q** placed thereinside mechanically linked to rotatable wheel **57w**. At the distal end of rotatable rod **57q** there is attached one end of a wire (or flexible rod) **57x**, which other end is attached to rotatable holder **57z** provided inside hinged head **57d**. In this way rotary motion of wheel **57w** is delivered via rod **57q** and wire **57x** to rotatable holder **57z**, which in turn delivers the rotary motion to the fastening rod **58** and anchoring means **45** assembly held by holding cup **56**.

Fig. 1K shows a perspective view of fastening rod **58** having an anchoring means **45** attached to it. As shown, fastening rod **58** comprises a central slit **58s** passing along a longitudinal section of its length. Central slit **58s** is adapted to receive and firmly hold the head section (**45a**) of anchoring means **45**. Fig. 1I shows a perspective view of holding cup **56** holding a fastening rod **58** (not shown) and anchoring means **45** assembly, wherein it is seen that holding cup **56** is made from a generally a cylindrical element **56c** having flanged edge **56f** over its opening **56p**, which is adapted to receive said fastening rod **58** and anchoring means **45** assembly.

Figs. 1M and 1N, are exemplifying attachment of anchoring means by means of screwing tool **57**. During this process the operator adjusts the angle of hinged head **57d** to allow its

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front side to face and access the heart **10**, and then the anchoring window **57n** of locator **57g** is placed over a previously placed anchoring means **45**, thus providing a tolerance for determining a suitable location for attaching the new anchoring means. Once the new location is determined the operator gently presses the front side of hinged head **57d** of screwing tool **57** against the wall of the heart **10** and rotates wheel **57w**, thereby screwing anchoring means **45** into the tissue.

Screwing tool **57** may be manufactured from stainless steel, Teflon, nitinol, polycarbonate, silicon, medical grade delrin, medical grade nylon, or from a biocompatible alloy, by means of extrusion, rapid prototyping, or metal working, for example. The length of screwing tool **57** may generally be about 200-500 mm and its diameter about 10-40 mm.

Figs. 10 to 1Q illustrate a preferred embodiment of a tool **60** designed for delivering and attaching several anchoring means **45** stacked in series inside its hollow shaft **60s** configured as a stack having a longitudinal slit **60i** along its length adapted to slidably hold the head sections (**45a**) of anchoring means **45**. The anchoring means **45** are pushed distally by spring **60p** and the most distal anchoring means **45** stacked inside shaft **60s** is attached to a screwing head **60t** configured to hold the head section **45a** of the anchoring means **45** and rotate it when push-button **60d** in proximal handle **60h** is pressed by the operator. Whenever pressed down, push-button **60d** activates an electrical motor (not shown) configured to deliver rotational motion to screwing head **60t**.

As seen in Fig. 10, tool **60** further comprises a movable rod **60a** passing along the length of its bottom side, said movable rod **60a** is mechanically linked to slider **60r**. With reference

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to Fig. 1Q, showing a top view of the proximal section of tool **60**, slider **60a** may be changed between two operation states, by retaining it in lateral slit **60q** or in lateral slit **60r**. Locator **60w** is placed over a previously placed anchoring means **45**, thus providing an anchor for determining a suitable location for attaching the new anchoring means. Once the new location is determined the operator gently push the movable rod **60a** into the lateral slit **60q** and push-button **60d** in proximal handle **60h** to operate the delivery tool **60** for implantation a new anchoring means **45**.

As seen in Fig. 10, the distal part of hollow shaft **60s** may comprise optical guiding means **60g** mounted on opposing sides thereof and adapted to emit light beams (e.g., by means of low-energy laser diodes) set in proper angles such that one light beam can point to a new location for placing a new anchoring means whenever the other light beam is placed over the location of a previously placed anchoring means, thereby aiding the operator in determining a proper distance between the anchoring means.

It is noted that the delivery tools **57** and **61** described hereinabove may be easily modified for delivering and attaching various embodiments of the anchoring means, such as anchoring means **69** (shown in Fig. 1F), anchoring means **53** (shown in Fig. 1D), described hereinabove, and modifications thereof.

Figs. 1R to 1T show various views of a delivery tool **59** designed for delivering an elastic element **43** (or other such elastic elements, such as for example, **43** shown in Fig. 1A, **54** shown in Fig. 1C, or **54'** shown in Fig. 1E) and attaching the same over previously placed anchoring means in a minimally invasive procedure. With reference to Fig. 1R, delivery tool

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59 comprises a hollow handle **59h** having a longitudinal slit **59s** passing along a portion of its length in which there is movably placed a slider element **59p**, a slidable shaft **59f** extending distally therefrom and which proximal portion is placed inside hollow handle **59h** and mechanically linked to slider element **59p** by means of slidable connector **59c**, and a longitudinal rod **59r** fixedly attached to handle **59h** at **59n** and passing inside, and along the entire lengths of, hollow handle **59h** and slidable shaft **59f**. The distal end of longitudinal rod **59r** comprises a retaining part **59k** configured to receive and hold the torsion loop(s) (**30**) of the elastic element.

As seen in fig. 1R longitudinal slit **59s** comprises a proximal recess **59b** and a distal recess **59y** in each of which slider element may be placed. In a first state of device **59**, shown in Figs. 1R to 1T, slider element **59p** is held in proximal recess **59b**, in which state slidable shaft **59f** is pulled proximally such that retaining part **59k** is exposed through distal end opening of slidable shaft **59f**. In a second state of device **59** (not shown) slider element **59p** is held in distal recess **59y**, in which state slidable shaft **59f** is pushed distally such that slidable shaft **59f** is pushed distally and retaining part **59k** is introduced into chamber **59g** provided inside slidable shaft **59f** at its distal end.

In Fig. 1T there is shown an enlarged view of the distal portion of delivery tool **59** when an elastic element **43** is retained in its retaining part **59k**. As seen, retaining part **59k** comprises of flat section **59e** on which there is a holding shoulder **59y** which upper protrusion is facing slidable sheath **59f**, and a tooth **59x** formed at its distal end. The distance between shoulder **59y** and tooth **59x** is configured such that torsion loop(s) **30** of the elastic element **43** are retained thereover by placing apex of the "V"-shaped elastic element **43**

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under the upper protrusion of shoulder **59y** and the opposing side of torsion loop(s) **30** over tooth **59x**. In this way, when slider element is placed in distal recess **59y** slidable shaft **59f** is pushed over retaining part **59k** and elastic element **43** held by it, such that arms **14a** and **14b** of elastic element **43** are bent distally into chamber **59g**.

In this way the elastic element **43** is delivered in a folded state (not shown) through a small incision and attached to the anchoring means previously placed on the heart by placing the distal end of tool **59** near the previously attached anchoring means and moving slider element **59p** back to proximal recess **59b**, which in turn retracts slidable shaft **59f** proximally and exposes elastic element out of chamber **59g**. The operator then simply maneuvers tool **59** and slider element **59p** for properly engaging "G"-shaped anchoring loops **43a** of elastic element **43** (or C-shaped graspers **54u** of elastic element **54**) in head sections **45a** of anchoring means **45**, as illustrated in Fig. 1B.

Delivery tool **59** may be manufactured from stainless steel, Teflon, nitinol, polycarbonate, silicon, medical grade delrin, medical grade nylon, or from a biocompatible alloy, by means of extrusion, rapid prototyping, or metal working, for example. The length of delivery tool **59** may generally be about 200-500 mm and its diameter about 10-40 mm.

Fig. 1U shows a perspective view of one preferred embodiment of ventricular function assisting device **40**. Device **40** is configured to encircle the heart **10** (shown in Fig. 1V) by at least two, upper and lower, restrictive elements, **41a** and **41b**, respectively. The upper and lower restrictive elements, **41a** and **41b**, are connected by means of springs **46** to a set of vertical bars **47** equally distributed about the perimeters of

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restrictive elements **41a** and **41b**. Springs **46** may be pulling and/or pushing springs and they are mainly used when device **40** is operated in the second mode of operation i.e., after restrictive elements, **41a** and **41b**, are secured to the wall of the heart by means of fastening mechanisms, **42a** and **42b**, respectively. Vertical bars **47** are preferably curved according to the curvature of the heart, but they may also be flexible enough to allow them to easily curve and assume a curvature more or less similar to the curvature of the heart.

Vertical bars **47** are attached to the wall of the heart by means of anchoring means **45** threaded into the wall of the heart **10** along their lengths. Vertical bars **47** are passed through the head sections (**45a**) of anchoring means **45**, such that minimal or negligibly small forces are applied over the wall of the heart by vertical bars **47** at the attachment points of anchoring means **45** when device **40** is operated in the first mode of operation.

The portion of device **40** mounted over the left ventricle further comprises elastic elements **43** which are mounted more or less horizontally between pairs of adjacent anchoring means **45** attached to the wall of ventricle. Restrictive elements, **41a** and **41b**, comprises a fastening mechanisms, **42a** and **42b**, respectively, which are initially in a state which allows encircling the heart by restrictive elements **41a** and **41b** without engaging the heart by said restrictive elements **41a** and **41b**. Fastening mechanisms **42a** and **42b** are configured to allow fastening restrictive elements over heart **10** at a later time after the mounting procedure of device **40** on the heart is completed.

In this way the operation of device **40** may be changed into its second mode of operation whenever needed, particularly if the

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patient develops systolic dysfunctions. The activation of fastening mechanisms, **42a** and **42b**, may be carried out by a minimally invasive procedure, for example, via a small incision, by connecting access tubes to device **40** each having one opening near fastening mechanism (e.g., **42a**) and another opening being externally accessible by the practitioner such that suitable instruments (e.g., clamps, tweezers) may be introduced therethrough for fastening restrictive elements over the heart.

Fig. 1V show the ventricular function assisting device **40** illustrated in Fig. 1U, when mounted on a heart **10**. Fig. 1W illustrates a possible implementation of a locking mechanism **42a** (or **42b**) suitable for fastening the ventricular function assisting device **40** over the heart **10**. In this implementation a pulling spring **50** is mounted over a gap **41g** in restrictive element **41a**. Pulling spring **50** may be mounted by means of two socket members **51** formed, or attached, on restrictive element **41a** near gap **41g**, and having respective sockets **51s** capable of receiving spring ends **50e** and securing the same to restrictive element **41a**.

Locking mechanism **42a** further comprises a supporting bar **52** configured to attach to restrictive element **41a** over the opening of gap **41g**. In this way gap **41g** is maintained in restrictive element **41a** due to supporting bar **52**, which prevents its closure by pulling spring **50**. Supporting bar **52** comprises attachment pins **52b** provided at its ends, said attachment pins **52b** are more or less perpendicular to supporting bar **52** for allowing them to be received in respective sockets **41s** provided in the opposing sides of restrictive element **41a**, having gap **41g** there between. Grip **52g** is attached, or formed, perpendicular to supporting bar **52** more or less about its center, for providing the practitioner

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a convenient grip for removing supporting bar **52** when the fastening of restrictive element **41a** over heart **10** by the closure of gap **41g** is needed, as shown in Fig. 1X. Conveniently, grip **52g** may include a head portion **52h** for improving the grip there over.

Restrictive elements **41** may be manufactured from a biocompatible metallic alloy, for example, from stainless steel or from a biocompatible polymer, for example silicon, preferably from stainless steel. The lengths of restrictive elements **41** should be adjusted according to the size of the treated heart, for example, the length of upper restrictive element **41a** may generally be in the range of 115 to 145 mm, preferably about 125 mm, and the length of lower restrictive elements **41b** may generally be in the range of 10 to 120 mm, preferably about 50 mm.

Vertical bars **47** may be manufactured from a biocompatible metallic alloy, for example stainless steel or Conichrome (fwm 1058) or from a biocompatible polymer, for example silicon, preferably from stainless steel. The lengths of vertical bars **47** may generally be in the range of 70 to 120 mm, preferably about 90 mm. Springs **46** are preferably small springs made from a biocompatible metal alloy, for example stainless steel or Conichrome (fwm 1058), configured to apply forces in the range of 0.7 to 1.2 N.

Referring now to figure 1W, Pulling spring **50** is preferably made from an elastic wire having a diameter generally in the range of 0.3 to 0.7 mm, preferably about 0.5 mm, and it is preferably made flat (e.g., having elliptic or rectangular spring loops) in its cross-sectional profile. Spring **50** may be manufactured by conventional spring manufacture techniques, from a type of biocompatible metallic alloy, for example

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stainless steel or Conichrome (fwm 1058), preferably from Conichrome. The length of spring **50** may generally be in the range of 10 to 20 mm, preferably about 15 mm.

Gap **41g** may generally be in the range of 5 to 20 mm, preferably about 10 mm. Supporting bar **52** may be manufactured from a biocompatible metallic alloy, for example stainless steel or Conichrome (fwm 1058), preferably from Conichrome. The diameter of supporting bar **52** may generally be in the range of 1 to 3 mm, preferably about 2 mm, and its length should be fitted to the length of gap **41g**.

Ventricular function assisting device **40** may be mounted on the heart of a treated subject in a procedure comprising the following steps: first in open chest surgery followed by thoracotomy, and at a later stage, when the systolic device needs to be functional, this may be performed utilizing minimal invasive thoracoscopy procedure. Normally, device **40** will be installed in its first mode of operation for treating diastolic dysfunctions. If at a later time the patient develops systolic dysfunction ailments the state of the device may be changed to operate in its second mode of operation by fastening restrictive elements **41** over the heart. The fastening of restrictive elements **41** may be carried out as follows: pull out the pin **52** by minimal invasive procedure and thereby causing restrictive elements **41** to fasten over the heart automatically.

Of course, device **40** may be installed on the heart of a treated subject initially in its second mode of operation, if treatment of both, diastolic and systolic dysfunctions is required.

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In the example illustrated in Figs. 1C and 1D, only two restrictive elements (**41a** and **41b**) are shown, however, it should be clear that embodiments of the invention may include more than two such elements.

Figs. 2A and 2B schematically illustrate an embodiment of the ventricular function assisting device **61** for treating systolic and diastolic dysfunctions, in which the restrictive elements **65a** and **65b** are implemented by tension springs (for example, having a wavy configuration) which increase their elasticity. Although in the figures only two such restrictive elements are illustrated, it should be clear that embodiments of the invention may include more than two such elements. Fig. 2A shows the side of device **61** which is installed over the right ventricle and Fig. 2B shows the other side of the device, which is installed over the left ventricle of the heart. In this embodiment vertical bars **47** may be connected directly to tension springs **65a** and **65b**, or by means of springs (not shown), as exemplified in Figs. 1C and 1D.

Device **61** may be installed on the wall of the heart of a treated subject by means of anchoring means **45**, as exemplified in Figs. 1A to 1D, and can partially or completely circumvent the heart. Preferably, the operation of device **61** may be changed between two operation modes by means of fastening mechanisms (e.g., **42a** demonstrated in figs. 1W and 1X) provided in its restrictive elements **65a** and **65b** (not shown), as exemplified hereinabove.

Alternatively, the embodiment shown in Figs. 2A and 2B the ventricular function assisting devices **61** may be operated in only one mode of operation, in which both diastolic and systolic dysfunctions are treated. Namely, after device **61** is installed on the wall of the heart of the patient, the

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operations of both the elastic elements **43** and of the restrictive elements **65a** are effective.

Figs. 3A and 3B schematically illustrate ventricular function assisting devices, **63** and **64**, respectively, for treating systolic and diastolic dysfunctions, which employ intermediate restrictive elements, **65c** and **41c**, respectively. In these embodiments shorter vertical bars **47s** are used for connecting between the restrictive elements. For example, in Fig. 3A, vertical bars **47s** are used for connecting upper restrictive element **65a** to intermediate restrictive element **65c**, and for connecting lower restrictive element **65b** to intermediate restrictive element **65c**. As previously explained, any number of such restrictive elements may be used, and the number of elements shown in Figs. 3A and 3B is provided by way of example only.

Vertical bars **47s** may be connected to the restrictive elements by means of springs **46s**. Furthermore, the lengths of vertical bars **47s** connecting between the upper restrictive element (e.g., **41a**) and the intermediate restrictive element (**41c**) may be different from the lengths of vertical bars **47s** connecting between the lower restrictive element (e.g., **41b**) and the intermediate restrictive element (**41c**).

In the device **63** shown in Fig. 3A restrictive elements **65** have a wavy configuration for increasing their elasticity. Restrictive elements **65a**, **65b** and **65c**, may be manufactured from a cobalt alloy or stainless steel, preferably from Conichrome (fwm 1058). As in the embodiment illustrated in Figs. 2A and 2B, device **63** may be operated in only the second mode of operation, in which both diastolic and systolic dysfunctions are treated. Device **63** may be similarly attached

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to the wall of the heart by means of anchoring means (**45** not shown).

The device **64** shown in Fig. 3B is principally similar to the device shown in Figs. 2A to 2D, where the main differences are in the use of intermediate restrictive element **41c**, and connecting the same to restrictive elements **41a** and **41b** by means of shorter vertical bars **47s**.

Figs. 4A to 4C schematically illustrates an implementation of a ventricular function assisting device **77** for treating combined systolic and diastolic dysfunctions which is configured to enclose the apex of the heart **10**. As illustrated in the perspective view shown in Fig. 4A, device **77** comprises a single restrictive element **41**, and as more clearly seen in the side view shown in Fig. 4C, vertical bars **47** are forming a closed connection point **48** at the bottom of device **77** (e.g., by means of cylinder pivot or a kind of joint).

Fig. 4B schematically illustrates a possible fastening mechanism based on threading. In this example, the fastening mechanism is based on a simple screw tightening method (e.g., gear clamp), wherein screw **42t** is used for tightening (or for loosening) restrictive element **41** about heart **10**. This mechanism may be manufactured from biocompatible materials similar to those discussed hereinabove, preferably from stainless steel, employing conventional standard manufacture techniques.

