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(71) Applicant *(for all designated States except US)*: **CORASSIST CARDIOVASCULAR LTD.** [IL/IL]; 32 Maskit St., P.O.Box 12571, Bet-Merkazim, 46733 Herzliya Pituach (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LIPPERMAN, Michal** [IL/IL]; 14 Moshe Sne St., 49223 Petach Tikva (IL). **MEYER-BRODNITZ, Gideon** [IL/IL]; 2 Hillel St., 33073 Haifa (IL). **ROSEN, Lior** [IL/IL]; 12 Shtruk st., 64042 Tel-Aviv (IL). **ALMOG, Remo Eyal** [IL/IL]; 7/6 Rembrandt St, 64045 Tel-Aviv (IL). **TUBISHEVITZ, Amit** [IL/IL]; 5/4 Nissan St, 69715 Tel-Aviv (IL).

(74) Agents: **PYERNIK RUTMAN** et al.; Beit Etzion, 91 Herzl St., P.O.Box 10012, 84106 Beer-Sheva (IL).

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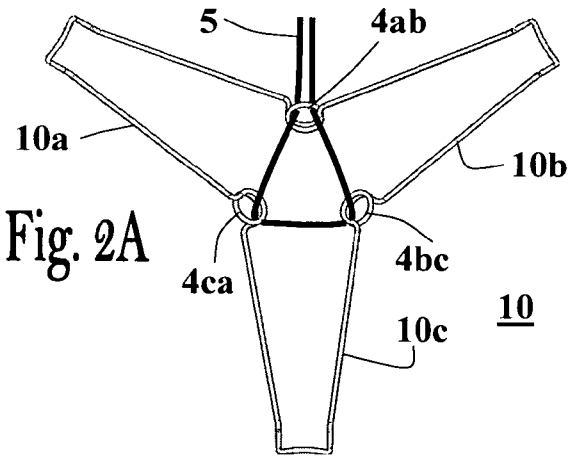

Fig. 2A

(57) **Abstract**: The present invention provides a ventricular function assisting device configured to be implanted in a heart ventricle designed in a form of flower-like configuration comprising two or more petals attached at a base section, said petals comprise elastic elements and/or portions capable of being elastically bent in radial directions and optionally also in sideway and/or longitudinal directions, which allow changing the state of the device between: i) a folded conformation, in which its petals are radially pressed inwardly towards each other to assume a reduced diameter of its flower-like configuration; and ii) a deployed conformation, in which the petals are opened in a radial outward direction as the device is discharged from the delivery tube or sheath into a heart ventricle and implanted thereinside in a preloaded state.

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VENTRICULAR FUNCTION ASSISTING DEVICE AND A METHOD AND APPARATUS FOR IMPLANTING IT

Field of the Invention

The present invention generally relates to a method and device for assisting a malfunctioning heart. More particularly, the invention relates to a device for improving the heart's left ventricular function, and to a method and apparatus for implanting said device in a treated heart.

Background of the Invention

Diastolic heart failure (DHF), a subset of congestive heart failure (CHF), is a clinical syndrome resulting from any structural or functional cardiac disorder that impairs the ability of the ventricle relax properly and fill with blood. The hospitalization rate of the patients suffering from DHF diastolic heart failure is similar to the hospitalization rate of patients suffering from systolic heart failure (SHF - a condition in which the heart is not contracting efficiently).

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 left ventricle muscle mass and/or changes in passive elastic properties of the myocardium, hence, the concern of an increase in the incidence of diastolic dysfunction as the aging of the western world population progresses.

To one of ordinary skill in the art, there is thus a need for, and it would be highly advantageous to have a method and device for improving heart ventricular function. 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 06/03310), PCT/IL04/00986 (WO 05/041745), PCT/IL04/00072 (WO 04/066805), PCT/IL2007/001180 (WO 08/038276) of the same assignee hereof, the descriptions of which are incorporated herein by reference. The aforementioned international patent applications describe elastic means used for improving diastolic function of the left ventricle of the heart by pushing and/or pulling, an inner and/or outer wall region respectively of the ventricle during the cardiac cycle while minimally disturbing the heart function. The operation of the devices described in these publications is based on storing energy from the myocardium during the systole and releasing it during diastole, thereby making it available to augment diastolic performance.

The present invention provides a device and a method for implanting it inside the left ventricle cavity, for assisting left ventricular function of the heart, which may be used independently, or in combination with imaging modalities such as Echocardiography and/or X-Ray Fluoroscopy.

It is therefore an object of the present invention to provide a method and device for augmenting diastolic performance in diastolic heart failure (DHF) patients.

It is another object of the present invention to provide a method and apparatus for implanting the ventricular function assisting device of the invention.

It is a further object of the present invention to provide minimally invasive methods for implanting the ventricular function assisting device of the invention through trans apical approach or through catheterization.

It is yet another object of the present invention to provide an imaging method and technique for guiding the implantation of the ventricular function assisting device of the invention in the left ventricle based on the inner morphology of the ventricle.

Other objects and advantages of the invention will become apparent as the description proceeds.

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 and 1B show an embodiment of a ventricular function assisting device of the invention comprising three-arms, wherein Fig. 1A shows a perspective view of the device with base point loops in an opened (free) state and Fig. 1B shows a perspective view of such device in a folded state;
- Figs. 2A to 2C show various ways for attaching a fixation suture string to the three arm of the ventricular function assisting device of the invention, wherein in Fig. 2A a single suture string is threaded through the base point

loops, in Fig. 2B a suture string is threaded through each pair of neighboring loops, and in Fig. 2C a suture string is attached to each loop;

- Figs. 3A and 3B show perspective views of a three-arms ventricular function assisting device of the invention, wherein the device in Fig. 3A comprises a biocompatible fabric material attached over the top end section of the arms of the device and in Fig. 3B the entire device is covered with such biocompatible fabric.
- Figs. 4A to 4D show another preferred embodiment of a three-arms ventricular function assisting device of the invention having base and vertex torsion loops, wherein Fig. 4A is a perspective view of the device, Fig. 4B is a top transparent view of the device encased inside a padding cover, Fig. 4C shows a perspective view of the device encased in the padding cover having fixation suture strings attached to the base torsion loops through the padding cover, and Fig. 4D shows a top view of the device having fixation suture strings attached to the padding cover near the base torsion loops;
- Figs. 5A to 5D show various possibilities for configuring the ventricular function assisting device of the invention, wherein Fig. 5A shows side and perspective views of a four-arms configuration in which the arms are curved outwardly, Fig. 5B shows side and perspective views of a four-arms configuration in which the arms are curved inwardly, Fig. 5C shows side and perspective views of a four-arms configuration having straightened arms, and Fig. 5D shows side and perspective views of a three-arms configuration having slanted arms;
- Figs. 6A to 6C show various configurations for the base and/or vertex (upper) points of the arms of the ventricular function assisting device of the invention, wherein Fig. 6A shows a "V"-like shape base point configuration made

without loops, Fig. 6B shows a "V"-like shape base point configuration comprising one or more torsion loops (multi-turn loops), and Fig. 6C shows a base point configuration comprising a single crossed loop (single loop);

- Figs. 7A to 7F show a configuration of a ventricular function assisting device of the invention that may be produced by laser cut, wherein Figs. 7A and 7B respectively show side and perspective views of a ventricular function assisting device of the invention which may be cut from a tube wherein the cuts are having a rectangular cross section, Fig. 7C shows a perspective view of a configuration having "Ω"-like shaped torsion sections in its arms, Fig. 7D shows a cut pattern in a opened deployed state wherein the arms of the device are formed by a laser cut forming a multi layered strip, Fig. 7E shows a close-up of a vertex of an arm in such multi layered strip configuration, and Fig. 7F shows the multi layered strip device in a folded conformation;
- Fig. 8A to 8E show implementations of the arms of the ventricular function assisting device of the invention with elastic elements, wherein Fig. 8A schematically illustrates an embodiment of the arms of the device by means of a wire having corrugated sections forming spring like structures, Figs. 8B and 8C show a perspective view of three-arms embodiments of the device of the invention having base torsion loops and corrugated sections forming spring structures in the arms of the device, Fig. 8D is a perspective view of a three-arms embodiment having corrugated sections forming spring structures in the arms and base sections of the device, and Fig. 8E schematically illustrates an embodiment of the arms of the device comprising pistons.
- Figs. 9A and 9B demonstrate a preferred method for establishing a direct channel to the left ventricle trough

a trans apical approach, by means of a trans apical sheath (tube), and a dilator, wherein Fig. 9A shows general structures of a trans-apical sheath and dilator which may be used in approaching the heart, and Fig. 9B shows the trans-apical sheath and dilator when the channel is established;

- Figs. 10A and 10B show longitudinal-section views of the trans apical sheath of the invention used for in the trans apical procedure, before (Fig. 10A) and after (Fig. 10B) introducing the dilator thereinto;
- Figs. 11A to 11F demonstrate a procedure for introducing a ventricular function assisting device of the invention by means of the delivery tool and trans apical sheath used in the trans apical approach into the left ventricle, wherein Fig. 11A illustrates insertion of the delivery tool with the ventricular function assisting device into the trans apical sheath, Fig. 11B shows a portion of the trans apical sheath introduced into the left ventricle with the delivery tool and the ventricular function assisting device inside its delivery tube in a folded state before released into the left ventricle, Fig. 11C shows the delivery tool and the ventricular function assisting device contained thereinside in a folded state and the mechanism of releasing the device from the delivery tool, Figs. 11D and 11E illustrate the state of the delivery tool components after the process of discharging the ventricular function assisting device inside the left ventricle, and Fig. 11F shows the implanted device inside the left ventricle after retracting back the delivery tool;
- Figs. 12A and 12B illustrate the final steps of implanting the ventricular function assisting device of the invention inside the left ventricle, of an optional fixation element wherein Fig. 12A illustrates attaching the device to an

external button, and Fig. 12B illustrates placing an apical cup externally over the apex of the heart;

- Figs. 13A to 13D schematically illustrate various techniques for deploying the ventricular function assisting device of the invention, wherein Fig. 13A illustrates using a delivery tool comprising an umbrella-like mechanism, Fig. 13B demonstrates a mechanism utilizing a balloon for opening the device, Fig. 13C demonstrates a mechanism employing wires forming basket-like shape, Fig. 13D demonstrates a mechanism employing two sets of wires;
- Figs. 14A and 14B respectively show bottom and top perspective views of four-arms ventricular function assisting device of the invention which arms are made from tube by laser cut;
- Figs. 15A and 15B respectively show a top view and a perspective view of a three-arms ventricular function assisting device of the invention, which arms are made in a stent-like configuration;
- Figs. 16A to 16F show perspective views of ventricular function assisting devices of the invention which arms comprise elastic slanted sections, wherein Figs. 16A and 16B show embodiments of a three-arms device, Figs. 16C and 16D show embodiments of three-arms devices which arms are manufactured in a stent-like configuration, Fig. 16E shows an embodiment of a four-arms device, and Fig. 16F shows a preferred embodiment of a six-arms device;
- Figs. 17A to 17C show perspective views of ventricular function assisting devices of the invention comprising a central post, wherein Figs. 17A and 17B show a three-arms embodiment of the device which arms comprise a slanted attachment section, and Fig. 17C show an embodiment of the device which arms further comprise elastic slanted sections;

- Figs. 18A to 18E schematically illustrate embodiment of the ventricular function assisting devices of the invention using spring elements in the devices' arms, wherein Figs. 18A and 18B respectively show a top view and a perspective view of a three-arms device which arms are attached via springs to a base section of the device, Fig. 18C shows a perspective view of an elastic arm comprising spring elements distributed along its length, Fig. 18D shows an embodiment of the elastic arm shown in Fig. 18C comprising interfacing members, and Fig. 18E shows a perspective view of a double wire embodiment of elastic arm shown in Fig. 18D;
- Fig. 19A and 19B respectively show a perspective view and a top view of three-arms embodiment of the ventricular function assisting device of the invention which arms form a spiral-star base section;
- Figs. 20A and 20B respectively show a perspective view and a top view of three-arms embodiment of the ventricular function assisting device of the invention which arms comprise a wavy portion and a portion forming a spiral-star base section;
- Figs. 21A and 21B show perspective views of ventricular function assisting devices of the invention comprising circular attachment sections, wherein Fig. 21A shows an embodiment comprising one circular attachment section, and Fig. 21B shows an embodiment comprising two circular attachment sections;
- Figs. 22A to 22E illustrate a delivery tube suitable for implanting the ventricular function assisting devices through a catheterization procedure, wherein Figs. 22A and 22B respectively show a side sectioned view and a transparent perspective view of the delivery tube with a three-arms ventricular function assisting device of the invention comprised in its distal end section in a folded

state, Fig. 22C shows a transparent perspective view of the delivery tube with the device having an anchoring helical element, Fig 22D shows a transparent perspective view of the delivery tube with the ventricular function assisting device shown in Fig. 21B comprised in its distal end section in a folded state, Fig. 22E shows a transparent perspective view of the delivery tube with the ventricular function assisting device shown in Figs. 15A and 15B comprised in its distal end section in a folded state;

- Figs. 23A to 23G schematically illustrate a possible catheterization implant procedure suitable and means for implanting the ventricular function assisting devices of the invention, wherein Figs. 23A to 23E schematically illustrate the steps of placing an anchoring element inside the heart ventricle by means of a torque wire (Fig. 23A), advancing the ventricular function assisting device towards the anchoring element (Fig. 23B), attaching the ventricular function assisting device to the anchoring element (Fig. 23C); deploying the ventricular function assisting device inside the heart ventricle, positioning of the device and removal of the delivery tube (Fig. 23D), removal of the torque wire (Fig. 23E), and wherein Figs. 23F and 23G respectively illustrate a side sectional view and a perspective view of the torque wire and anchoring element in an engaged (Fig. 23F) and detached (Fig. 23G) states;
- Figs. 24A and 24B schematically illustrate a delivery tube suitable for implanting the ventricular function assisting devices of the invention by a single step catheterization procedure;
- Figs. 25A to 25F schematically illustrate various anchoring elements suitable for attaching the ventricular function assisting devices in catheterization approach shown in Figs. 14 to 18 to a ventricular apex, wherein Fig. 25A illustrates an anchoring element comprising a

helical/spiral anchor, Fig. 25B illustrate an anchoring element comprising fixating barbs, and Figs. 25C to 25F illustrate a procedure of implanting an anchoring element of the invention comprising several hooks which is introduced into the myocardium through a needle;

- Figs. 26A to 26C show a simulation of an implantation procedure following the catheterization approach of the invention by means of the delivery tube shown in Fig. 16B; and, wherein Fig. 26A shows the step of attaching the ventricular function assisting device comprised inside the delivery tube in a folded state, Fig. 26B shows removal of the delivery tube, and Fig. 26C shows deployment of the ventricular function assisting device inside the heart ventricle.

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.

Summary of invention

The present invention provides a ventricular function assisting device configured to be implanted in a heart ventricle by means of trans apical or catheterization procedures. In general, the ventricular function assisting device of the invention is designed in a form of flower-like configuration (also referred to herein as star configuration) comprising two or more petals (also referred to herein as arms) attached at a base section, said petals comprise elastic elements and/or portions capable of being elastically bent in radial directions and optionally also in sideway and/or longitudinal directions, thus allowing changing the state of the ventricular function assisting device

between: i) a folded conformation, in which its petals are radially pressed inwardly towards each other to assume a reduced diameter of its flower-like configuration (i.e., a closed flower structure), thereby increasing the potential energy stored in the elastic elements and/or portions provided in the petals, such that it is capable of being placed inside a delivery tube or sheath; and ii) a deployed conformation, in which the petals are opened in a radial outward direction as the device is discharged from the delivery tube or sheath into a heart ventricle and implanted thereinside in a preloaded state such that the potential energy stored in the elastic elements or portions provided in the petals is constantly applying pressure against the walls of ventricle.

The diameter (in top view) of the ventricular function assisting device in a fully deployed state (also referred to herein as a free state i.e., when no energy is stored in the elastic elements/portions of the arms) is preferably somewhat greater than its diameter in its deployed conformation inside the heart ventricle. This configuration ascertains that the ventricular function assisting device is essentially implanted in a preloaded state (i.e., energy is stored in the elastic elements/portions of the arms).

The base section of the ventricular function assisting device may comprise a relatively thin (e.g., 0.1 to 0.7 mm) disk element comprising a central pass through bore for attaching it to the apex inside the heart ventricle, and a circumferential surface to which the bases of the petals are attached. Alternatively, the base section of the ventricular function assisting device comprises elastic torsion loops elements configured to elastically connect between bases of adjacent petals of the ventricular function assisting device, said torsion loops elements are advantageously employed to attach the

ventricular function assisting device to the apex inside the heart ventricle by means of fixation suture strings passing and/or attached to the torsion loops elements.

The ventricular function assisting device may be implanted in a heart ventricle by a trans apical or a catheterization procedure. Implanting the ventricular function assisting device in a minimally invasive trans apical procedure is preferably carried out utilizing a delivery tool comprising: a delivery tube adapted to receive and hold the ventricular function assisting device in a folded state in its distal end section; and a hollow inner shaft slidably passing inside the delivery tube, said hollow inner shaft comprising a clamping mechanism adapted to releasably hold suturing string(s) attached to the base section of the ventricular function assisting device thereby allowing pushing or pulling the ventricular function assisting device placed inside the delivery tube by means of the hollow inner shaft. The trans apical implantation procedure may include the following steps:

Opening a passage to the heart apex through the patient's chest;

marking the papillary muscles for visualization by suitable marking means (radiopaque marker, tag, needle, or screwable spring);

performing a purse string at the heart apex for the insertion of a trans-apical sheath thereinto by means of a dilator;

after the dilator is removed, introducing the delivery tool into the trans-apical sheath and advancing it distally through the trans-apical sheath until the distal end of the delivery tube is introduced into the ventricle via the distal opening of the trans-apical tube;

advancing the ventricular function assisting device in a folded state through the delivery tube of delivery tool into the

heart by means of the inner hollow shaft, and positioning it thereinside according to the papillary muscles marker;

manipulating the orientation of the ventricular function assisting device relative to the papillary muscles markers for properly positioning it inside the heart ventricle;

discharging the ventricular function assisting device inside the heart ventricle by distally pushing the inner hollow shaft, during which the ventricular function assisting device unfolds into a preloaded deployed state;

retracting delivery tool proximally;

retracting trans-apical sheath from the incision such that the trailing ends of the suturing string(s) threaded through the base section of the ventricular function assisting device are proximally withdrawn through the incision;

fastening the purse string to close the incision;

Suturing the incision by the purse string wires interlaced by the suturing string(s) to the apex tissue, thereby attaching the base section of the ventricular function assisting device to the bottom part of the ventricle.

In a catheterization procedure the implantation of the ventricular function assisting dvice of the invention may include the following steps:

Making a small incision in an artery or vein, according to the implantation route selected among either options described later on (e.g. transfemoral, axillary, subclavisn, retroperitoneal, trans-septal, or the like) by means of a needle, or any other standard equipment generally used for performing catheterization procedures for accessing into a blood vessel;

introduction through the incision a guiding tube comprising a torque wire slidably passing thereinside, wherein the distal end of the torque wire comprises an anchoring element releasably attached to it by means of a connecting mechanism;

advancing the guiding tube with the torque wire comprised in it through the vascular system of the patient into the heart ventricle by suitable visualization means Xray (e.g., fluoroscopy, angiography, ventriculography), echocardiography (e.g. trans-esophageal, trans-thoracic, intra-cardiac, 3D echo), MRI, or the like;

anchoring the anchoring element into the apex inside the ventricle;

retracting delivery tube proximally and removing it from the vascular system of the patient;

advancing a delivery tube into the ventricle over the torque wire, said delivery tube comprising a flexible distal section and the device placed inside the distal end portion thereof until the delivery tube reaches the anchoring element;

attaching the base section of the ventricular function assisting device to the anchoring element;

manipulating the orientation of the ventricular function assisting device according to the internal anatomy of the ventricle to properly place it thereinside;

retracting proximally and removing the delivery tube thereby discharging the ventricular function assisting device such that its arms are pressed against the inner walls of ventricle in a preloaded state (i.e., with some energy stored in the elastic elements/portions provided in the arms);

inserting a delivery catheter into the ventricle, said delivery catheter comprising a securing element;

attaching the securing element to the anchoring element;

releasing the attachment of the torque wire to the anchoring element and removing it from the patient's body.

According to one aspect the present invention is directed to a ventricular function assisting device comprising two or more arms each of which comprising a bottom end, a free top end and an intermediate section extending between said ends, wherein

said bottom ends of said two or more arms are attached in a base section of said device thereby forming a flower cup configuration, and wherein said two or more arms comprise elastic elements or portions configured such that they are capable of being elastically bent in radial directions relative to longitudinal axis of said flower cup configuration, and wherein said device is capable of being set into at least two conformations: i) a folded conformation, in which said two or more arms are pressed inwardly in a radial direction towards each other thus allowing fitting it in a delivery tube or sheath in said folded conformation; and ii) a deployed conformation, in which said two or more arms are opened in a radial outward direction, wherein said device is adapted to be attached at its base section to an apex inside a heart ventricle in said deployed conformation such that at least its free top ends are pressed against the walls of said heart ventricle thereby allowing said two or more arms to elastically bent in radial directions during contractions of said heart ventricle, and thereby store potential energy in said elastic elements or portions provided thereof, and to release said energy during expansions of said heart ventricle.

Portions of the arms of the ventricular function assisting device, or their entire length, or the whole ventricular function assisting device, may be adapted to be pressed against the wall of the heart ventricle, preferably in a preloaded state such that some energy is stored in the elastic elements/portions provided in the arms in its deployed state inside the heart ventricle.

Optionally, portions of the arms, or their entire surfaces, are covered by a padding element, said padding element is preferably adapted to promote tissue ingrowth. Alternatively or additionally, portions of the arms may comprise apertures

adapted to promote tissue ingrowth. Advantageously, the padding element may be adapted to release a drug into the tissue of the heart. Additionally, portions of the arms, or their entire area, may be covered by a layer of material suitable for promoting tissue growth and/or with hemocompatible coating.

Advantageously, the two or more arms may be adapted to elastically bend in sideway directions in response to twist movements and longitudinal movements of the heart ventricle in which it is implanted.

The base section of the ventricular function assisting device may comprise a disk element comprising a central pass through bore adapted for attaching it to the apex inside the heart ventricle, and a circumferential surface to which the bases of the one or more arms are attached.

The base sections of the ventricular function assisting device may comprise elastic torsion loops elements configured to elastically connect the bottom ends of adjacent arms of said ventricular function assisting device, wherein said torsion loops are further employed to attach said ventricular function assisting device to the apex inside the heart ventricle by means of suture strings passing through and/or attached to said torsion loops elements. The base section of the ventricular function assisting device may comprise a cup shaped element having an attachment bore provided in its base and a circumferential surface to which the arms of said ventricular function assisting device are attached.

The arms of the ventricular function assisting device may be manufactured to form an elastic mesh having rhombus, or other geometry, shaped apertures. Alternatively, the ventricular

function assisting device may be manufactured from an elastic wire or from a layered structure of elastic strips.

The arms of the ventricular function assisting device may further comprise elastic corrugations formed along their lengths, in their free top end, and/or in their bottom ends.

Advantageously, the arms of the ventricular function assisting device may comprise one or more bent sections for improving their flexibility.

The arms of the ventricular function assisting device may be attached to the base section by means of springs. Additionally or alternatively, the arms of the ventricular function assisting device may comprise one or more springs provided along their lengths for improving their flexibility.

In one specific embodiment the bottom sections of the arms of said ventricular function assisting device are curved such that a spiral star structure is formed in the base section.

According to another embodiment the ventricular function assisting device comprises one or more elastic circular attachment sections attached by means of a connecting strip the base section of the device, said base section comprising a pass through attachment bore for attaching the device to an anchoring element in a ventricle of the heart, wherein the elastic circular attachment sections are adapted to be mounted inside the heart ventricle such that their outer surface is pressed against the heart tissue. The elastic circular attachment sections may comprise a plurality of apertures distributed over their surfaces for promoting tissue ingrowth and adhesion. The elastic circular attachment sections are preferably designed to be rolled to allow placing the device inside a delivery tube

such that when the device is discharged from said delivery tube inside the heart ventricle the rolled elastic circular attachment sections open and become pressed over a circular sector (e.g., 90 to 350 degrees) of the wall of the ventricle.

According to another aspect the present invention is directed to a method for implanting the ventricular function assisting device by a trans apical or catheterization procedure, as described hereinabove and hereinbelow.

According to yet another aspect the present invention is directed to a delivery tool, as described hereinabove and herein below, for delivering and implanting the ventricular function assisting device of the invention by a trans apical procedure.

The present invention is also directed to a delivery system, suitable for implanting the ventricular function assisting devices of the invention by a single step, or multi steps, catheterization procedure, said delivery system comprising a delivery tube comprising: a proximal handle adapted for steering, turning, pushing and pulling the delivery tube, wherein the distal section of the delivery tube is made flexible and have a tapering tip configured to receive said ventricular function assisting device in a folded state (i.e., wherein the elastic arms of the device are pressed toward each other); a torque tube passing inside delivery tube along its length, said torque tube is made in a form of a hollow tube; a guidewire slidably passing inside the torque tube; and an anchoring element releasably attached to torque tube, said anchoring element comprising a waist section adapted to receive the base section of said ventricular function assisting device, a distally attached helical or spiral anchor, and an internal passage provided along its length being such that the guide wire

may be passed through the internal passage of the anchoring element.

A possible implantation procedure utilizing this delivery system may include the following steps:

making a small incision in an artery or vein as described hereinabove and introducing the guidewire through the vascular system into the heart ventricle;

fitting a ventricular function assisting device of the invention over the waist section provided in the anchoring element;

advancing the delivery tube comprising the torque tube, the anchoring element, and the ventricular function assisting device in its flexible distal portion, via the vascular system over the guide wire into the treated heart ventricle;

advancing the helical or spiral anchor outside of delivery tube via it tapered end tip by pushing torque tube distally;

screwing helical or spiral anchor into the heart tissue by turning of the torque tube via its handle;

adjusting the orientation of the ventricular function assisting device according to the internal anatomy of the ventricle by manipulating delivery tube;

discharging the ventricular function assisting device by retracting delivery tube proximally such that its arms change into a deployed preloaded conformation as they become pressed against the internal walls of the ventricle;

retracting distally the delivery tube;

releasing the attachment between the torque tube and the anchoring element; and

retracting proximally the delivery tube with the torque tube and guidewire inside it.

Detailed Description of Preferred Embodiments

The present invention provides a ventricular function assisting device configured to be implanted in one of the ventricles of the heart preferably in the left ventricle of a DHF heart. After implanting the device inside the ventricle it stores energy, originated from the heart motion, taken from the myocardium movement during the systole, and releases the energy stored in it during the diastole, thereby augmenting diastolic performance of the heart. More particularly, the ventricular function assisting device of the invention generally comprises two or more "arms" connected to each other at one end, wherein said arms are made from an elastic material, or comprise elastic elements, and the device is implanted in a ventricle in a preloaded state (i.e., the diameter of the device outside of the heart ventricle in a top view perspective when its arms are in a fully deployed state is greater than the diameter of the ventricle). Thus, additional elastic potential energy is stored in the bent arms of the device during the systole, as the arms are further pressed radially inward by the wall of the heart toward each other, whereas in diastole, as the ventricle walls are expanded and the arms of the device move radially outward, the elastic potential energy stored therein is released, while said preload ensures that the device is continuously loaded with elastic potential energy until the end of the diastolic phase, thereby available for diastolic performance augmentation.

According to one preferred embodiment of the invention the ventricular function assisting device is implanted inside a left ventricle such that the part where its arms are connected (also referred to as base area herein) is placed inside the ventricle at the apex of the heart, on the endocardial surface, and its arms are bent upwardly relative to said base points such that the arms rest on the inner walls of the ventricle. In this way,

the arms of the ventricular function assisting device are forced to bend toward each other during heart systole, and thereby store potential energy, due to their elasticity. Correspondingly, during heart diastole the potential energy stored in the arms of the device is converted into kinetic energy as said arms push the walls of the ventricle radially outward and thereby assist in heart expansion. The arms of the ventricular function assisting device preferably have a round and curved shape such that they fit the left ventricle shape and rest on the inner walls of the ventricle. The vertices of the arms of the device are preferably curved and rounded in order to provide a smooth and safe implantation of the device on the endocard, and for preventing them from being caught in the tissue of the inner walls of the ventricle. Additionally, the vertices of the arms may comprise elastic corrugations and/or elastic elements embedded therein for allowing them the flexibility to be loaded with energy taken from movement of the walls of the heart ventricle in radial and/or sideway and/or longitudinal directions in response to contraction, expansions, circumferential twists and longitudinal motions of the heart.

Fig. 1A shows a preferred embodiment of the ventricular function assisting device **10** of the invention comprising three arms, **10a**, **10b** and **10c**. In this preferred embodiment ventricular function assisting device **10** is made from an elastic wire **10w** formed in a shape of a three-arms star. The elastic wire **10w** is shaped such that three loops, **4ab**, **4bc** and **4ca**, are wound at the connections of the base points connecting arms **10a**, **10b** and **10c**. Suturing string (e.g., **5** shown in Fig.2A) are preferably passed through loops **4ab**, **4bc** and **4ca**, for fixation by suturing the device inside the ventricle, and for folding and retracting back the device inside the delivery tool (shown in Fig. 11A) used in the implantation process of the device. The device **10** can be also

attached to the heart tissue by small hooks, needles or screws, for example.

In the ventricular function assisting device exemplified in Fig. 1A each of the arms **10a**, **10b** and **10c**, comprises a relatively wide waist section **13** near the base area comprising loops, **4ab**, **4bc** and **4ca**, and the width of the arms is gradually decreased towards a relatively narrow neck section **14** located near their rounded vertices, such that a head section **15** is formed at the apexes of the arms.

The ventricular function assisting device **10** shown in Fig. 1A is in a free state, namely, no potential energy is stored in the device at this state. Fig. 1B illustrates the ventricular function assisting device **10** of the invention in a folded state, wherein the arms of the device are pressed toward each other for introducing it into the delivery tool (shown in Figs. 11A-C).

Ventricular function assisting device **10** may be made from any biocompatible material suitable for implementing an elastic wire, such for example stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The ventricular function assisting device may be manufactured from a radiopaque material, or alternatively, it may comprise radiopaque markers. The diameter of the elastic wire of the ventricular function assisting device may generally be in the range of 0.2 to 1 mm. The length of each arm **10a 10b 10c** may generally be in the range of 25 to 60 mm, preferably about 45 mm. The width at waist section **13** of the arms may generally be in the range of 10 to 20 mm, preferably about 15 mm, and at the neck section **14** generally in the range of 4 to 10 mm, preferably about 6 mm. The upper diameter encircling the device in top view

when in a fully deployed state (free state) may generally be in the range of 40 to 90 mm and its lower diameter in the same conditions may generally be in the range of 15 to 50 mm. It is however noted that the parameters defined above may vary depending on the dimensions of the heart to be treated.

As demonstrated in Figs. 2A to 2C, a fixation suture string (**5**) can be attached to the ventricular function assisting device **10** in various ways. Fig. 2A illustrates an example wherein a single suture string **5** is threaded through the base loops, such that it is passed circularly through the base loops **4ab**, **4bc** and **4ca**, formed at the bases of the arms. In this example string **5** introduced through loop **4ac**, passes through base loops **4ab** and **4bc**, and then passed again through base loop **4ac**. In Fig. 2B separate suture strings, **5a**, **5b** and **5c**, are threaded through corresponding pairs of neighboring base loops,(**4ca** and **4ab**), (**4ab** and **4bc**) and (**4bc** and **4ca**). In the example shown in Fig. 2C separate suture strings, **5ab**, **5bc** and **5ca**, are attached to corresponding base loops, **4ab**, **4bc** and **4ca**.

Figs. 3A and 3B show perspective views of two preferred embodiment wherein the ventricular function assisting device **10** of the invention further comprise padding covering portions of the device, or its entirety. Fig. 3A shows a preferred embodiment wherein end vertices sections of the arms, **10a**, **10b** and **10c**, of device **10** comprise corresponding padding elements, **8a**, **8b** and **8c**. The padding elements may be made from a biocompatible fabric configured to partly or totally cover the device's arms or even cover the whole device. For example, padding elements **8a**, **8b** and **8c**, may comprise a grid or a fabric/polymeric in a knit, braid, or woven structure. Preferably, padding elements **8a**, **8b** and **8c**, are made from PET, synthetic or biological polymer, and/or from other suitable biocompatible fabric materials, stretched over end vertex

sections of the arms' of device **10** for promoting tissue growth and adhesion thereof to the heart tissue. The adhesion of padding elements, **8a**, **8b** and **8c**, by tissue ingrowth to the heart tissue assists in distributing the forces applied by the arms of the device over the heart tissue, and in preventing penetration of the tips of the arms into the heart tissue. Of course, other suitable materials and designs may be used for the padding elements.