Figs. 5A and 5B schematically illustrate a device **80** for treating systolic and diastolic dysfunctions which is based on a magnetic mechanism. Device **80** comprises an upper restrictive element **41a** and a lower restrictive element **41b** which are connected by means of curved vertical bars **47**. Vertical bars

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47 provide a support for a set of one or more horizontal rings **49** encircling heart **10**. Each horizontal ring **49** comprises a set of electromagnets **81a**, each of which is connected to a controllable power source (e.g., current source, piezoelectric, not shown). A corresponding set of permanent magnets **81b** is attached to the wall of the heart **10** opposite to electromagnets **81a**, such that pairs of adjacent electromagnets **81a** and permanent magnets **81b** are obtained.

As exemplified in Fig. 5B, which shows a portion of device **80** without heart **10**, permanent magnets **81b** may be attached to the wall of the heart **10** by means of anchoring means **45**, or by a modification or any of the various variations thereof exemplified hereinabove, adjusted to include a permanent magnet **81b** at their head section (**45a** not shown). Control means (not shown) is used to control the operation of the power source used for energizing electromagnets **81**. In cases of systolic dysfunctions, during systole, the control means operates the power source to activate electromagnets **81a** such that the polarity of the magnetic field produced thereby causes repulsion forces to evolve between electromagnets **81a** and permanent magnets **81b**, in order to assist the systolic heart contraction. In cases of diastolic dysfunctions, during diastole, the control means operates the power source to activate electromagnets **81a** such that the polarity of the magnetic field produced thereby causes attraction forces to evolve between electromagnets **81a** and permanent magnets **81b**, and thereby assist in the diastolic heart expansion.

Of course, the operation of the electromagnets should be synchronized with the heart activity. The synchronization may be achieved by monitoring ECG signal, signals received from a pacemaker, or by means of a suitable internal sensor.

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Horizontal rings **49** may be manufactured from the same material of vertical bars **47**, and they may be attached to said vertical bars **47** by a rigid or non-rigid connection. The pairs of electromagnets **81a** and permanent magnets **81b** are adapted to produce repulsion/attraction forces generally in the range of 0.7 to 1.2 N. Permanent magnets **81b** may be manufactured from a magnet with biocompatible cover. Electromagnets **81a** may be implemented by small coils having a core made from a paramagnetic or ferromagnetic material (e.g., magnesium, molybdenum, lithium, or tantalum); said coils may be manufactured from copper. The distances between electromagnets **81a** and permanent magnets **81b** may generally be in the range of 0 to 10 mm.

In another preferred embodiment of the invention the ventricular function assisting device is based on a plunger mechanism designed to - i) augment the relaxation of the left ventricle of the heart during diastolic phase, which assists in reducing the pressure thereinside and in pumping blood thereinto; and ii) help the left ventricle during systolic function, to pump out the blood from said ventricle.

The plunger mechanism device generally consists of two hollow sections, a front section and a rear section, which interiors are communicated by a mutual opening, wherein said hollow sections comprise mechanically linked slidable plungers installed in each of said sections. The hollow sections and their respective plungers are aligned along a longitudinal axis of the device (also referred to as axis of movement) such that said plungers are free to move thereinside along said longitudinal axis. The plungers are mechanically linked to an elastic or shape memory device, preferably in a form of a spring, which is adapted for applying mechanical forces on

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said plungers for sliding the same in their respective sections.

The front and rear hollow sections of the device are designed to communicate with a chamber of the heart and to pump in, and pump out, volumes of blood from/to said chamber. The front hollow section of the device comprises a front opening, preferably aligned with the axis of movement of the plungers, adapted to communicate with a chamber of the heart via a first aperture in the wall of the heart. The rear hollow section of the device comprises a lateral opening which is adapted to communicate with the chamber of the heart via a tube, said tube being connected to said lateral opening at one end thereof and to a second aperture in the wall of the heart by another end thereof.

The plungers may be mechanically linked by a rod connecting between the centers of said plungers. The surface areas of the plungers are designed such that different forces are applied thereover responsive to the pressure in the chamber of the heart to which the device is connected. More particularly, the surface area of the plunger installed in the front hollow section is configured to be smaller than the surface area of the plunger installed in the rear hollow section of the device, and the cross sectional area of said hollow sections is configured correspondingly to snugly fit over said plungers. The elastic/shape memory device is adapted to apply mechanical forces over the plunger's assembly (the plungers and the rod connecting them) for pushing the same towards the rear section of the device.

The different surface areas of the plungers and the forces applied by the elastic/shape memory device are designed such that during diastolic function the forces applied over the

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front plunger by the blood pressure in the chamber of the heart and by the elastic/shape memory (pushing spring) device force the plungers assembly to move towards the rear section of the device, thereby increasing the volume of the heart chamber, assisting in pumping blood thereinto, and reducing the pressure thereinside. During the systole function, due to the increased blood pressure, the forces applied over the rear plunger are greater than the forces applied over the front plunger by the blood pressure and the elastic/shape memory (pushing spring) device, such that the plungers assembly is forced to move toward the front section of the device, thereby reducing the volume of the heart chamber and assisting in pumping out blood therefrom.

Figs. 6A and 6B schematically illustrate the structure and operation of one preferred embodiment of a ventricular function assisting device **12** based on a plunger mechanism. Ventricular function assisting device **12** comprises a front hollow section **12f** and a rear hollow section **12r** having a mutual opening **12m** connecting their interiors. Front plunger **14f** is slidably installed inside front hollow section **12f**, and rear plunger **14r** is slidably installed inside rear hollow section **12r**. Rod **15** is used for connecting the center of front plunger **14f** to the center of the rear plunger **14r**.

Front hollow section **12f** of the device **12** comprises a front opening **12o** adapted to communicate with the interior of the heart **10** via a first aperture **10b** formed in heart **10**. Support **19**, preferably implemented by a rod, is mounted in front opening **12o** to provide a support for spring **13** (pushing spring) mounted thereon, such that spring **13** is capable of applying mechanical forces over front plunger **14f** along a longitudinal axis **6** of device **12**. Tube **17** communicates with the interior of rear hollow section **12r** via a lateral opening

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121 provided in said rear section **12r**. Tube **17** comprises an angled or curved section which more or less aligns opening **17o** of tube **17** with opening **12o** of front hollow section **12f**. Opening **17o** is adapted to communicate with the interior of heart **10** via a second aperture **10a** formed in the wall of heart **10**.

In one specific preferred embodiment of the invention (not shown) the pressure changes in heart **10** are affected inside ventricular function assisting device **12** via tube **17** by means of intermediate means, such that blood is not flown through the entire length of tube **17**. In one possible implementation pressure sensors are used for measuring the pressure in the openings **121** and **10a**, and pressure inside ventricular function assisting device **12** is adjusted accordingly. Alternatively, pressure changes may be affected in ventricular function assisting device **12** by filling tube **17** with a type of biological fluid (non compressible) capable of transferring the pressure changes into device **12**. In yet another implementation, springs and plunger assembly may be used to transfer the pressure from lateral opening **121** to second aperture **10a**.

The front and rear plungers, **14f** and **14r**, are designed such that different powers are applied there over by the blood pumped in and out of heart **10**. For this purpose the surface area (A_f , e.g., 78 to 710 mm²) of front plunger **14f** is made smaller relative to the surface area (A_r , e.g., 78 to 710 mm²) of rear plunger **14r**. Spring **13** is configured to apply forces (e.g., F_x , e.g., 1 to 10 N) over front plunger **14f** which enables the plungers assembly to slide along longitudinal axis **6** responsive to pressure variations in heart chamber to which the device is connected.

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Fig. 6A illustrates the operation of the device **12** during the diastole, in which the pressure in the heart chamber is reduced such that the sum of forces applied over the front plunger **14f** due to the diastolic pressure (P_d) in the heart chamber ($P_s \cdot A_f$) and by spring **13** (F_x), is greater than the force applied over rear plunger **12r** due to said diastolic pressure (P_d) i.e., $P_d \cdot A_f + F_x > P_d \cdot A_r$. In response, the plungers' assembly (i.e., front plunger **14f**, rear plunger **14r**, and rod **15** connecting them) is forced to slide towards rear section **12r** of device **12**. As demonstrated by arrows **8i** the rearward movement of the plungers assembly increases the chamber volume and assists in pumping blood thereinto. In response, portion of the blood in device **12** is discharged into heart **10**, as demonstrated by arrows **7o**.

Fig. 6B illustrates the operation of the device **12** during the systole, in which the pressure in the heart chamber is increased such that the sum of forces applied over the front plunger **14f** due to the systolic pressure (P_s) in the chamber ($P_s \cdot S_f$) and by spring **13** (F_x), is smaller than the force applied over rear plunger **14r** due to said systolic pressure (P_s) i.e., $P_s \cdot A_f + F_x < P_s \cdot A_r$. In response, the plunger assembly is forced to slide towards front section **12f** of device **12**. As demonstrated by arrows **8o**, this movement of front plunger **14f** assists in pumping out blood from the ventricle. In response, a volume of blood is pumped into device **12** via tube **17**, as demonstrated by arrows **7i**.

Fig. 7A shows a perspective view of a ventricular function assisting device **12**, as illustrated in Figs. 6A and 6B, wherein the front section **12f** and the rear section **12r** are implemented by two sealably connected hollow bodies. In this embodiment spring **13** (not shown) is mounted on a small disk **9** provided on supports **19**. Fig. 7B is a longitudinal-section

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view illustrating an embodiment wherein pulling spring **13a** is used, said pulling spring **13a** is mounted in a spring enclosure **13e** provided between rear plunger **14r** and a rear wall **12w** of rear section **12r**. Spring **13a** is sealably enclosed in spring enclosure **13e** to prevent the blood moving in device **12** from contacting the spring.

Fig. 8A is a longitudinal-section view of an embodiment of the diastolic function assisting device of the invention wherein the interior of the front section **12f** communicates with the interior of the heart via a short tube **18**. In this embodiment front section **12f** comprises a front wall **18w** used for closing the front side of front section **12f**, wherein said front wall **18w** has a tapering shape and comprises an opening (not shown) adapted to communicate with tube **18**. Tube **18** and wall **18w** are adapted to be attached to the wall of the heart **10**, as illustrated in Fig. 8E. In this configuration Blood may be flown via an opening **18o** of tube **18**, into, or out from, device **12**. Fig. 8E is a longitudinal section view of the embodiment shown in Fig. 8A showing said device mounted on the wall of the heart **10**.

Fig. 8B is a longitudinal-section view illustrating an embodiment of device **12** configured to be connected to the wall of the heart **10** by means of front wall **18w** and tube **18**, as in Fig. 8A, wherein pulling spring **13a** is used, said pulling spring **13a** is mounted between rear plunger **14r** and rear wall **12w** of rear section **12r**. Fig. 8C illustrates a longitudinal section view of this embodiment when mounted on a wall of heart **10**.

Fig. 8D is a longitudinal-section view of an embodiment of device **12** configured to be connected to the wall of the heart **10** by means of front wall **18w** and tube **18**, as in Fig. 8A,

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wherein pulling spring **13a** is mounted in a spring enclosure **13e** between rear plunger **14r** and rear wall **12w** of rear section **12r**. Spring enclosure **13e** may be a type flexible tube made of silicon, polyurethane, or any kind of flexible polymer, suitable for sealing spring **13a** and preventing blood from contacting it.

Ventricular function assisting device **12** may be manufactured, for example, by machining or injection, from type of biocompatible materials, such as for example, stainless steel, cobalt alloy, silicon, or Teflon, preferably from stainless steel. Spring **13** (or pulling spring **13a**) may be manufactured from a suitable type of elastic or shape memory material, such as, but not limited to biocompatible metal alloy, preferably from stainless steel. The length of spring **13**, or of pulling spring **13a**, may generally be in the range of 5 to 25 mm, preferably about 15 mm, and its diameter may generally be about 0.1 to 1 mm.

Front hollow section **12f** is preferably made from a cylindrical body having a diameter generally in the range of 10 to 30 mm and a length generally in the range of 5 to 25 mm. Rear hollow section **12r** is preferably also made from a cylindrical body having a diameter generally in the range of 15 to 45 mm and a length generally in the range of 5 to 25 mm. Front and rear sections may be manufactured as integral parts of device **12**, or alternatively, as separate parts which may be connected, for example, by means of screws.

Tube **17** is preferably manufactured as an integral part of rear section **12r**, and it may be manufactured from the same material said rear section is made from. Similarly, tube **18** and front wall **18w** are preferably manufactured as integral parts of

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front section **12f**, and they are made from the same material from which said front section is made.

Front and rear plungers, **14f** and **14r**, may be implemented by bodies having a disk shape made from stainless steel or silicon, preferably from silicon, adapted to be slidably installed in front and rear hollow sections, **12f** and **12r**, respectively.

Figs. 9A and 9B schematically illustrate a ventricular function assisting device **90** employing an electromagnetically driven plunger **93**. Device **90** is preferably made from a hollow cylindrical body which interior may be accessed via bore **90p** provided in its front wall **90t**. Front wall **90t** may be advantageously formed in a conical shape having a flare **90f** at its tip for assisting in mounting it in the wall of heart **10**. Said mounting of ventricular function assisting device **90** is preferably carried out by forming a small incision **10a** in the wall of the heart and introducing the flaring front end **90f** of device **90** thereinto such that the opening **90a** of bore **90p** communicates with an interior of a heart chamber. Device **90** may be secured in its mounted state to the heart **10** by means of pressure, tightening or suturing. Volumes of blood may thus be injected/ discharged into/from device **90**.

With reference to Fig. 9B, ventricular function assisting device **90** further comprises an electromagnetic plunger **93**, and a first coil **91a**, winded over (or inside) a rear section of cylindrical body of device **90**, and a second coil **91b** wound over (or inside) a front section of device **90** near its front wall **90t**, said coils are adapted to receive electrical currents and apply opposing magnetic fields generally perpendicular to the plane of magnetic plunger **93**, such that

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said electromagnets may be activated alternately to apply back and forth driving forces over magnetic plunger **93**.

More particularly, during the diastole second coil **91b** is activated to apply axial forces over plunger **93** for sliding it towards the rear side of device **90** (i.e., by applying magnetic repulsion forces) and thereby pump a volume of blood (e.g., about 10-200 ml) thereinto and assist in reducing the pressure in heart **10** and in pumping blood into it. The rearward movement of plunger **93** may be limited by a stopper **90s** formed in, or attached on, a rear section of the internal wall of device **90**. During the systole, the first coil **91a** is activated to apply axial forces over plunger **93** for sliding it towards the front side of device **90** (i.e., by applying magnetic attraction forces) and thereby discharge a volume of blood therefrom and assist in increasing the pressure in heart **10** and in pumping blood therefrom.

Ventricular function assisting device **90** may be manufactured from a type of biocompatible metallic material, for example stainless steel, or alternatively from a type of biocompatible polimer, preferably from stainless steel, its diameter may generally be in the range of 10 to 60 mm, preferably about 25 mm, and its length may generally be in the range of 10 to 40 mm, preferably about 30 mm. The volume of device **90** may generally be in the range of 10 to 200 ml, preferably about 50 ml. Coils **91** are preferably made from an electrically conducting wire made from copper the diameter of the wires and the number of turns are preferably adjusted for generating a magnetic field in the range of 0.000001 to 0.1 Tesla responsive to electrical currents in the range of 0.0001 to 10 amperes.

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The electrical current may be supplied to coils **91** by an implantable battery (not shown). The operation of coils **91** may be activated by an implantable control logic and/or programmable controller (not shown), employing ECG sensing means (or pacemaker) for synchronizing device operation with the heart function.

Magnetic plunger **93** is a permanent magnet made from a type of magnetic material, such as for example stainless steel, its thickness may generally be in range of 0.5 to 3 mm, and its diameter is adjusted to allow it to smoothly slide inside device **90** along its length. The magnetic strength of magnetic plunger **93** may generally be in the range of 0.001 to 1000 gauss.

Ventricular function assisting device **90** may be connected to the heart in a minimal invasive procedure via a small opening formed in the patient's chest. The device may be connected to the tissue of the left ventricle by suturing, insertion under pressure and/or threading it into the tissue.

Device **12** may be installed on the wall of the heart of a patient in a procedure comprising the following steps: open chest surgery, thoracotomy, or minimal invasive thoracoscopy. Apertures **10a** and **10b** may be formed in the wall of heart **10** by a surgical cutting device or by a needle, and device **12** may be attached to the wall of the heart **10** by pressure, surgical sutures, stapling devices or adhesives.

Figs. 10A and 10B schematically illustrate a method and device **95** for delivering treatment device **100** into the heart **10** and for mounting the same on its inner wall. Delivery tool **95** generally comprises a tube **97** and a guide wire **99** passing there inside. At the first step of an insertion procedure the

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guide wire **99** is inserted at the desired location to mark the device implantation trajectory. The device **100** can be placed at different locations, e.g., between the lateral wall to the septum, or between the anterior to the posterior walls. Tube **97** is introduced into heart **10** over guide wire **99** via a small incision **10i** formed in the free wall **10w** of the heart **10**, such that opening **97a** of tube **97** is placed more or less in front of the distal wall **10d**.

In this state a device **100** (e.g., bent spring) may be installed inside heart **10**. The device to be installed is advanced through tube **97** and it may be installed by performing the following steps: advancing a portion of device **100** such that a first expandable element **98a** of device **100** is released through opening **97a**, the state of said first expandable element **98a** is then changed into an open (deployed) state and pressed against the distal wall **10d** of heart **10** by distal anchoring means **98c** (e.g., bars, screw, hook); retracting tube **97** proximally such that a second expandable element **98b** is released via opening **97a**, said second expandable element **98b** is then changed into its deployed state and pressed against the proximal wall **10w** of heart **10** by wall anchoring means **98d** (e.g., bars, screw, hook) as tube **97** is withdrawn from heart **10** via incision **10i**.