Fig. 3B shows an embodiment **60** wherein the entire device (**10**) is covered with a padding element **61** made from a biocompatible material suitable for promoting tissue ingrowth and adhesion as discussed above. In this preferred embodiment the padding element **61** comprises inverted "V"-shaped sleeves **60a 60b 60c** designed to enclose the arms (**10a 10b 10c**) of the ventricular function assisting device of the invention, and corresponding base pockets **1ab 1bc 1ca** designed to enclose the torsion base loops of the device (**4ab 4bc 4ca**).

Figs. 4A to 4D show a preferred embodiment of a three-arms ventricular function assisting device **11** of the invention having torsion loops **4ab 4bc 4ca** at the base of the arms, and vertex torsion loops **7a 7b 7c** provided in the vertex of each of the arms **11a 11b 11c**. Fig. 4A shows a perspective view of device **11** and Fig. 4B shows a top transparent view of device **11** encased inside a padding cover **12**. Padding cover **12** comprises inverted "V"-shaped sleeves designed to enclose arms **11a 11b 11c** of device **11** and their vertex torsion loops **7a 7b 7c**, and corresponding base pockets **6ab 6bc 6ca** designed to enclose the torsion base loops **4ab 4bc 4ca** of device **11**. Figs. 4C and 4D respectively show a perspective view and a top view of device **11** encased in padding cover **12** further comprising fixation suture strings **9ab 9bc 9ca** attached to the base torsion loops (**4ab 4bc 4ca** seen in Fig. 4B) through the padding cover **12** or attached to

the padding cover **12** near the base torsion loops at the bottom of the base pockets **6ab 6bc 6ca.**

Ventricular function assisting device **10** or **11** can be designed in different shapes suitable for fitting to the left ventricle morphology, as demonstrated in Figs. 5A to 5D, with different number of arms, with different arm shapes and lengths, with different enclosing diameters at the upper (vertex) and lower (base) loops, and with different numbers and diameters of loops at the arms vertex and at the base area of the devices. Fig. 5A shows side and perspective views of a rounded four-arms configuration **3a** of the ventricular function assisting device of the invention, in which the arms are curved outwardly. Fig. 5B shows side and perspective views of a four-arms configuration **3b** in which the arms are curved inwardly. Fig. **5C** shows side and perspective views of a four-arms configuration **3c** in which the arms are relatively straight. Fig. 5D shows side and perspective views of a three-arms configuration **3d** having relatively straight arms, wherein said arms are slanted relative to a longitudinal axis **3x** of the device and comprise one or more base torsion loops formed from wire loops/turns.

Figs. 6A to 6C illustrate preferred configurations of the arms base sections, wherein Fig. 6A shows a base point configuration made without loops, Fig. 6B shows a base point configuration comprising one or more torsion loops, and Fig. 6C shows a base point configuration comprising a single-turn (crossed) loop.

The ventricular function assisting device of the invention may be produced by means of laser cutting, as exemplified in Figs. 7A to 7F. Figs. 7A and 7B respectively show side and perspective views of a ventricular function assisting device **50** of the invention comprising elastic corrugations wherein the vertex sections **50u** of the arms are configured in a "M"-like shape, and

the base section **50b** connecting said arms are configured in a "W"-like shape. This "M"-like and "W"-like curve shaping of the vertex and base areas of the arms of device **50** is designed to reduce stresses which may develop at those areas during operation of the ventricular function assisting device, when implanted inside a ventricle. Of course, vertex sections **50u** and base sections **50b** may be configured to comprise additional elastic corrugations for adding more flexibility in these areas of the device. Fig. 7C shows a perspective view of a specific embodiment **53** wherein the arms further comprise "Ω"-like shaped torsion sections **55** for adding flexibility in sideway directions, thus further reducing stresses that may develop over the arms during device operation, particularly stresses related to the ventricular twist and longitudinal motion.

Ventricular function assisting devices **50** and **53** may be manufactured by laser cutting techniques, such that it may be cut from a tube made for example from stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The diameter of devices **50** and **53** in top view when in a fully deployed state (free state) may generally be in the range of 40 to 90mm, preferably about 65mm, and the thickness of the cut material may generally be in the range of 0.4 to 1.5mm, preferably about 0.8mm. In this way, the laser cutting the tube (not shown) in the desired shape produce rectangular cross section wires, **50w** and **53w**, from which devices **50** and **53** are respectively formed. The geometric dimensions of rectangular cross section wires **50w** and **53w** of ventricular function assisting devices **50** and **53** may generally be in the range of 0.4×0.4 to 1.5×1mm, preferably about 0.5×0.5mm.

Figs. 7D to 7F illustrate another specific embodiment **51** wherein the arms of the device are made from a multi layered strip. Similarly, device **51** can be manufactured by means of laser cutting techniques, and it is similarly designed with "M"-like and "W"-like curve shaping of the vertex (**51u**) and base (**51b**) areas of the arms. As best seen in Fig. 7E, showing a close-up of vertex **51u** of an arm in multi layered strip configuration device **51**, in this example the arms are cut to comprise three layers which are interconnected at the central vertex points **51t** of the "M"-like and "W"-like curved sections. Fig. 7F shows the multi layered strip device **51** in a folded conformation.

The multi layered strip device **51** is mainly designed to reduce the stresses that may develop while maintaining the applied forces in the rectangular cross section of ventricular function assisting devices **50** and **53**. Multi layered strip device **51** may be manufactured by laser cutting techniques, such that it may be cut from a tube made for example from stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The diameter of multi layered strip device **51** in top view when in a deployed state may generally be in the range of 40 to 90 mm, preferably about 65 mm, and the overall thickness of its layered structure may generally be in the range of 0.4 to 1.5 mm, preferably about 0.8 mm. In this specific embodiment, the laser cutting the tube (not shown) in the desired shape produce three adjacent elongated strips **51s** (shown in Fig. 7E) forming the layered strip of device **51**. The geometric dimensions of each strip **51s** in ventricular function assisting device **51** may generally be in the range of 0.4×0.1 to 1.5×0.4 mm, preferably about 0.8×0.2 mm, and the gap between such adjacent strips **51s** is preferably about 0.1 to 0.4 mm.

Figs. 8A to 8E demonstrate specific embodiments of three-arms ventricular function assisting devices of the invention configured to comprise means for reducing operation stresses which may develop over the arms of the devices. Fig. 8A schematically illustrates an embodiment of the arms (e.g., **10a**, **10b** and **10c** in Fig. 1A) of the ventricular function assisting device of the invention comprising corrugated (wavy) sections **10s** designed for assisting in the longitudinal contraction of the arms.

Fig. 8B shows a specific embodiment **70** of the three-arms ventricular function assisting device of the invention comprising base torsion loops **7ab 7bc 7ca**, wherein the upper section of the arms **70a 70b 70c** comprise corresponding elastic corrugated sections **71a 71b 71c**. More particularly, in each inverted "V"-shaped arm (**70**) a pair of sinusoidal-shape corrugated sections (**71**) are formed at the upper portion of the arm, said pair of sinusoidal-shape corrugated sections (**71**) are formed in the plane of the arm and preferably being symmetric relative to the longitudinal axis of the arm (not shown). In this example each corrugated sections (**71**) is made to consist of two consecutive sinusoidal patterns designed to absorb forces applied along the longitudinal direction of the arms.

Fig. 8C shows another specific embodiment **72** of the three-arms ventricular function assisting device of the invention comprising base torsion loops **7ab 7bc 7ca**, wherein the arms **72a 72b 72c** comprise corresponding pairs of elastic corrugated sections **73a 73b 73c** formed along a substantial portions of their lengths. Similarly, each inverted "V"-shaped arm (**72**) comprise a pair of sinusoidal-shape corrugated sections (**73**) formed in the plane of the arm and which are preferably being symmetric relative to the longitudinal axis of the arm (not shown). In this example each corrugated sections (**71**) is made to

consist of 4.5 consecutive sinusoidal patterns. Of course other wavy patterns having more or less corrugations are also possible. This specific embodiment is designed to absorb forces applied along the longitudinal direction of the arms and also to allow the arms to elastically bend in sideway directions responsive to heart circumferential twists occurring during its operation.

Fig. 8D shows another specific embodiment **74** of the three-arms ventricular function assisting device of the invention wherein the arms **74a 74b 74c** of device **74** are formed from elastic corrugations **75a 75b 75c** formed along the entire length of the arms, and wherein arms **74a 74b 74c** are connected at the base area of device **74** by means of corresponding cascaded "Ω"-like shaped torsion sections **Ωab Ωbc Ωca**. Similarly, the corrugations (**75**) formed in each arm comprise a pair of sinusoidal-shape corrugated sections (**75**) formed in the plane of the arm and which are preferably being symmetric relative to the longitudinal axis of the arm (not shown). In this example the corrugations (**75**) consist of 7.5 (not obligating) consecutive sinusoidal patterns, but of course other wavy configurations comprising more, or less, elastic corrugations may be equally used. This specific embodiment is also designed to absorb forces applied along the longitudinal direction of the arms and to elastically bend in sideway directions responsive to heart twist movements.

Fig. 8E schematically illustrates an embodiment of the arms of the ventricular function assisting device comprising pistons **10p** designed for absorbing longitudinal movement of the heart.

The ventricular function assisting device of the invention is intended for on-pump, or off-pump, beating heart implantation after left thoracotomy or open chest surgery or minimal invasive

procedure (for trans-apical implantation procedure), or catheterization (for example, but not limited to, for Aortic retrograde, subclavian, axillary, retroperitoneal approachs or Antegrade femoral venous route) performed by cardiac surgeons or interventional cardiologist. With reference to Figs. 9A, 9B, 10A, 10B, 11A to 11F and 13A to 13D the implantation procedure of the ventricular function assisting device of the invention by a trans-apical approach, may be performed as follows:

Initially, the papillary muscles (PM) **27** (as shown in Fig.9A) boundaries are marked for visualization by means of standard imaging methods (e.g., X-ray, TEE, U.S etc) or with external marker **28m**, generally a radiopaque marker, tag, or needle, preferably by means of a spring made of a stainless steel alloys, or a type of super alloy (e.g., 35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy. The PM marker **28m** having a length generally in the range of 3 to 9mm, preferably about 7mm, an outer diameter generally in the range of 3 to 6mm, preferably about 4.2mm and a pitch generally in the range of 1 to 3mm, preferably 2mm. The PM marker **28m** is placed externally to the left ventricle, screwed into the heart tissue **28**, at the gap between the papillary muscles **27**. PM marker **28m** is then utilized under echocardiography guidance for aiding the implantation process and placing the device in a proper location inside heart **28**; The PM marker can be removed post device implantation. The PM can be also marked through an internal marker by a catheterization procedure (e.g. contrast media injection). The device guidance in relation to the PM location can be performed through imaging modalities (e.g. Trans Esophageal Echo, Intra Cardiac Echocardiography etc.).

A purse string is then performed at the heart apex **28x** for the insertion of a trans-apical sheath **31** thereinto by means of a dilator **35**, in order to set a route for the insertion of the distal section **32d** of the trans-apical tube **32** into the heart **28** through a small dissection **28a** located at the middle of the

purse string (The trans-apical sheath **31** is washed prior to the insertion, generally with saline solution, preferably with saline and heparin, introduced thereinto through a washing port (**33s**, shown in Figs. 10A-10B);

After the purse string is performed, dilator **35** is retracted backwardly out from the trans-apical sheath **31**;

As demonstrated in Fig. 11A, the delivery tube **22** of delivery tool **30** is then introduced into trans-apical sheath **31**, after being washed generally with saline, preferably with saline and heparin introduced thereinto through inlet **38**. The delivery tool **30** is then advanced distally through trans-apical sheath **31** until the distal end **22d** of delivery tube **22** is introduced into the ventricle via the distal opening **32n** of tube **32** of trans-apical tube **31**;

Ventricular function assisting device **10** is then advanced in a folded state (shown in Figs. 11A and 11B) through the delivery tube **22** of delivery tool **30** into the heart **28**, and positioned thereinside according to the PM marker **28m**, or any other method used for marking and/or observing the PM (e.g., any suitable imaging modality such as TEE). Proper positioning of device **10** inside the heart **28** may be achieved by placing ventricular function assisting device **10** inside trans-apical sheath **32** such that one of its arms is aligned with the clamp **34s** provided on delivery tool's handle **34h**. In this way the device **10** can be advanced and discharged out of the delivery tool **30** into a proper position inside ventricle **28**, by maintaining a straight line between the external marker **28m** and clamping means **34s**. In other words, the location of the device's arm to be placed between the papillary muscles **27** is represented by the clamping means **34s** passing through the delivery tool's handle **34h**.

After ventricular function assisting device **10** is released inside heart ventricle **28**, during which it unfolds into a preloaded deployed state (shown in Fig. 11E), the delivery tool

30 is retracted out. Thereafter the trans-apical sheath **32** is slowly retracted out from incision **28a** such that the trailing ends of the fixation suturing string threaded through the base points of the device arms are withdrawn externally to the heart through incision **28a** and the purse string is immediately fastened to close the incision **28a;**

Incision **28a** is then sutured by the purse string wires interlaced by the suturing string wires **5** to the apex tissue, thereby attaching the loops of the ventricular function assisting device **10** to the bottom part of the ventricle.

Fig. 11B schematically illustrates the implantation of ventricular function assisting device **10** in heart ventricle **28,** by means of the delivery tool **30** of the invention. As shown, device **10** is introduced via incision **28a** made at the apex (**28x** Fig. 9A) of heart **28.** Device **10** is shown in Fig. 11D in its deployed state after being delivered into the heart **28** through delivery tube **22** of delivery tool **30.** In its folded state (shown in Figs. 11A-11C), the arms of device **10** are closely held together so that the diameter of device **10** is reduced to about 7mm, which allows sliding it through tube **22.**

With reference to the sectional view shown in Fig. 10A, trans apical sheath **31** generally comprises a distal tube **32** communicated with a proximal hollow connector element **33,** comprising a distal seal **33a,** which completely seals the trans-apical sheath **31** when it is closed (i.e., before introducing any additional device into the trans apical sheath), and a proximal seal **33b** having a centralized hole for the insertion and seal around the dilator **35,** or around the delivery tool **30,** which are introduced thereinto during the procedure and change distal seal **33a** into an opened state.

Fig. 10B shows a sectional view of trans-apical sheath **31** with dilator **35** passing distally thereinside via proximal and distal seals, **33b** and **33a**, and via tube **32**. The distal tip **35d** of dilator **35** comprises a graded diameter designed to allow the surgeon to dilate incision **28a**. The dilator **35** is introduced into trans-apical sheath **31** via proximal opening **33p** of hollow connector **33**, and passed therethrough until its distal end **35d** emerges via the distal opening of tube **32**.

As best seen in Fig. 9B, distal portion **32d** of trans-apical tube **32** and distal end **35d** of dilator **35** are introduced into heart **28** via incision **28a** until flange stopper **32f** at the distal end **32d** abuts the wall of heart **28**. With reference to Fig. 10B, in this state distal seal **33a** is fully opened and thus significant portions of the blood pressure are exerted over proximal seal **33b**. On the other hand, as seen in Fig. 10A, when dilator **35** is removed from trans-apical sheath **31**, the distal seal **33a** is closed and thus blood pressure is entirely exerted over distal seal **33a**. In this way, the distal ends **35d** of dilator **35** and **32d** of tube **32**, may be introduced via incision **28a**, and dilator **35** may be removed, while leaving tube **32** attached to heart **28** and preventing blood loss.

The delivery tool is inserted into the trans-apical sheath **31** after being washed generally with saline, preferably with saline and heparin through the fluid inlet **38**. When the delivery tool **30** is introduced into the trans-apical sheath **31** device **10** is folded and placed at the distal part of the trans-apical sheath **31** (possible with crimper device - not shown) as shown in Figs. 11A and 11B. A mechanism of a linear movement **34** comprising a movable handle **34h** operated by a motor (not shown) or manual screwing mechanism and clamping means **34s** are then distally progressed to release the device **10** from the delivery tool **30** into the heart **28** by pushing distally the inner (hollow) shaft

39, as shown in Fig. 11C-11D. The trailing ends of fixation suture string **5** passing, through and along the delivery tool **31**, are clamped and sealed around by clamping means **34s** provided in handle **34h**. As shown in Fig. 11D, distal seal **40** is placed around the fixation suture strings **5** for preventing blood leakage from the inner shaft **39** around the suture strings **5**, and proximal seal **41** is placed around the inner shaft **39**, for preventing blood leakage form the distal tube **32** around the inner shaft **39**. Handle **34h** may be retracted backwardly (proximally) for inserting ventricular function assisting device **10** back into trans-apical tube **32** for its relocation, if needed. After ventricular function assisting device **10** is released inside the heart ventricle, as shown in Fig. 11D, the fixation suture string **5** is discarded from the holding of clamping means **34s**, and it is then interlaced with the purse string wire **52** to the apex, as shown in Fig.11F.

Both the trans-apical sheath **31** and the delivery tool **30** can be made of a biocompatible material for short term use such as metal or plastic, and may be combined with radiopaque markers.

Trans-apical tube **32** may be made from a biocompatible material for short term use such as metal or plastic, preferably from PC or Stainless Steel, having a length generally in the range of 50 to 150 mm, preferably about 90 mm, and its outer diameter may be generally in the range of 6 to 15 mm, preferably about 8.3 mm, and its inner diameter may be generally in the range of 5 to 14 mm, preferably about 8 mm.

The Delivery Tool **30** may be made from a type of biocompatible material for short term use, such as, stainless steel, for example, or stainless steel 303, its length may generally be in the range of 150 to 350 mm, preferably about 250 mm, its outer diameter may generally be in the range of 5 to 14 mm, preferably

about 8 mm and its inner diameter may generally be in the range of 4 to 14 mm, preferably about 7.3 mm. The washing tube **38** may be made from a type of biocompatible plastic or PC for short term use.

As demonstrated in Figs. 12A and 12B, fixation suture string **5** may be attached to an external button **55**, or to an apical cup **56**, for providing a firm fixation and location of the ventricular function assisting device **10**.

With reference to Fig. 13A to 13D, the ventricular function assisting device **10** can be opened into a deployed state by means of different deployment means, capable of gradually opening its arms in the radial direction, from the bottom to the top of the device or from the top to the bottom of the device. With reference to Fig. 13A the ventricular function assisting device of the invention **120** may be deployed into the heart **28** by means of a delivery tool comprising an umbrella-like mechanism **126** comprising movable arms **126a** attached at the end of inner tube **39** which are adapted to open device **120** against the heart tissue. Fig. 13B demonstrates another possible opening mechanism, wherein balloon **122** attached at the end of inner tube **39** is utilized for opening the device **120**, by filling it with an inflation media. In another alternative implementation, demonstrated in Fig. 13C, wires **124**, attached to the lower part of device **120**, such that a basket like-shape is formed, are utilized for deploying device **120** in heart **28**. In another alternative implementation, demonstrated in Fig. 13D, two sets of wires, **127** and **128**, are used for deploying device **120**, wherein one set of wires **127** is attached to the upper part of the arms of device **120**, and the second set of wires **128** is attached to the lower part of the arms of device **120**.

The present invention is also directed to ventricular function assisting devices suitable for implantation by means of a delivery tube, and to catheter apparatuses and methods for carrying such catheterization implantations. In these embodiments of the ventricular function assisting device of the invention two or more "arms" are connected at one end thereof to a base element adapted to be attached to the apex inside the left ventricle by means of anchoring means, wherein the free ends of the arms and/or portions thereof are disposed over inner wall sections of the ventricle. At least some portion(s) of the arms of the ventricular function assisting device are made elastic such that it capable of storing energy originated from the heart motion, taken from the myocardium movement during the systole, and releases the energy stored in it during the diastole, thereby augmenting diastolic performance of the heart. The device may be implanted in a ventricle in a preloaded state (i.e., the diameter of the device outside of the heart ventricle in a top view perspective when its arms are in a fully deployed state is greater than the diameter of the ventricle). In this way, additional elastic potential energy is stored in the bent arms of the device during the systole, as the arms are further pressed radially inwardly by the wall of the heart toward each other, whereas in diastole, as the ventricle walls are expanded and the arms of the device move radially outward, the elastic potential energy stored therein is released, while said preload ensures that the device is continuously loaded with elastic potential energy until the end of the diastolic phase, thereby available for diastolic performance augmentation.

Figs. 14A and 14B show perspective views of four-arms ventricular function assisting device **130** of the invention designed for implantation by a catheterization or trans apical procedures. In this preferred embodiment **130** the arms **139** are attached perpendicularly relative to each other to a base

section **132**, thus forming a cross shape in top or bottom view (not shown). The base section **132** is preferably made from a relatively thin disk element comprising a pass through bore **133** for attaching device **130** to the apex inside the ventricle. The upper portion of the free end of arms **139** preferably comprises an array of holes **135** adapted for promoting tissue ingrowth. Arms **139** are preferably elastic curved arms having a outward curvature corresponding to heart ventricle shape, said elastic arms are preferably manufactured from biocompatible materials having elastic properties by a laser cutting or metalworking process, preferably by laser cutting. The length 0f arms **139** may generally be in the range of 30 to 60 mm, preferably about 45 mm, and their thickness may generally be in the range of 0.1 to 1 mm, preferably about 0.3 mm. The diameter of holes **135** may be about 0.1 to 0.5 mm. The diameter of base section **132** may be of about 1 to 5 mm, and the diameter of pass through bore **133** of about 1 to 5 mm. Of course, these sizes may be changed according to specific dimensions of a treated heart.

Figs. 15A and 15B respectively show top and perspective views of a three-arms ventricular function assisting device **140** of the invention designed for implant by a catheterization or trans apical procedures, which arms **149** are made in a stent-like configuration. Arms **149** are preferably, but not necessarily, attached to base section **142** in a typical three-arm star conformation, forming 120° angles between them. Base section **142** comprises a pass through bore **143** for allowing attaching it to the apex inside the ventricle by means of suitable anchoring means. Arms **149** may be manufacture by laser cutting from, but not limited to, Stainless steel, biocompatible metal alloy, nitinol, or conichrome alloy, forming mesh structure having rhombus, or other suitable geometry, shaped apertures (e.g., 3x stent geometry), thereby producing elastic arms capable of being elastically bent along their lengths. This mesh configuration of

the arms promotes tissue ingrowth and allows the arms to elastically bend inwardly in radial direction responsive to systolic heart retractions, and in sideway directions along their lengths responsive to heart twist movements. The length of arms **149** may generally be in the range of 30 to 60 mm, preferably about 45 mm, and their thickness may generally be in the range of 0.1 to 0.5 mm, preferably about 0.3 mm.

Figs. 16A to 16F show perspective views of ventricular function assisting devices of the invention designed for implant by a catheterization or trans apical procedures, which arms comprise elastic slanted sections. Device **150** in Fig. 16A is a three-arms device comprising elastic arms **159** attached to a base section **152**, preferably but not necessarily, in a typical three-arms conformation, wherein the upper portions **159b** of elastic arms **159** is bent outwardly and their tip sections are bent upwardly perpendicular to upper portions **159b** in order to define an attachment surface **159c** with the heart tissue. Tip sections **159c** of elastic arms **159** preferably comprise an array of apertures **159p** adapted for promoting tissue ingrowth. Lower sections **159a** of elastic arms **159** are preferably slanted relative to the longitudinal axis **155** of device **159** forming an acute angle **α** of about 20 to 80 degrees therebetween. The upper sections **159b** of elastic arms **159** is preferably bent to put upper portions **159b** more or less parallel to base section **152**. Base section **152** is preferably made in form of a cup comprising a central hole **153** in its base for allowing attachment thereof to the apex inside the heart ventricle by means of suitable anchoring means. This configuration allows elastic movements of upper section **159b** relative to lower section **159a** in response to systolic and diastolic heart movements.

Fig. 16B shows a similar three-arms device **110** wherein the upper portions **119b** of elastic arms **119** are bent such that an acute

angle is established between its lower section **119a** and its upper section **119b**. This configuration provides improved elasticity between the lower sections **119a** and the upper sections **119b** of elastic arms **119**. Elastic arms **119** are attached to base section **112** in a typical three-arms star conformation, said base section **112** is made in form of a cup comprising a central hole **113** in its base for allowing attachment thereof to the apex inside the heart ventricle by means of suitable anchoring means. The tip sections **119c** of elastic arms **119** are bent upwardly to define an acute angle between them and upper sections **159b** in order to define an attachment surface with the heart tissue. Tip sections **119c** of elastic arms **119** preferably comprise an array of apertures **119p** adapted for promoting tissue ingrowth. Lower sections **119a** of elastic arms **119** are preferably slanted relative to the longitudinal axis **115** of device **110** forming an acute angle **α** of about 20 to 80 degrees therebetween. The upper sections **119b** of elastic arms **119** is preferably bent in a downward direction thus forming an angle **β** of about 20 to 120 degrees between the upper section **119b** and the lower sections **119a** of elastic arms **119**. Similarly, this configuration allows elastic movements of upper section **119b** relative to lower section **119a** in response to systolic and diastolic heart movements.

Devices **150** and **110** are preferably manufactured from biocompatible materials having elastic properties by a laser cutting or metalworking process, preferably but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The lengths of arms **159** and **119** may generally be in the range of 30 to 60 mm, preferably about 40 mm, and their thickness may generally be in the range of 0.1 to 0.5 mm, preferably about 0.3 mm. The diameter of holes

159p and **119p** provided in tip section **159c** and **119c** may be of about 0.1 to 0.5 mm. The diameter of cup shaped base sections **152** and **112** may be of about 1 to 5 mm, and the diameter of their central holes **153** and **113** is preferably about 1 to 5 mm.

Fig. 16C shows another embodiment **130** of the ventricle function assisting device **110** shown in Fig. 16B, wherein the arms **139** of device **130** are made by laser cutting in a stent-like configuration forming a sequence of serially connected rhombus shaped sections. Of course other geometrically shaped sections may be produced by the laser cutting in the manufacture process of arms **139**. Arms **139** are attached to a cup-shape base section **132**, preferably not necessarily in a typical three-arms star conformation, wherein the cup-shaped section **132** comprises a central hole **133** in its base for allowing it to be attached to the apex inside the heart ventricle by means of suitable anchoring means. In a similar fashion, upper section **139b** of arms **139** is bent to form an acute angle relative to lower section **139a**. The tip sections **139c** of arms **139** are preferably flat rectangular sections forming an acute angle relative to upper sections **139b**, wherein each of the tip sections **139c** comprises an array of apertures **139p** adapted to promote tissue ingrowth. This configuration of ventricular function assisting device **130** allows the arms to elastically bend in a radial direction inwardly in response to systolic heart movements, and in sideway directions in response to heart twist movements.

Fig. 16D show a three-arms device **135** similar to device **130** shown in Fig. 16C, which arms are manufactured in a stent-like configuration forming a mesh of rhombus shaped holes. Of course, other geometrical shapes of the holes may be alternatively used. Similarly, arms **136** of device **130** are attached to a cup-shaped base section **134**, preferably but not necessarily in a typical three-arms conformation. The upper sections **136b** of arms **136** are

bent to form an acute angle relative to their lower sections **136a**, and the tip sections **136c** are bent to define attachment surface with heart tissue thereby forming an acute angle relative to upper sections **136b**. The tip sections **136c** are preferably also made in a stent-like configuration having rhombus shaped holes to promote tissue ingrowth.

Devices **130** and **135** are preferably manufactured from elastic biocompatible materials suitable for laser cutting, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The lengths of arms **139** and **136** may generally be in the range of 30 to 60 mm, preferably about 40 mm, and their thickness may generally be in the range of 0.1 to 0.52 mm, preferably about 0.3 mm. The diameter of holes **139p** provided in tip section **139c** may be of about 0.1 to 0.5 mm. The diameter of cup shaped base sections **137** and **134** may be of about 1 to 5 mm, and the diameter of their central holes **133** and **137** is preferably about 1 to 5 mm.

Fig. 16E shows an embodiment of a four-arms device **115** of the invention comprising elastic arms **116** attached to a cup-shaped base section **114** such that straight angles are obtained between adjacent arms, thereby forming a cross shape in top or bottom view (not shown). Lower sections **116a** of elastic arms **116** are preferably slanted relative to the longitudinal axis **117** of device **115** thus forming an acute angle **α** of about 20 to 80 degrees therebetween. The upper sections **116b** of elastic arms **116** is preferably bent in a downward direction thus forming an angle **β** of about 20 to 120 degrees between upper sections **116b** and the lower sections **116a** of elastic arms **116**. Similarly, this configuration allows elastic movements of upper section **116b** relative to lower section **116a** in response to systolic and

diastolic heart movements. Elastic arms **116** further comprise tip sections **116c** defining attachment surfaces with heart tissue, said tip sections **116c** are bent upwardly such that acute angles are formed relative to upper sections **116b**. An array of apertures **116p** is preferably provided in tip sections **116c** in order to promote tissue ingrowth.

Fig. 16F shows a preferred embodiment of a six-arms ventricular function assisting device **161** of the invention. Device **161** comprises a set of three long elastic arms **165** and another set of three short elastic arms **167**, said arms are attached to a cup-shaped base section **162** having a central attachment hole **164** in its base and they are arranged such that between two neighboring arms from the set of long arms **165** there is disposed one arm from the set of short arms **167**. Long arms **165** comprise lower, upper and tip, sections, as in arms **119** and **116**, which sections are bent in a similar fashion to form acute angles therenetween, and which tip section also comprise an array of apertures for promoting tissue ingrowth. Short arms **167** are preferably bent relative to the longitudinal axis (not shown) of device **161** forming an acute angle relative to it, said acute angle is more less the same as the angle formed between the lower sections of long arms **165** and said longitudinal axis. Short arms **167** further comprise tip sections at their free end, said tip sections are bent downwardly to define attachment surfaces with the heart tissue, said attachment surfaces are more or less parallel to the longitudinal axis of the device. Device **161** may be manufactured from similar materials and using similar manufacture techniques, as of devices **110** and **115**. The lengths of long arms **165** may generally be in the range of 30 to 60 mm, preferably about 40 mm, the lengths of short arms **167** may generally be in the range of 10 to 30 mm, preferably about 20 mm, and the thicknesses of both sets of arms may generally be in the range of 0.1 to 0.5 mm, preferably about 0.3 mm.

Figs. 17A to 17C show perspective views of ventricular function assisting devices of the invention having elastic arms arranged on a central post and which are designed for implant by a catheterization or trans apical procedures. Figs. 17A and 17B show a three-arms device **160** having elastic arms **169** having a long section **169a** attached to the upper end of post **160p**. Long sections **169a** of arms **169** are slanted downwardly relative to post **160p**, such that acute angles **α** are formed therebetween. Arms **169** further comprise a short section **169b** which is slanted upwardly to define an attachment surface with the heart tissue, thereby forming an acute angle **β** relative to the long sections **169a** of arms **169**. The attachment surfaces of short sections **169b** preferably have a curved shape for improved contact with the heart tissue. Post **160p** comprises a central pass through bore **160a** for attaching it to the apex inside heart ventricle by means of screws or barbs, for example.

Fig. 17C shows another embodiment of a three-arms device **163** which elastic arms **166** are arranged on a central post **163p**, wherein each of said arms **166** comprises a first section **166a** attached to post **163p**, said first section **166a** is bent downwardly such that an acute angle **α** of about 20 to 80 degrees is obtained relative to post **163p**. Arms **166** further comprise upwardly slanted intermediate sections **166b** forming angles **β** of about 50 to 150 degrees relative to first sections **166a**, and downwardly slanted tip sections **166c** forming angles **γ** of about 20 to 120 degrees relative to intermediate section **166b**, thereby defining attachment surfaces with the heart tissue. Attachment surfaces **166c** may comprise anchoring pins **166q** adapted to achieve a grip to the heart tissue. The lengths of arms **166** may generally be in the range of 20 to 60 mm, preferably about 35 mm, and their thickness may generally be in the range of 0.1 to 0.52 mm, preferably about 0.3 mm.

Figs. 18A to 18E illustrate embodiment of the ventricular function assisting devices of the invention using springs elements in the devices' arms. Figs. 18A and 18B respectively show a top view and a perspective view of a three-arms device **20** which arms **21** are attached by means of springs **23s** to a base section **23** comprising a pass through bore **23b** configured to attached device **20** to the apex inside the heart ventricle. Arms **21** are preferably curved about their longitudinal axis to define a curved attachment surface **21f** with the heart tissue. Arms **21** may comprise a base portion **21a** at their lower ends to which spring elements **23s** are attached, and an outwardly curved portion **21b** adapted to contact the heart tissue. Spring elements **23s** are preferably a type of torsion springs comprising one or more torsion loops configured as an elastic hinge for connecting between base portions **21a** of arms **21** and base section **23** and for allowing radial movement of arms **21** thereabout. Arms **21** may be manufactured from rigid biocompatible materials, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The lengths of arms **21** may generally be in the range of 20 to 60 mm, preferably about 45 mm. Spring elements may be manufactured form any suitable elastic biocompatible material, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol.