Tube **97** may be manufactured from Nylon, Silicon, Teflon, or any kind of suitable polymer, preferably from Teflon, and its diameter may generally be about 2 to 10 mm.

Device **100** may be used for applying forces over heart walls **10w** and **10d** by means of, but not limited to: buckling bar, torsion spring (not shown), or pressing spring (not shown).

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Wall anchoring **98d** and/or distal anchoring **98c** may be used as electrical connecting means for delivering electrical signals produced by pacemaker **85**. When pacemaker **85** is attached to the wall anchoring **98d** and distal anchoring **98c** that is implanted in the heart tissue and used to conduct the electric signal from pacemaker **85** via electrical cables **85w** to heart tissue and to pace the left ventricle, or the right ventricle, or both of them.

Expandable elements **98a** and **98b** may be manufactured from an elastic material, preferably from nitinol, and it may be formed in a shape of a flower which leaves (e.g., having 3 to 12 leaves each having a length of about 3 to 20 mm) are configured to allow it to be packed compactly such that it may be delivered through tube **97** and open laterally when it is released therefrom. Expandable elements **98a** and **98b** may be manufactured from a thin and elastic wire having a diameter of about 0.1 to 2 mm.

Distal anchoring **98c** and wall anchoring **98d** may be manufactured from nitinol or Conichrome (fwm 1058), for example, in shape of short tubes having a length of about 3 to 20 mm and inner diameter of about 1 to 10 mm. Distal anchoring **98c** and wall anchoring **98d** are preferably connected to the centers of expandable elements **98a** and **98b** and perpendicular to their plains when in their deployed state, to allow them to be delivered over guide wire **99**. Distal anchoring **98c** and wall anchoring **98d** are configured to be introduced into the wall of the heart for attaching treatment device **100**. This is preferably achieved by screwing or sticking.

Pacemaker **85** can be implant together with device **100**, or later if required, through tube **97**. Pacemaker **85** is implanted in the patient's body in substantially the same way as in

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conventional pacemaker procedures, such that it may be placed under the chest or abdomen skin of the patient, but instead of using the conventional pacemaker electrodes the electrical signals it produces are delivered to the patient's heart through anchoring means the wall anchoring **98c** and/or the distal anchoring **98d**.

All of the above mentioned parameters are given by way of example only, and may be changed in accordance with the differing requirements of the various embodiments of the present invention. Thus, the abovementioned parameters should not be construed as limiting the scope of the present invention in any way. In addition, it is to be appreciated that the different plungers, tubes, springs, and other members, described hereinabove may be constructed in different shapes (e.g. having oval, square etc. form in plan view) and sizes differing from those exemplified in the preceding description.

The above examples and description have of course been provided only for the purpose of illustration, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

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CLAIMS

1. A ventricular function assisting apparatus comprising anchoring means capable of being attached to the wall of the heart, elastic elements capable of being attached to said anchoring means, at least two restrictive elements adapted to encircle a perimeter of the heart, said restrictive elements are capable of being changed between an engaging state and a non-engaging state over the heart, and elongated flexible elements capable of being attached between said restrictive elements via their extremities while being movably engaged in said anchoring means along portions of their lengths,

wherein said elastic elements are capable of being elastically deformed and store potential energy in them during the systolic phase and release said stored energy during the diastolic phase and thereby apply radially outward and tangentially directed forces over the wall of the heart,

and wherein said ventricular function assisting device is capable of being selectively changed between two modes of operation by changing the state of said restrictive means between their non-engaging and engaging states over the heart.

2. The ventricular function assisting apparatus according to claim 1 wherein the elastic elements are made in a "v"-like shape having torsion loop(s) at its apex and two arms attached by one of their ends to said torsion loops, where each of said side arms comprising attachment components at their other end.

3. The ventricular function assisting apparatus according to claim 1 wherein the elastic elements are made from an elastic wire coiled into a "V"-like shape such that torsion loop(s) are formed at its apex with two side arms, wherein the end portions of said side arms are curved to form attachment

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components capable of being received and held in the anchoring means.

4. The ventricular function assisting apparatus according to claim 2 or 3 wherein the attachment components are made in a "G"-like shape.

5. The ventricular function assisting apparatus according to claim 2 or 3 wherein the attachment components are made in a "C"-like shape.

6. The ventricular function assisting apparatus according to claim 1 wherein the anchoring means are made from a turned wire having a bottom and top portions, wherein said bottom portion is formed in a helical shape adapted to be screwed into a soft tissue and its top portion comprises one or more retaining parts configured to receive the attachment components of the elastic elements.

7. The ventricular function assisting apparatus according to claim 6 wherein the retaining parts are adapted to movably hold a portion of the elongated flexible elements.

8. The ventricular function assisting apparatus according to claim 6 wherein the retaining parts are made from a curved wire configured to receive and hold the attachment components of the elastic elements while allowing non-interlocking passage of the elongated flexible elements through it.

9. The ventricular function assisting apparatus according to claim 6 wherein the top portion of the anchoring means comprises a flanged rod having circumferential gaps formed between its flanges capable of receiving and holding the attachment components of the elastic elements.

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10. The ventricular function assisting apparatus according to claim 6 wherein the top portions of the anchoring means further comprise a dome-like cover.

11. The ventricular function assisting apparatus according to claim 1 wherein the restrictive elements are made from a rigid, or semi-rigid, circular stripe having a fastening mechanism capable of changing its circumference from a non-engaging state into an engaging state by reducing its circumference.

12. The ventricular function assisting apparatus according to claim 11 wherein the fastening mechanism comprises a fastening screw.

13. The ventricular function assisting apparatus according to claim 11 wherein the fastening mechanism comprises a spring and a removable support bar attached over a gap formed in the restrictive element.

14. The ventricular function assisting apparatus according to claim 11 wherein the restrictive elements have a flexible wavy configuration.

15. The ventricular function assisting apparatus according to claim 1 wherein the flexible elongated elements are attached to the restrictive elements by means pulling, or pushing, springs.

16. The ventricular function assisting apparatus according to claim 1 wherein the flexible elongated elements are attached at one end to a restrictive element while their other ends are

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attached together by a connecting component near the apex of the heart.

17. The ventricular function assisting apparatus according to claim 1 wherein the elastic elements are attached to anchoring means placed over the left ventricle of the heart

18. A kit comprising the elements of ventricular function assisting device according to any one of claims 1 to 17, fastening means capable of holding the top portion of the anchoring means, and a screwing tool comprising: a proximal handle having a rotatable wheel disposed in it; a hollow shaft attached to said handle, said hollow shaft comprises a rotatable rod mechanically linked to said rotatable wheel; a hinged head attached at the distal end of said hollow shaft in which there is a rotatable holder capable of receiving and holding said fastening means in it, wherein said rotatable rod and said rotatable holder are mechanically linked such rotations of said wheel are delivered thereby to said rotatable holder. The hinged head may further comprise foldable locator capable of indicating the distance between adjacent anchoring means place on the wall of the heart.

19. The kit according to claim 18, further comprising a delivery tool having an elongated stack capable of holding a plurality of anchoring means, said elongated stack comprising a pushing spring adapted to advance the anchoring means distally toward a distal opening wherein there is a screwing head mechanically linked to an electrical motor and capable of holding the distal-most anchoring means in said stack and move it out of said stack via said distal opening.

20. The delivery tool of claim 19, further comprising optical guiding means mounted on opposing sides in a distal section of

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said delivery tool, said optical guiding means are adapted to emit a light beam capable of designating a new location for placing a new anchoring means.

21. The kit according to claim 18 further comprising a delivery tool suitable for delivering and attaching the elastic elements, comprising a proximal handle having a slider element movably placed therein and capable of being moved between proximal and distal states, a slidable hollow shaft comprising mechanically linked to said slider element, and an elongated rod fixedly attached to said proximal handle and passing inside said handle and said slidable hollow shaft, wherein said elongated rod comprises a retaining part adapted to receive and hold the torsion loop(s) of an elastic element when said slider element in its proximal state, such that the arms of said elastic elements are capable of being folded into said slidable hollow shaft by changing the state of said slider element into its distal state.

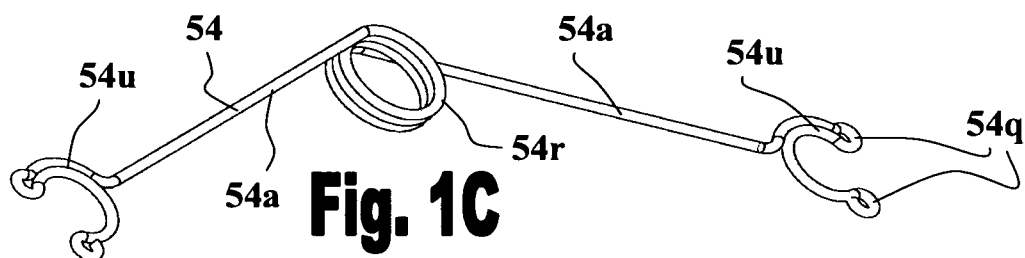
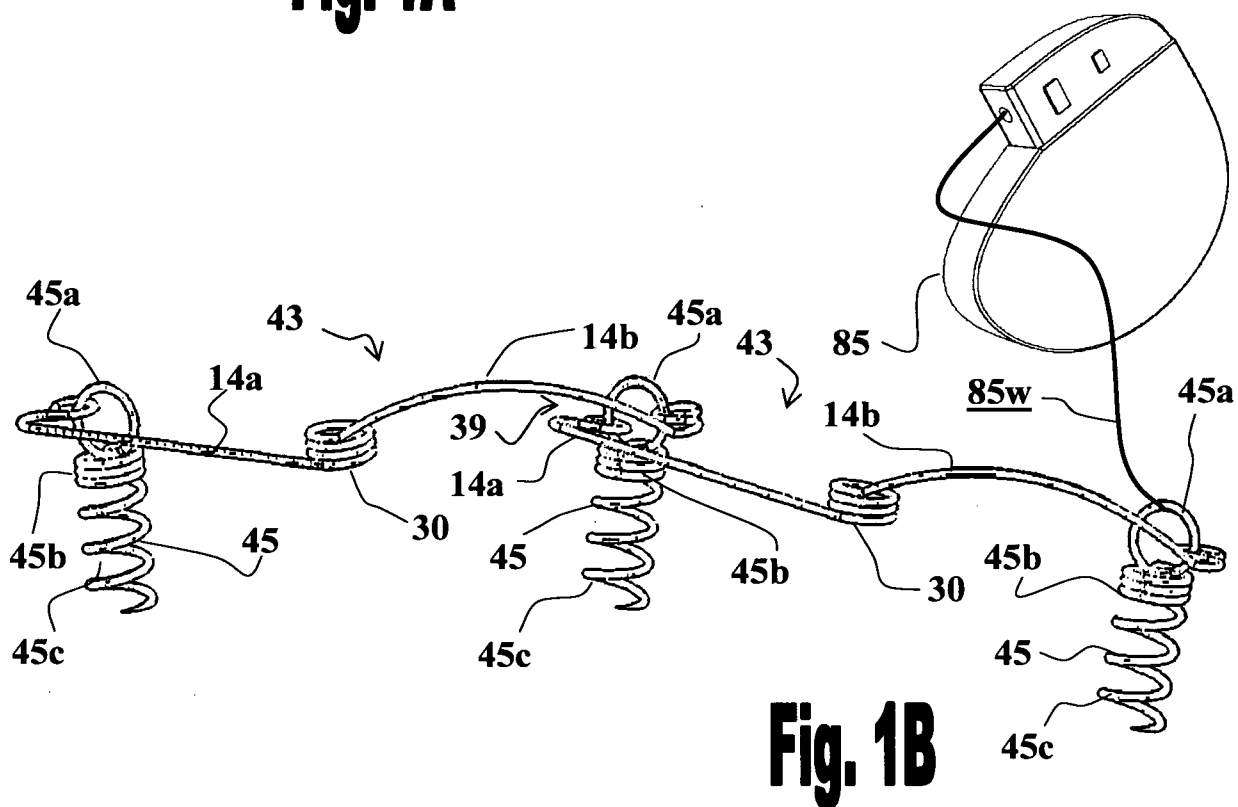
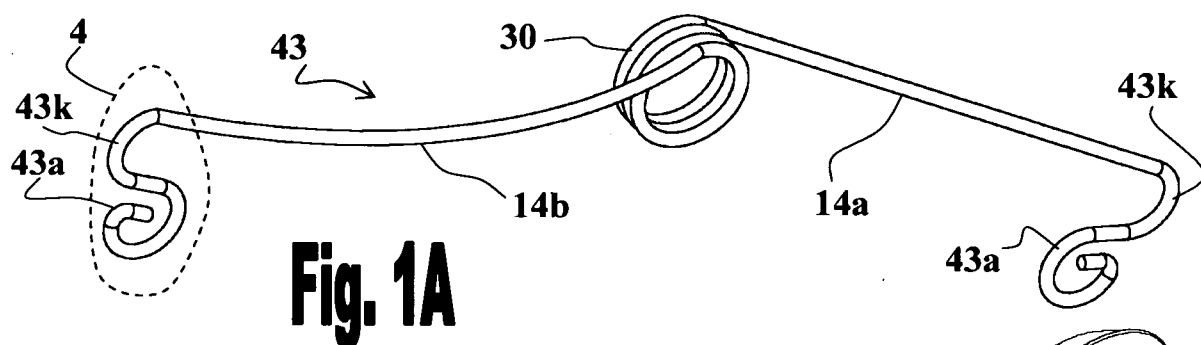
22. A ventricular function assisting device comprising a cylindrical housing having a front section having a front opening capable of being sealably attached to a first opening formed in a ventricle of the heart, and a rear section to which there is attached a conduit capable of communicating between said rear section and said ventricle via a second opening formed therein to which said conduit is capable of being sealably attached, each of said sections of said housing comprises a slidable plunger movably disposed thereinside, said plungers are mechanically linked by a connecting rod, wherein the cross-sectional area of the plunger in the rear section is greater than the cross-sectional area of the plunger in the front section, and wherein said plungers are mechanically linked to an elastic element mounted inside said housing and adapted to push, or pull said plungers

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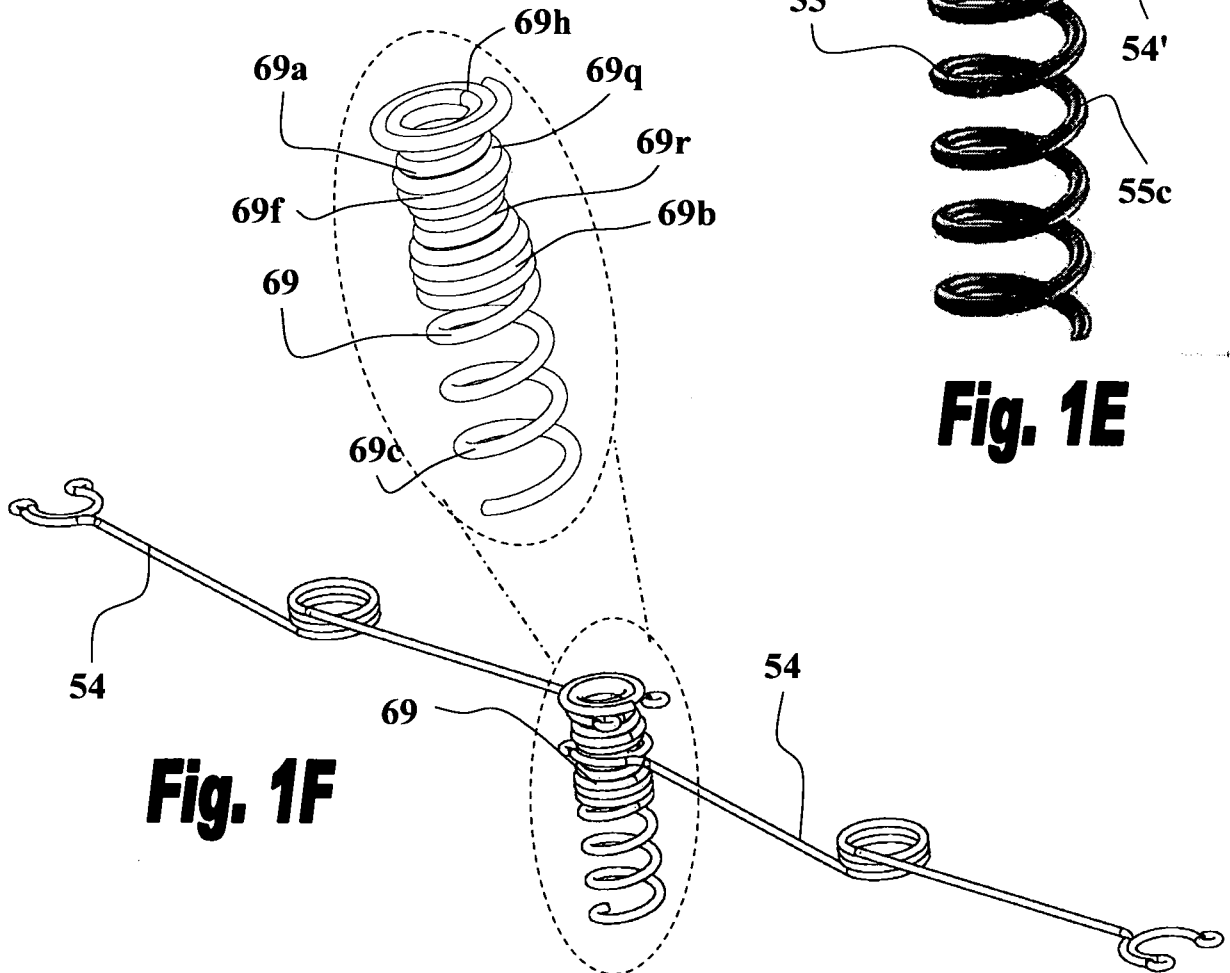
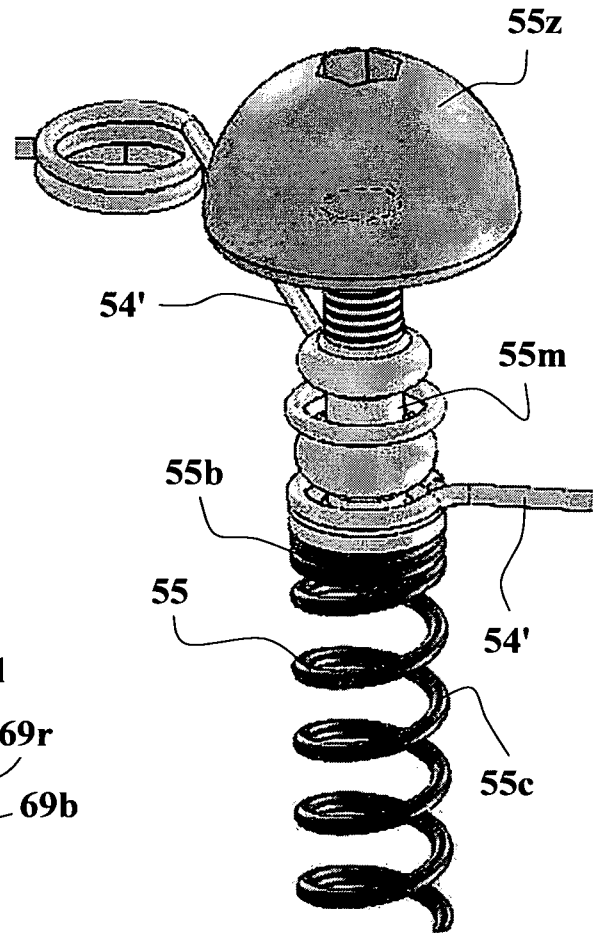
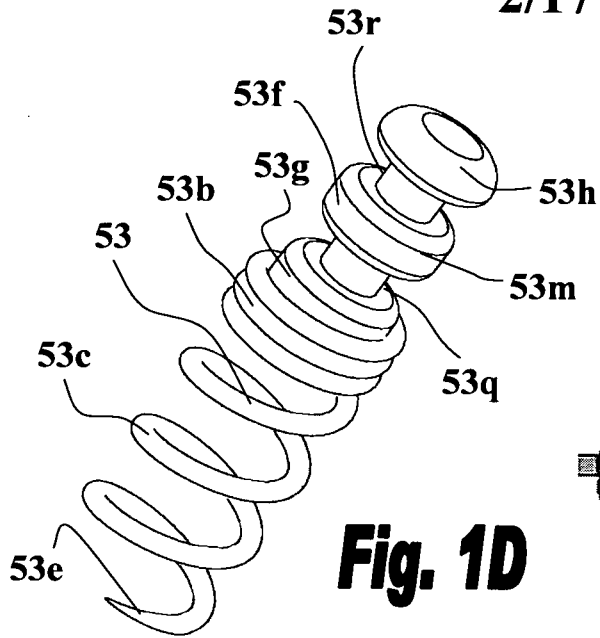
thereinside, and wherein said plungers and said elastic element area arranged such that said plungers are forced to move rearward during the diastolic phase and to move forward during the systolic phase.

23. A ventricular function assisting device comprising: a cylindrical housing; a slidable plunger slidably disposed inside said cylindrical housing, said slidable plunger is made from a magnetic or ferromagnetic material; a front and rear coils wound on, or in, the wall of said cylindrical housing; and a front opening, or passage, capable of being attached to an opening formed in a ventricle of the heart and communicating between said cylindrical housing and said ventricle, wherein said coils are capable of being electrically connected to a controllable current source configured to activate said coils, or one of them, to apply magnetic forces for sliding said slidable plunger rearwardly during the diastole, and to apply magnetic forces for sliding said slidable plunger forwardly during the systole.

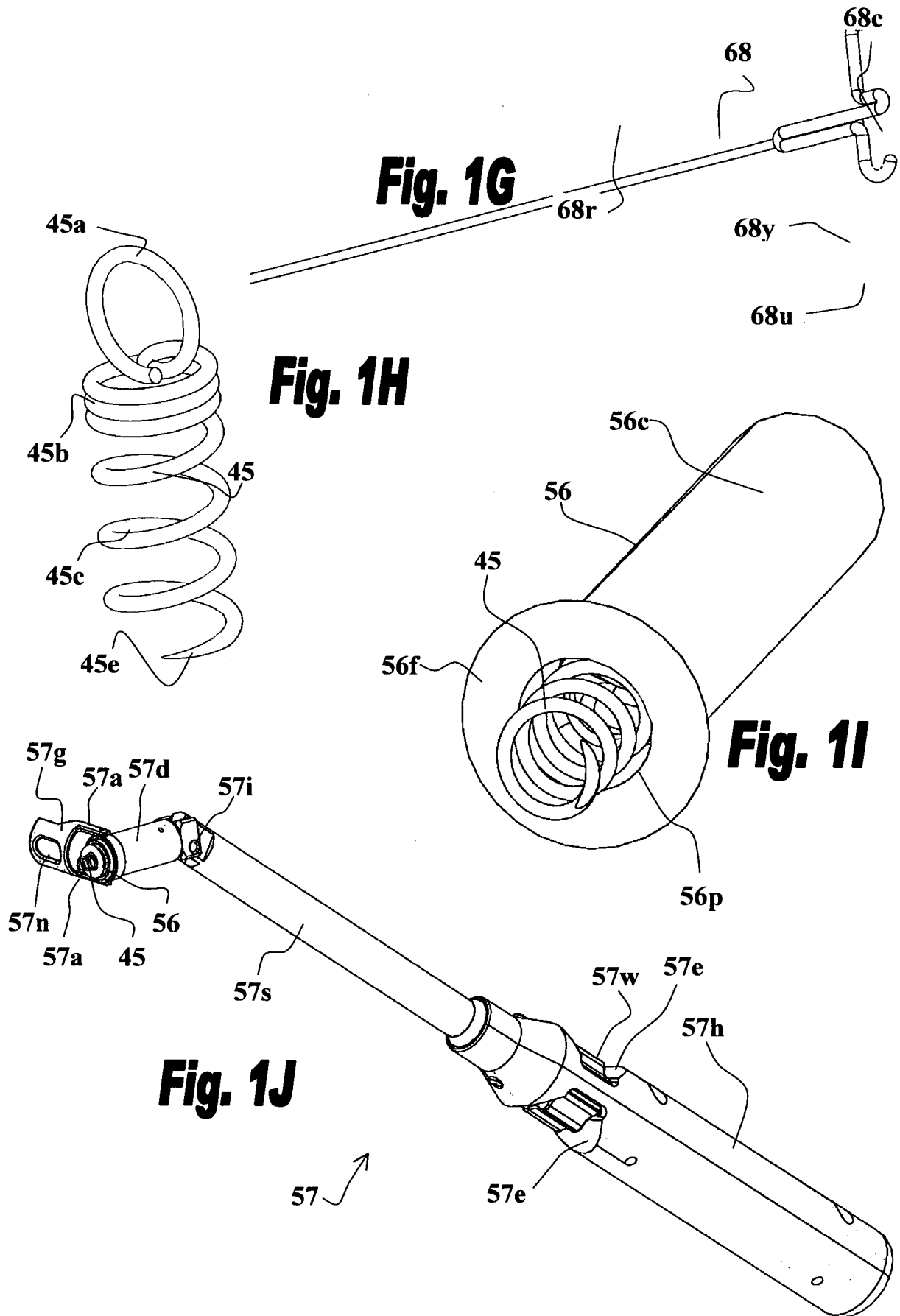
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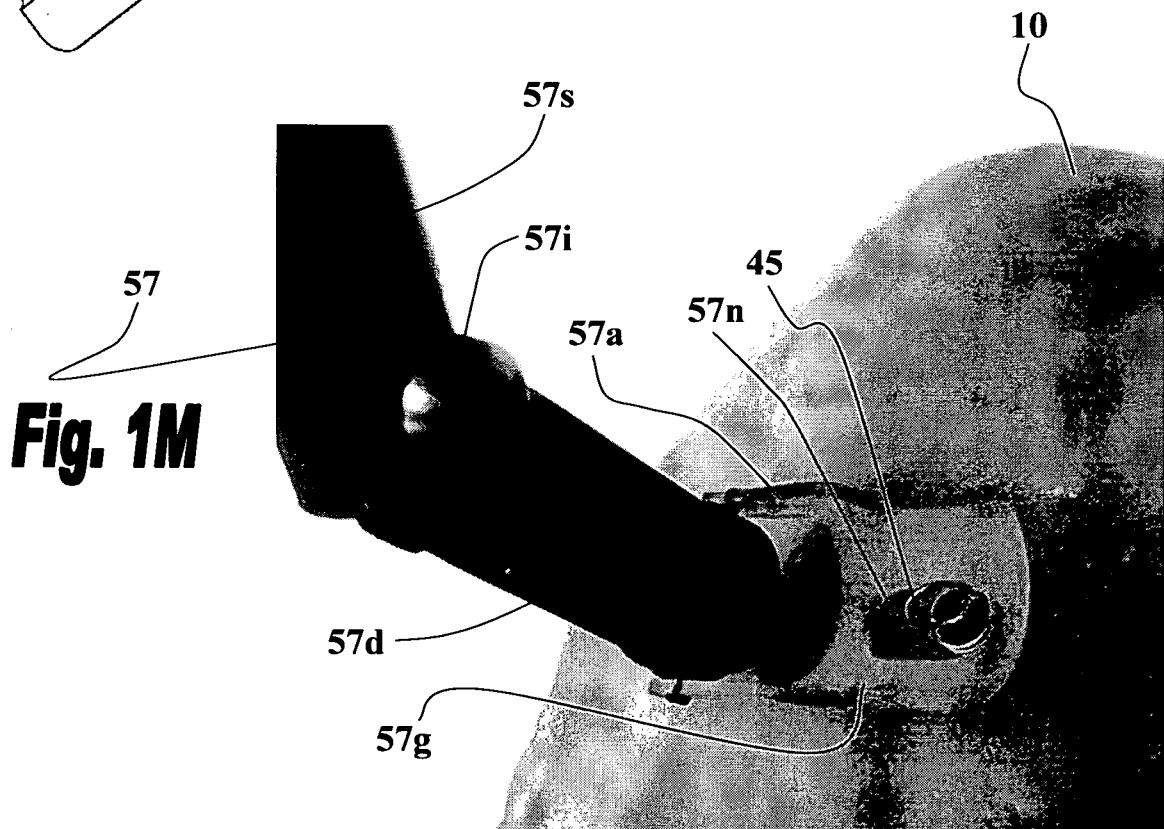
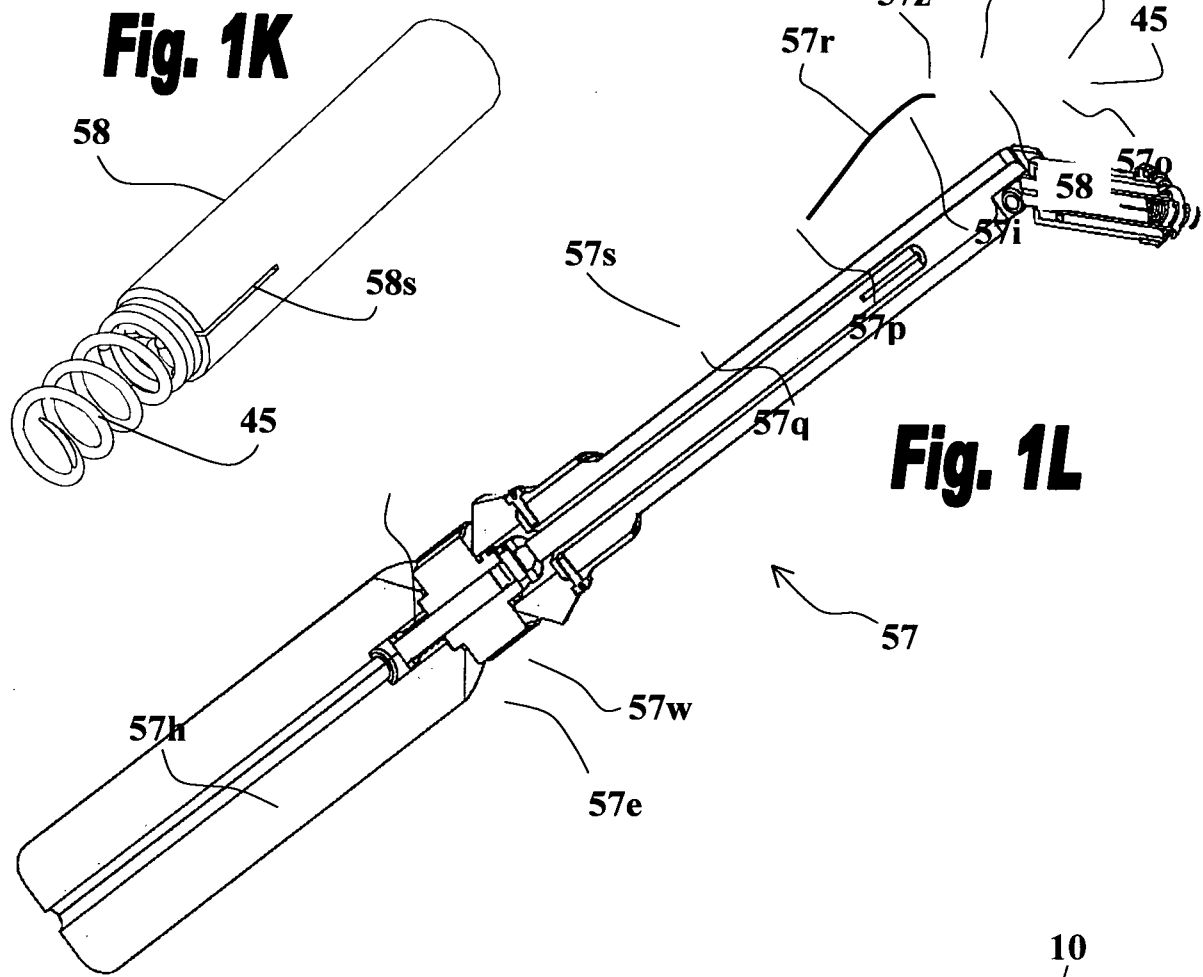
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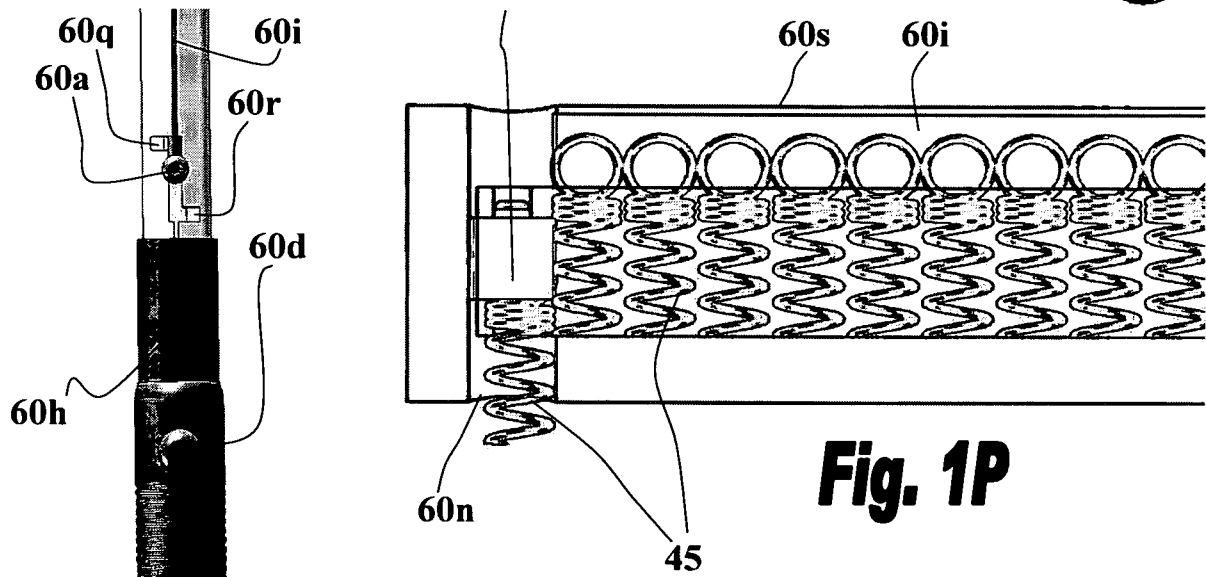
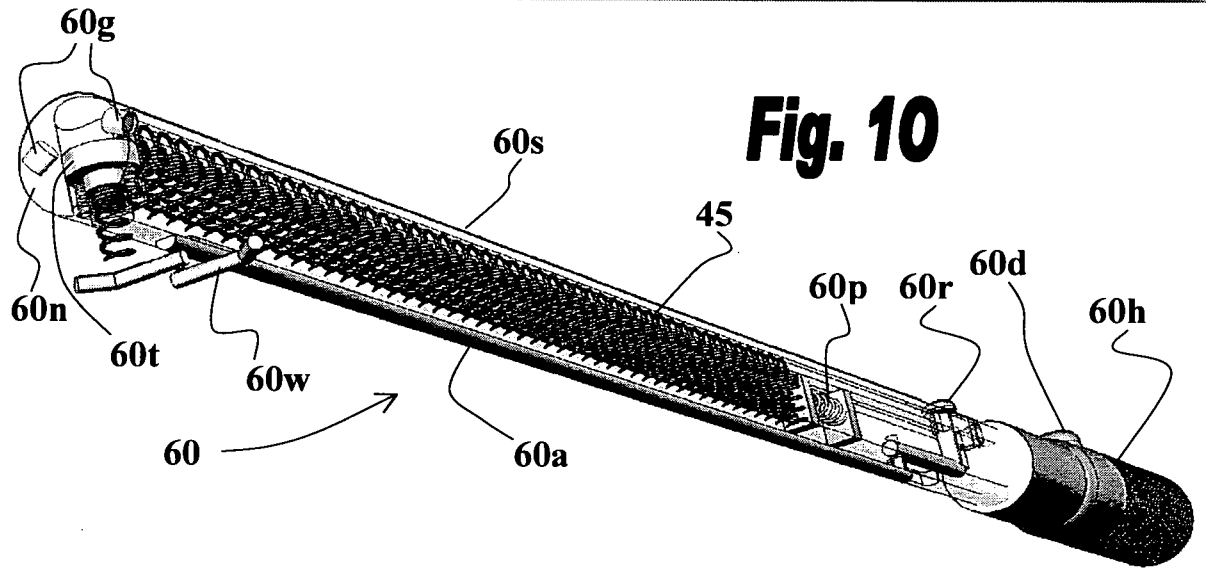
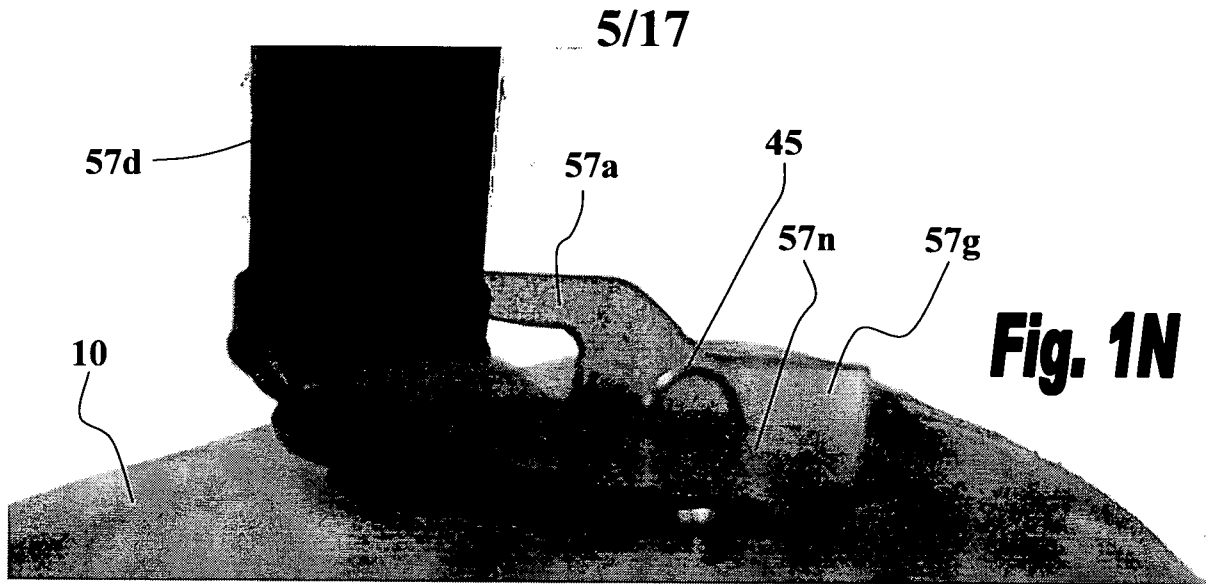