Fig. 18C shows a perspective view of an elastic arm **29** comprising spring elements **29a 29b 29c** distributed along its length, where said spring elements **29a 29b 29c** are preferably made in a form of torsion springs comprising one or more torsion

loops. Elastic arms **29** is preferably made from a turned wire made from an elastic biocompatible material, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The length of elastic arm **29** may be the same as of arms **21** shown in Figs. 18A and 18B, and few such elastic arms may be similarly connected to a base section **23** by means of connecting pin **29f** formed at its lower end and thereby construct a ventricular function assisting device which arms **29** are capable of being bent radially and in sideway directions in response to ventricular heart movements.

Fig. 18D shows an embodiment **26** of the elastic arm **29** shown in Fig. 18C comprising interfacing members **26a 26b 26c**. Interfacing member **26a** is attached between spring elements **29a** and **29b**, and interfacing member **26b** is attached between spring elements **29b** and **29c**, where interfacing member **26c** is attached to the longer section of elastic arm **29** extending from spring element **29c** to the upper tip of the elastic arm. Interfacing members **26a 26b 26c** may comprise a central groove configured to receive and hold the respective portions of elastic arm **29** attached to these interfacing members. Interfacing members may be manufactured from an elastic biocompatible material, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol.

Fig. 18E shows a perspective view of a double wire embodiment **77** of elastic arm **29** shown in Fig. 18D. In this embodiment elastic arm **77** is made from a turned elastic wire such that a pair of parallel arms **29'**, each similar in shape and structure to arm **29**

shown in Fig. 18C, are obtained. Accordingly, elastic arm **77** comprises pairs of adjacent spring elements **29a' 29b' 29c'**, and a pair of connecting pin **29f'** which may be used to connect a number of elastic arms **77** to a base section and thereby construct a ventricular function assisting device which arms **77** are capable of being bent radially and in sideway directions in response to ventricular heart movements.

Fig. 19A and 19B respectively show a perspective view and a top view of three-arms embodiment **24** of the ventricular function assisting device of the invention having elastic arms **24a** and a spiral-star base section **24s**. Ventricular function assisting device **24** may be attached to the apex inside the heart ventricle by means suitable anchoring means attached to a bore **24c** formed at the point of connection of elastic arms **24a** in the spiral star base section **24s**. As seen in Figs. 19A and 19B the upper portions of arms **24a** is relatively straight and having a slight outward curve to better interface it with the internal shape of the heart ventricle, while their lower portions spirally curved downwardly to form an inverted spiral star dome shape of base section **24s**. This configuration of device **24** allows its arms **24a** to be bent both in radial and sideway directions as it responses to ventricle heart movements. Device **24** may be manufactured by laser cutting technique, from elastic biocompatible materials, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The lengths of the relatively straight portion of arms **24a** may generally be in the range of 20 to 60, preferably about 45 mm, and the diameter of inverted spiral star dome of base section 24s may generally be in the range of 20 to 60 mm, preferably about 35 mm.

Figs. 20A and 20B respectively show a perspective view and a top view of three-arms embodiment **25** of the ventricular function assisting device **24** shown in Figs. 19A and 19B, wherein the upper portions **25r** of the arms **25a** of device **25** comprise elastic corrugations and their lower portions **25s** are spirally curved downwardly to form an inverted spiral star dome shape. In this embodiment, which is substantially similar to device **24** shown in Fig. 19, the flexibility of the upper portions of arms **25a** is improved by means of the corrugated configuration which allows it to be bent in sideway and longitudinal directions along its length.

Figs. 21A and 21B show perspective views of ventricular function assisting devices of the invention designed for implantation by a catheterization or trans apical procedures, and which comprise elastic circular attachment sections. Device **170** shown in Fig. 21A comprise an elastic circular attachment section **175** attached by means of a connecting strip **172** to a base section **174** comprising a pass through attachment bore **176**. Elastic circular attachment section **175** is adapted to be mounted inside the heart ventricle such that its outer surface is pressed against the heart tissue. Elastic circular attachment section **175** preferably comprises a plurality of apertures **171** distributed over its surface for promoting tissue ingrowth and adhesion. Elastic circular attachment section **175** is preferably designed to span over a circular sector of about 90 to 350 degrees, its width may generally be in the range of 1 to 20 mm, its thickness in the range of 1 to 4 mm, and the diameter of circular attachment section **175** may generally be in the range of 50 to 100 mm.

The device **178** shown Fig. 21B comprises an upper circular attachment section **175a** and a lower circular attachment section **175b**, both attached by means of a connecting strip **172** to a base section **174** comprising a pass through attachment bore **176**. The

geometrical dimensions of circular attachment sections **175a** and **175b** are substantially similar to those of circular attachment section **175** of device **170** shown Fig. 21A, where the diameter of lower circular attachment section **175b** are generally be in the range of 15 to 50 mm.

Ventricular function assisting devices **170** and **178** may be manufactured by laser cutting or metalworking, from suitable elastic biocompatible materials, such as but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. In addition, the various ventricular function assisting devices described hereinabove may further be covered by a layer of material suitable for promoting tissue growth and/or with hemocompatible coating and/or drug delivery agents, such as, but not limited to, Dacron, Teflon, ePTFE, or any other biocompatible polymeric material suitable for these purposes.

Figs. 22A to 22E illustrate a delivery tube **180** suitable for implanting the ventricular function assisting devices shown in Figs. 14 to 18 in a catheterization procedure. In Figs. 22A and 22B the delivery tube **180** comprises an elongated flexible tube **181** comprising a three-arms ventricular function assisting device **182** of the invention placed in its distal end section **181d** in a folded state. In this state the elastic arms **182a** of device **182** are pressed in a radial inward direction toward each other in order to reduce the device diameter to allow it to be inserted into the distal end section **181d** of tube **181** via distal opening **181n**. Ventricular function assisting device **182** also comprise tip sections **182q** having attachment surfaces **182d** on which anchoring pins **182e** may be formed.

Fig. 22C shows ventricular function assisting device **182** placed inside distal end section **181d** of tube **181** with an anchoring helical element **182s** disposed in the attachment bore **182p** of its base section **182b**. Fig. 22D shows delivery tube **180** with ventricular function assisting device **178** (shown Fig. 21B) placed inside distal end section **181d** of tube **181**, wherein the circular attachment sections **175a** and **175b** are tightly rolled to accommodate device **178** inside distal end section **181d** of tube **181**. Fig. 22E shows delivery tube **180** with ventricular function assisting device **140** (shown Figs. 15A and 15B) placed inside distal end section **181d** of tube **181** in a folded state wherein its elastic arms **149** are radially pressed toward each other in order allow fitting inside distal end section **181d** of tube **181**.

Figs. 23A to 23E schematically illustrate a possible catheterization implantation procedure suitable for implanting the ventricular function assisting devices shown in Figs. 14 to 18 for treating DHF. Fig. 23A schematically illustrates introduction of a delivery system into the left ventricle **190**, the delivery system comprises a guiding tube **191** and a torque wire **193** passing thereinside. The inner diameter of the delivery system is preferably not greater than 12Fr. The distal end of torque wire **193** comprises an anchoring element **192** attached to it by means of a connecting mechanism, said connecting mechanism may be implemented by means of screwing, clicking, or a push-pull mechanism. Anchoring element **192** comprises a helical (or spiral) section **192s** capable of being screwed into the heart tissue. As shown in Fig. 23A, once helical section **192s** is screwed into the tissue at the apex inside the ventricle **190** delivery tube **191** is retracted proximally and removed from the vascular system of the treated subject.

Fig. 23B schematically illustrates insertion of the delivery tube **180** into ventricle **190** over torque wire **193** with

ventricular function assisting device **182** of the invention placed inside distal end portion **180d** of delivery tube **180**.

In Fig. 23C the delivery tube reaches anchoring element **192** and the attachment bore provided in the base section of device **182** engages a retaining post **192p** of anchoring element **192**, said retaining post **192p** comprises conical shape stopper **192c** configured to receive base section of device **182** and prevent it from being released from the grip obtained by anchoring element **192**. Fig. 23C schematically illustrates removal of delivery tube **180** by retracting it proximally, which as shown in Fig. 23D, results in the discharge of ventricular function assisting device **182** and deployment of its elastic arms on the inner walls of ventricle **190**. In steps shown in Figs. 23C and 23D the orientation of device **182** is adjusted according to the internal anatomy of the ventricle by manipulating delivery tube **180**. Finally in Fig. 23E delivery catheter **191** (not shown) is inserted into ventricle **190** with a securing element **199** which is attached to stopper **192c** by an attachment mechanism for preventing device **182** from being released from anchoring element **192**. Thereafter, the torque wire **193** is released and removed.

Figs. 23F and 23G respectively illustrate a side sectional view and a perspective view of the torque wire **191** and anchoring element in an engaged and detached states. As exemplified in these figures anchoring element **192** may be configured in a form of a cylindrical body comprising a distal flange **192f** forming a neck section **192n** on which helical anchoring screw **192s** is attached. The proximal side of anchoring element is made hollow to form a socket **192b** and a waist section **192w** between said socket **192b** and said flange **192f**, said waist section **192w** is designed to be received in the attachment bore **182p** of ventricular function assisting device **182**. The distal end of torque wire **191** comprises a releasable attachment spring lock

mechanism **191h** adapted to fit into socket **192b** and attach thereinto by means of press springs **191k**. Press springs **191k** are configured to fit into vertical slots **192t** provided in opposite sides of socket **192b**. The connection obtained between releasable attachment spring lock mechanism **191h** and anchoring element **192** may be released by introducing an additional tube (not shown) which is adapted for pressing internally press springs outside of vertical slots **192t** and thereby release the attachment between these components.

Figs. 24A and 24B schematically illustrate a delivery tube **201** suitable for implanting the ventricular function assisting devices of the invention by a single step catheterization procedure. The delivery tube **201** preferably comprises a proximal handle (not shown) adapted for steering, turning, pushing and pulling delivery tube **201**, and its inner diameter is preferably about 16-18Fr. The distal section **201d** of delivery tube **201** is preferably made flexible and it is configured to receive a ventricular function assisting device **182** of the invention in a folded state (i.e., wherein the elastic arms of the device are pressed toward each other). Torque wire **202** passing along the length of delivery tube **201** is made in a form of a hollow tube in which guide wire **205** is passed. In this embodiment an anchoring element **203** having an internal passage is attached to the distal end of torque wire **202**, such that guide wire **205** also passes through the internal passage of anchoring element **203**. Ventricular function assisting device **182** is fitted over a waist section provided in anchoring element **203**, and a helical or spiral anchor **203s** is provided attached to anchoring element for allowing it to be screwed into the heart tissue.

The delivery tube preferably comprises a proximal handle (not shown) adapted for steering, turning, pushing and pulling

delivery tube **201**, and its inner diameter is preferably about 16-18Fr.

In this implantation procedure the delivery tube **201** comprising torque tube **202**, anchoring element **203**, and ventricular function assisting device **182**, is advanced via the vascular system over guide wire **205** into the treated heart ventricle. Inside the heart ventricle the helical or spiral anchor **203s** is advanced outside of delivery tube **201** via it tapered end by pushing torque tube **202** distally. Thereafter, helical or spiral anchor **203s** is screwed into the heart tissue by turning of the torque wire **202** via its handle (not shown). Then, the ventricular function assisting device **182** is gradually discharged by retracting delivery tube proximally, and the orientation of device **182** is adjusted according to the internal anatomy of the ventricle by manipulating delivery tube **201**. Once the needed orientation is obtained, the entire length of device **182** is discharged from delivery tube **201** such that its flexible arms change into a deployed preloaded conformation as they are pressed against the internal walls of the ventricle. Finally, the delivery tube **201** is retracted distally, the attachment of torque tube **202** to anchoring element **203** is released, and torque tube **202** and guide wire **205** are retracted proximally outside of the vascular system.

Figs. 25A to 25F schematically illustrate various anchoring elements suitable for attaching the ventricular function assisting devices in catheterization approach shown in Figs. 14 to 18 to a ventricular apex. Fig. 25A schematically illustrates an anchoring element **210** comprising a helical/spiral anchor **210s** configured to be screwed into the tissue of ventricle **190**, and screw head **210t** attached to helical/spiral anchor **210s**. Helical/spiral anchor **210s** may be implemented by a simple spring, preferably made from a radiopaque material, such as, but

not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The diameter of Helical/spiral anchor **210s** may generally be in the range of 1 to 5 mm, and the diameter of the wire from which it is made may be between 0.2 to 0.5 mm. The length of Helical/spiral anchor **210s** is adapted such that it will not pass the entire width of the ventricle tissue, for example in range of 4 to 20 mm.

Fig. 25B illustrates an anchoring element **211** comprising fixating barb elements **211b**. In this implementation anchoring element **211** is passed through the width of the ventricle wall and it is fixated in this state by means of barb element **211b** attached at each of its ends. Each of the barb elements **211b** preferably comprises 3 to 6 barbs. Anchoring element **211** and its bar elements **211b** are preferably made from a radiopaque material, such as, but not limited to stainless steel alloys, super alloys (35N LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The diameter of anchoring element **211** may generally be in the range of 0.5 to 1.5 mm, and its length between 4 to 20 mm.

Figs. 25C to 25F illustrate a procedure of implanting an anchoring element **215** of the invention comprising several hooks **215v**, which is introduced into the myocardium **190** by means of a needle **214**. In this procedure needle **214** with anchoring element **215** comprised in its distal end is introduced into the apex tissue, and the anchoring element **215** is then discharged into the tissue by pulling needle **214** out of the tissue. Anchoring element **215** is preferably made from a radiopaque material, such as, but not limited to stainless steel alloys, super alloys (35N

LT, MP35N, L605 etc.), preferably from FWM1058 alloy (also known as Conichrome™ - a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7) or Nitinol. The diameter of anchoring element **215** may generally be in the range of 0.5 to 3 mm, and its length between 3 to 20 mm, depending on the width of apex wall.

Figs. 26A and 26B show a simulation of an implantation procedure following the catheterization approach of the invention by means of the delivery tube **180** shown in Fig. 16B. Fig. 26A shows the step of attaching the ventricular function assisting device **110** (shown in Fig. 16B) comprised inside the delivery tube **180** in a folded state. Fig. 26B shows removal of the delivery tube **180**, and Fig. 26C shows deployment of the ventricular function assisting device **110** inside the heart ventricle **190**.

All of the abovementioned 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 tubes, shafts, 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.

CLAIMS

1. A ventricular function assisting device comprising two or more arms each of which comprising a bottom end, a free top end and an intermediate section extending between said ends, wherein said bottom ends of said two or more arms are attached in a base section of said device thereby forming a flower cup configuration, and wherein said two or more arms comprise elastic elements or portions configured such that they are capable of being elastically bent in radial directions relative to longitudinal axis of said flower cup configuration, and wherein said device is capable of being set into two conformations: i) a folded conformation, in which said two or more arms are pressed inwardly in a radial direction towards each other thus allowing fitting it in a delivery tube or sheath in said folded conformation; and ii) a deployed conformation, in which said two or more arms are opened in a radial outward direction, wherein said device is adapted to be attached at its base section to an apex inside a heart ventricle in said deployed conformation such that at least its free top ends are pressed against the walls of said heart ventricle thereby allowing said two or more arms to elastically bent in radial direction during contractions of said heart ventricle and thereby store potential energy in said elastic elements or portions provided therein, and to release said energy during expansions of said heart ventricle.

2. A ventricular function assisting device according to claim 1, wherein portions of the arms, or their entire length, are adapted to be pressed against the wall of the heart ventricle.

3. A ventricular function assisting device according to claim 1, wherein said device is configured to be implanted inside the heart ventricle in a preloaded state.

4. A ventricular function assisting device according to claim 1, wherein the two or more arms are further adapted to elastically bend in sideway directions in response to twist movements and longitudinal movements of the heart ventricle in which it is implanted.

5. A ventricular function assisting device according to claim 1, wherein the base section of said ventricular function assisting device comprises a disk element, said disk element comprising a central pass through bore adapted for attaching it to the apex inside the heart ventricle and a circumferential surface to which the bases of the one or more arms are attached.

6. A ventricular function assisting device according to claim 1, wherein the base sections of said ventricular function assisting device comprises elastic torsion loops elements configured to elastically connect the bottom ends of adjacent arms of said ventricular function assisting device, wherein said torsion loops are further employed to attach said ventricular function assisting device to the apex inside the heart ventricle by means of suture strings passing through and/or attached to said torsion loops elements.

7. A ventricular function assisting device according to claim 1, wherein the base section of said ventricular function assisting device comprises a cup shaped element having an attachment bore provided in its base and a circumferential wall to which the arms of said ventricular function assisting device are attached.

8. A ventricular function assisting device according to claim 1, wherein portions of the arms, or the entire surface, of said

ventricular function assisting device are covered by a padding element.

9. A ventricular function assisting device according to claim 8, wherein the padding element is adapted to promote tissue ingrowth.

10. A ventricular function assisting device according to claim 8, wherein the padding element is adapted to release a drug into the tissue of the heart.

11. A ventricular function assisting device according to claim 1 or 2, wherein the portions of the arms adapted to be pressed against the wall of the heart ventricle comprise apertures adapted to promote tissue ingrowth.

12. A ventricular function assisting device according to claim 1, wherein portions, or the entire area, of the arms, or the entire ventricular function assisting device, are covered by a layer of material suitable for promoting tissue growth.

13. A ventricular function assisting device according to claim 1, wherein the arms of said ventricular function assisting device are made from an elastic mesh having rhombus, or other geometry, shaped apertures.

14. A ventricular function assisting device according to claim 1, wherein the arms of said ventricular function assisting device further comprise elastic corrugations formed along their lengths, in their free top end, and/or in their bottom ends.

15. A ventricular function assisting device according to claim 1, wherein the arms of said ventricular function assisting device comprise one or more bent sections.

16. A ventricular function assisting device according to claim 1, wherein the arms of said ventricular function assisting device are attached to the base section by means of springs.

17. A ventricular function assisting device according to claim 1, wherein the arms of said ventricular function assisting device comprise one or more springs.

18. A ventricular function assisting device according to claim 1, wherein the bottom sections of the arms of said ventricular function assisting device are curved such that a spiral star structure is formed in the base section.

19. A ventricular function assisting device according to claim 1, wherein said device is made from an elastic wire or from a layered structure of elastic strips.

20. A method for implanting the ventricular function assisting device according to any one of claims 1 to 19, the method comprising:

Opening a passage to the heart apex through the patient's chest;

marking the papillary muscles for visualization by suitable marking means;

performing a purse string at the heart apex for the insertion of a trans-apical sheath thereinto by means of a dilator;

introducing delivery tool into the trans-apical sheath and advancing it distally through the trans-apical sheath until the distal end of the delivery tube is introduced into

the ventricle via the distal opening of the trans-apical tube, wherein said delivery tool comprises a delivery tube adapted to receive and hold the ventricular function assisting device in a folded state in its distal end section and a hollow inner shaft slidably passing inside the delivery tube, said hollow inner shaft comprising a clamping mechanism adapted to releasably hold suturing string(s) attached to the base section of the ventricular function assisting device;

advancing the ventricular function assisting device in a folded state through said delivery tube of said delivery tool into the heart by means of said inner hollow shaft;

manipulating the orientation of the ventricular function assisting device relative to the papillary muscles markers for properly positioning it inside the heart ventricle;

discharging the ventricular function assisting device inside the heart ventricle by distally pushing said inner hollow shaft, during which the ventricular function assisting device unfolds into a preloaded deployed state;

retracting said delivery tool proximally;

retracting said trans-apical sheath from the incision;

fastening the purse string to close the incision; and

Suturing the incision by the purse string wires and the suturing string(s) to the apex tissue.

21. A method for implanting the ventricular function assisting device according to any one of claims 1 to 19, the method comprising:

Making a small incision in an artery or vein, by means of a needle, or any other standard equipment generally used for performing catheterization procedures for accessing into a blood vessel;

introduction through said incision a guiding tube comprising a torque wire slidably passing thereinside, wherein the distal end of the torque wire comprises an

anchoring element releasably attached to it by means of a connecting mechanism;

advancing said guiding tube with the torque wire comprised in it through the vascular system into the heart ventricle;

anchoring said anchoring element into the apex inside the ventricle;

retracting said delivery tube proximally and removing it from the vascular system of the patient;

advancing a delivery tube flexible distal section into said ventricle over said torque wire until the delivery tube reaches the anchoring element, said delivery tube comprising said ventricular function assisting device placed inside a distal end portion thereof;

attaching the base section of said ventricular function assisting device to said anchoring element;

manipulating the orientation of said ventricular function assisting device to properly place it thereinside;

retracting proximally and removing said delivery tube thereby discharging said ventricular function assisting device such that its arms are pressed against the inner walls of ventricle in a preloaded state;

releasing said torque wire from the anchoring element and removing it from the patient's body.

22. The method according to claim 21, further comprising inserting a delivery catheter comprising a securing element into the ventricle and attaching said securing element to the anchoring element.

23. A delivery system for implanting a ventricular function assisting device according to any one of claims 1 to 19, comprising a delivery tube having a flexible distal section and comprising a tapering tip configured to receive said

ventricular function assisting device in a folded state, a torque tube passing inside said delivery tube along its length, said torque tube is made in a form of a hollow tube, a guidewire slidably passing inside the torque tube, and an anchoring element releasably attached to said torque tube, wherein said anchoring element comprises a waist section adapted to receive the base section of said ventricular function assisting device, a distally attached helical or spiral anchor, and an internal passage provided along its length.

24. A method for implanting a ventricular function assisting device by means of the delivery system of claim 23, comprising:

making a small incision in an artery or vein as described hereinabove and introducing the guidewire through the vascular system into the heart ventricle;

advancing the delivery tube comprising the torque tube, the anchoring element, and the ventricular function assisting device in its flexible distal portion, via the vascular system over the guide wire into the treated heart ventricle;

advancing the helical or spiral anchor outside of delivery tube via it tapered end tip;

screwing helical or spiral anchor into the heart tissue;

adjusting the orientation of the ventricular function assisting device according to the internal anatomy of the ventricle;

discharging the ventricular function assisting device by retracting delivery tube proximally such that its arms change into a deployed preloaded conformation as they become pressed against the internal walls of the ventricle;

retracting distally the delivery tube;

releasing the attachment between the torque tube and the anchoring element; and

retracting proximally the delivery tube with the torque wire and guidewire inside it.