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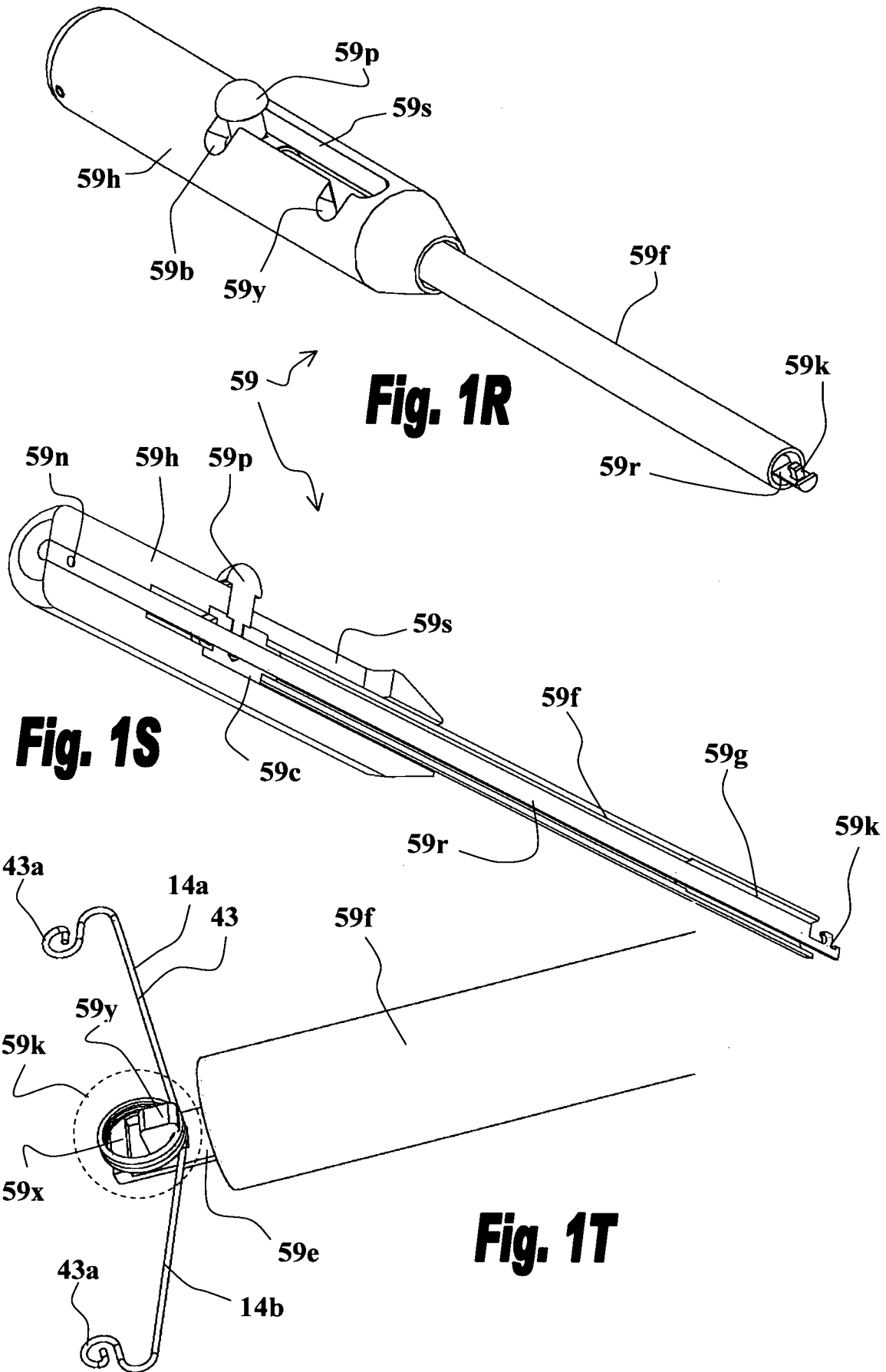


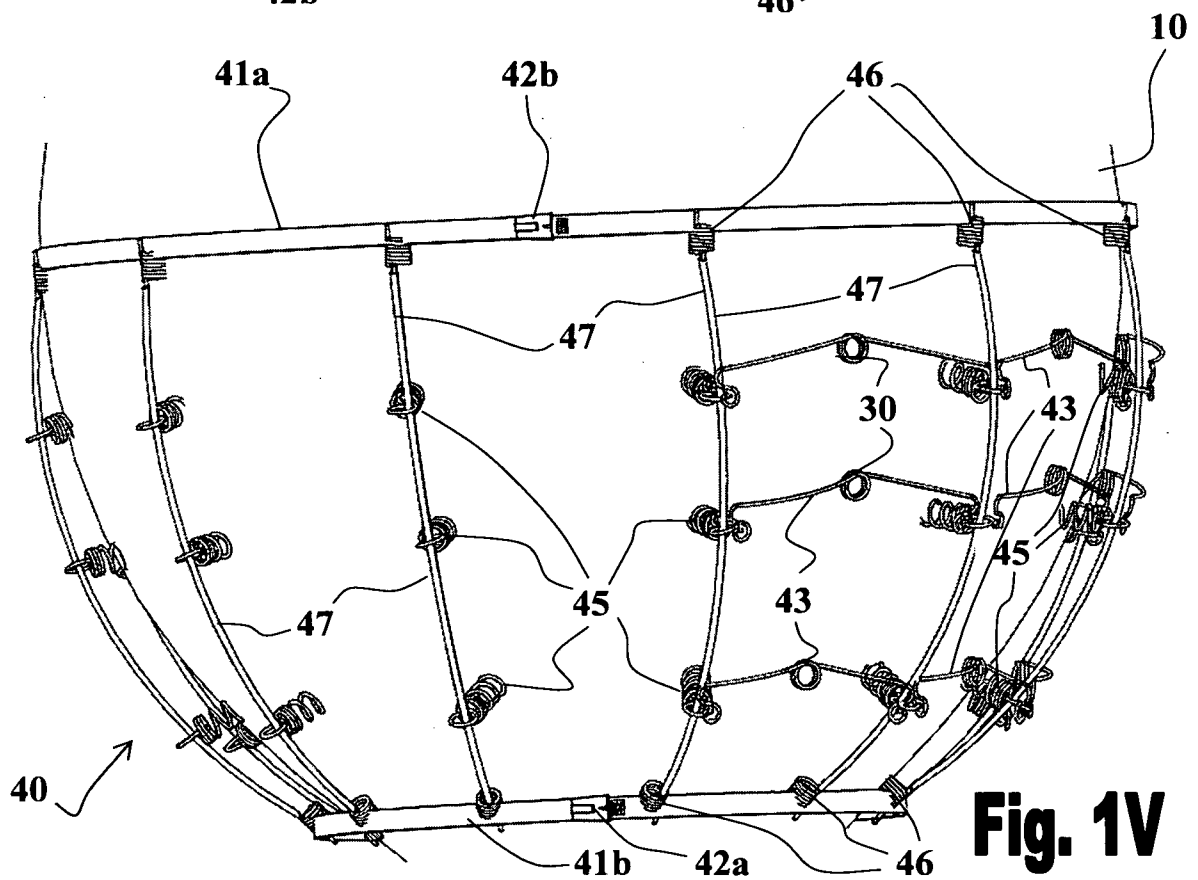
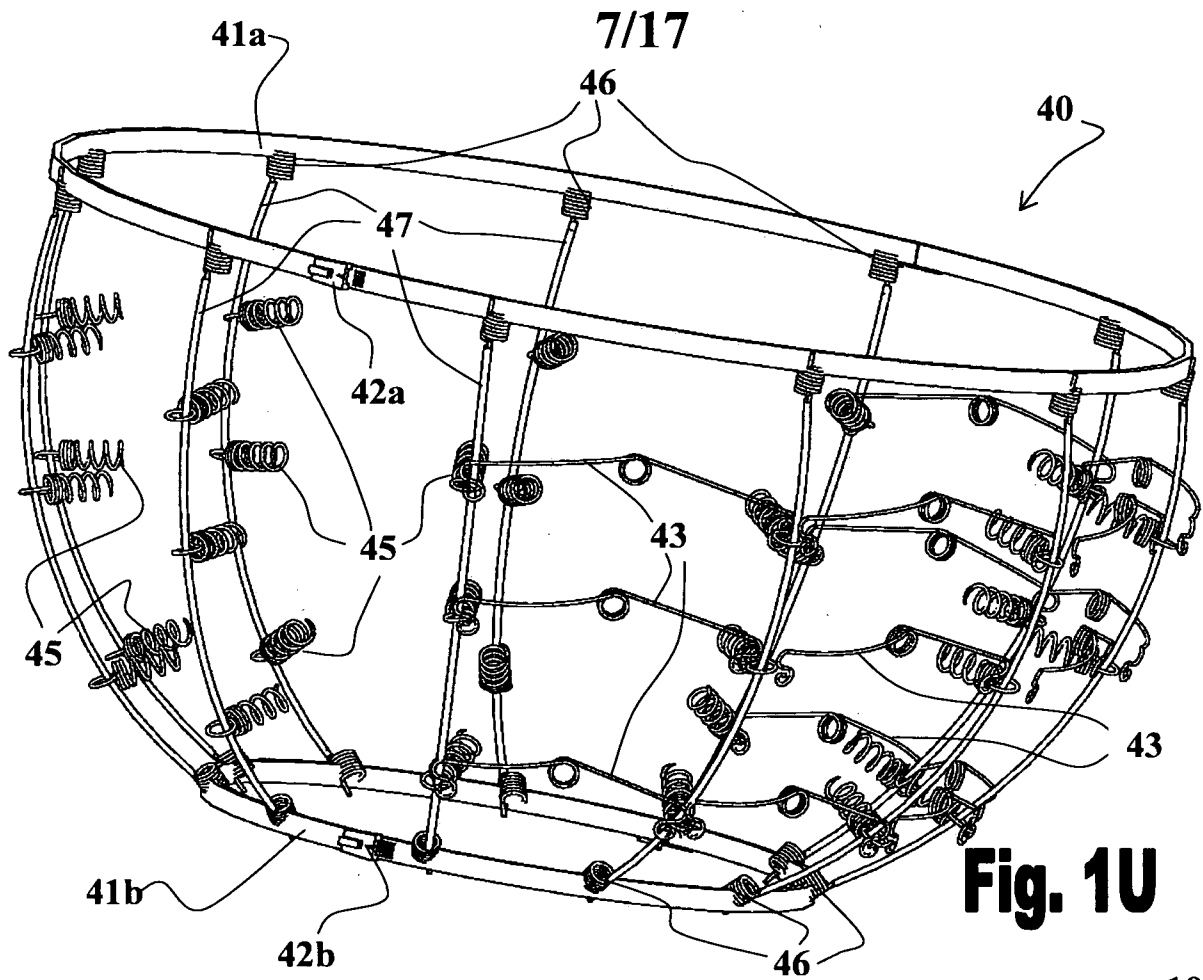
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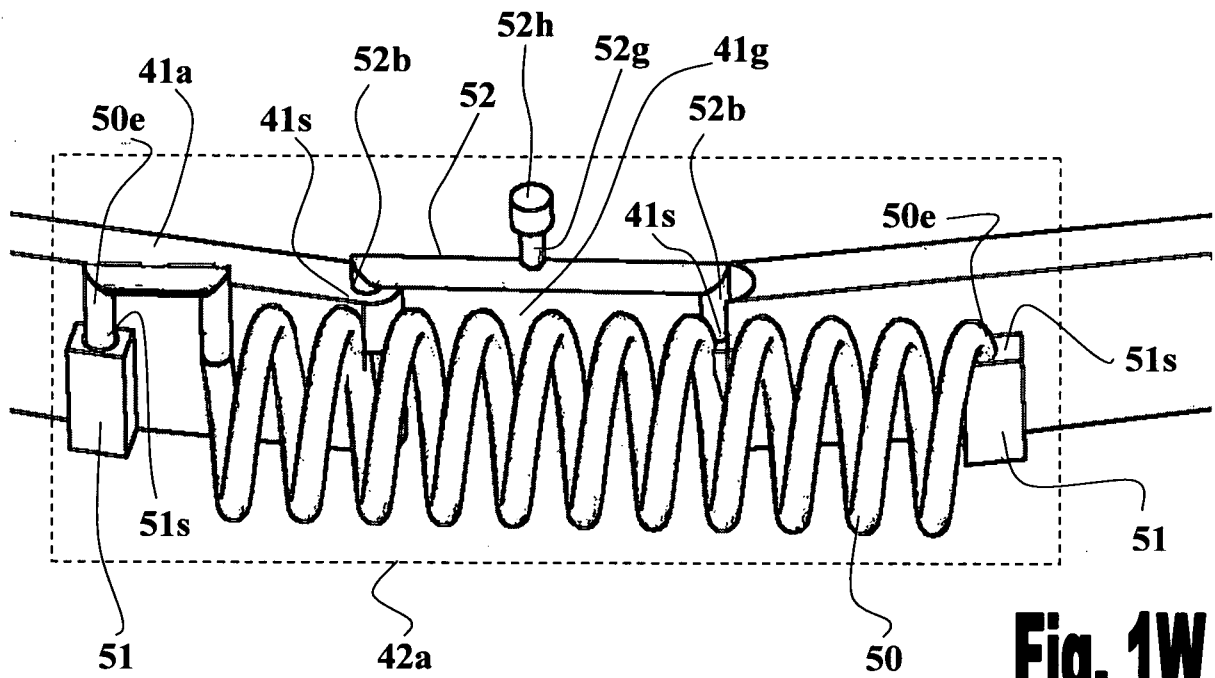