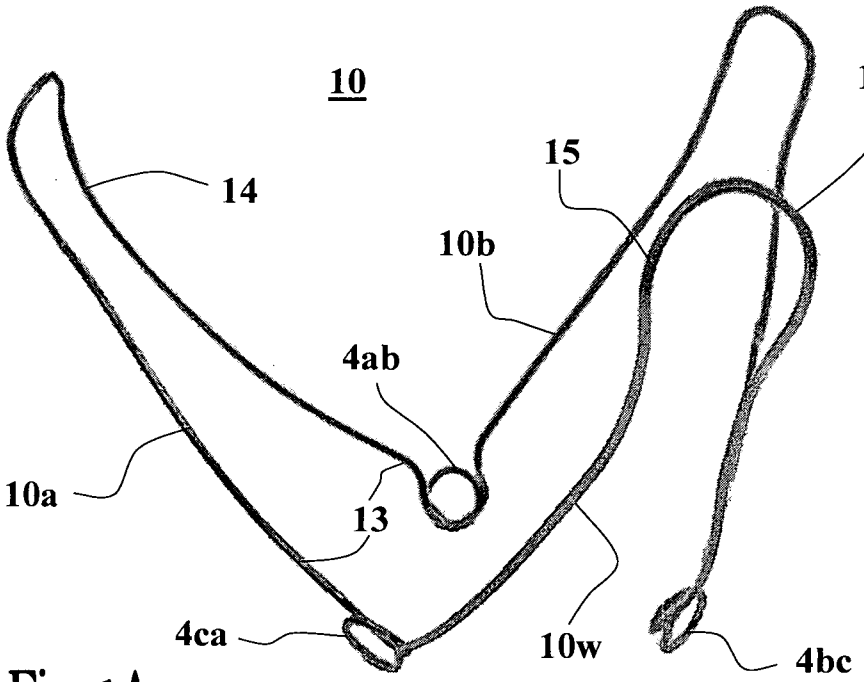


Fig. 1A

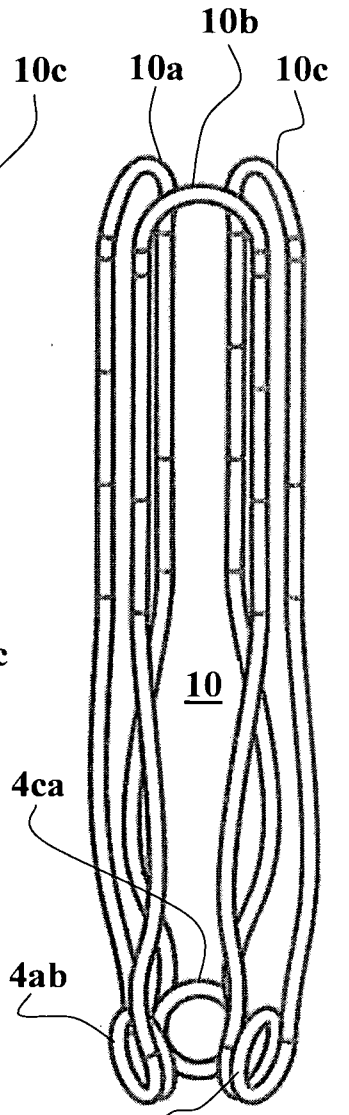


Fig. 1B

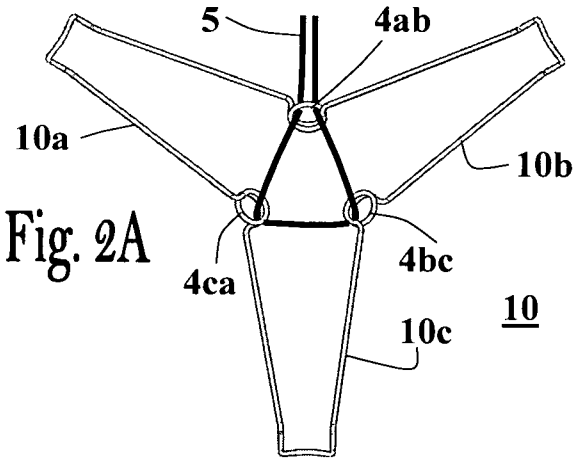


Fig. 2A

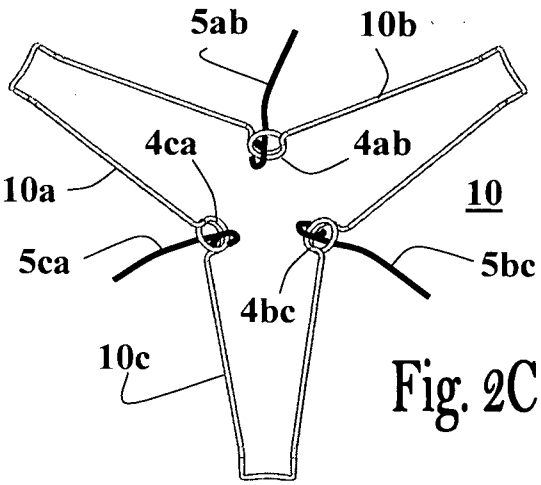


Fig. 2C

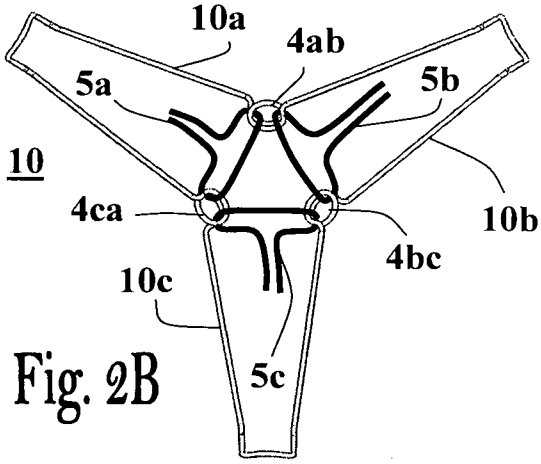


Fig. 2B

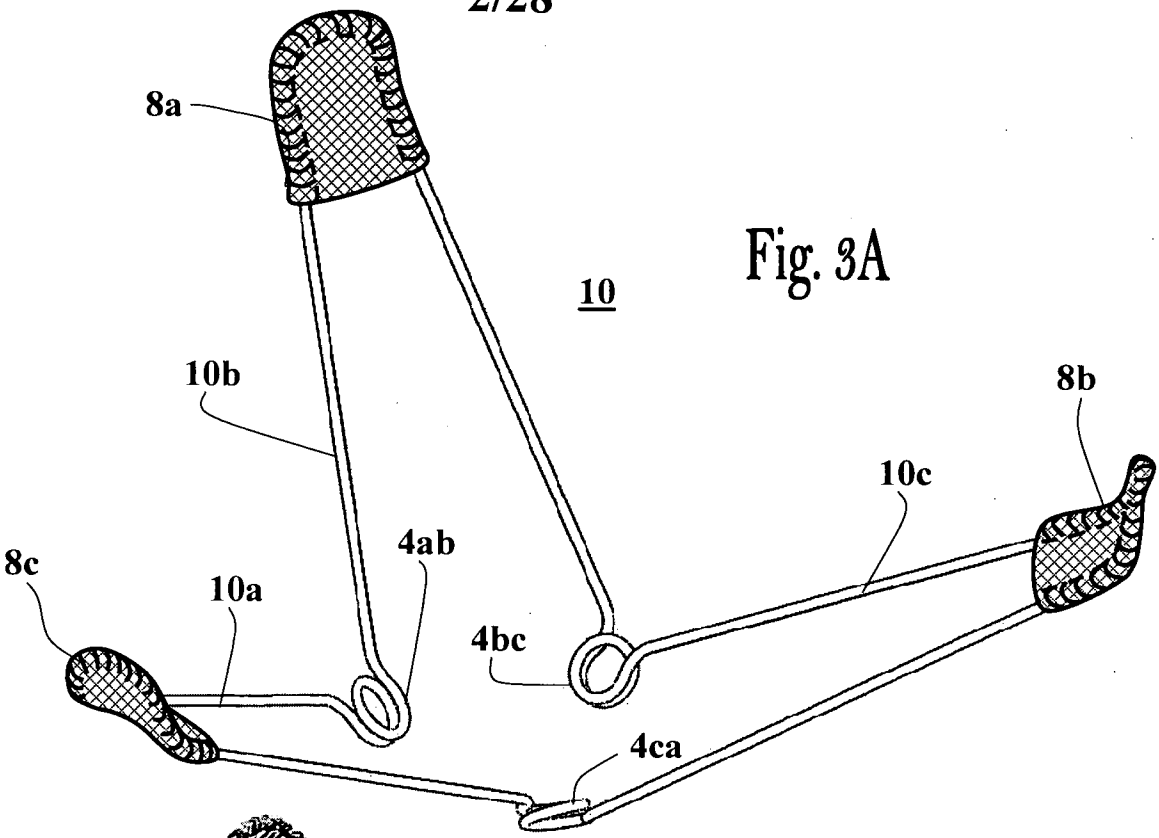


Fig. 3A

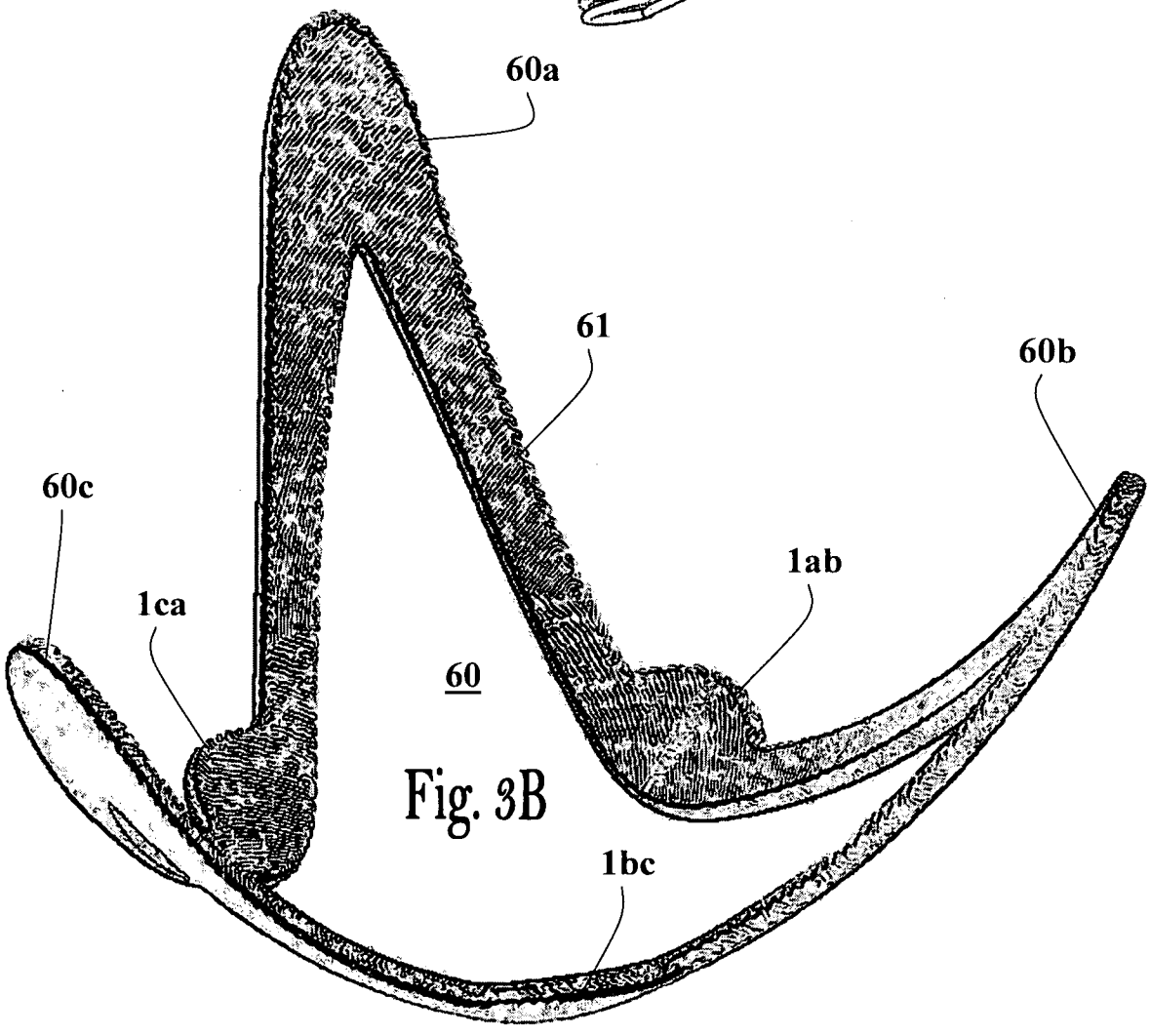


Fig. 3B

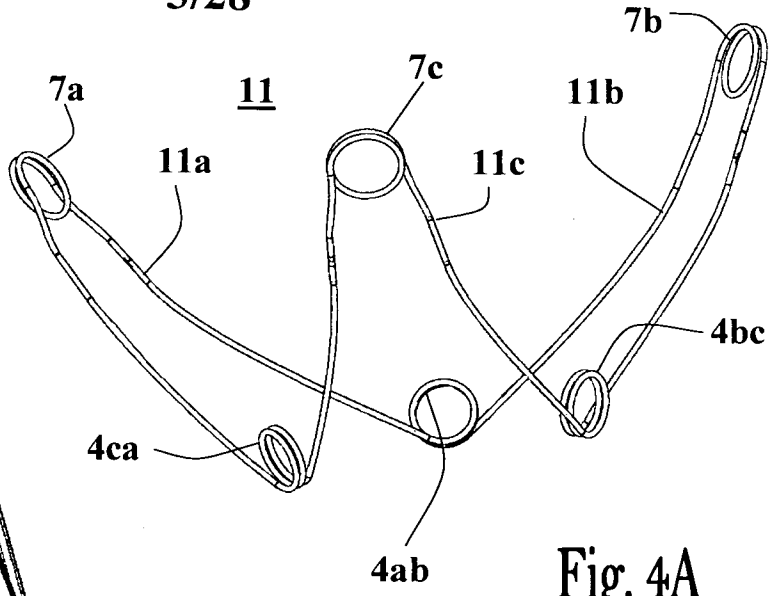


Fig. 4A

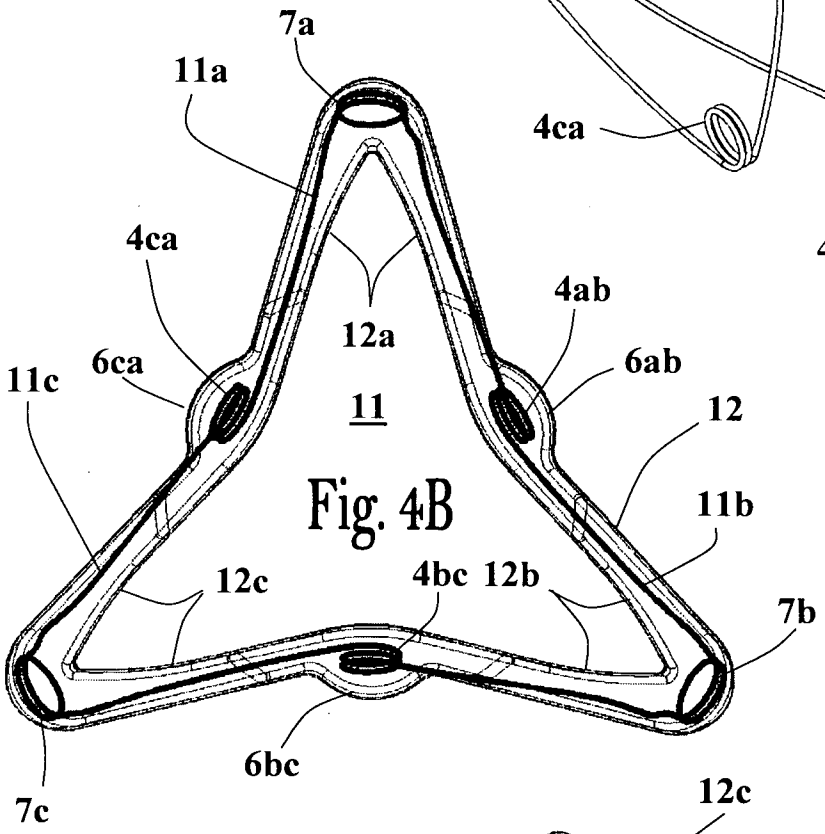


Fig. 4B

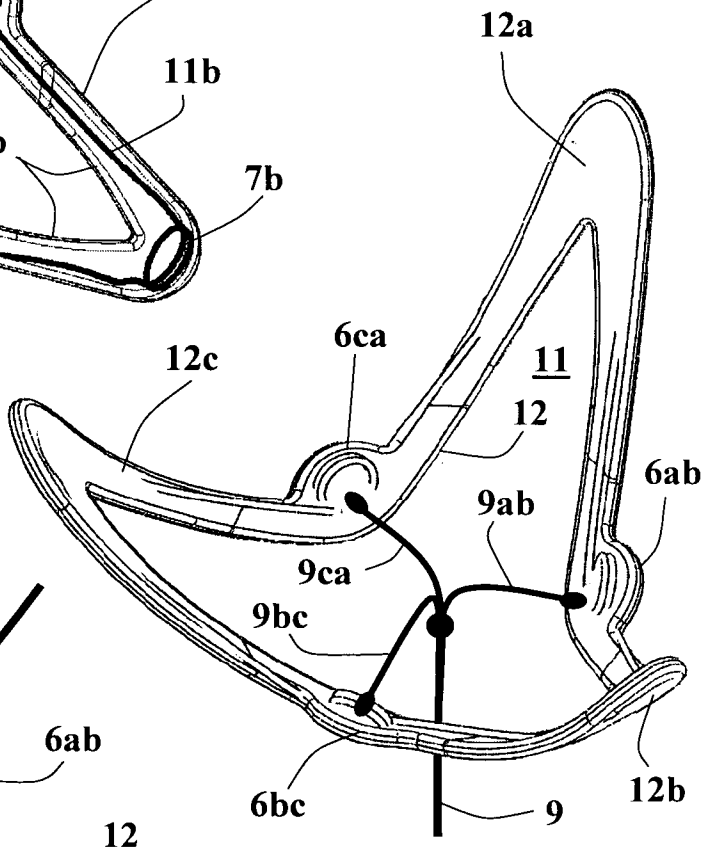


Fig. 4C

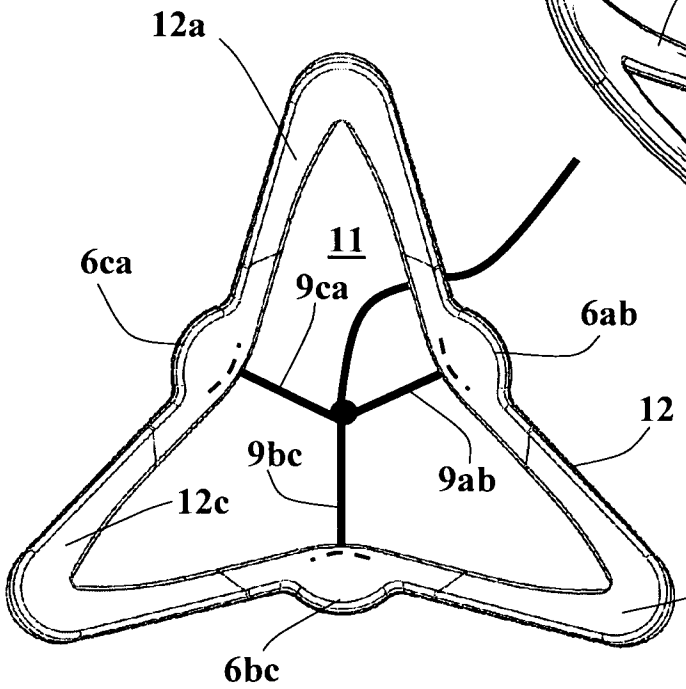


Fig. 4D

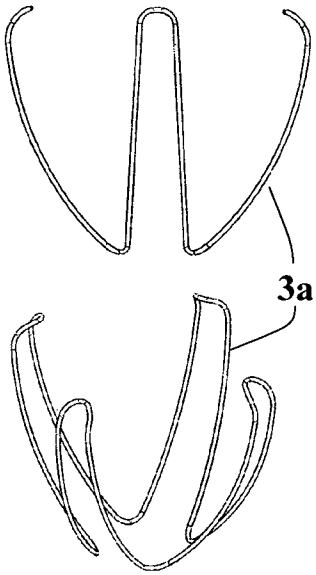


Fig. 5A

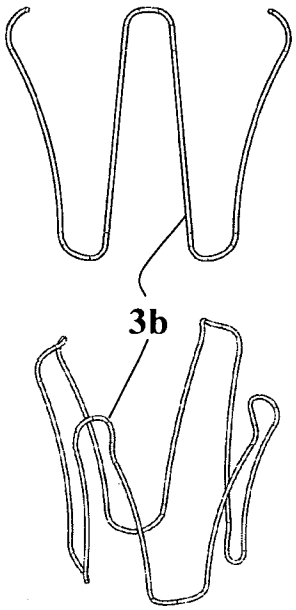


Fig. 5B

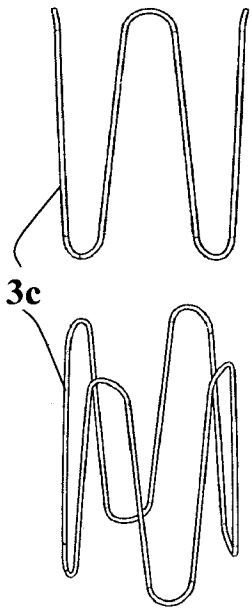


Fig. 5C

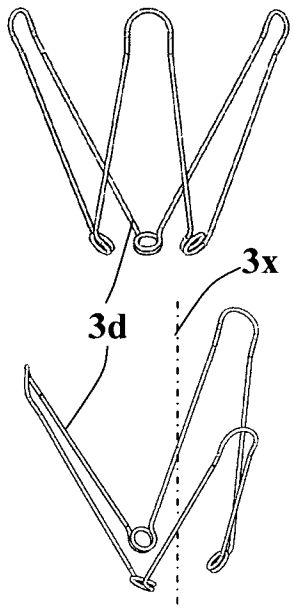


Fig. 5D

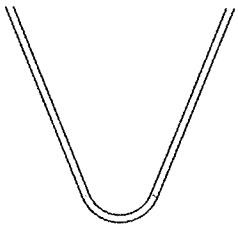


Fig. 6A

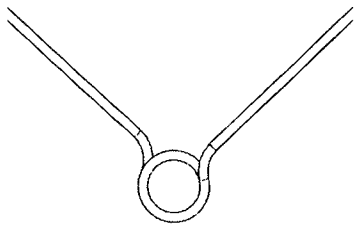


Fig. 6B

Fig. 6C

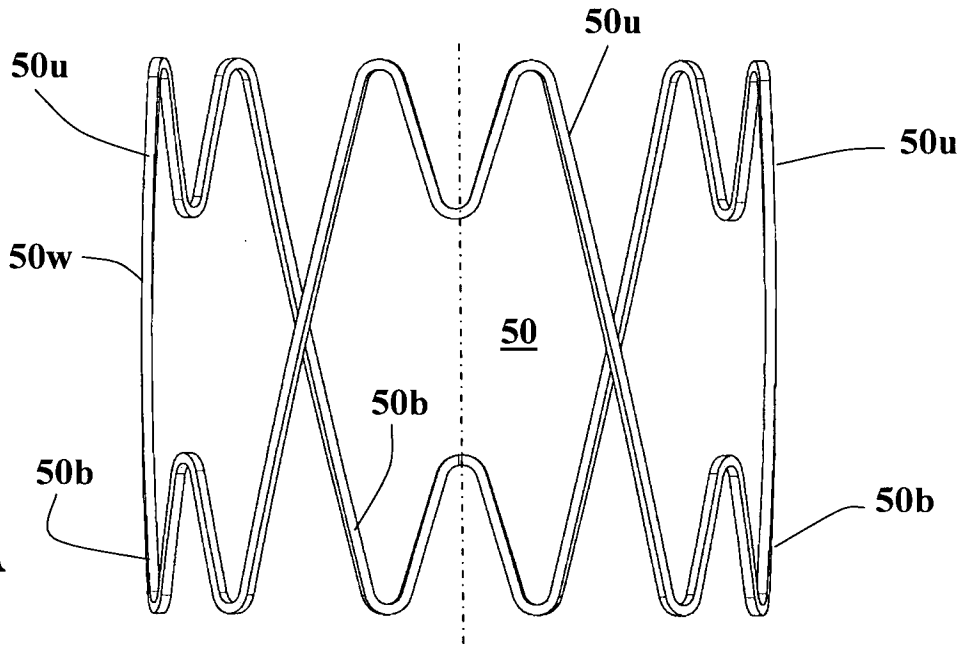


Fig. 7A

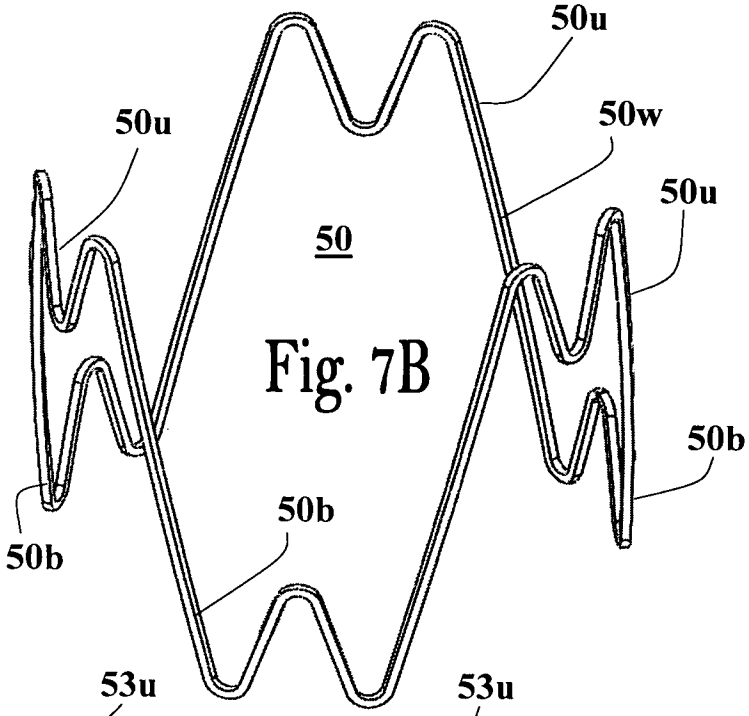


Fig. 7B

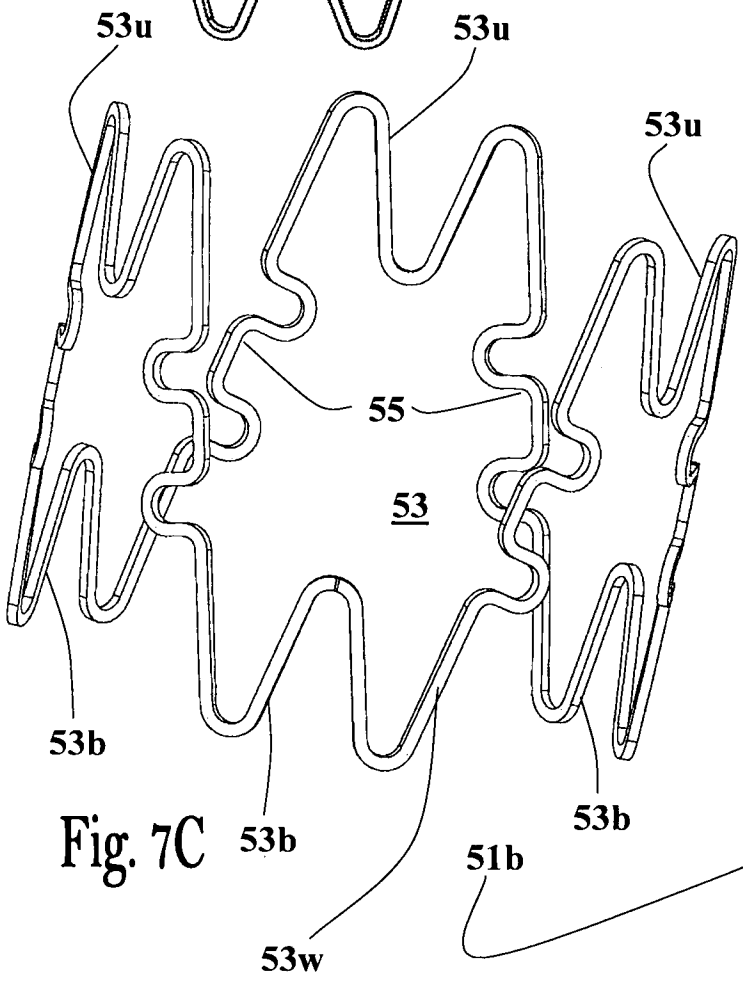


Fig. 7C

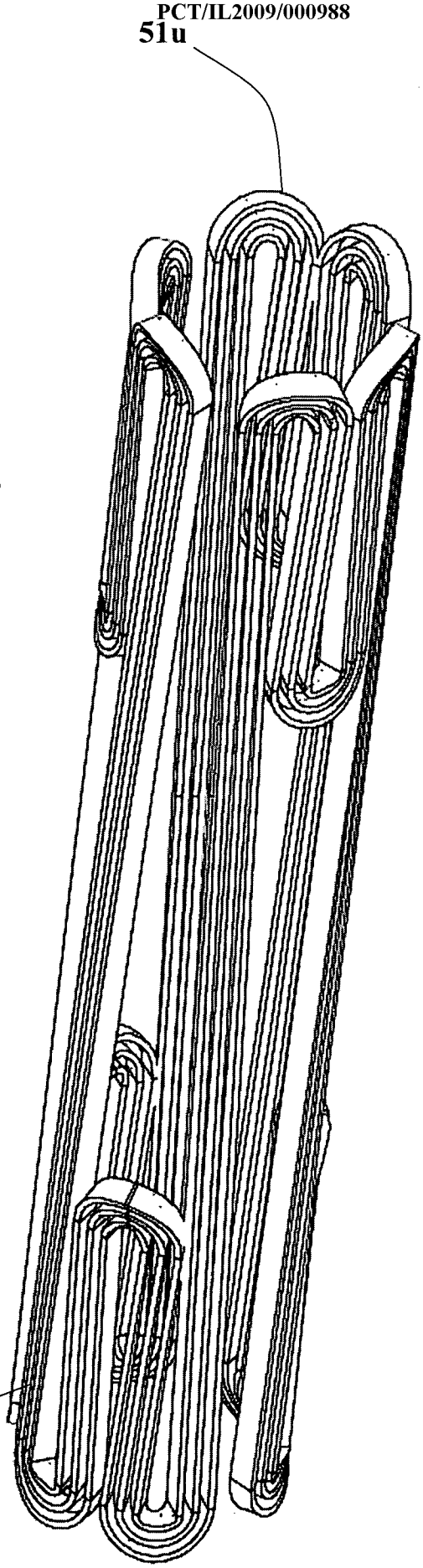


Fig. 7F

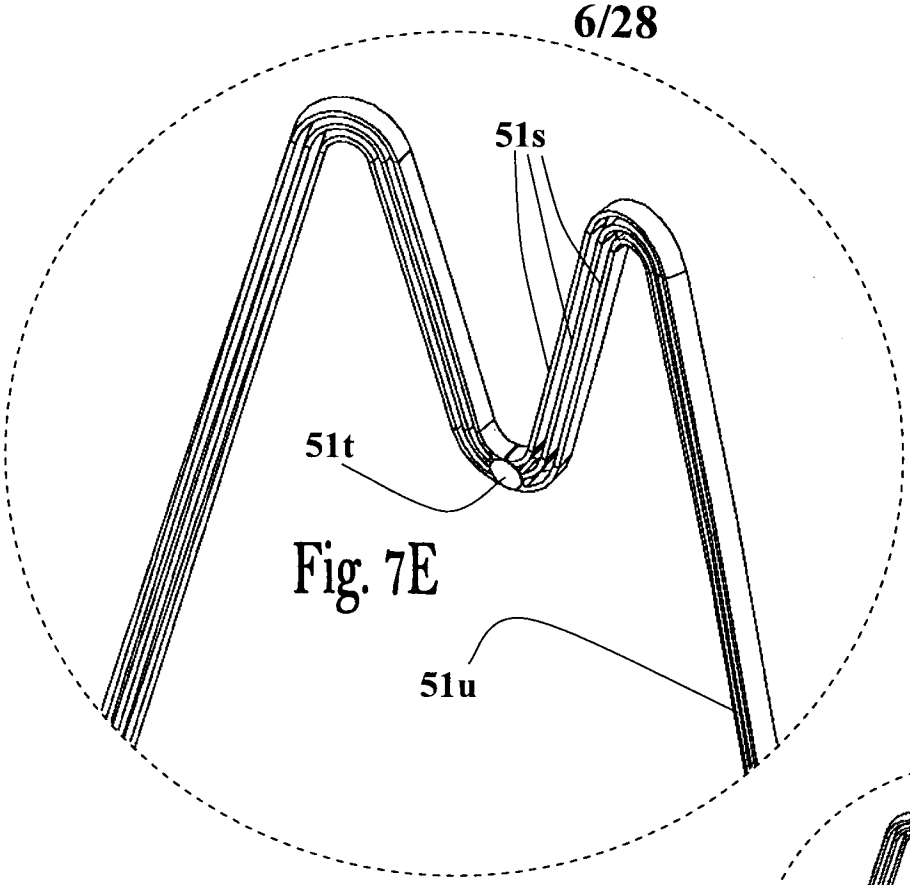


Fig. 7E

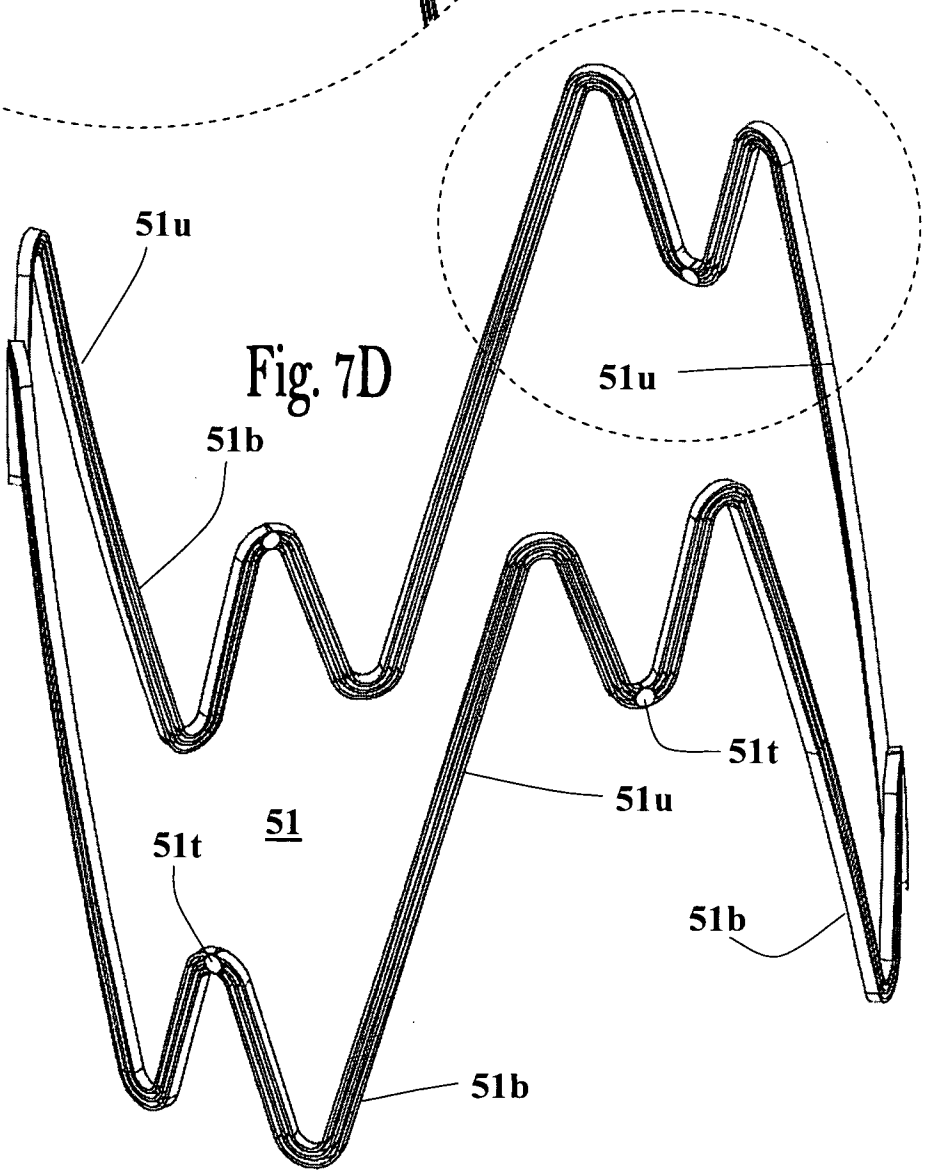


Fig. 7D

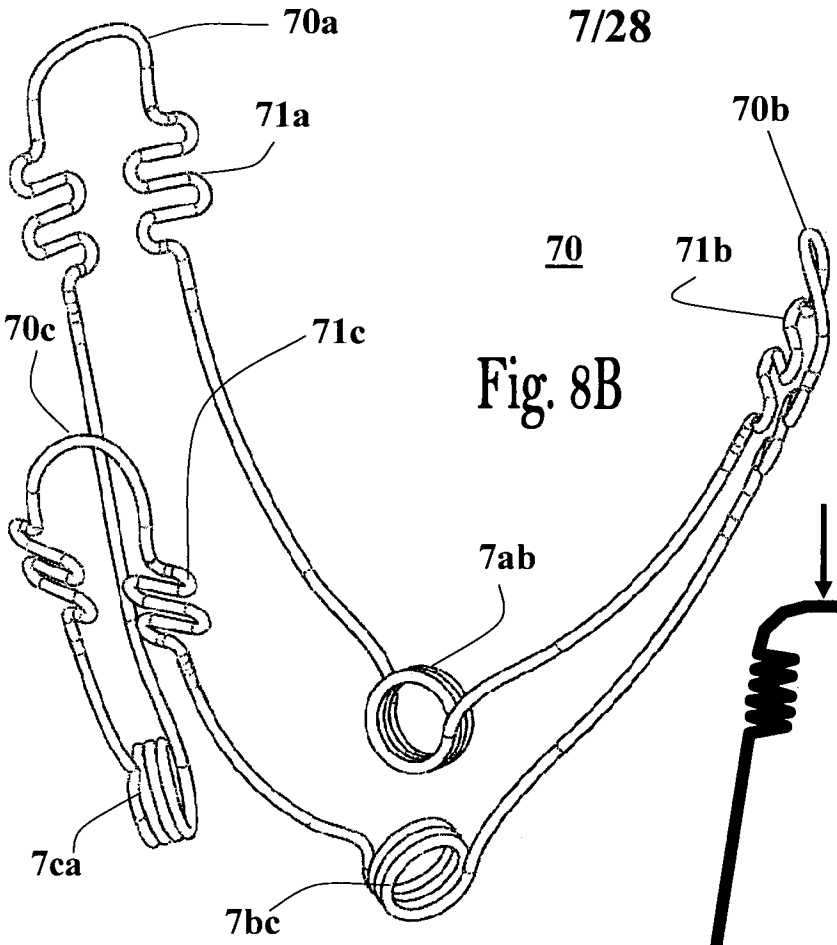


Fig. 8B

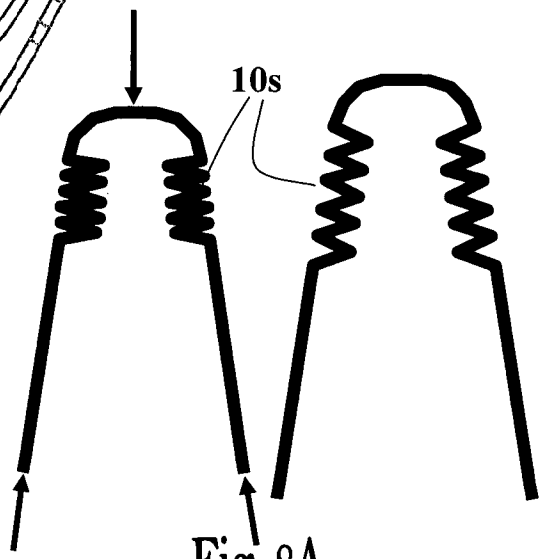


Fig. 8A

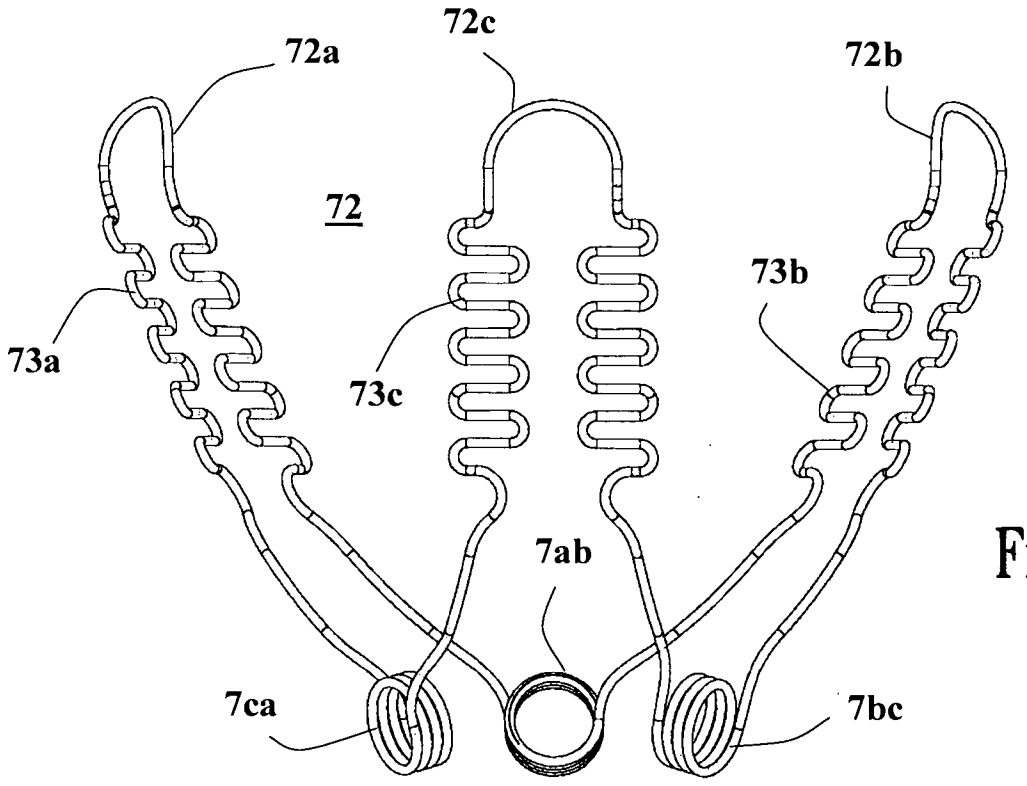
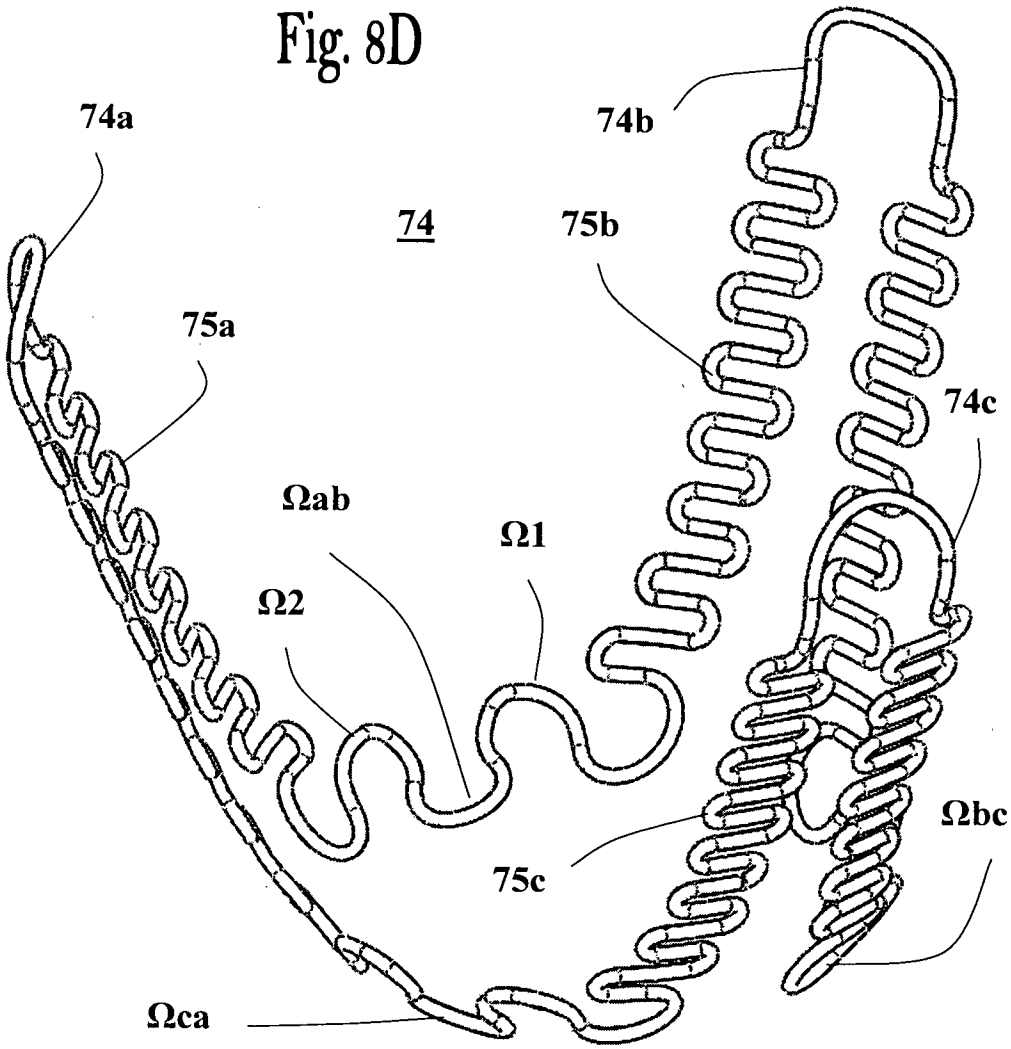