Fig. 1W

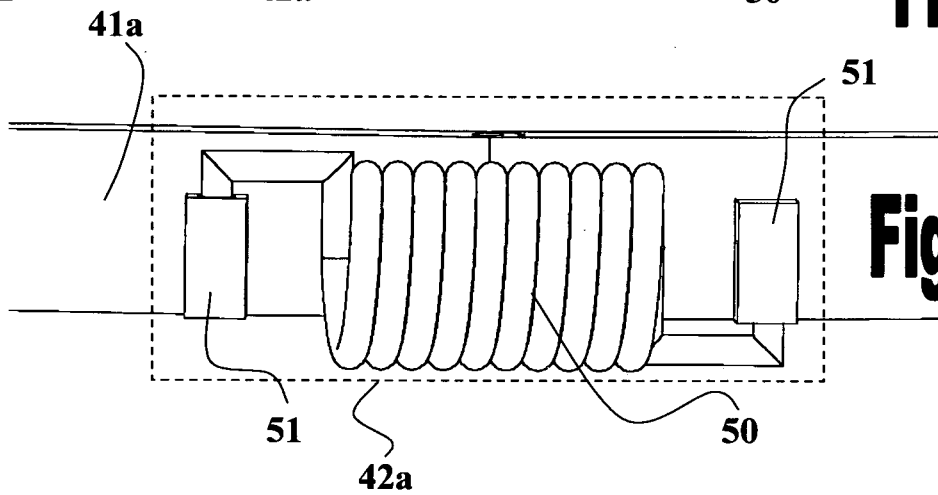


Fig. 1X

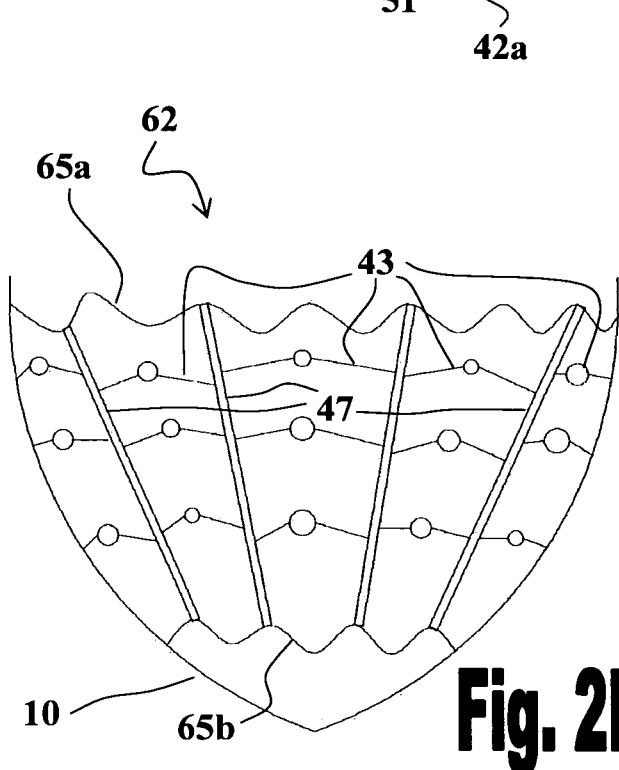


Fig. 2B

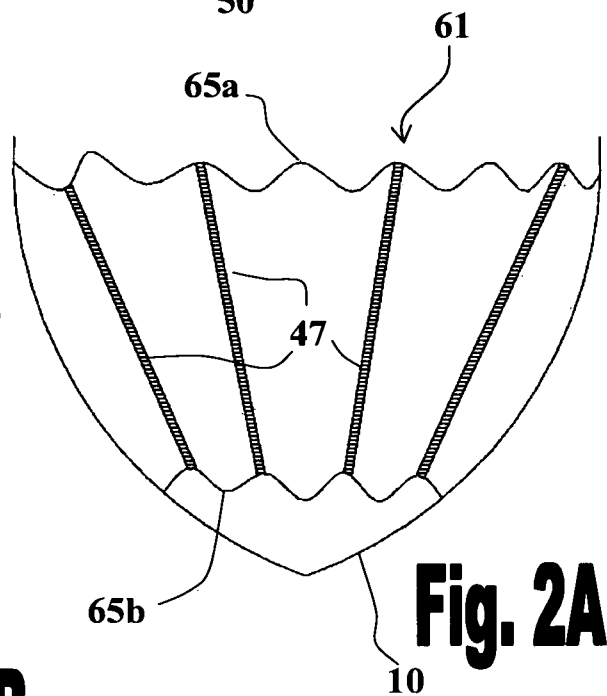
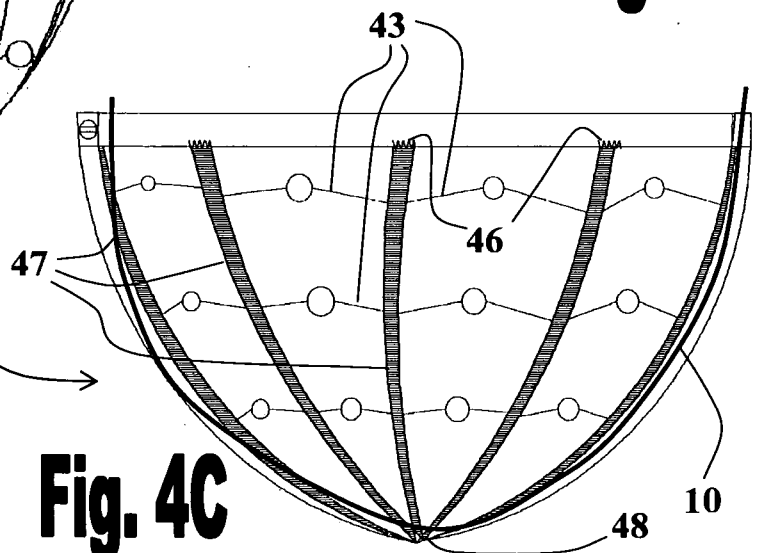
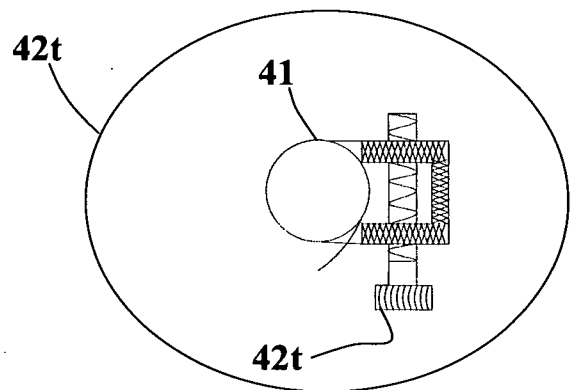
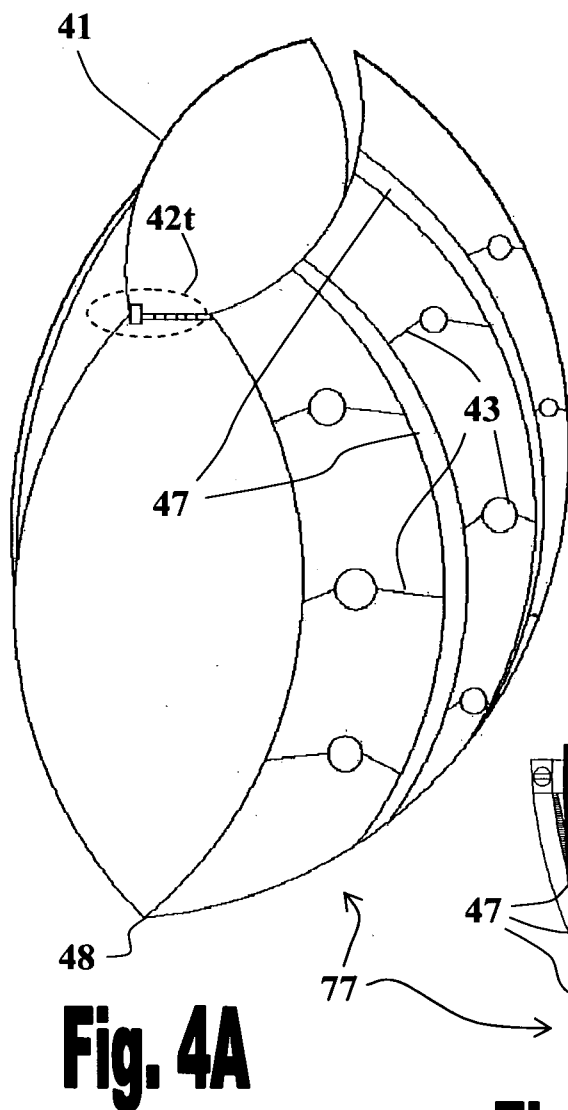
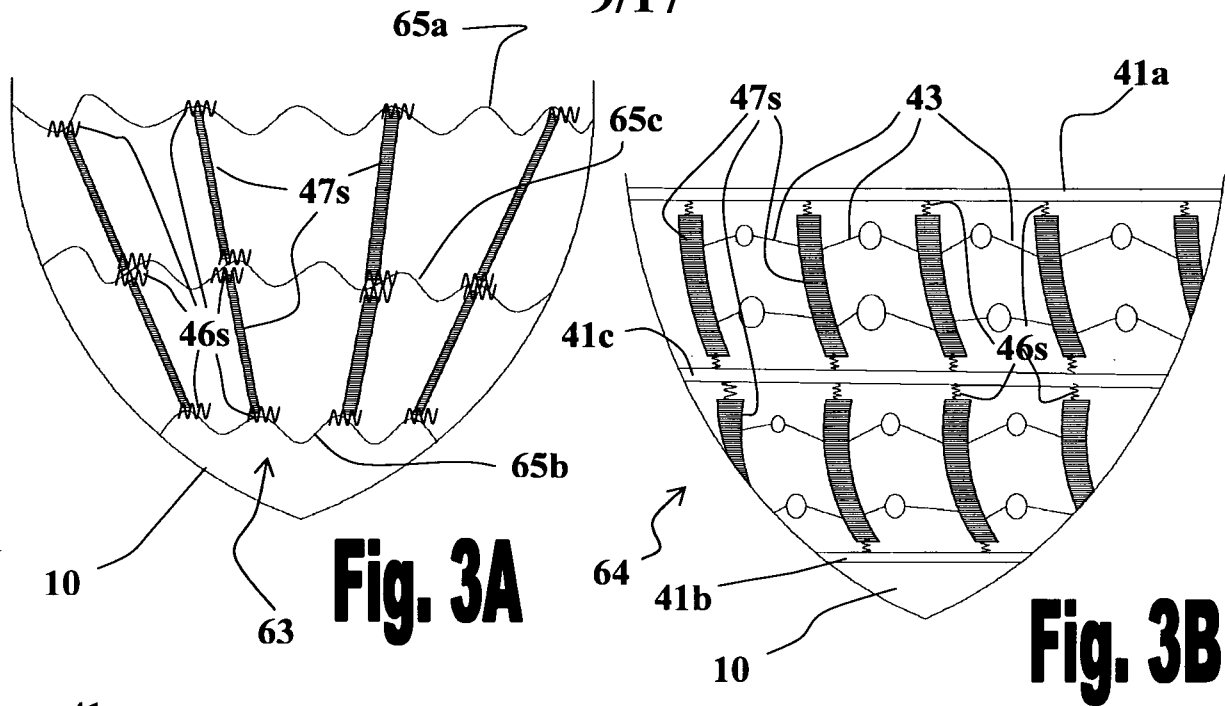


Fig. 2A

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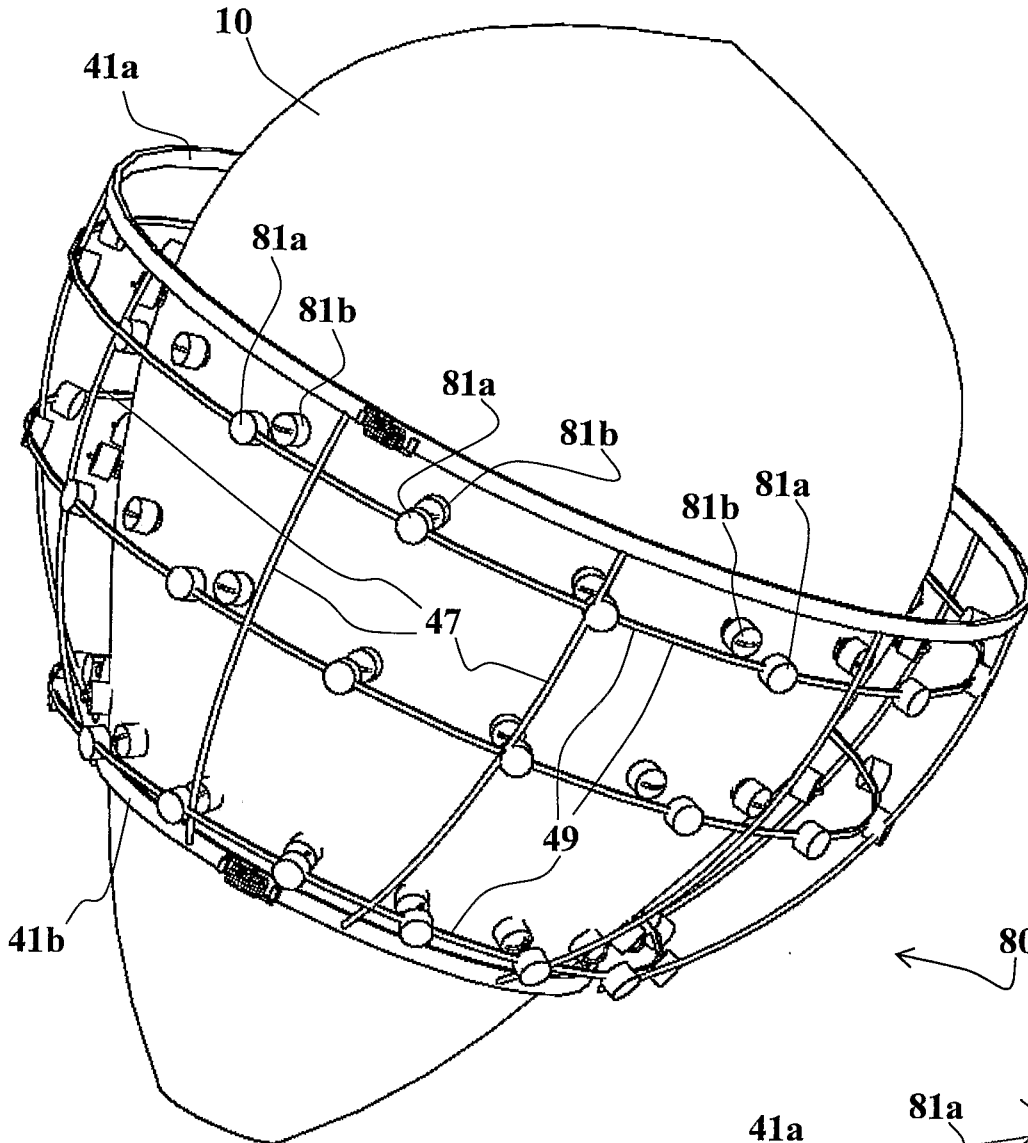
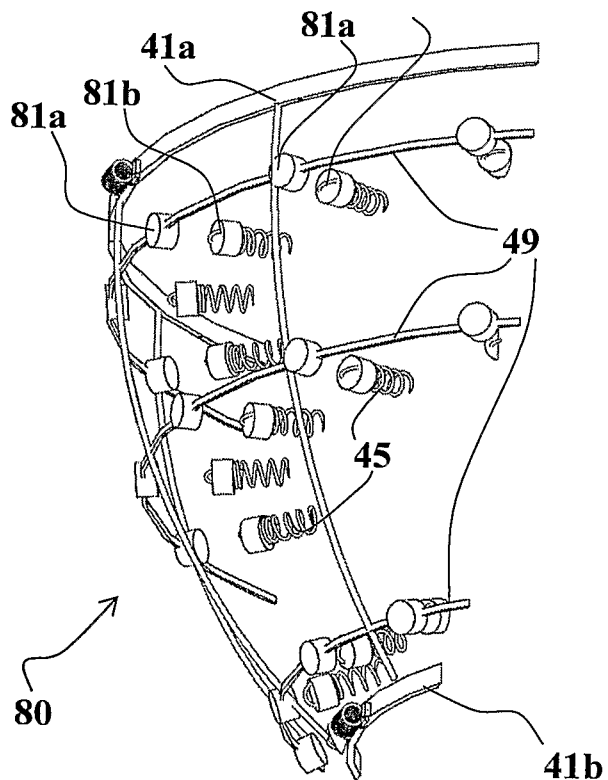


Fig. 5A

Fig. 5B



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Fig. 6A

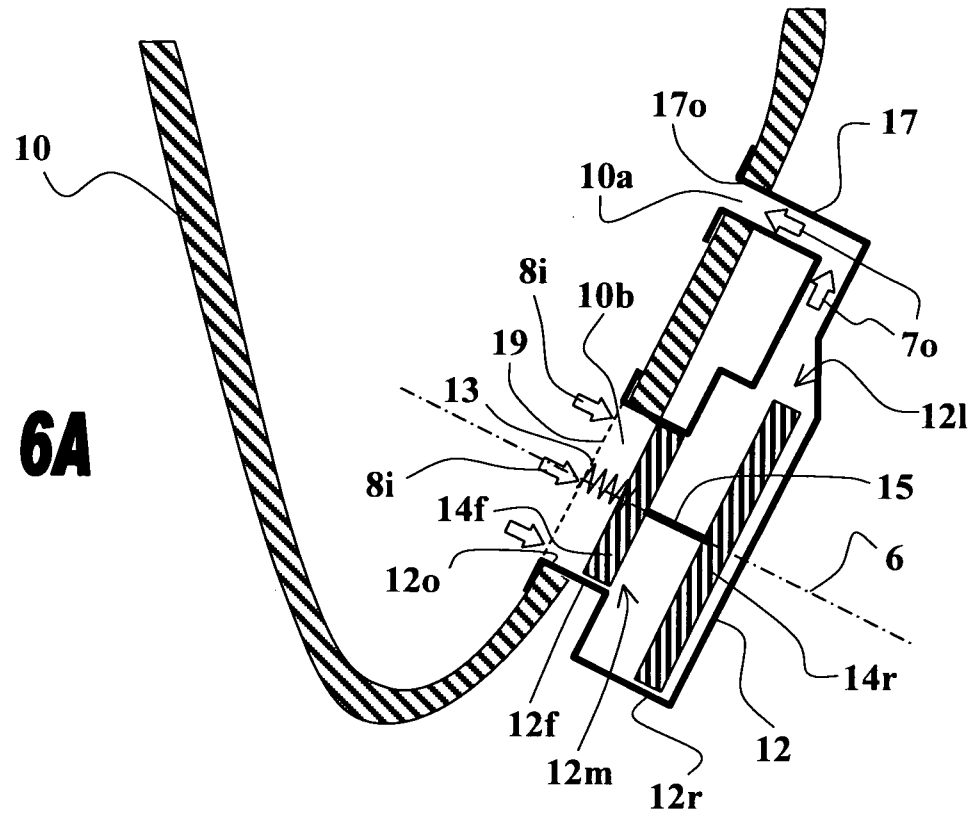
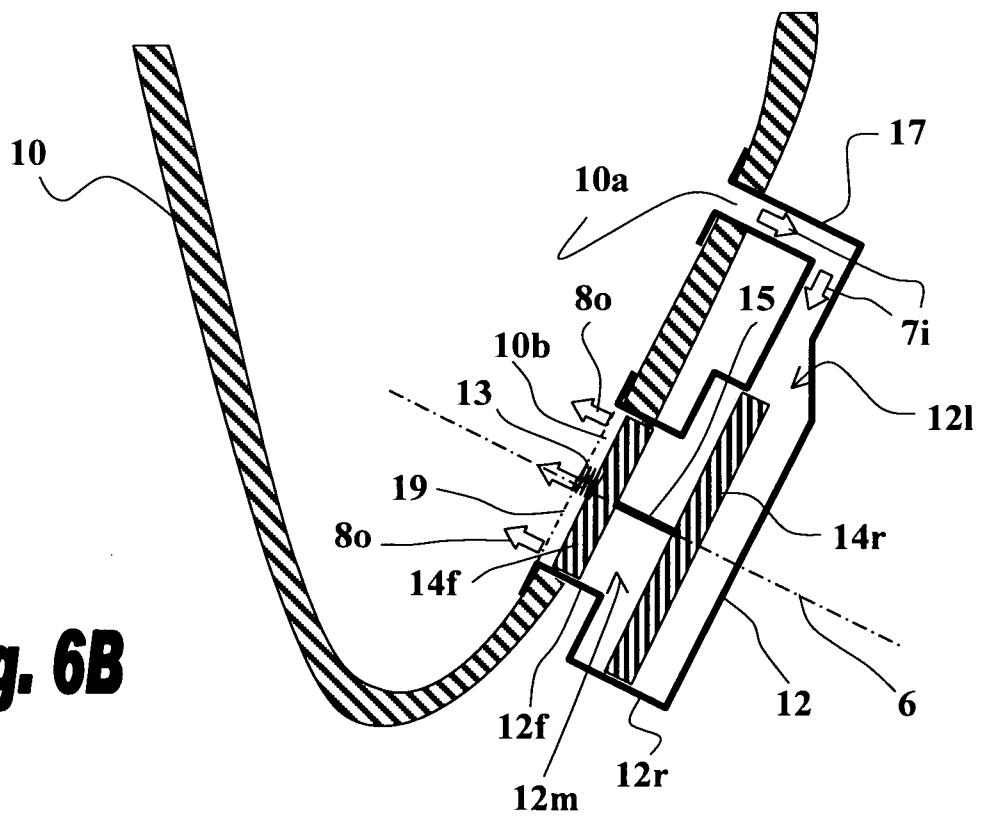


Fig. 6B



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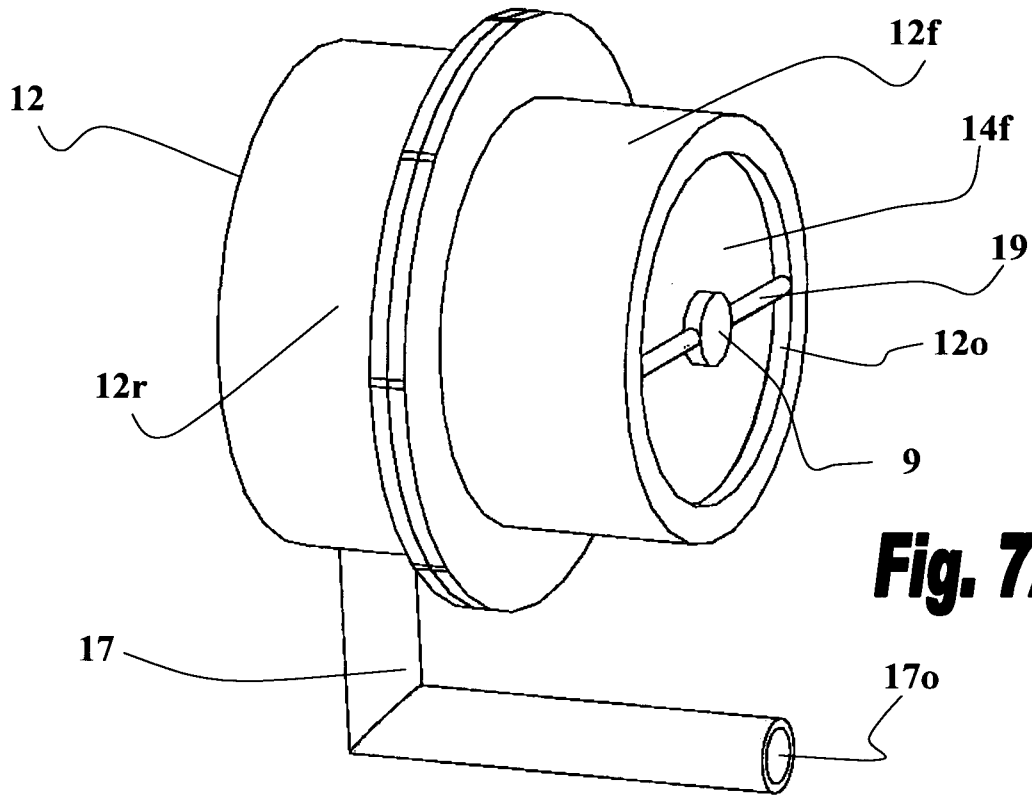


Fig. 7A

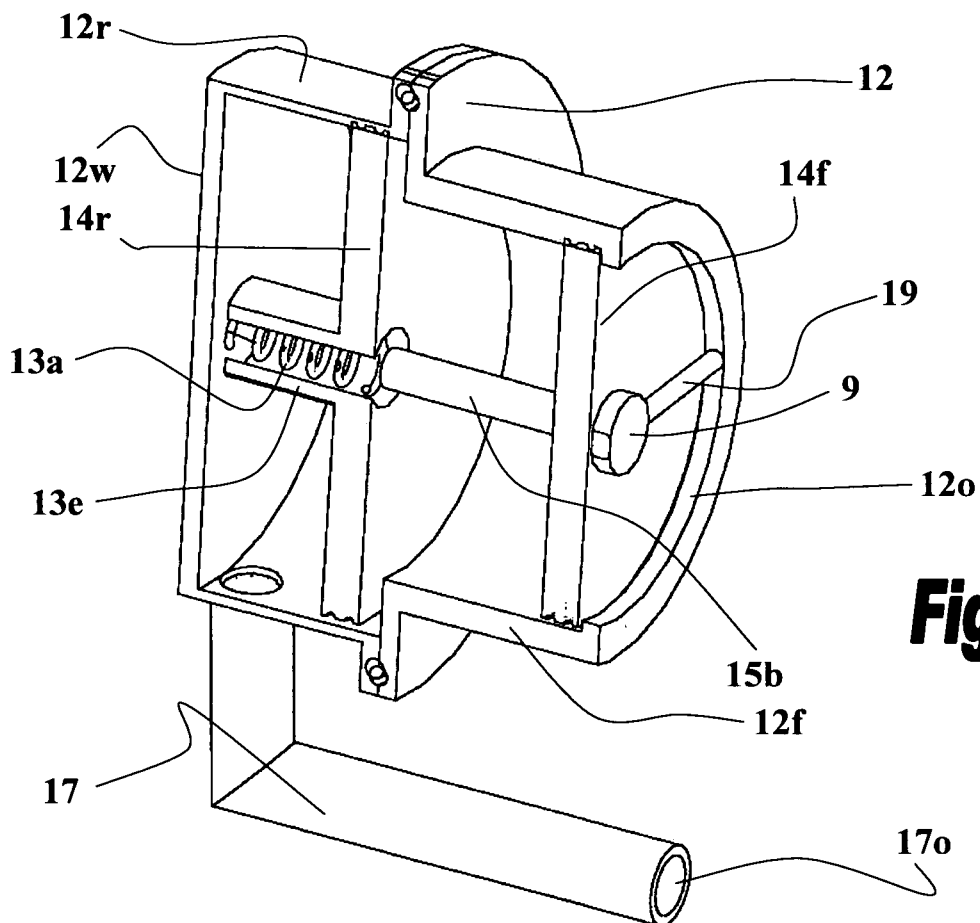
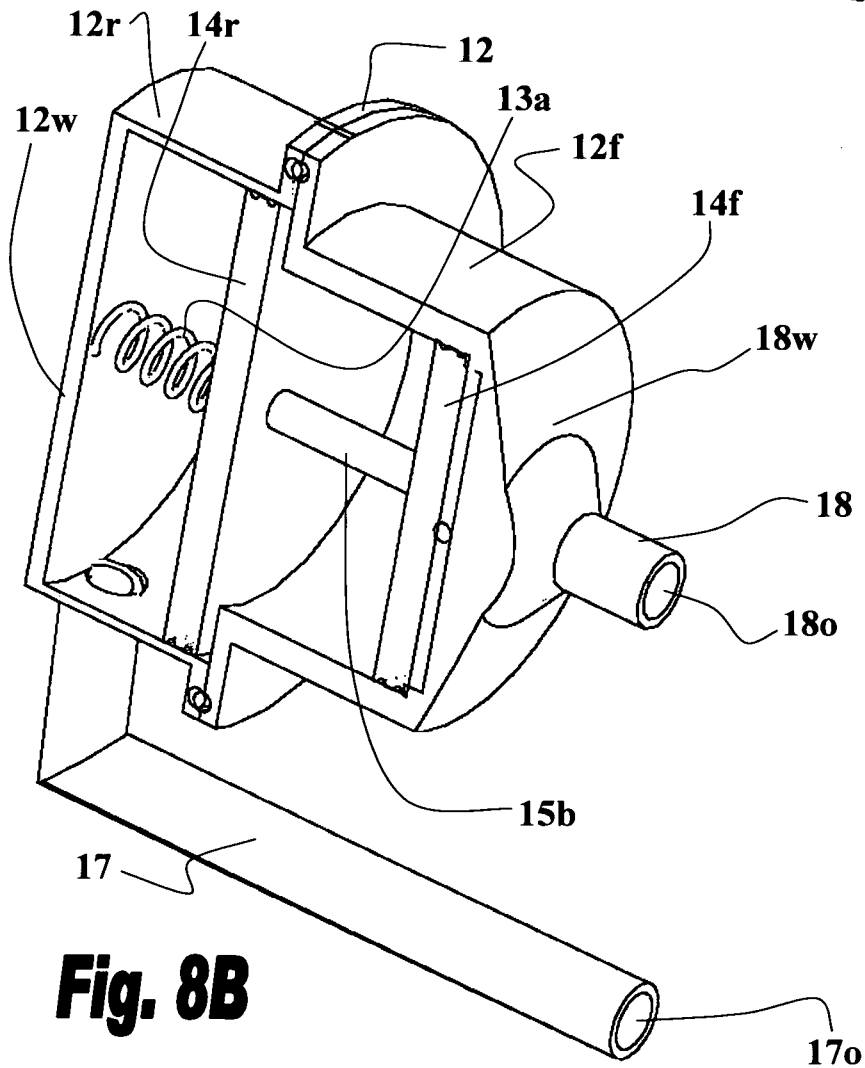
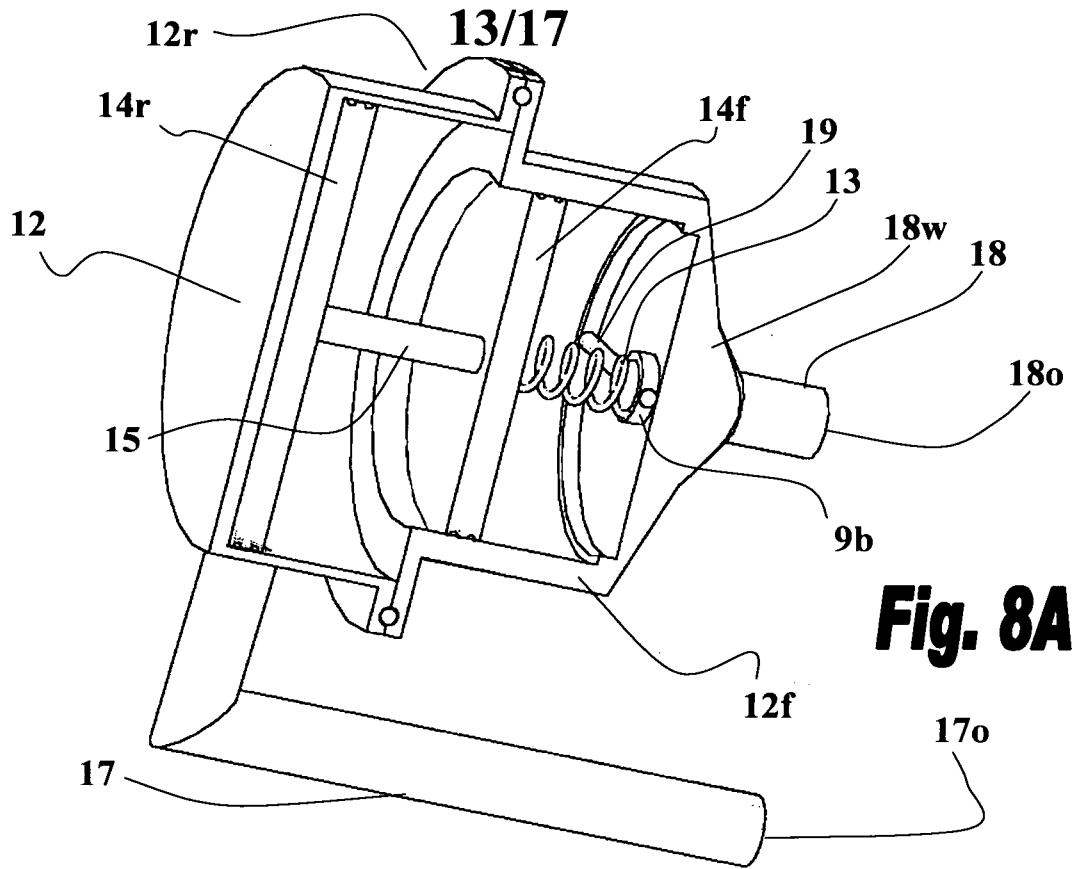


Fig. 7B



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Fig. 8C

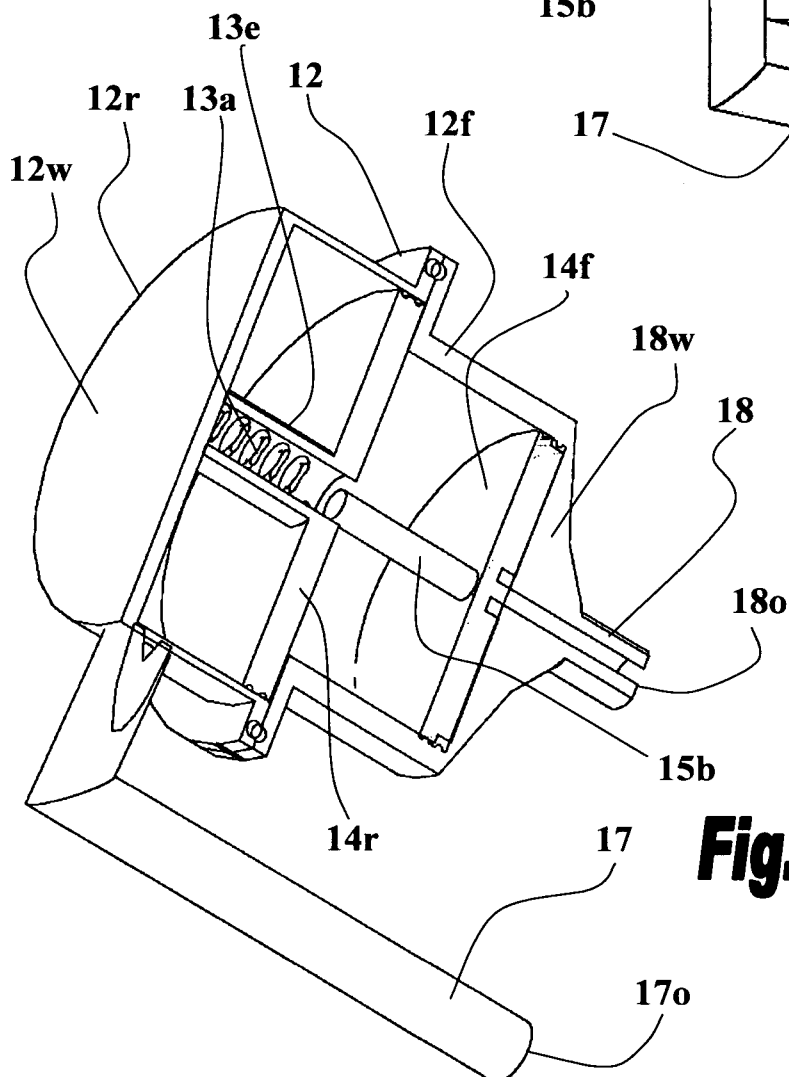
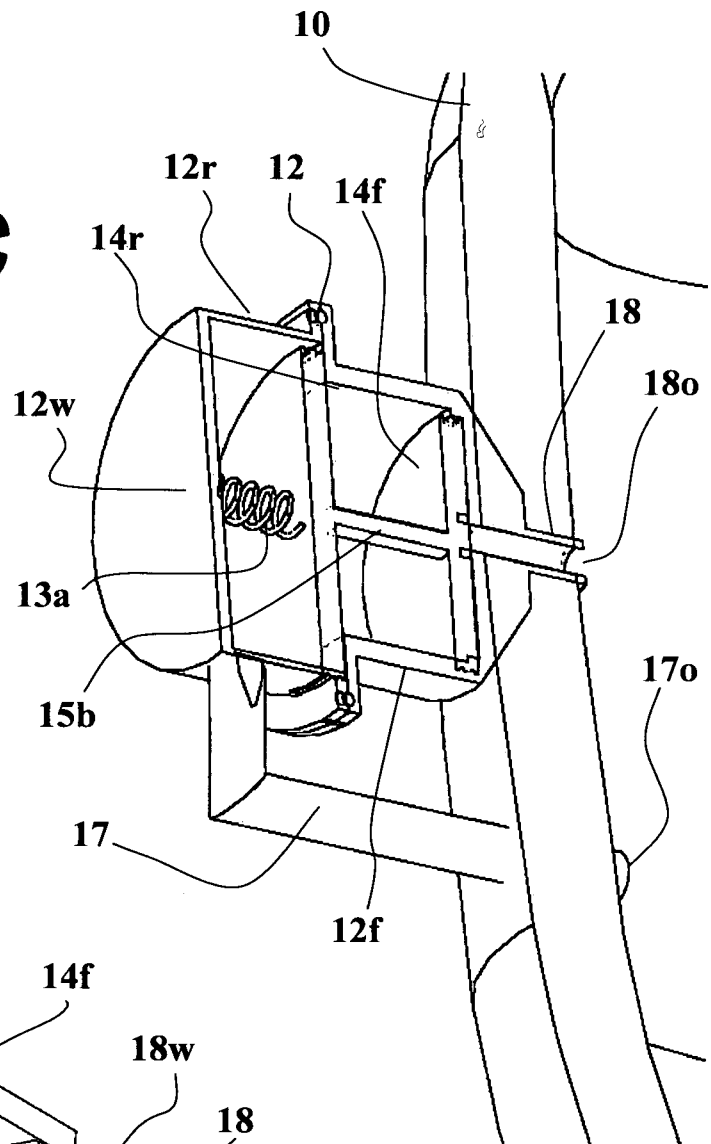