Fig. 8C

Fig. 8D



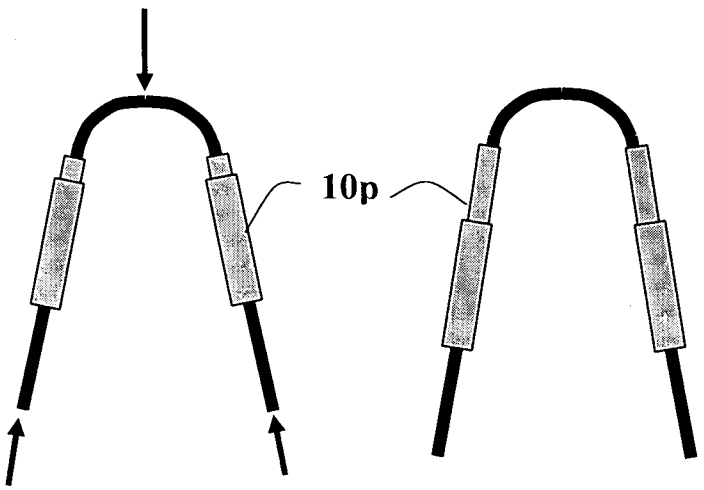


Fig. 8E

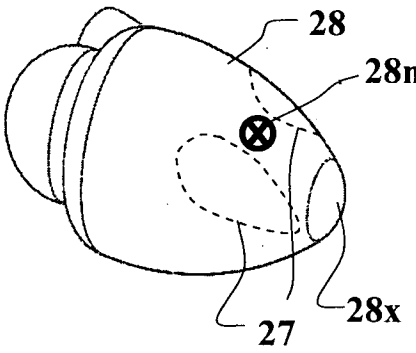
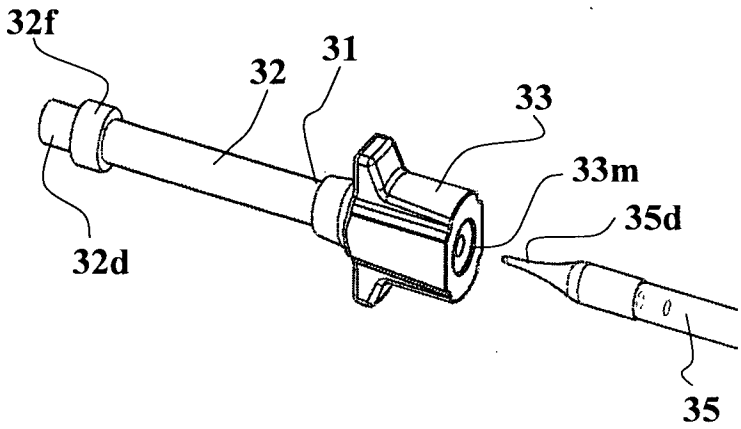