Fig. 8D

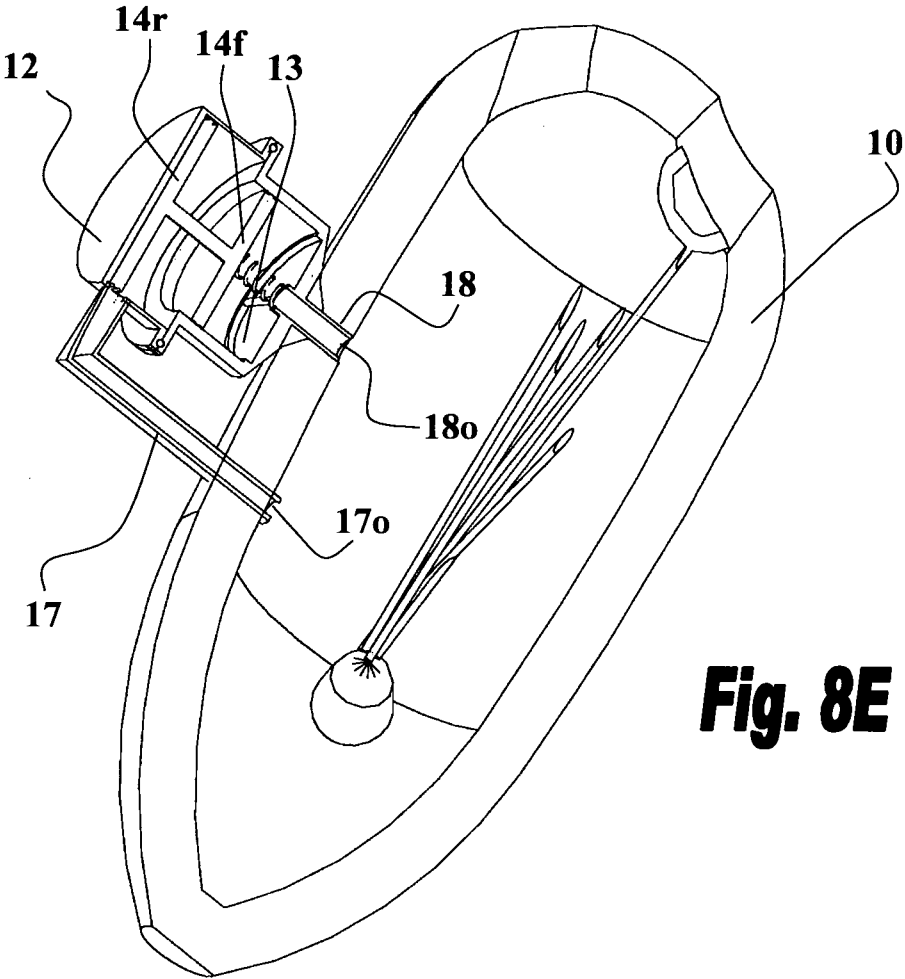


Fig. 8E

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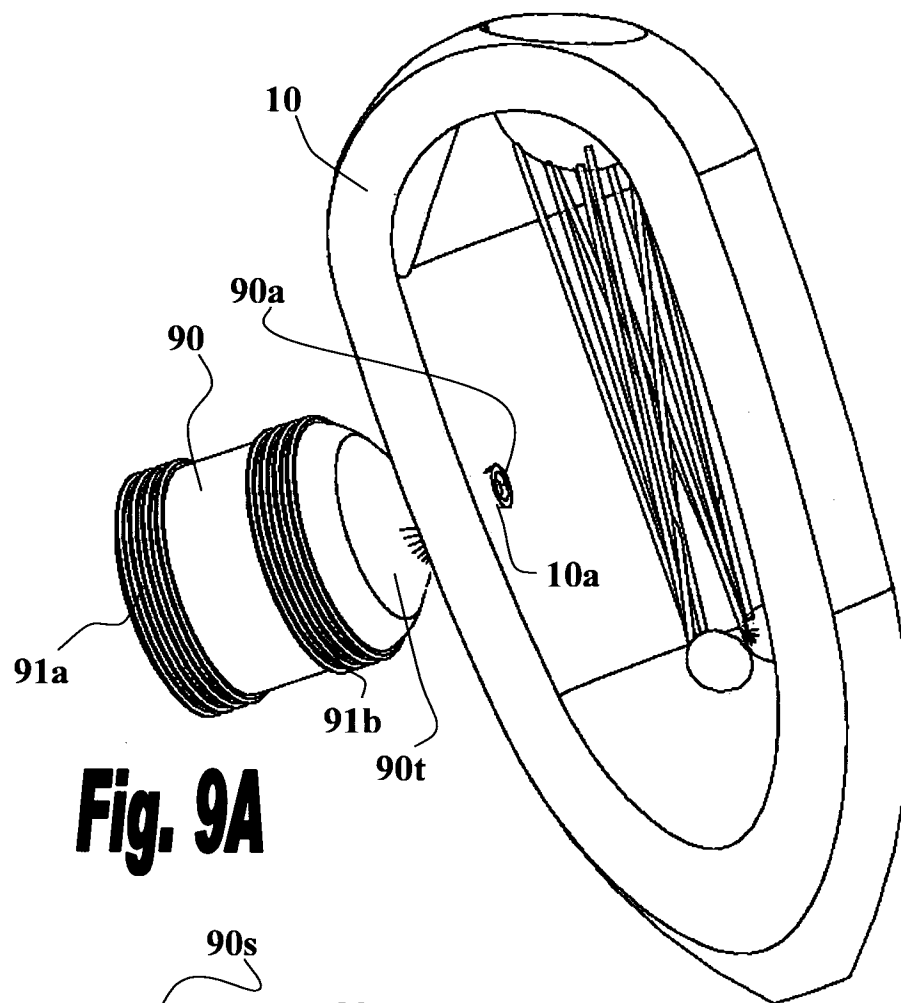


Fig. 9A

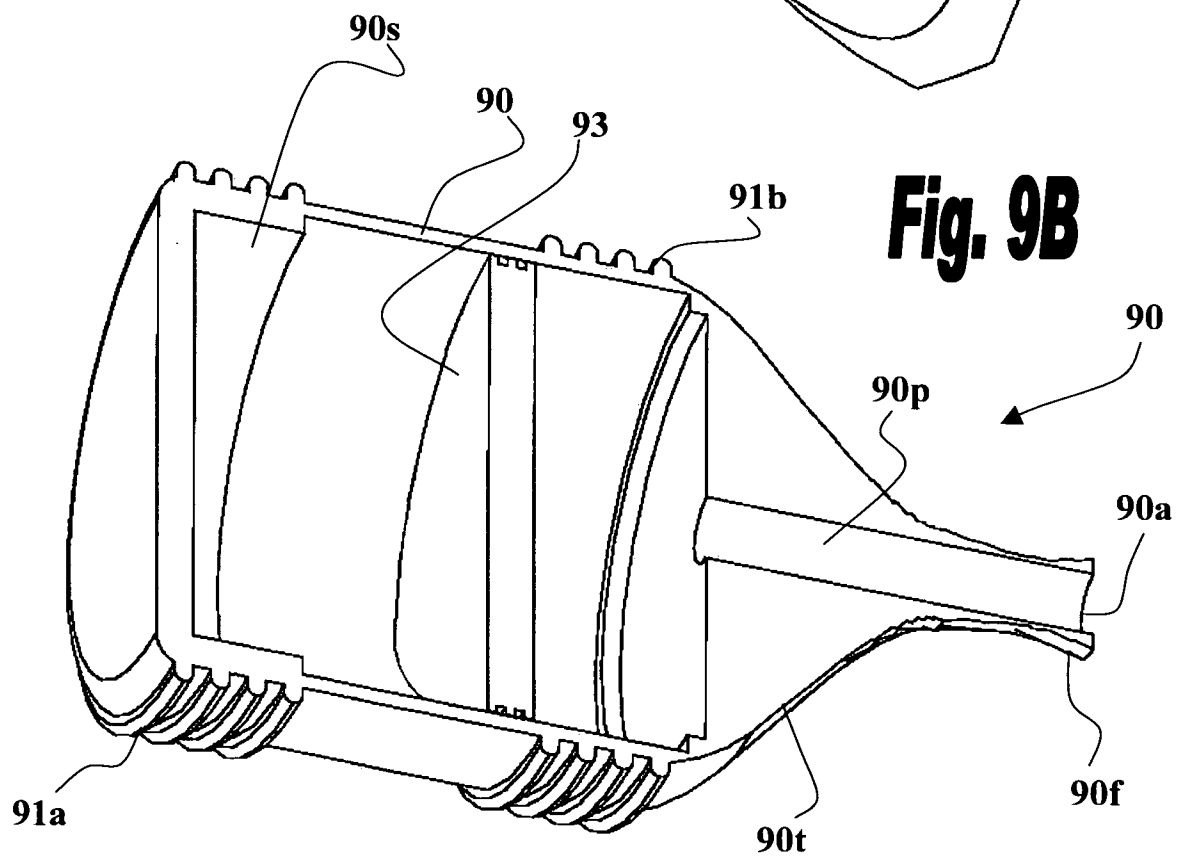


Fig. 9B

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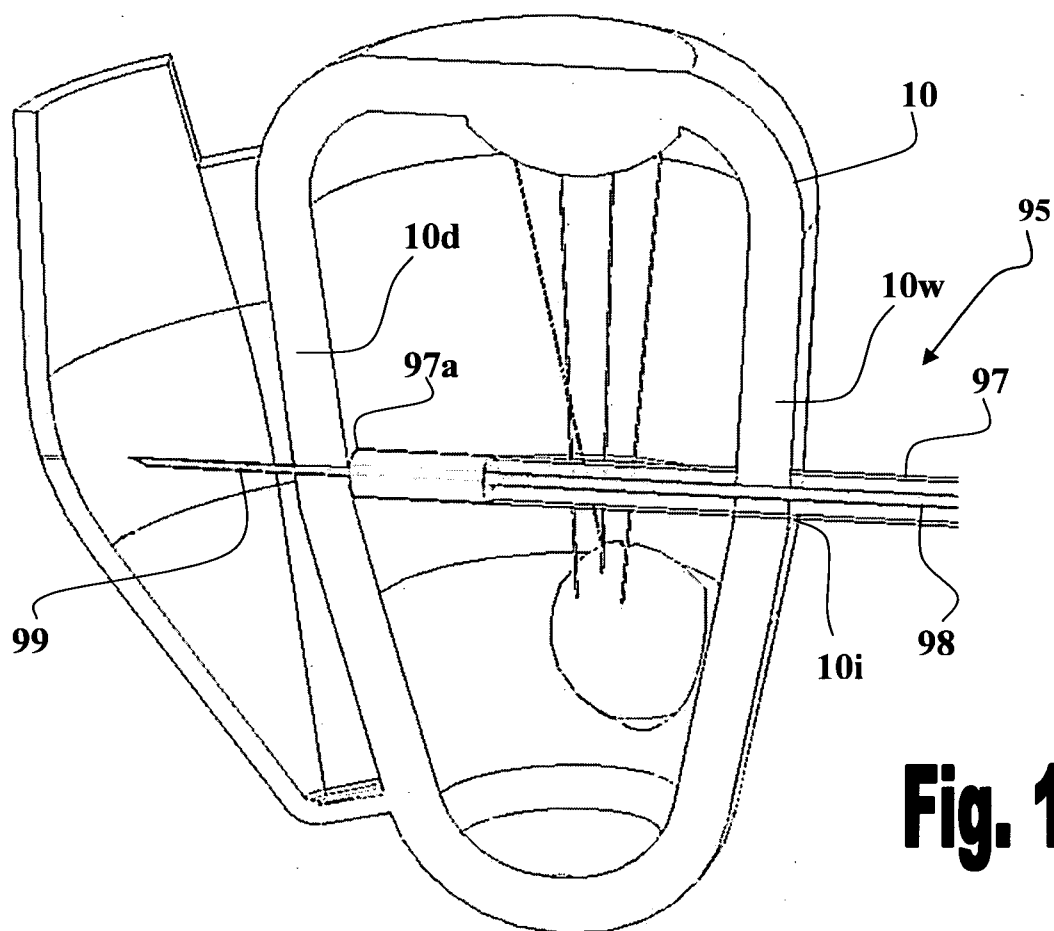


Fig. 10A

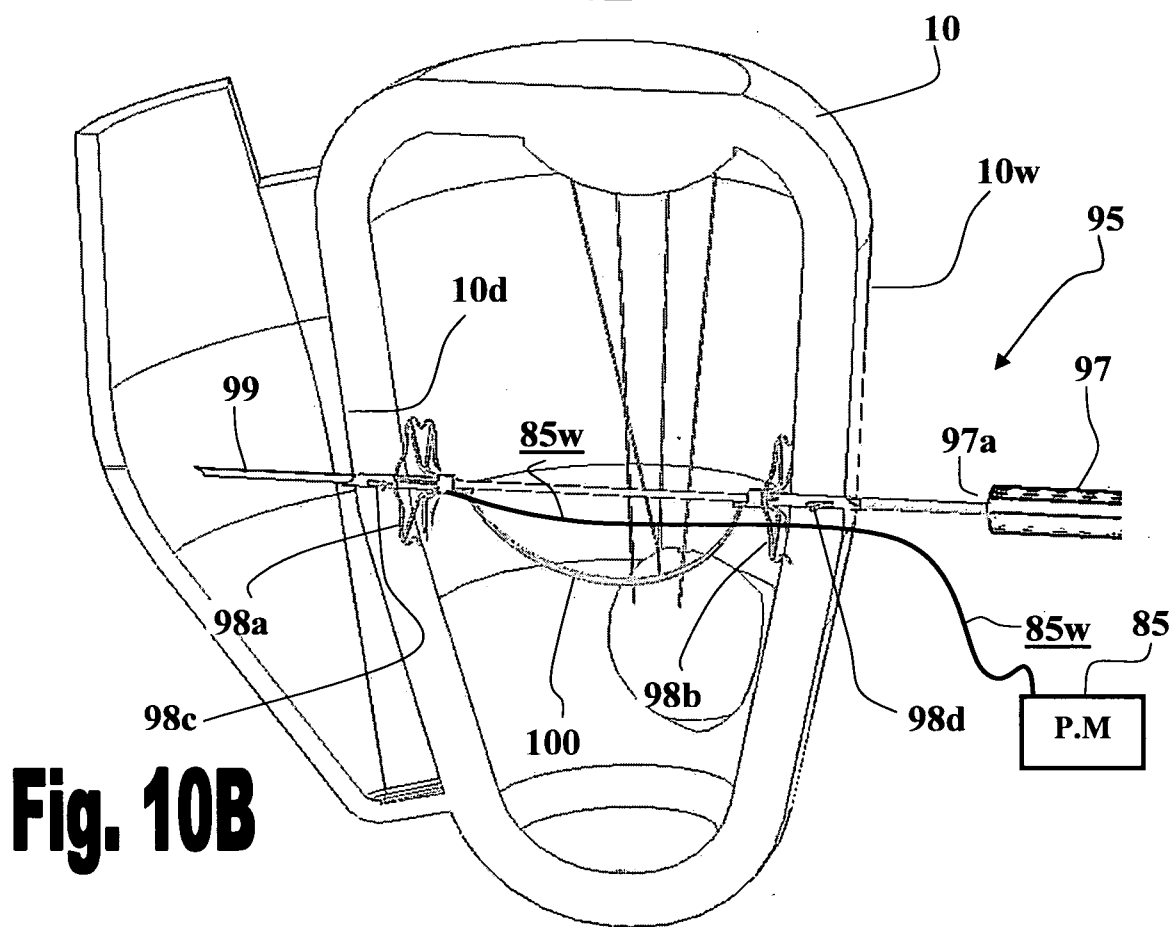


Fig. 10B