Fig. 9A



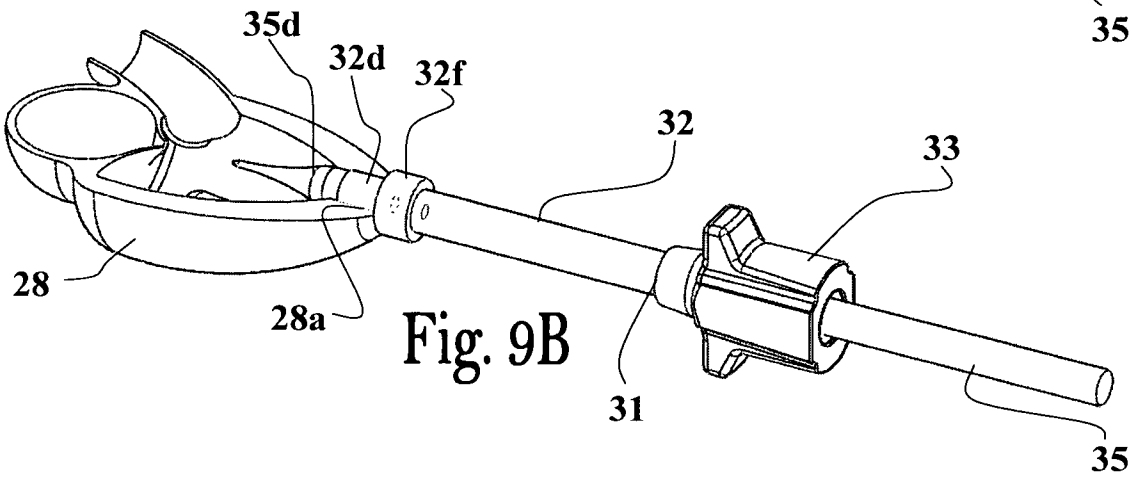


Fig. 9B

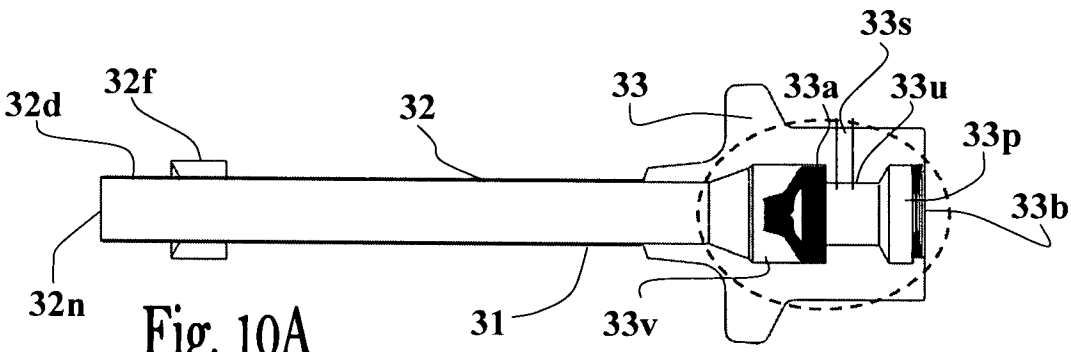


Fig. 10A

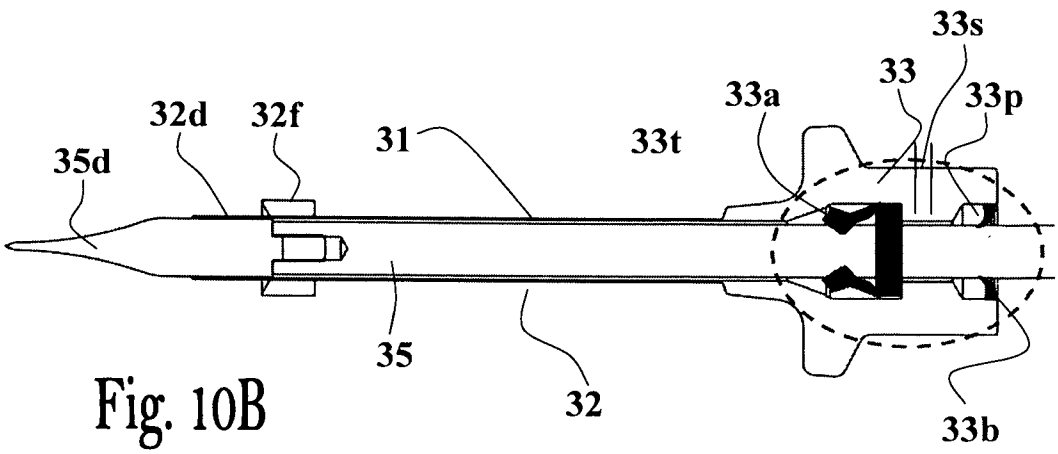


Fig. 10B

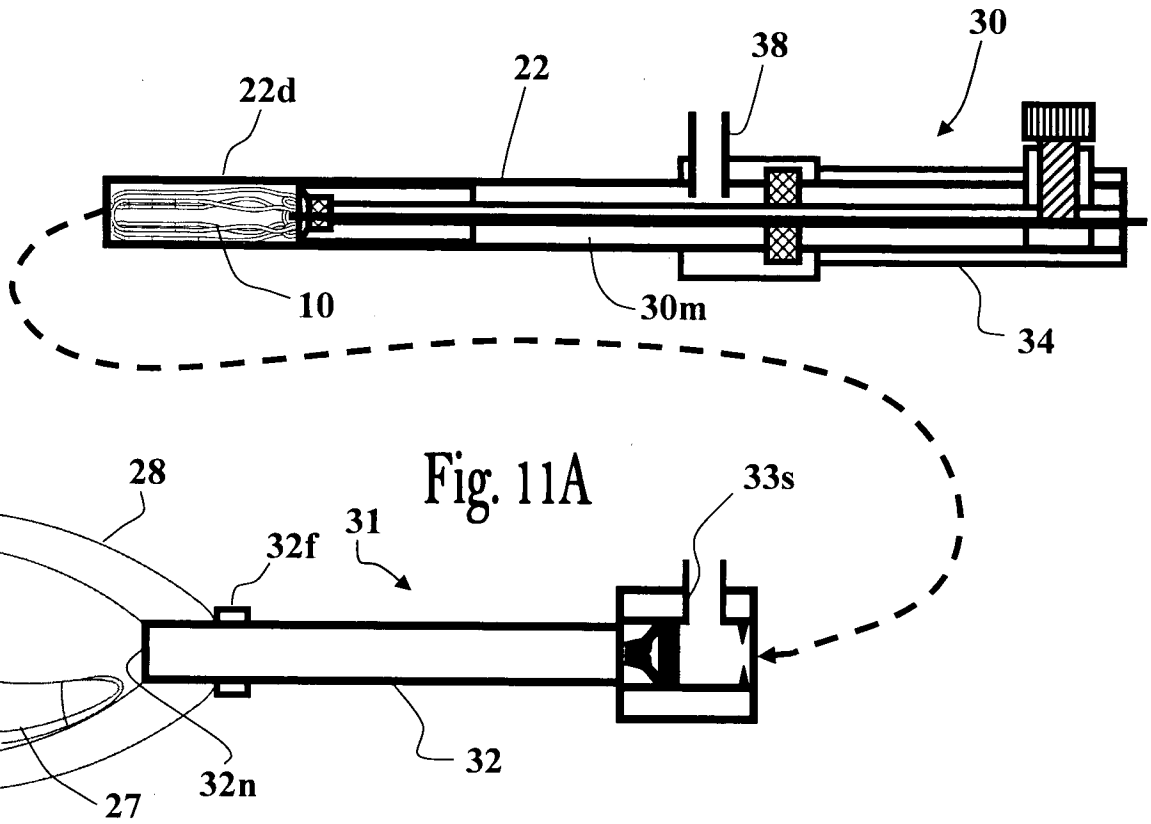


Fig. 11A

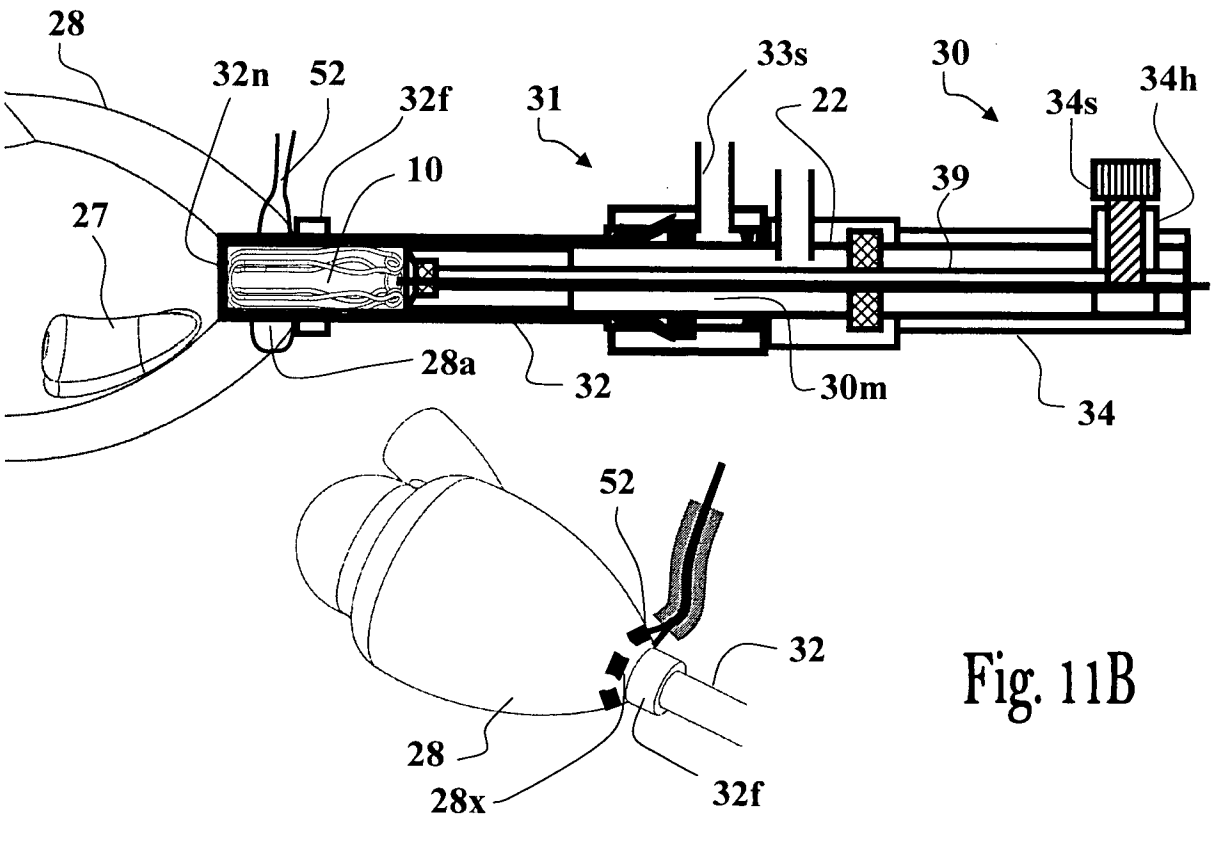


Fig. 11B

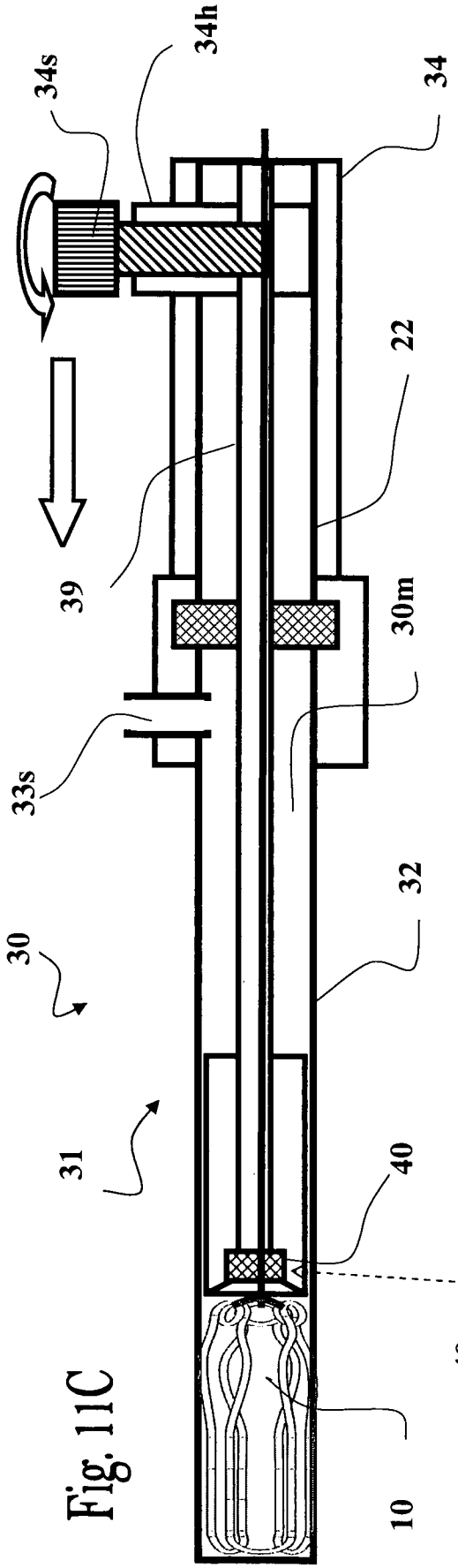


Fig. 11C

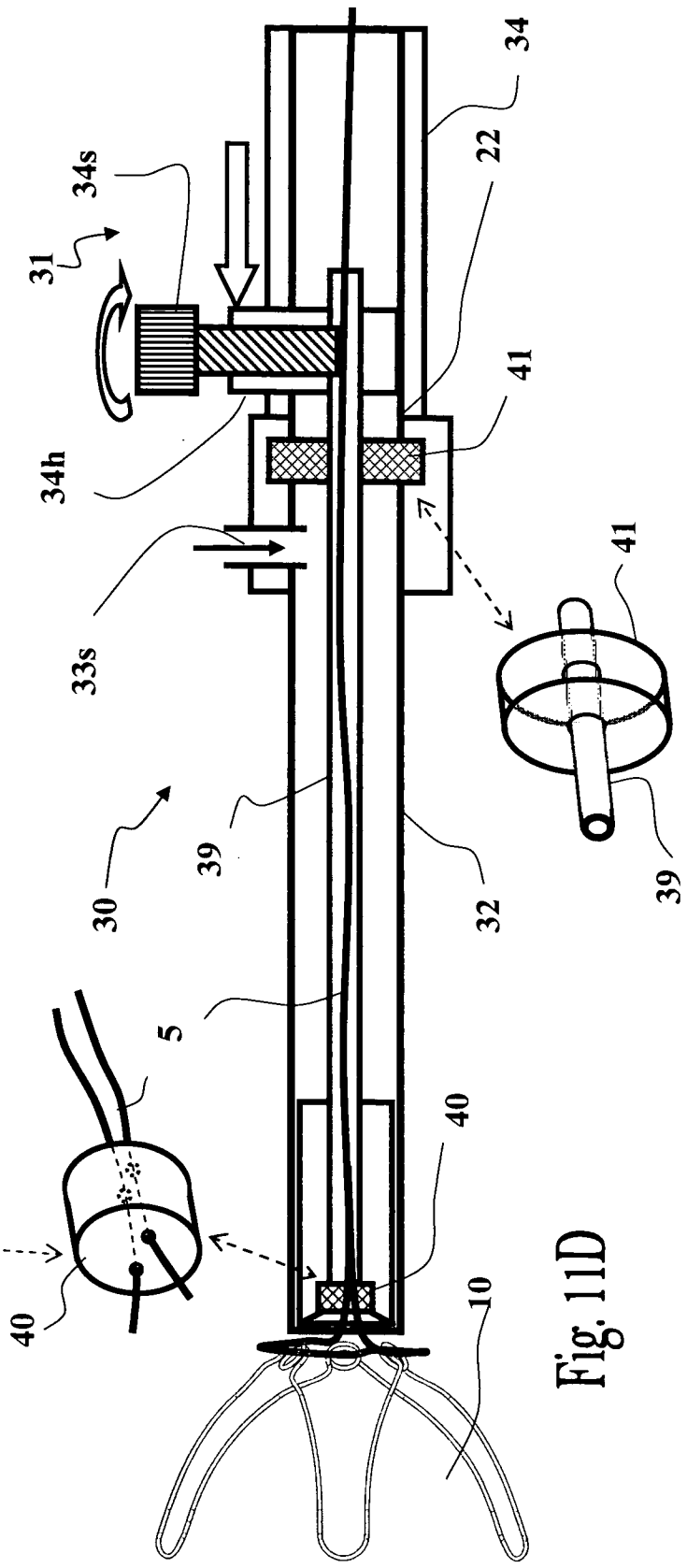


Fig. 11D

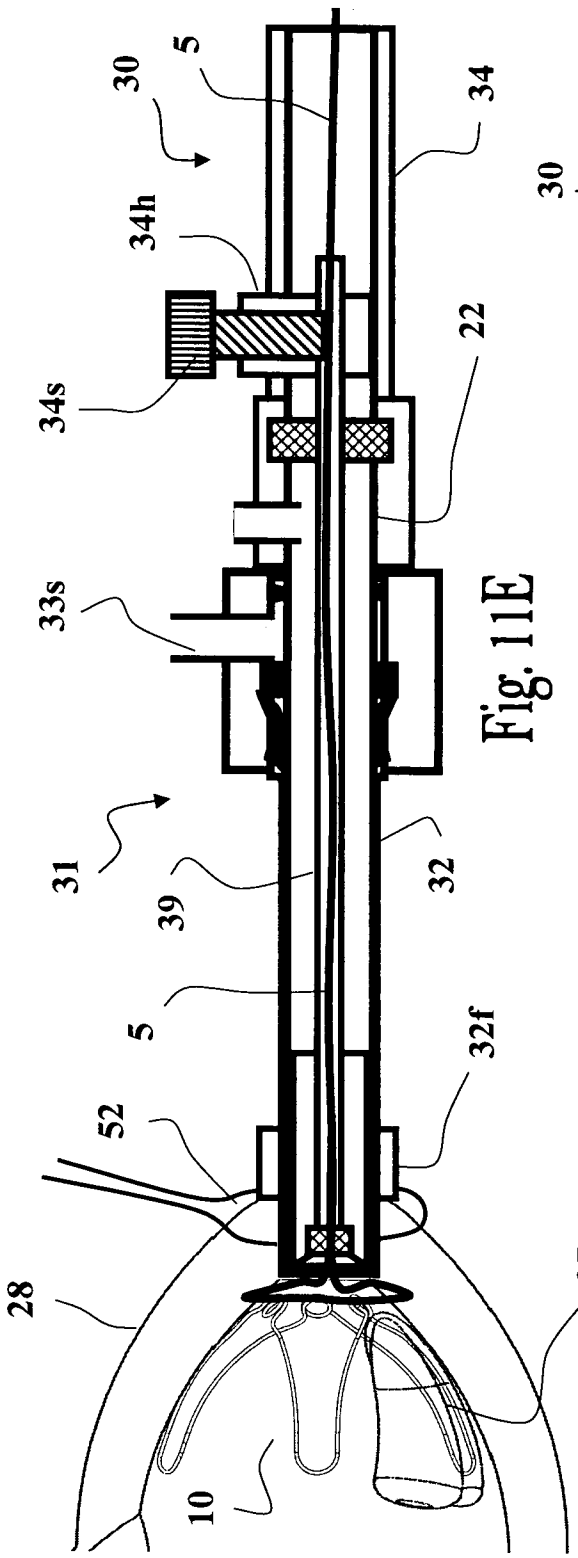


Fig. 11E

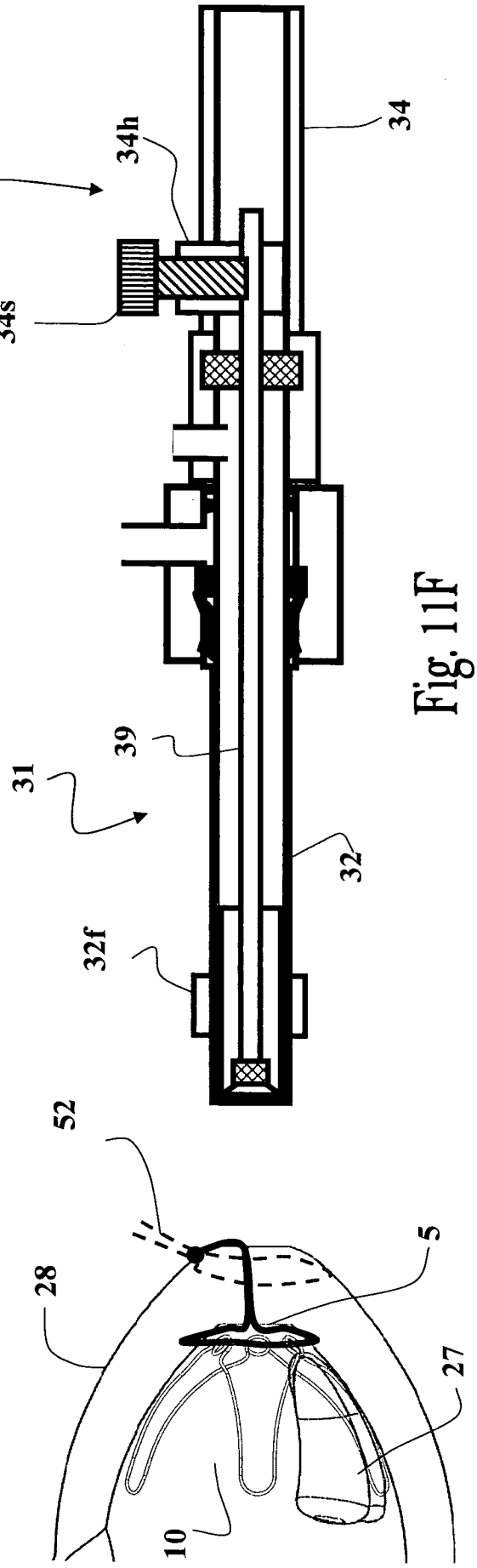


Fig. 11F

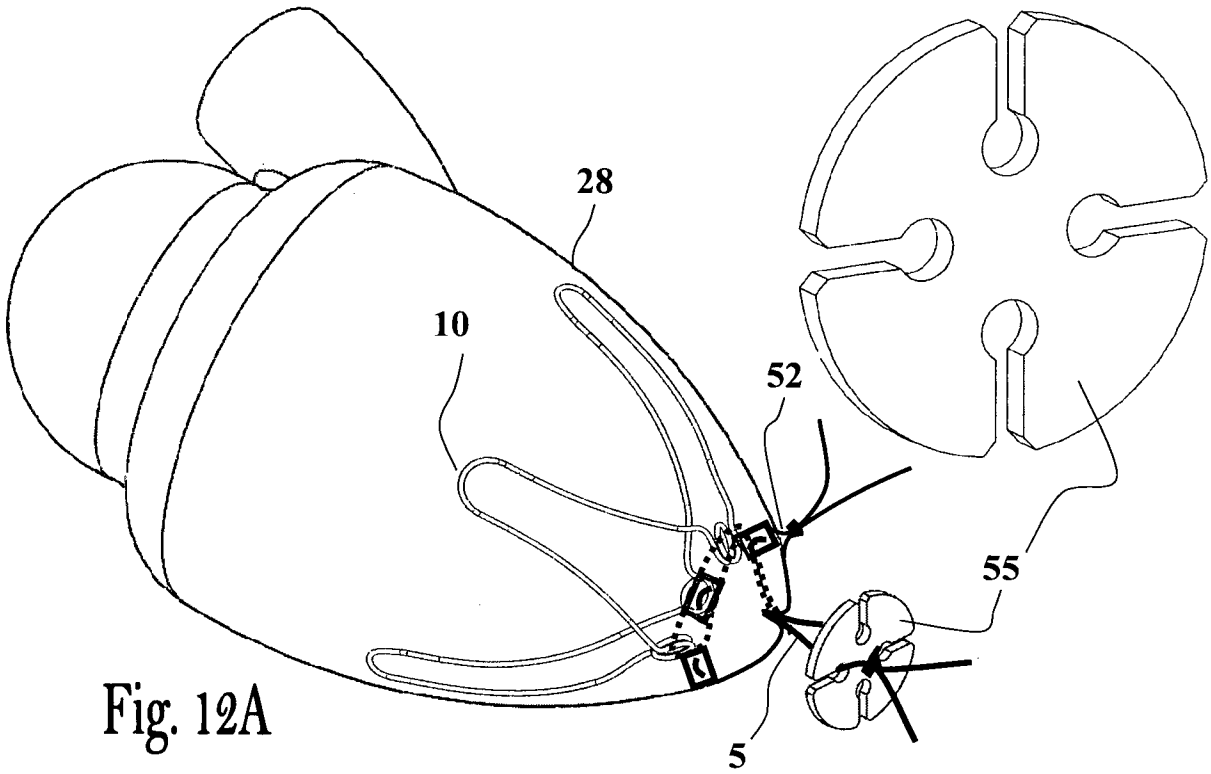


Fig. 12A

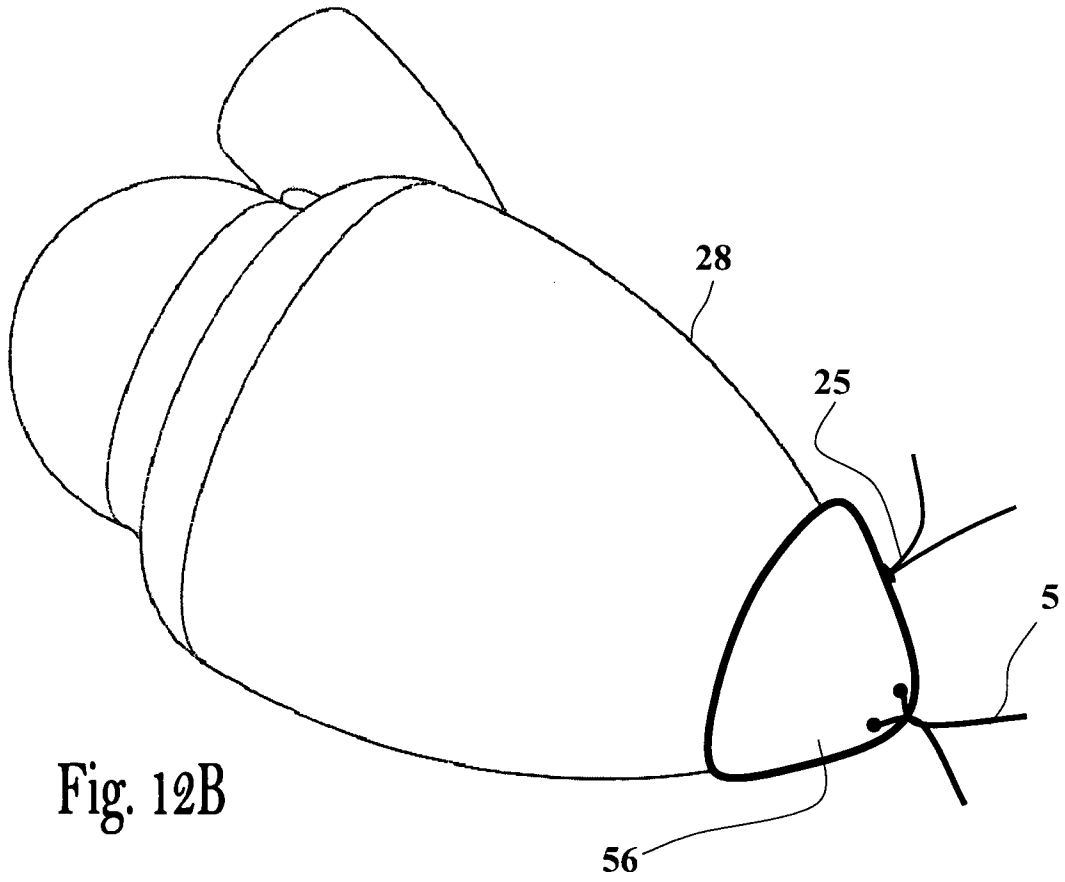


Fig. 12B

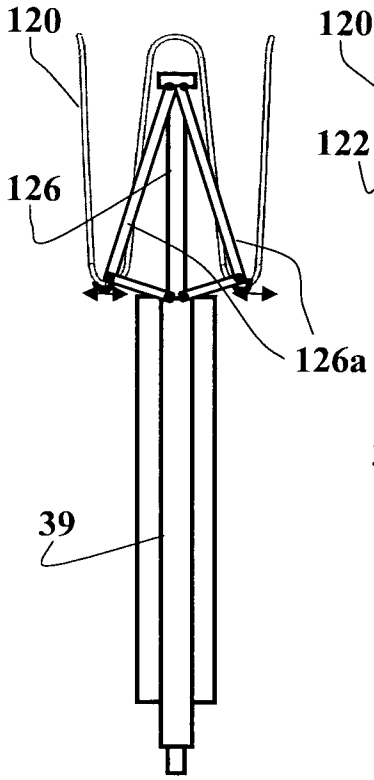


Fig. 13A

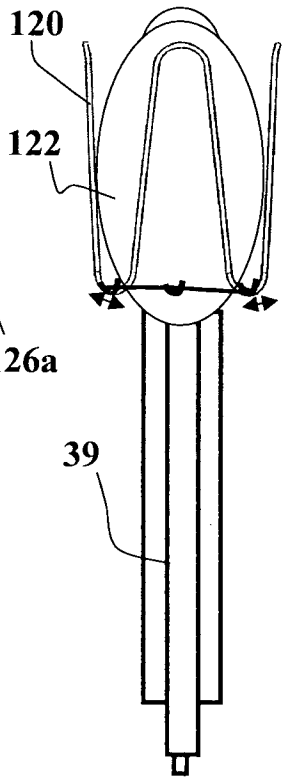


Fig. 13B

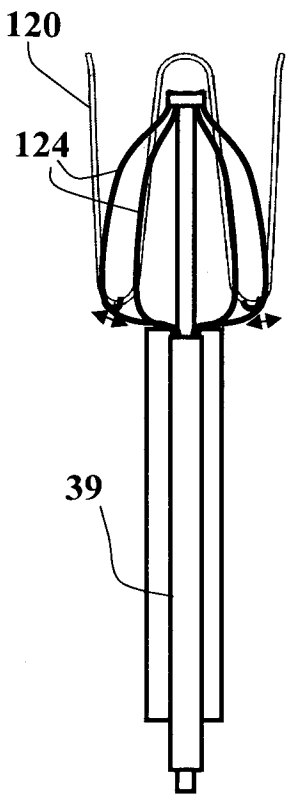


Fig. 13C

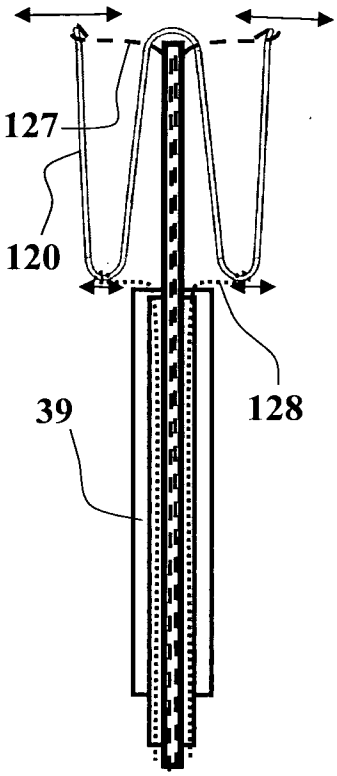


Fig. 13D

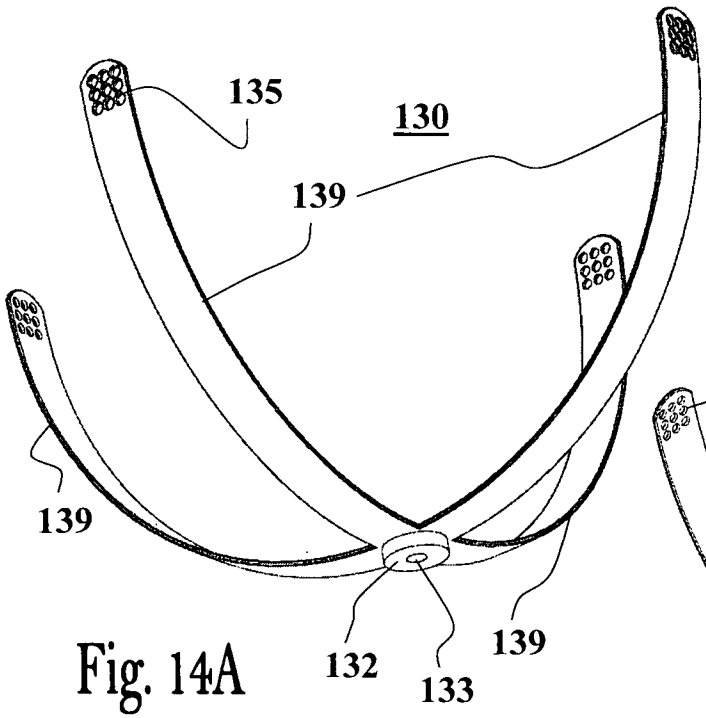


Fig. 14A

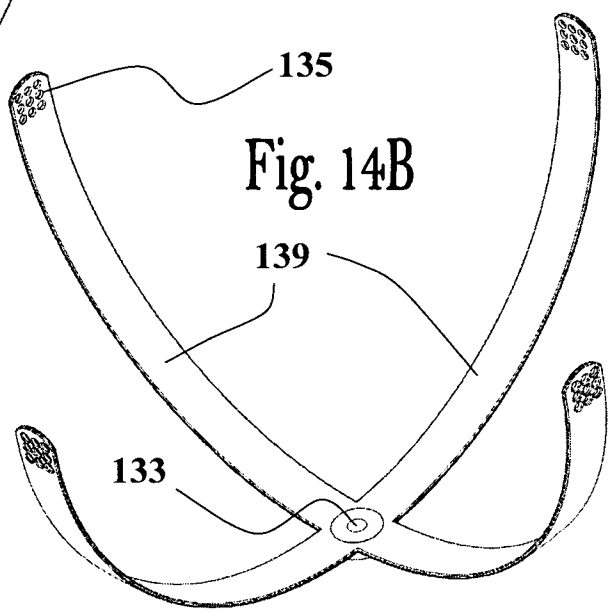


Fig. 14B

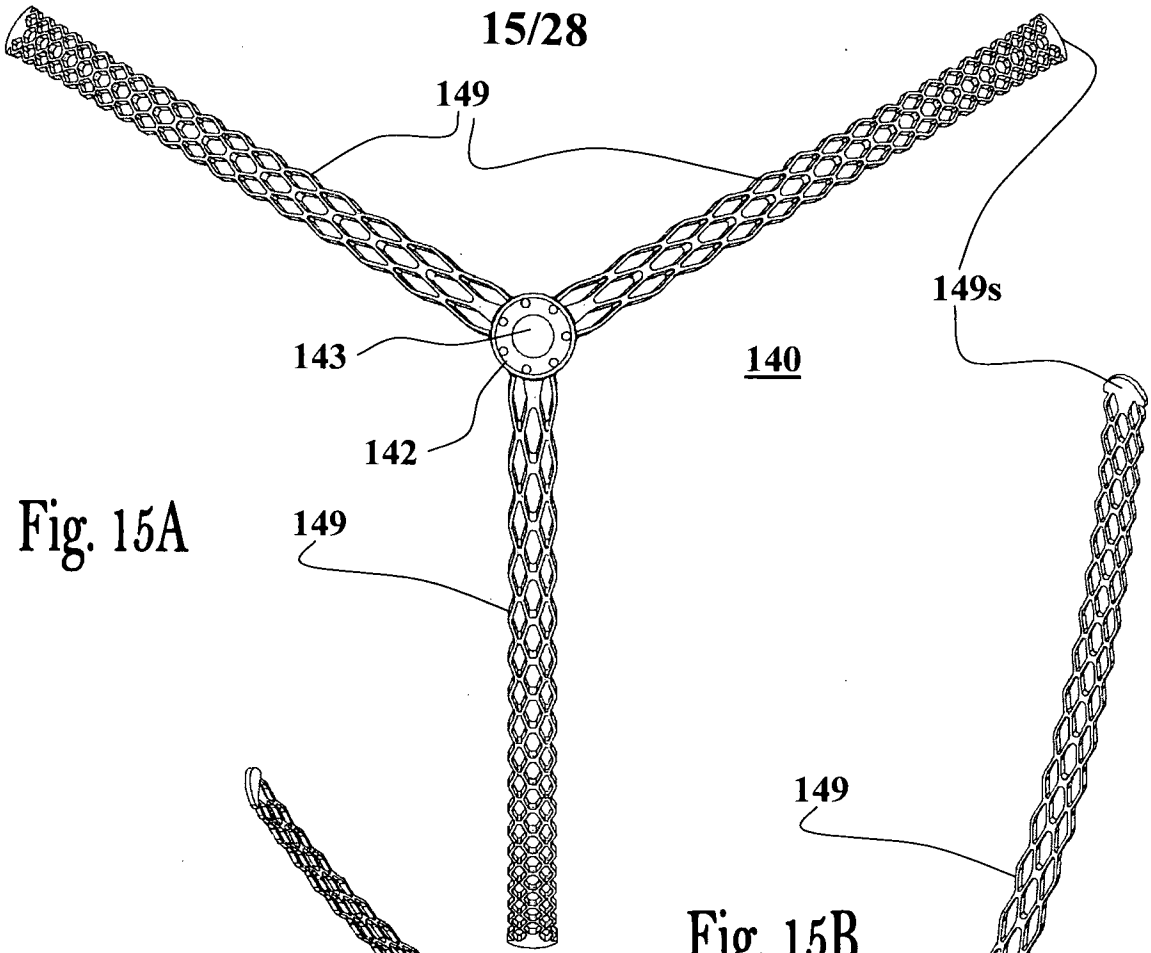


Fig. 15A

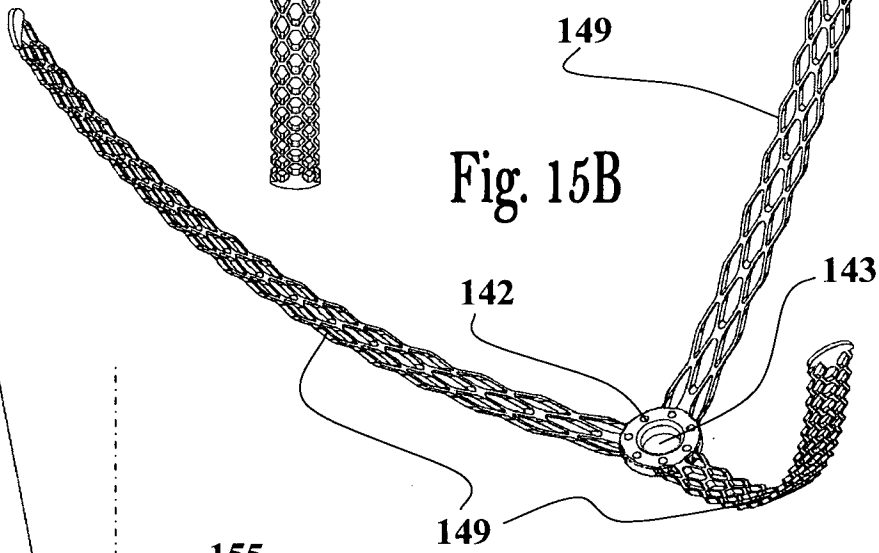


Fig. 15B

Fig. 16A

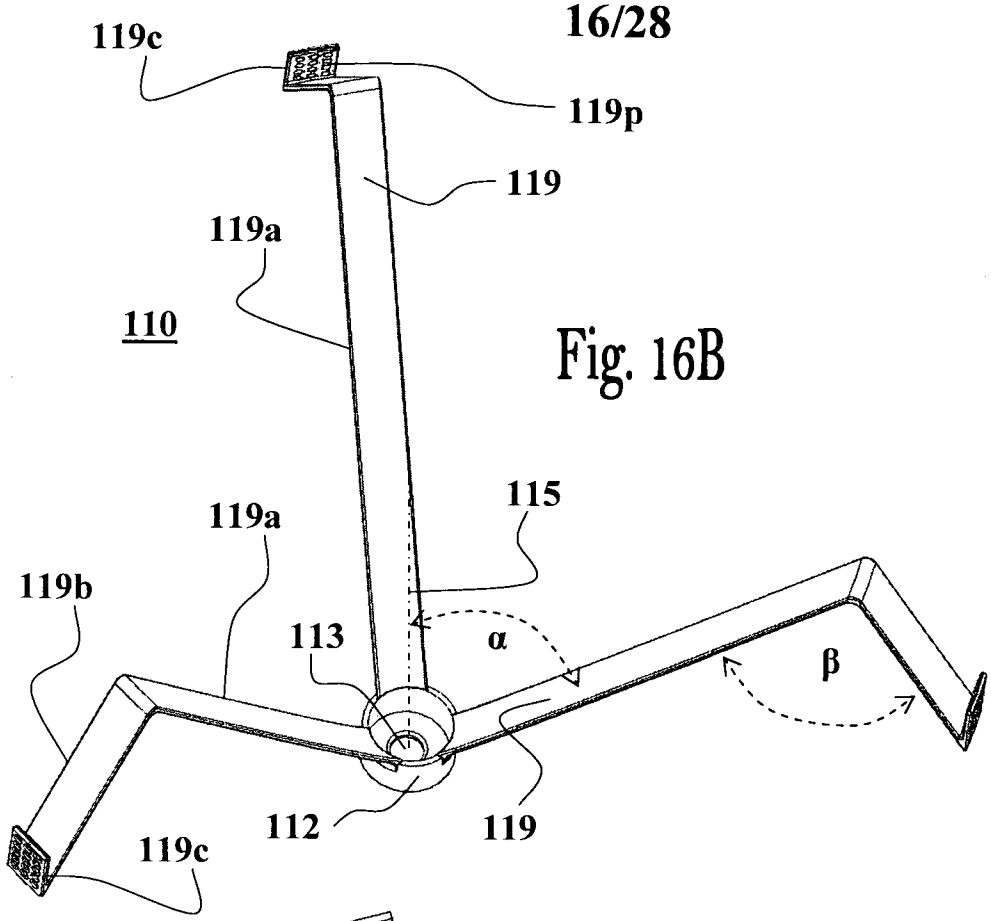


Fig. 16B

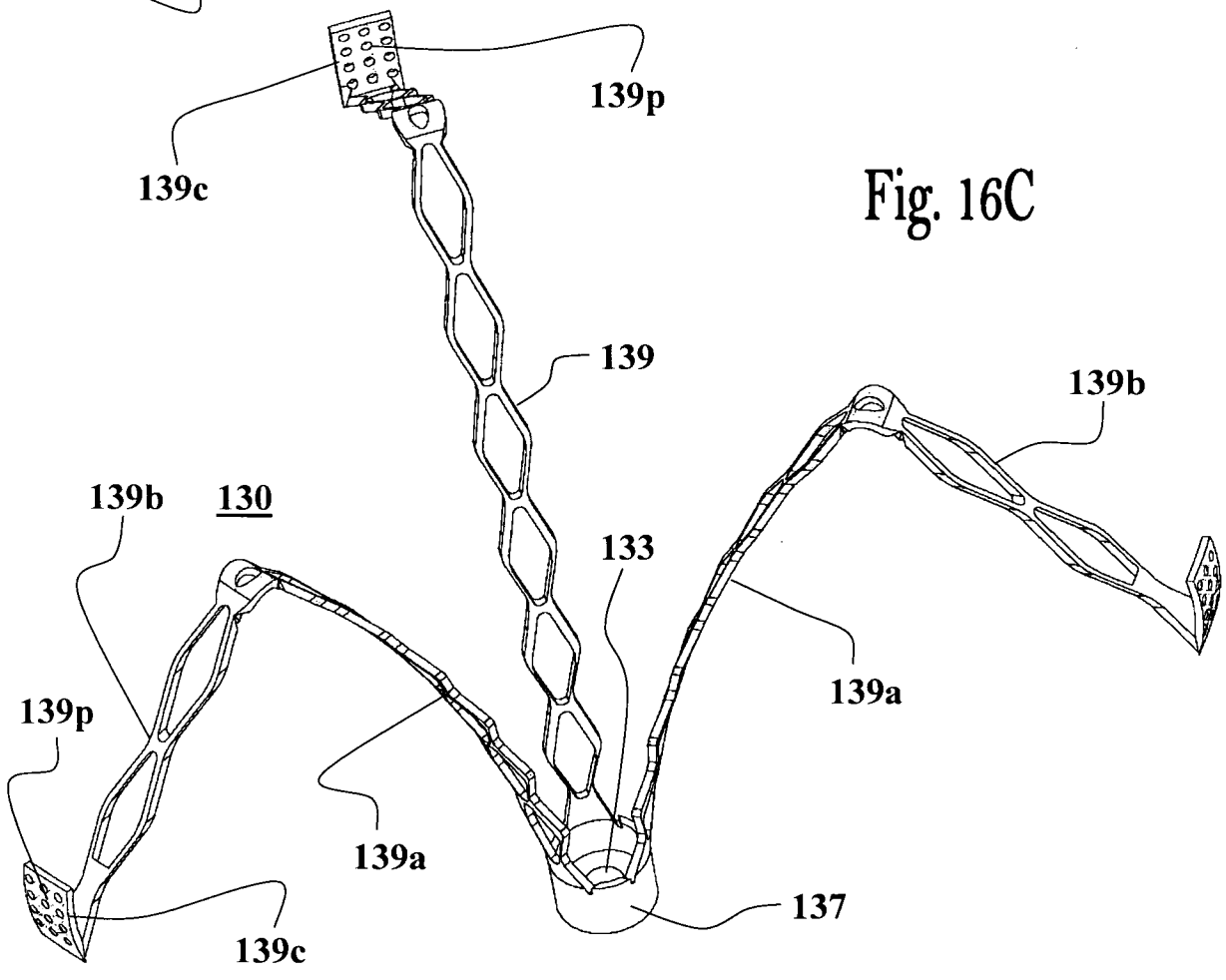


Fig. 16C

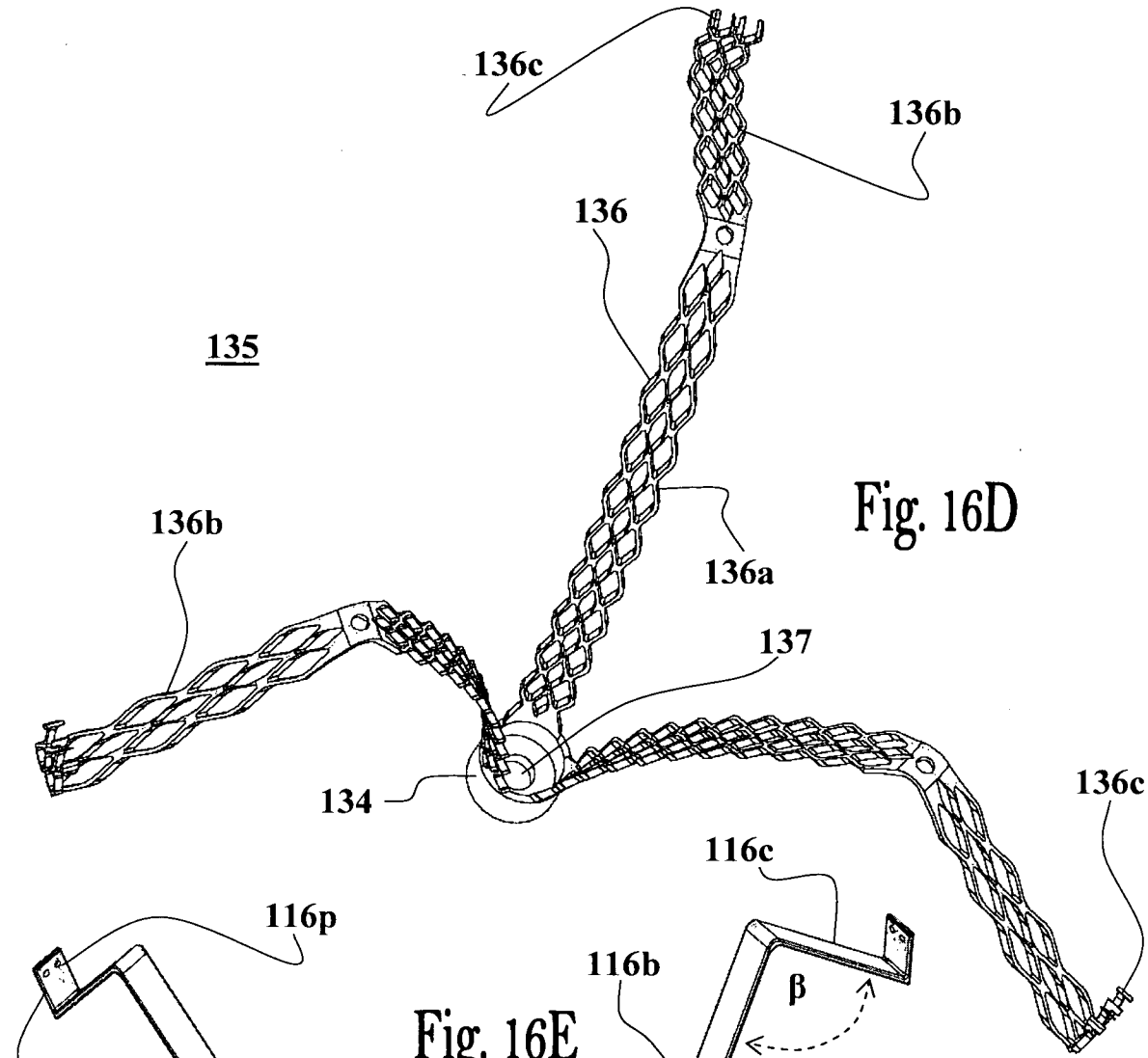


Fig. 16D

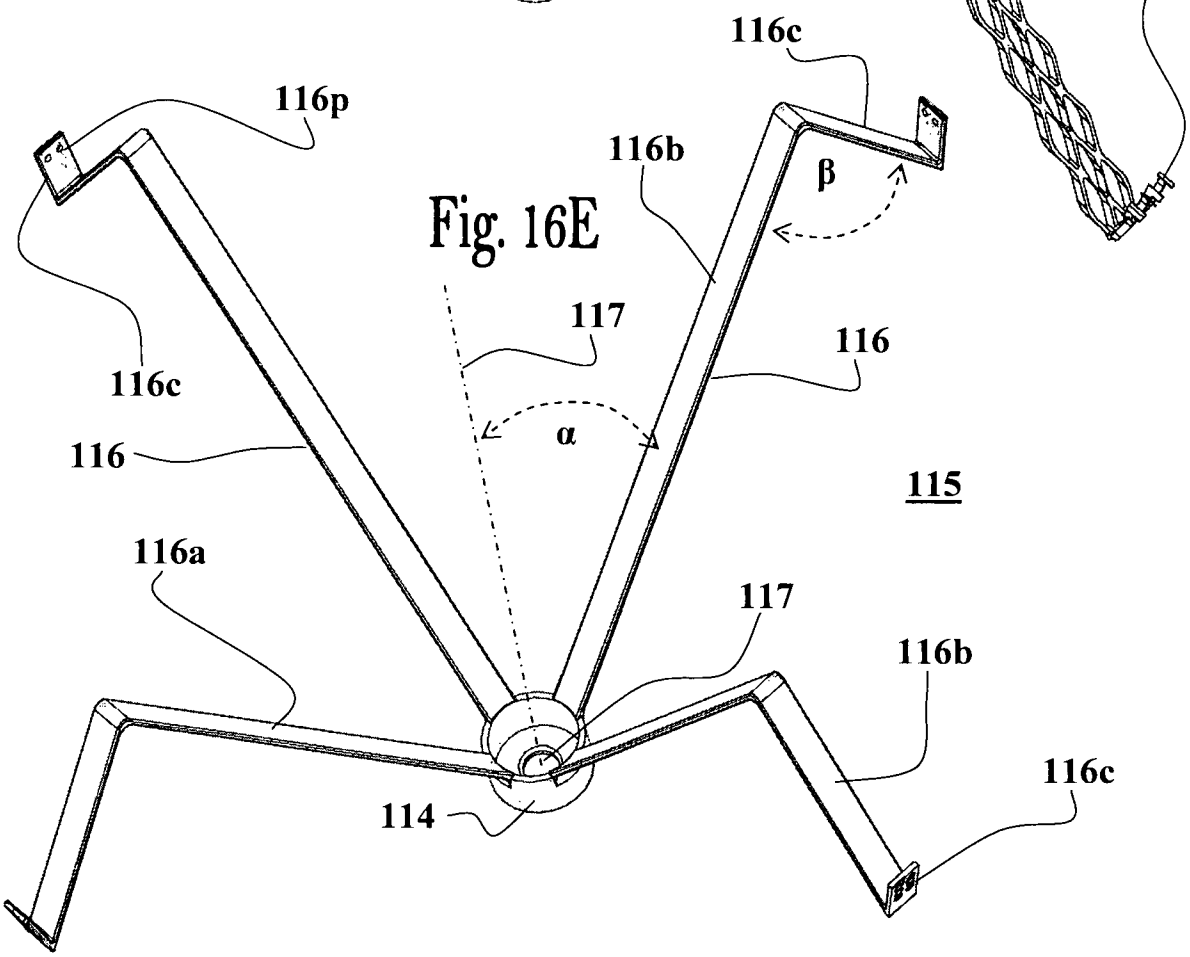


Fig. 16E

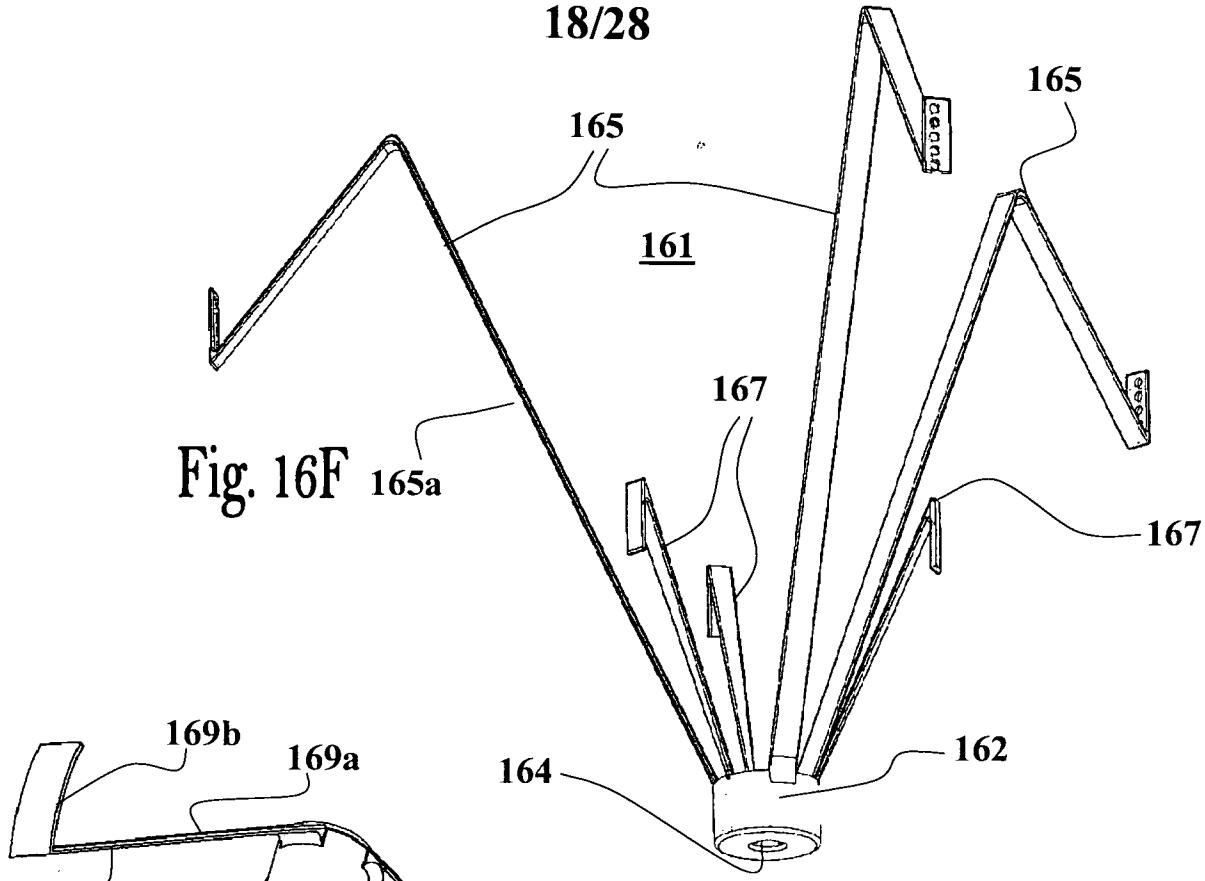


Fig. 16F

Fig. 17A

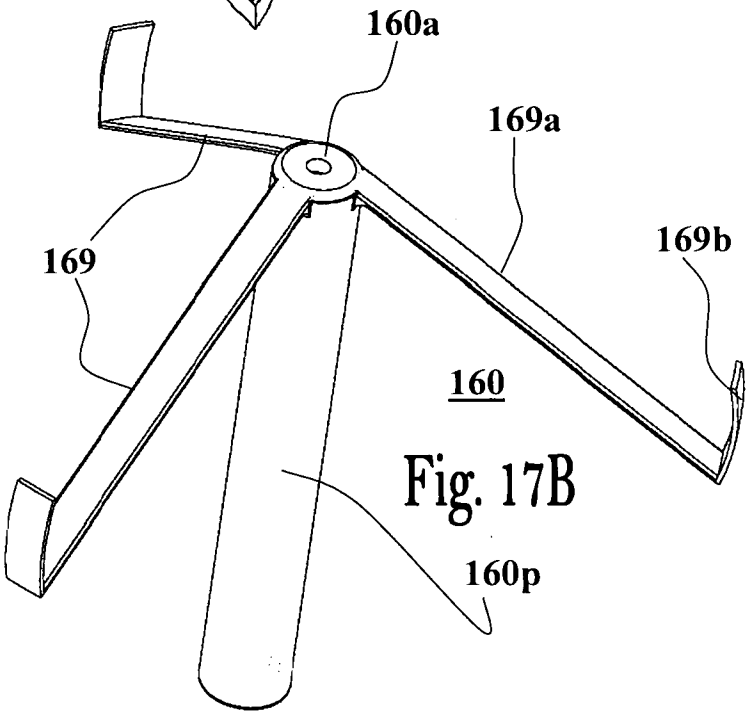


Fig. 17B

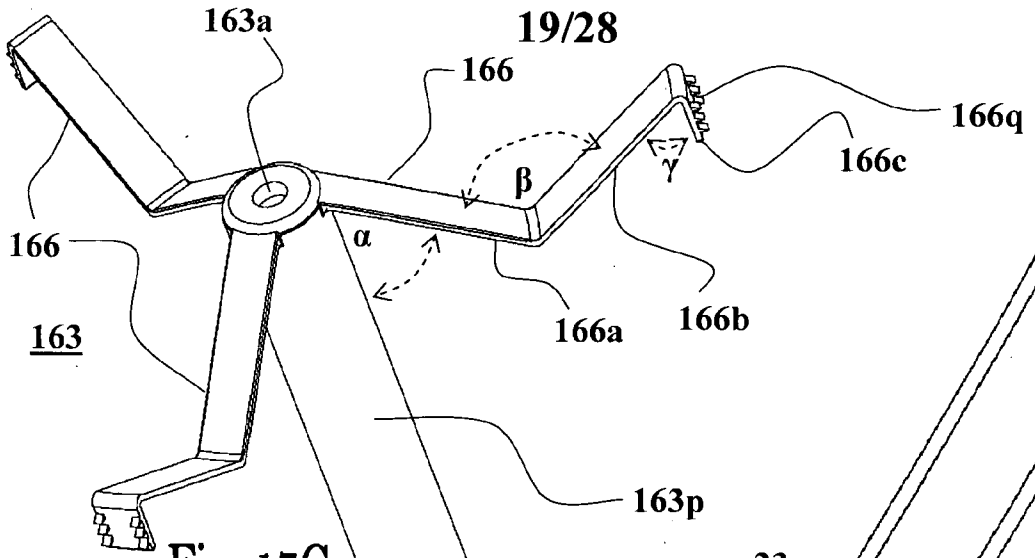


Fig. 17C

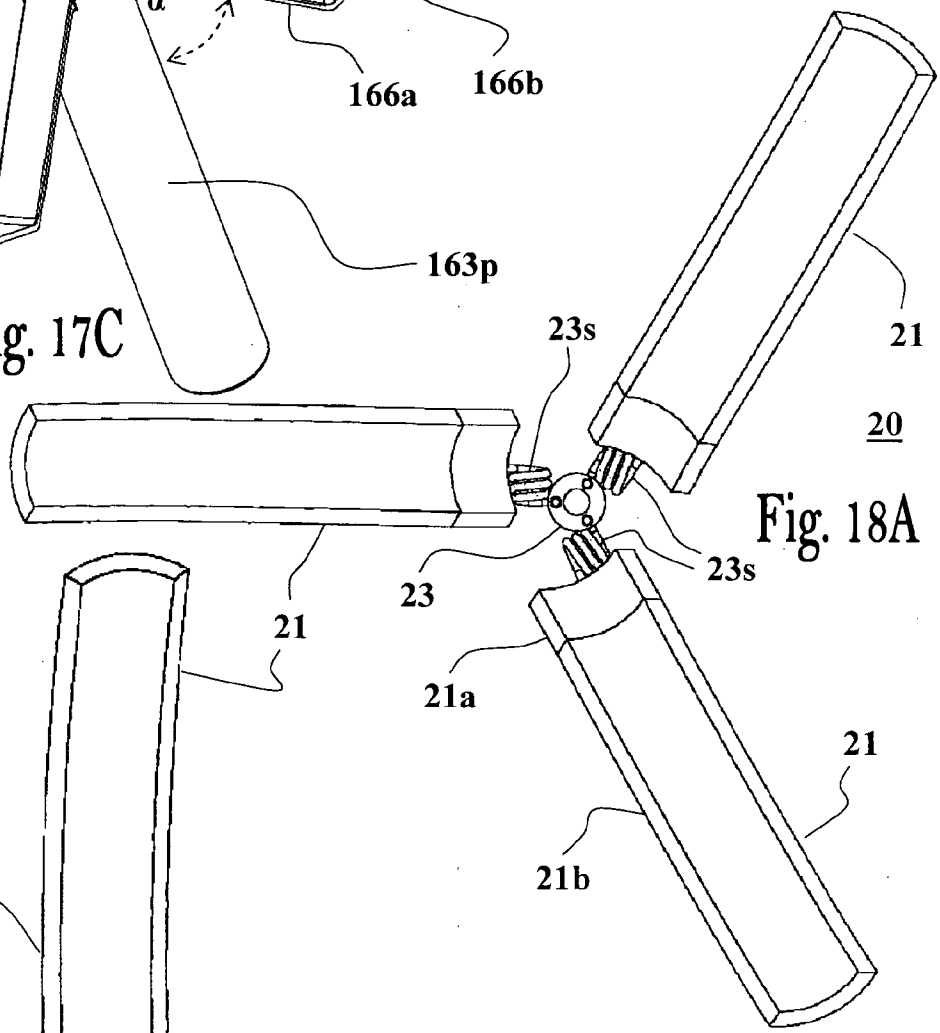


Fig. 18A

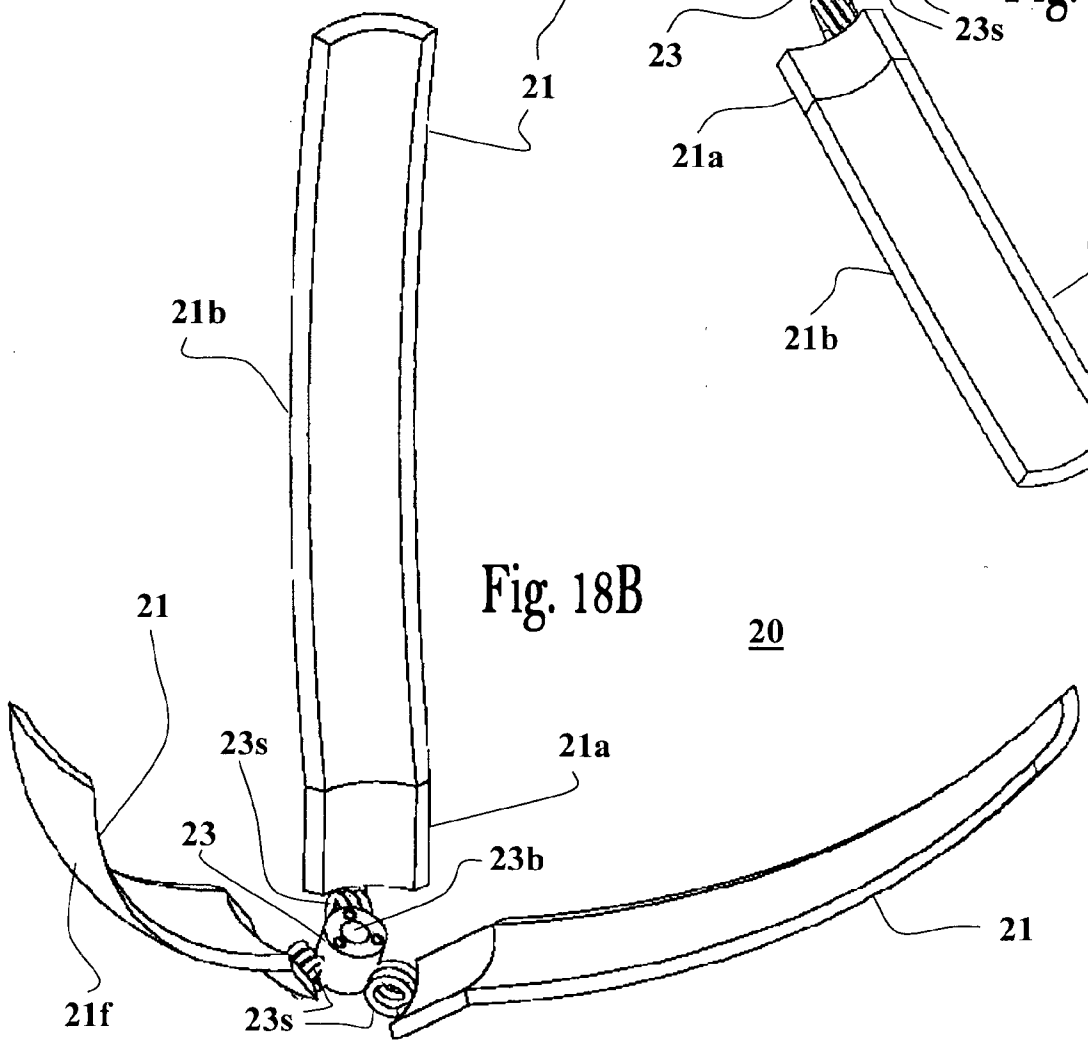


Fig. 18B

20

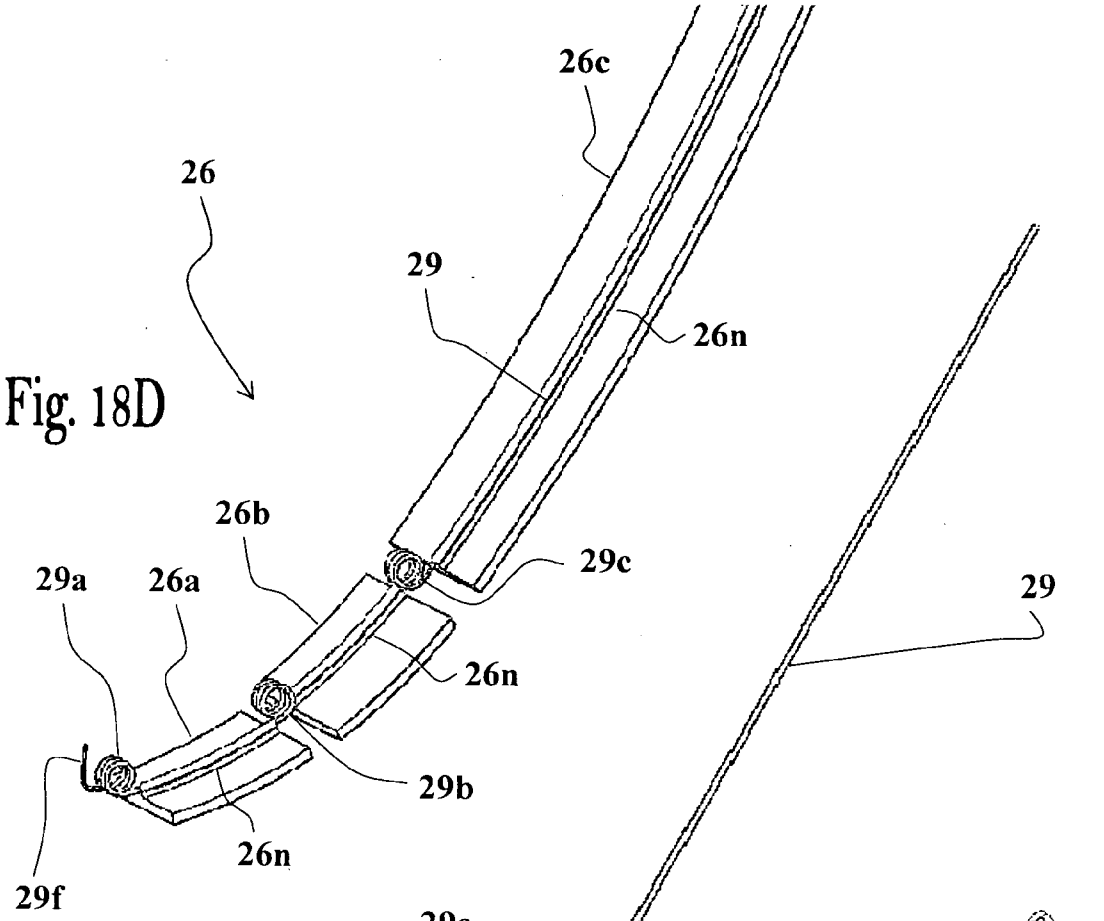


Fig. 18D

Fig. 18C

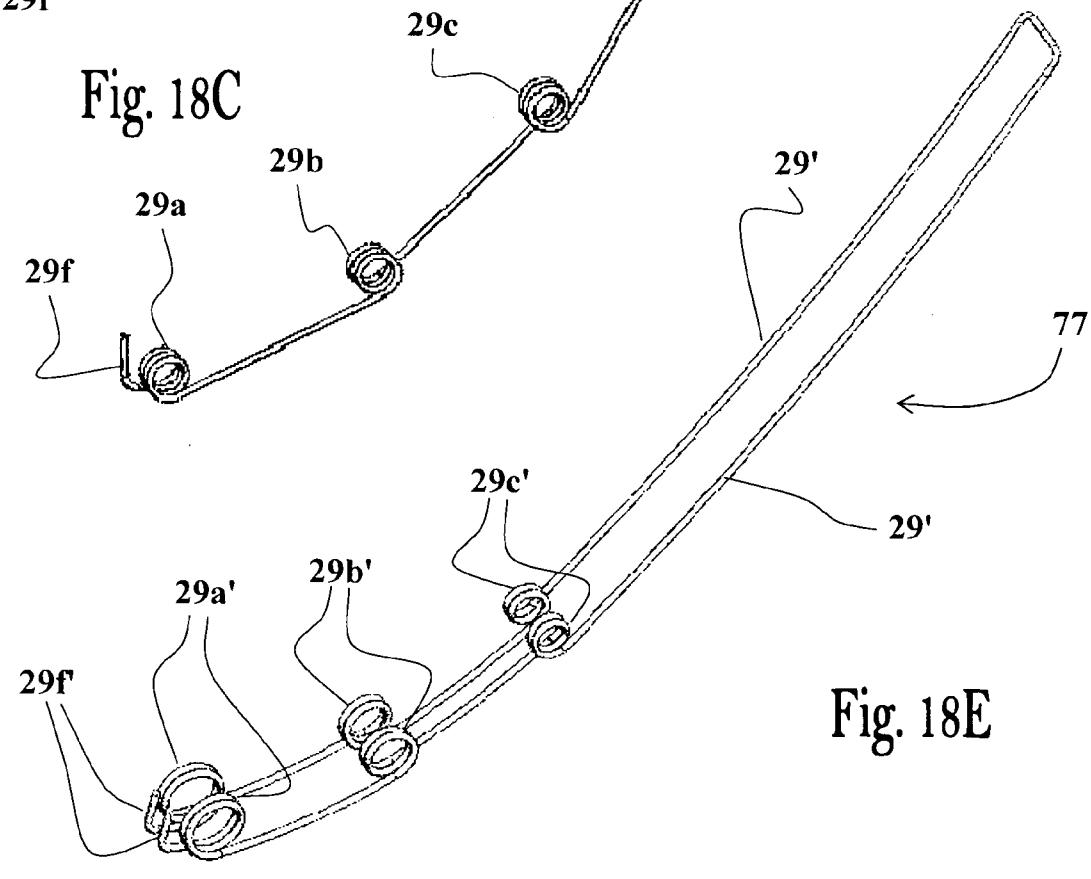


Fig. 18E

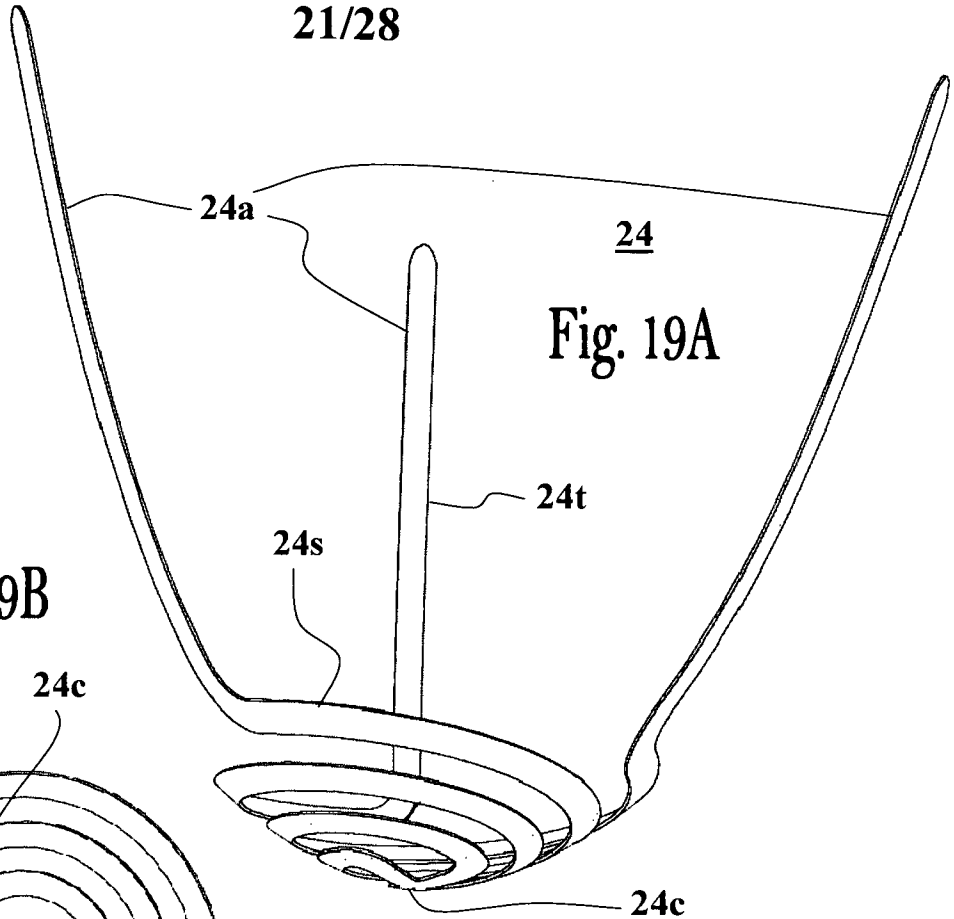


Fig. 19A

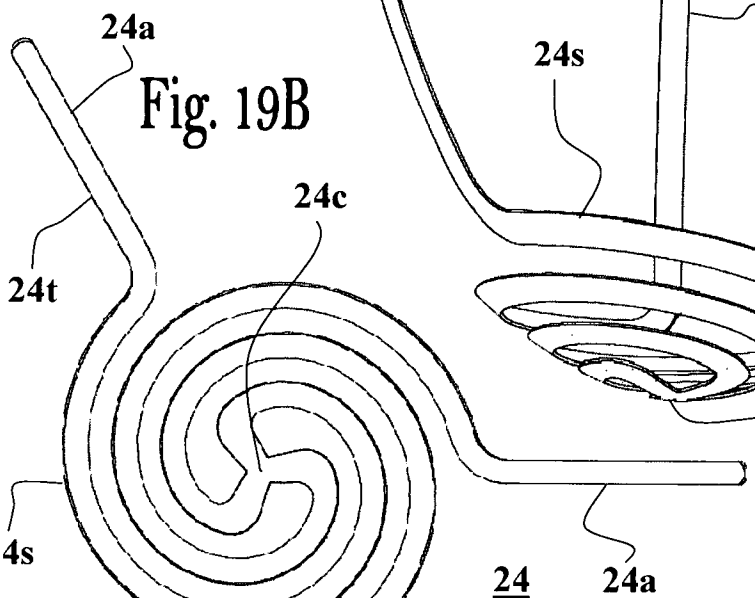


Fig. 19B

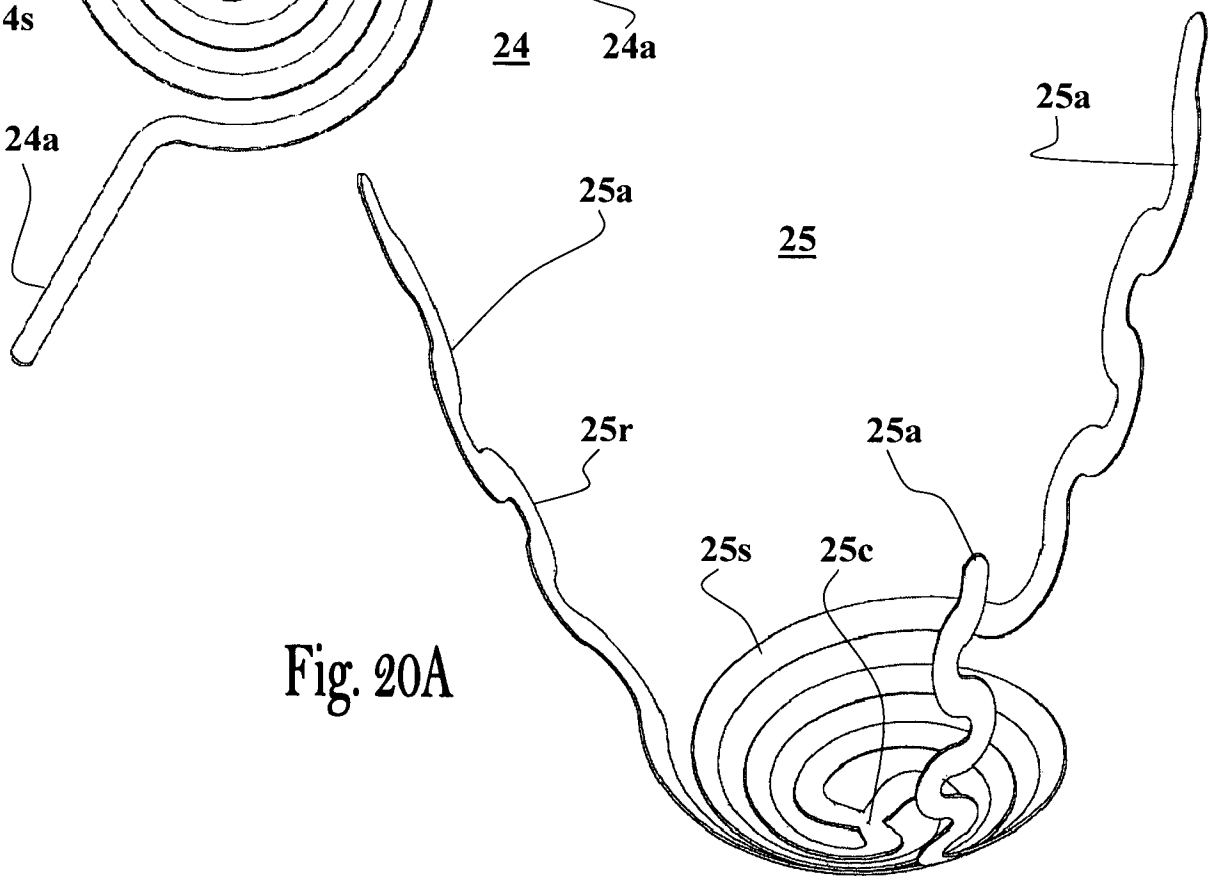


Fig. 20A

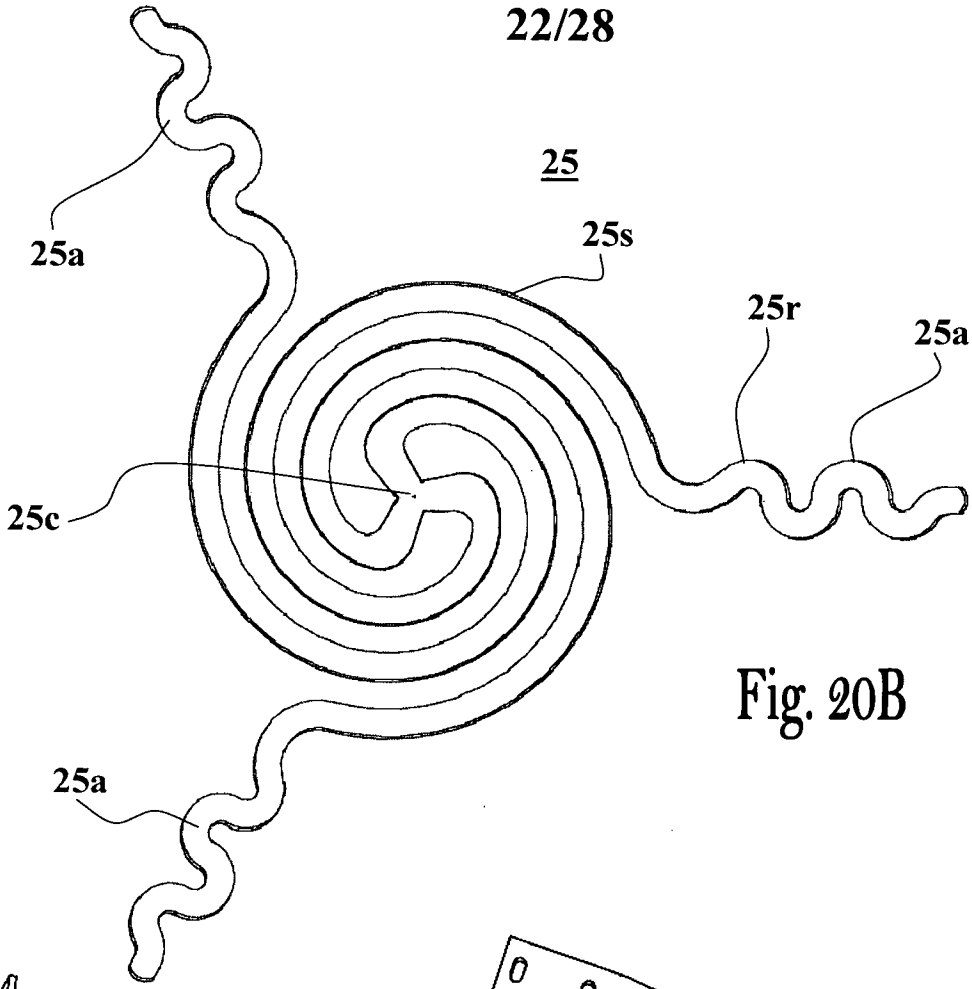


Fig. 20B

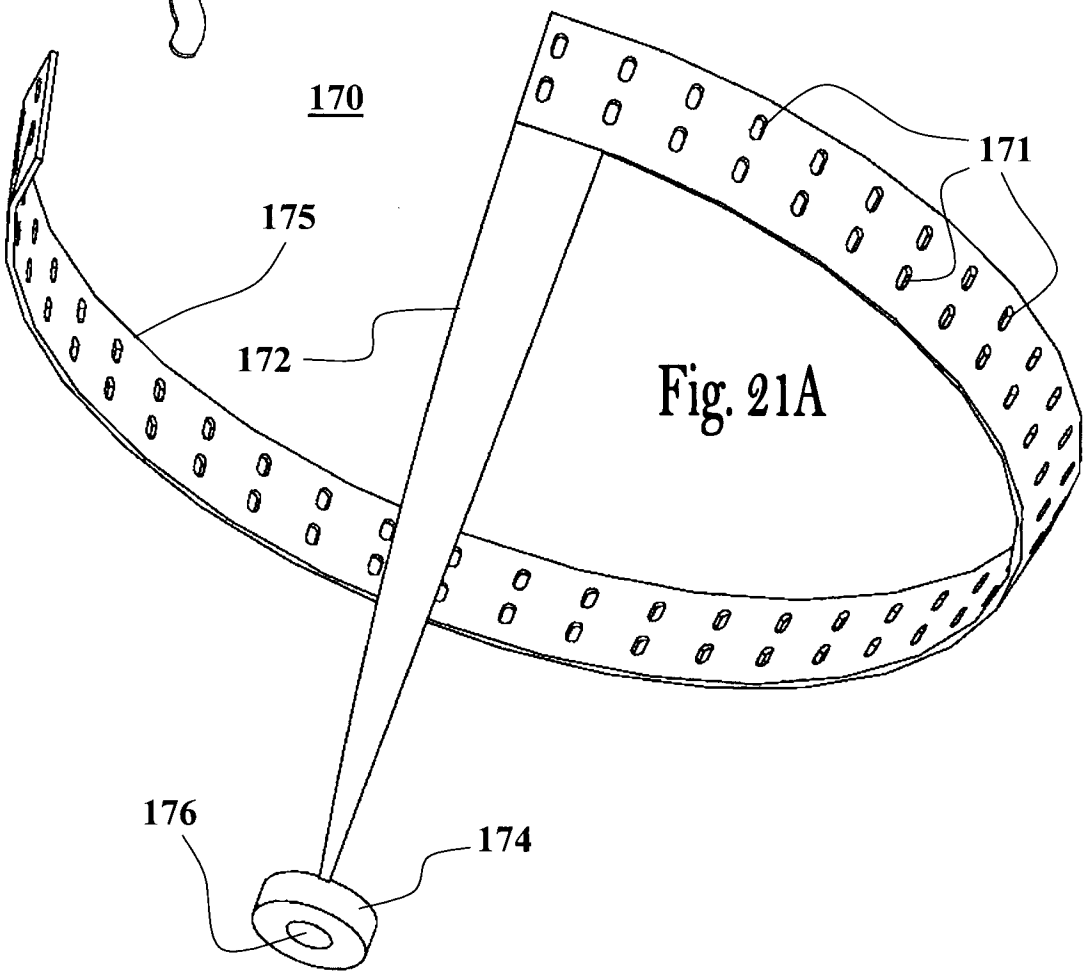


Fig. 21A

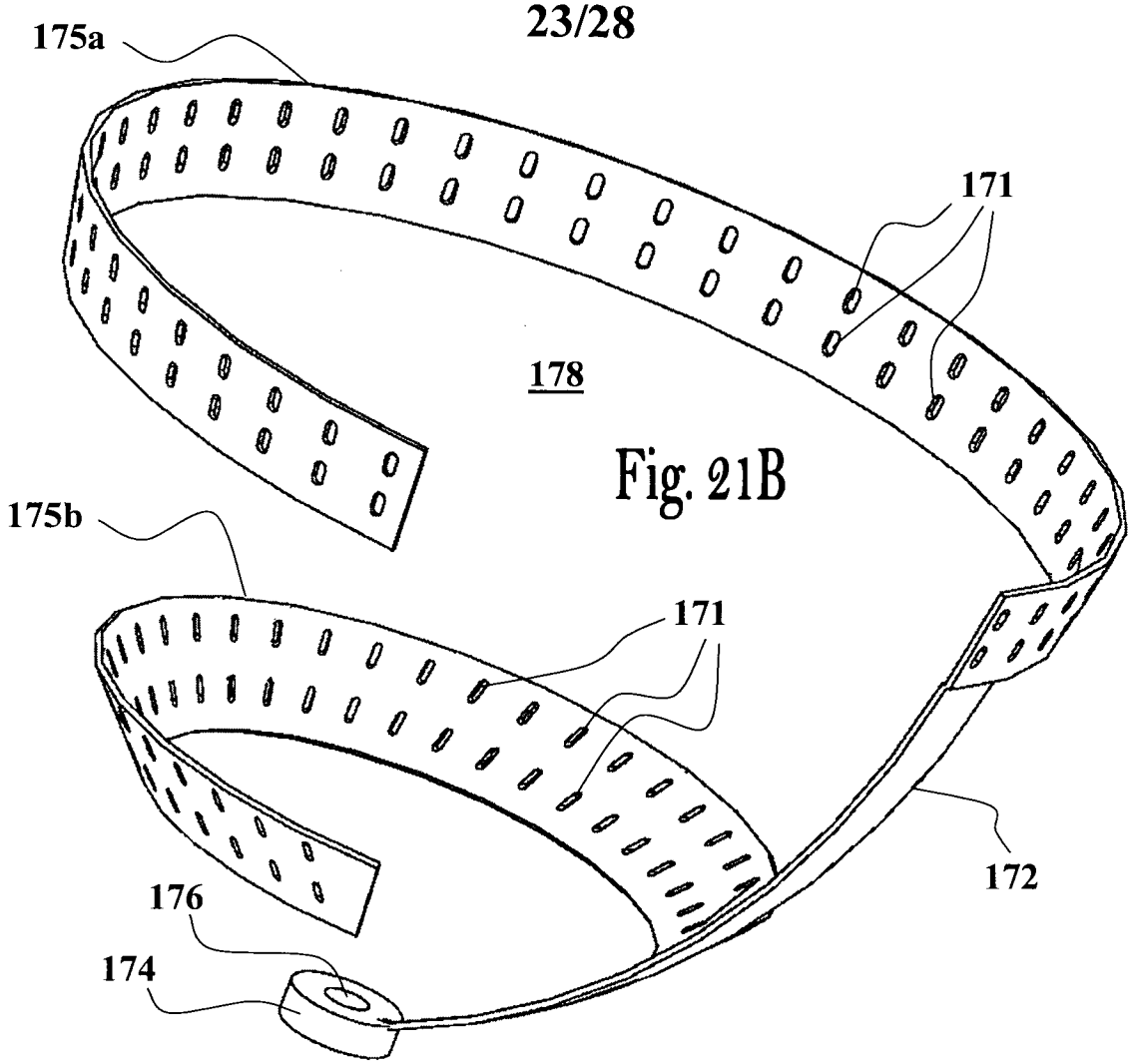


Fig. 21B

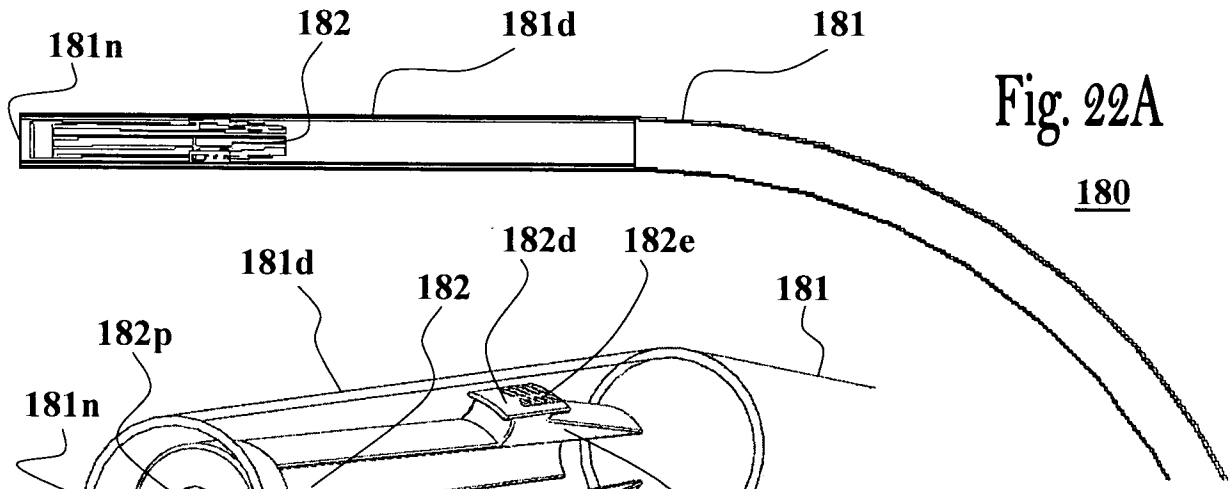


Fig. 22A

Fig. 22B

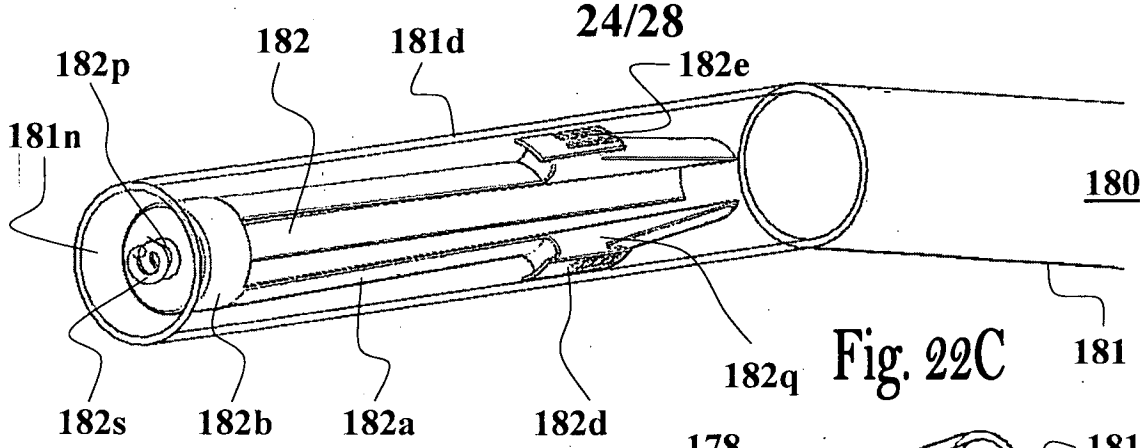


Fig. 22C

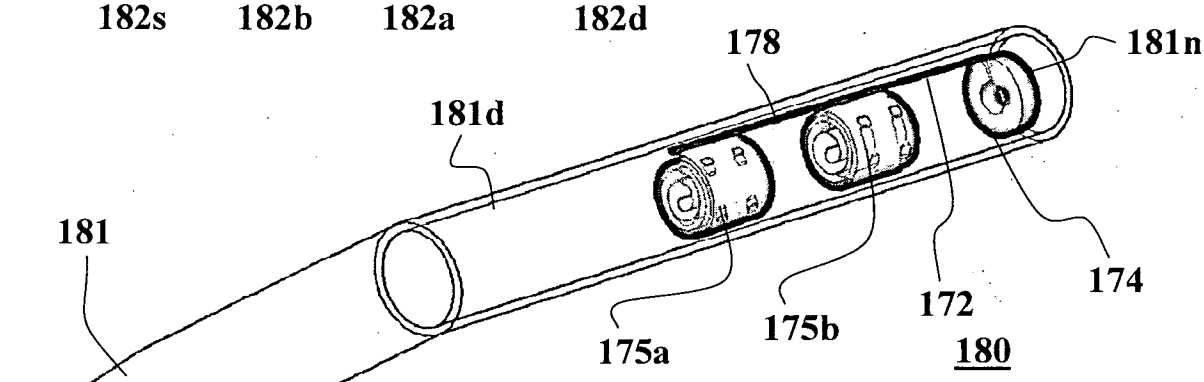


Fig. 22D

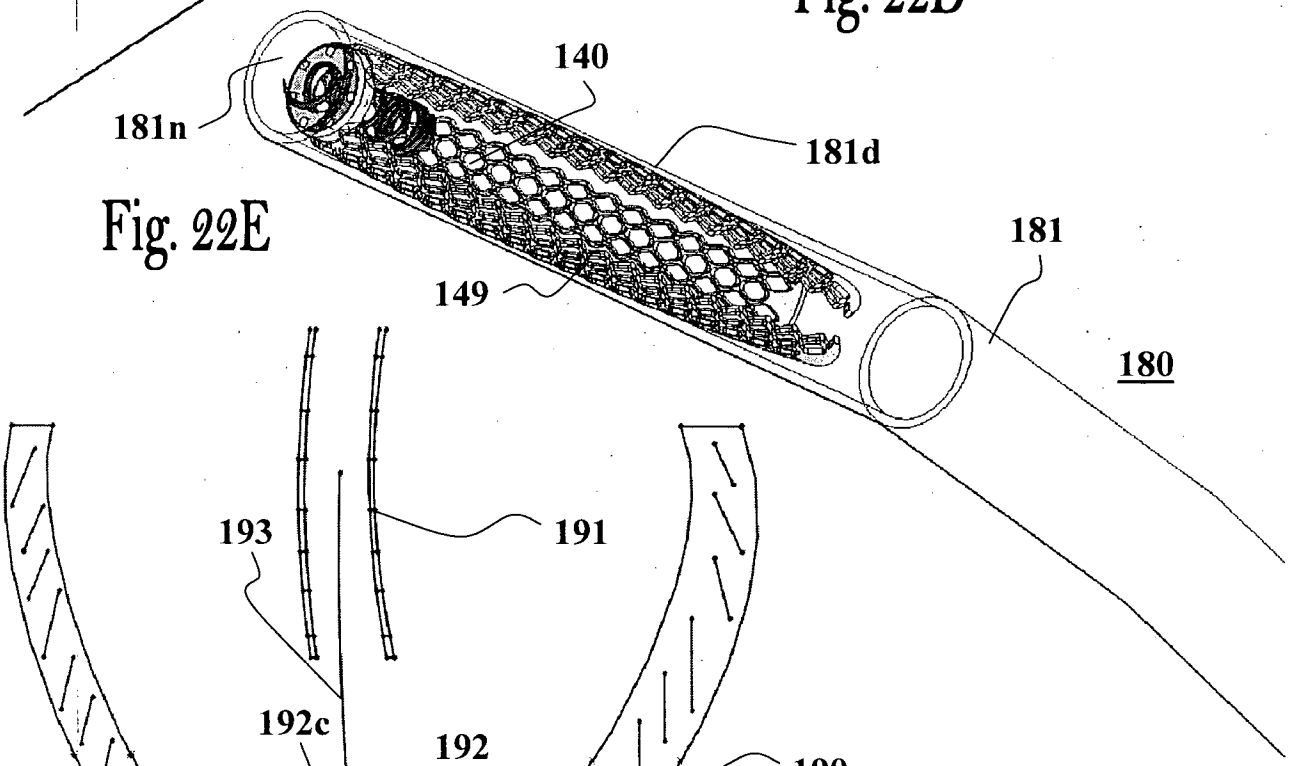


Fig. 22E

Fig. 23A

Fig. 23B

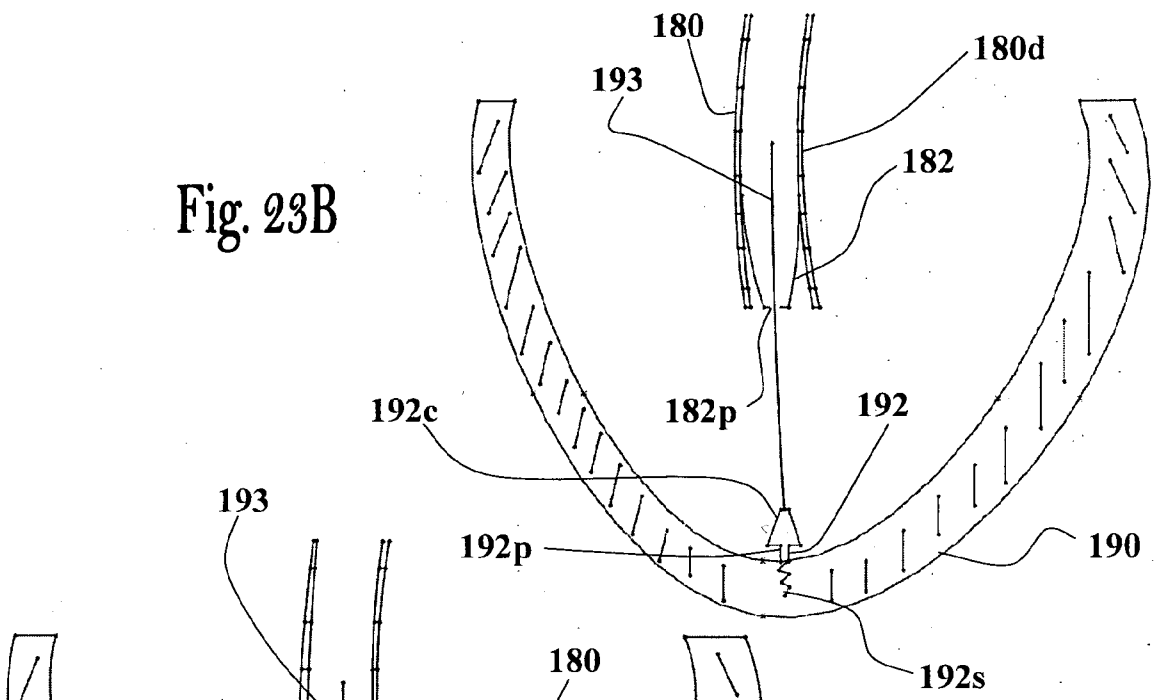


Fig. 23C

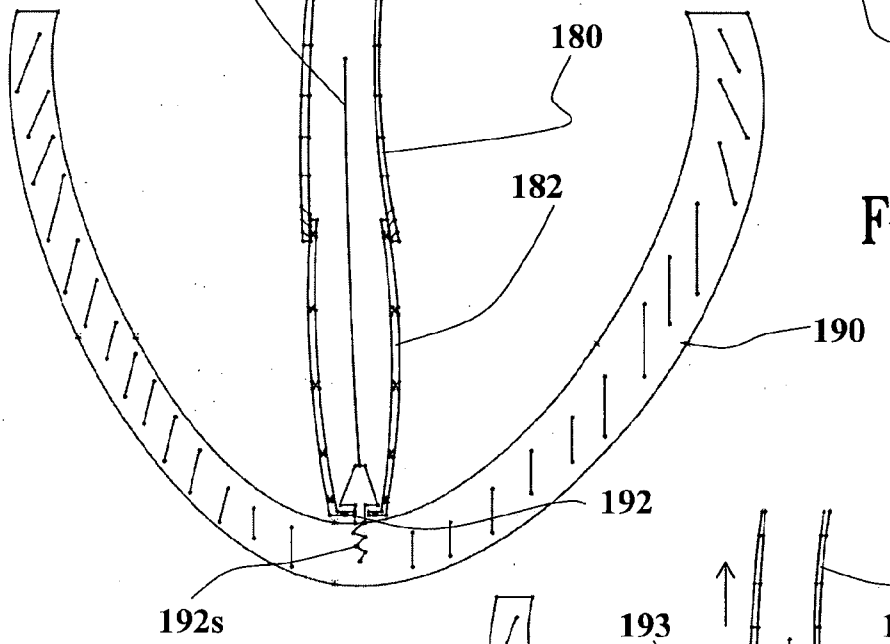
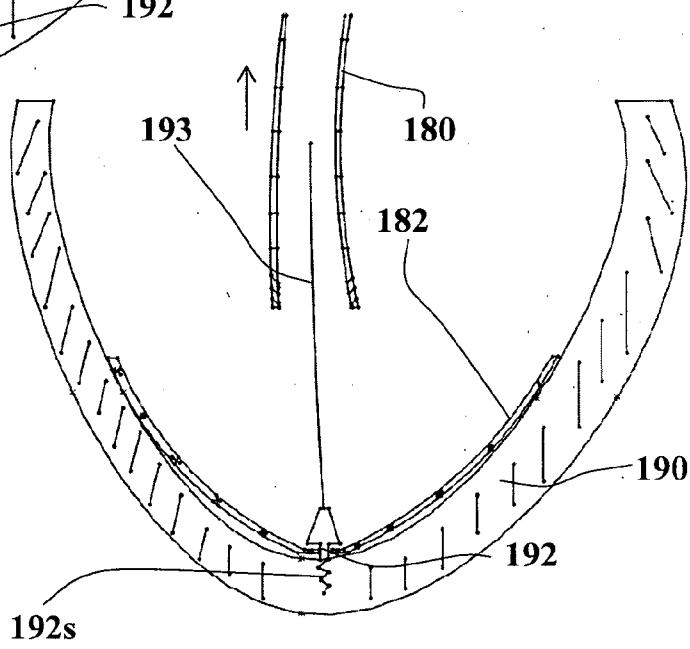


Fig. 23D



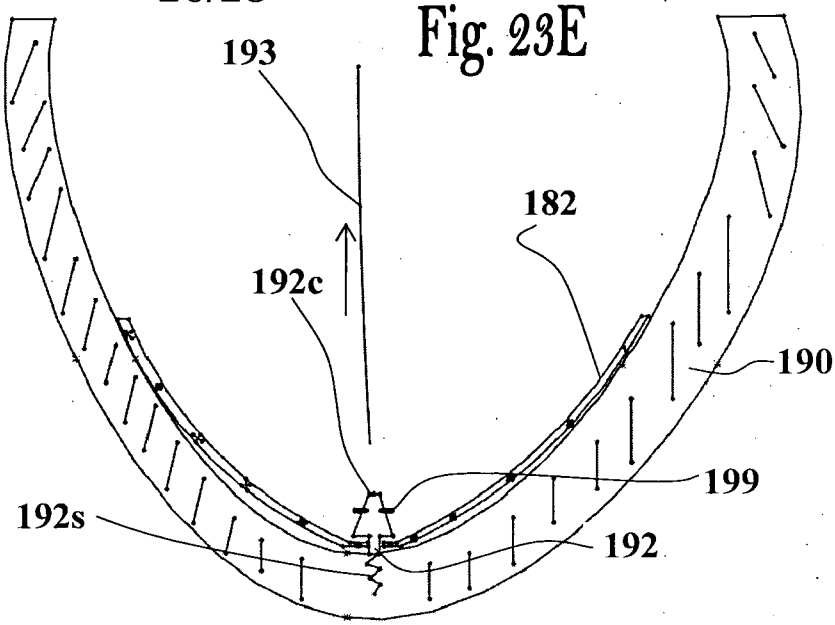


Fig. 23E

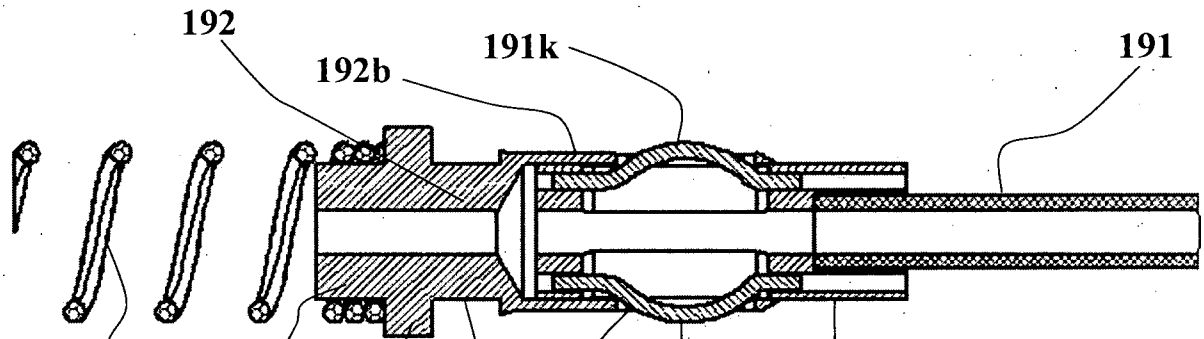


Fig. 23F

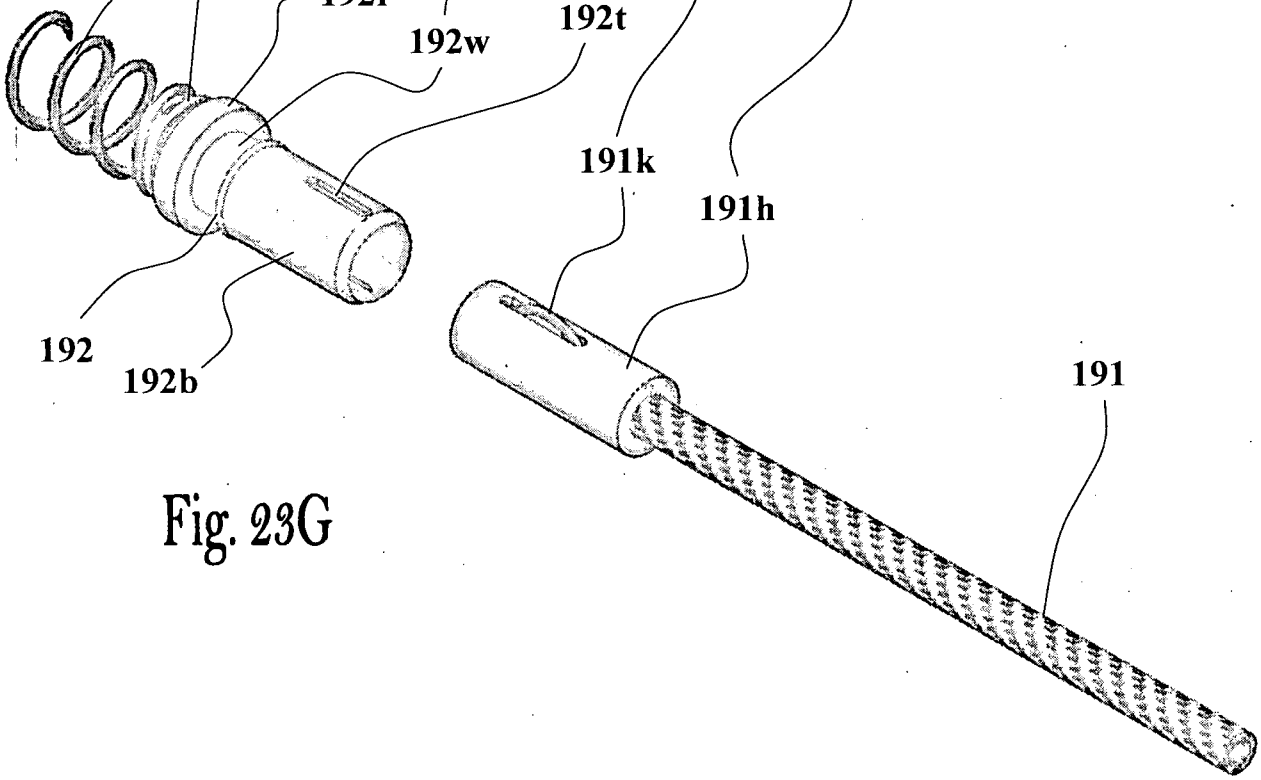


Fig. 23G

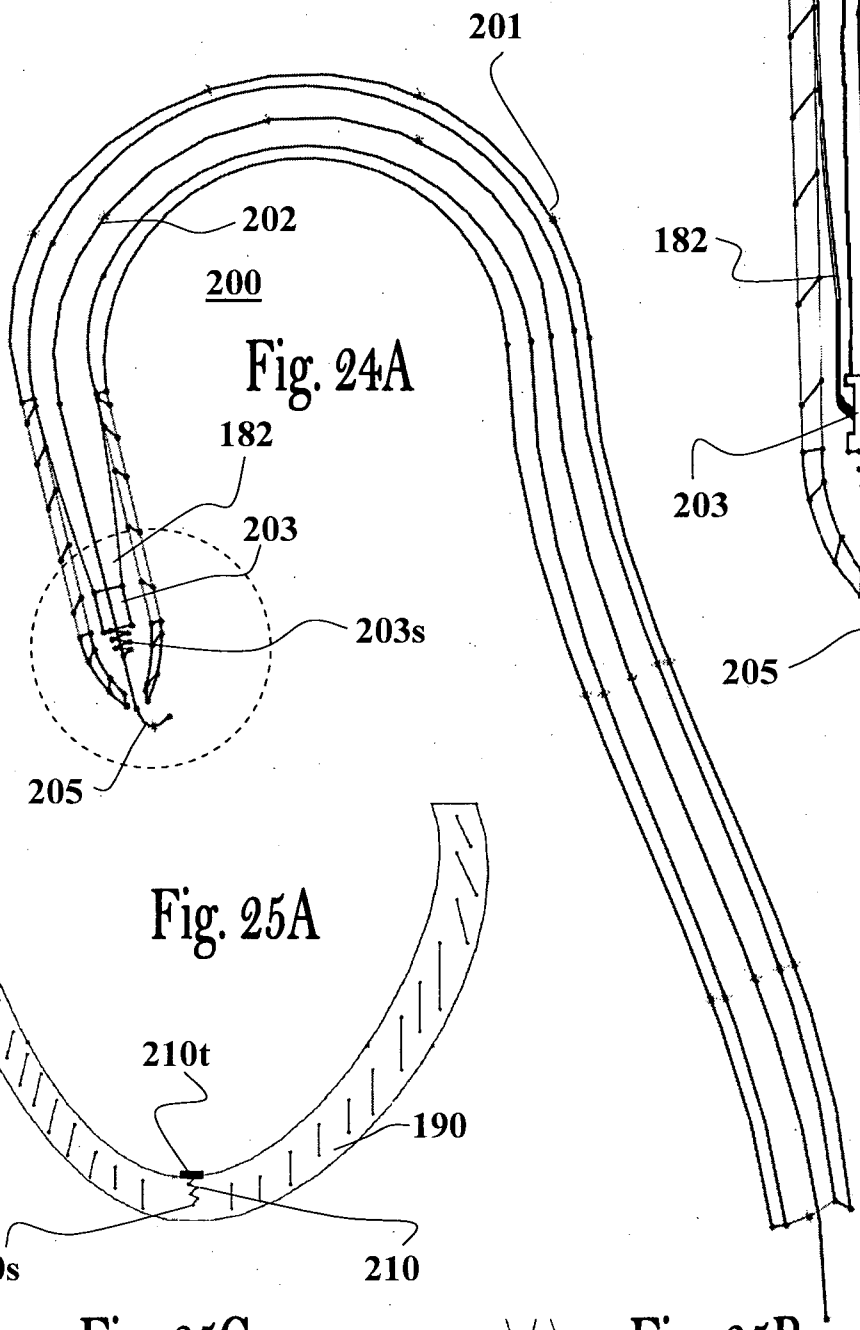


Fig. 24A

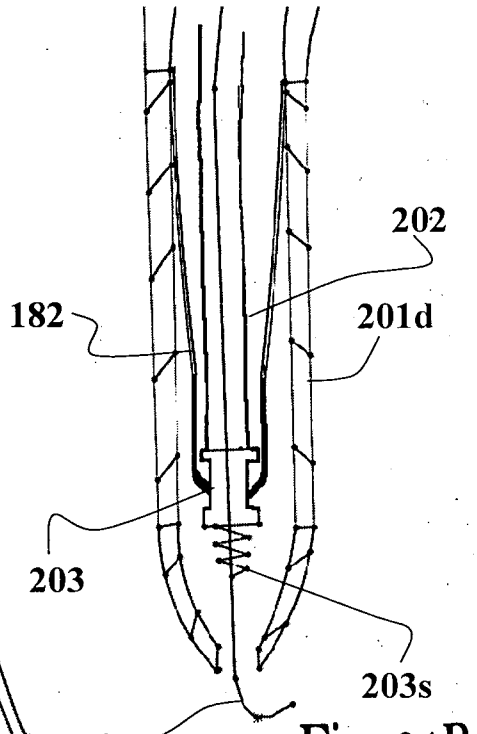


Fig. 24B

Fig. 25A

Fig. 25C

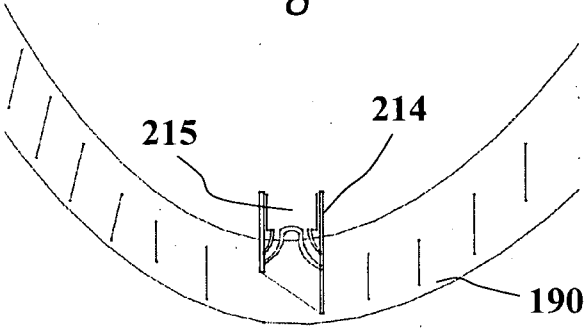
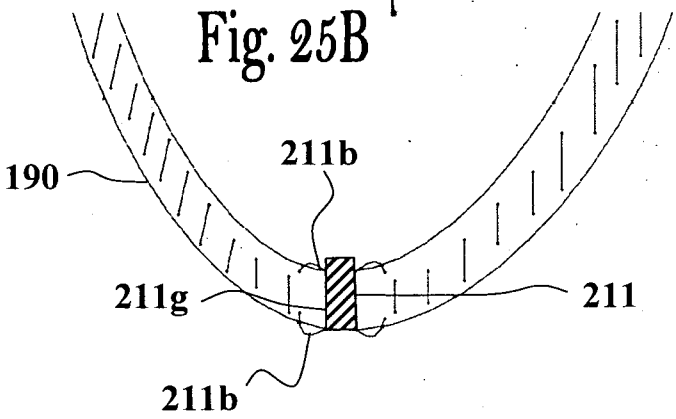


Fig. 25B



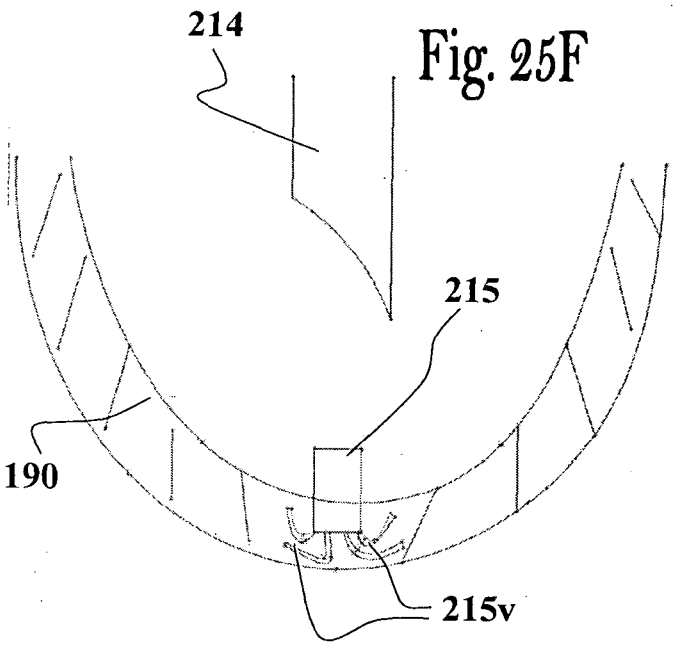


Fig. 25F

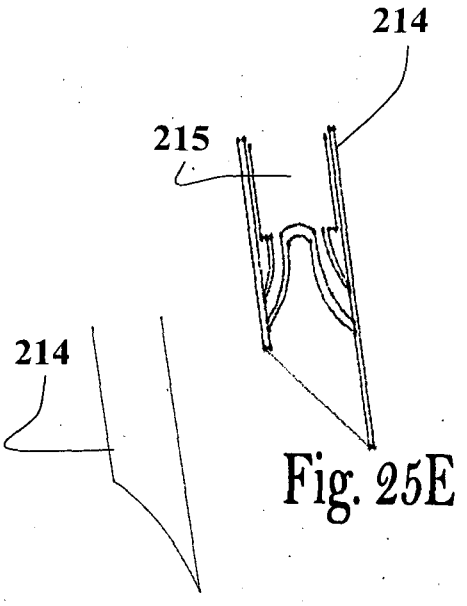


Fig. 25E

Fig. 25D

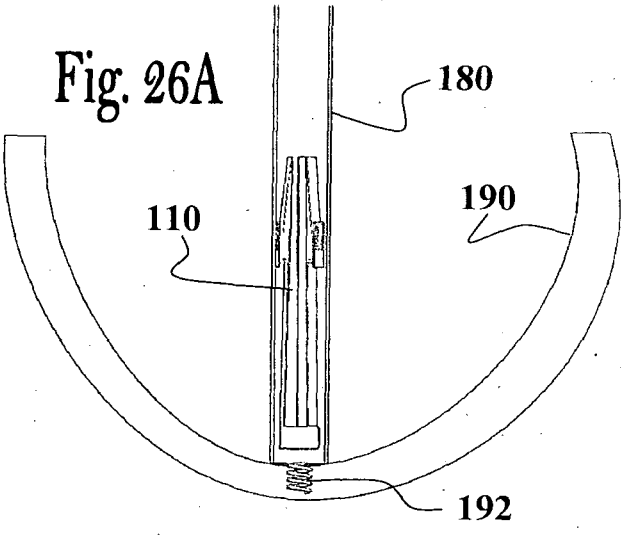


Fig. 26A

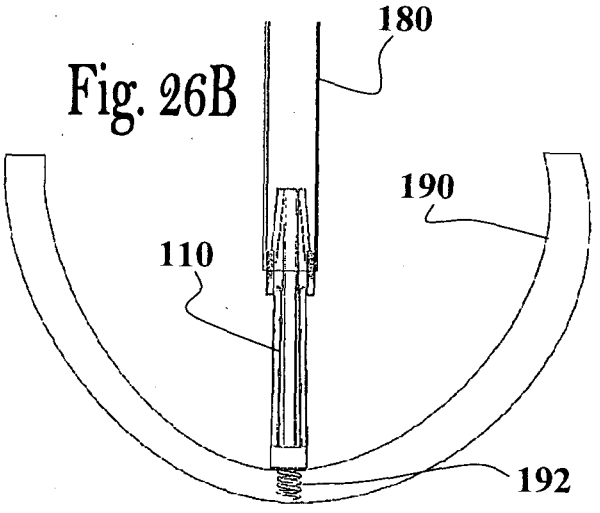


Fig. 26B

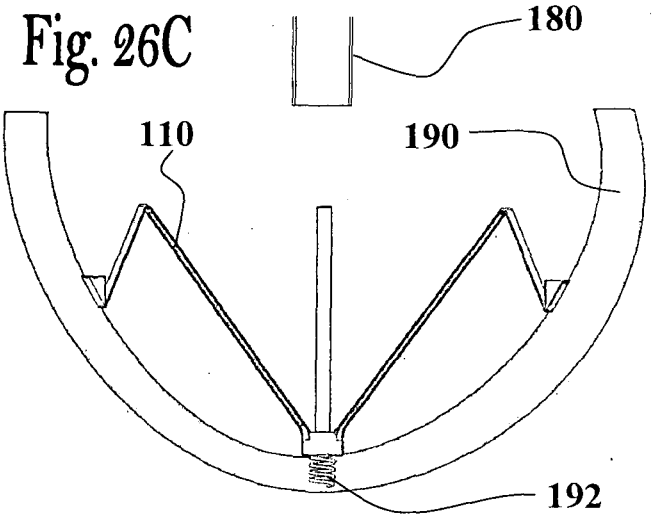


Fig. 26C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 09/00988

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2010.01)
USPC - 623/1.2
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61F 2/06 (2010.01)
USPC: 623/1.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
additional USPC: 623/1.1, 623/1.15, 623/1.21, 623/1.28, 623/1.29, 623/2.1

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Google Patents, Google, Google Scholar, WIPO
Search terms used: ventricular, ventricle, arms, stent, radial, folded, heart ventricle wall, implant$$, disk, disc, suture$, padding, tissue growth, mesh, elastic, spring$, star, flower, papillary muscles, heart apex, diastolic heart failure

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---------- Y	US 2006/0025800 A1 (Suresh) 2 February 2006 (02.02.2006) Figs 13, 14, 17, 19, 27, 28, 33; para [0011]; para [0145]; para [0149]-[0150]; para [0154]; para [0156]-[0157]; para [0165]-[0168]; para [0171]; para [0176]-[0178]; para [0182]; para [0187]; para [0192]; para [0194]-[0195]; para [0202]; para [0204]; para [0209]-[0211]; para [0234]-[0237]; para [0248]	1-3, 5, 8-15, 19 ---------- 4, 6-7 and 16-18
Y	US 2008/0086164 A1 (Rowe) 10 April 2008 (10.04.2008) para [0003]-[0004]; para [0077]	4 and 6
Y	US 2005/0113810 A1 (Houser et al.) 26 May 2005 (26.05.2005) Figs 12a-12c; para [0056]; para [0130]; para [0145]	7 and 16-18

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2010 (25.05.2010)	03 FEB 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 09/00988

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 20-24
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.