



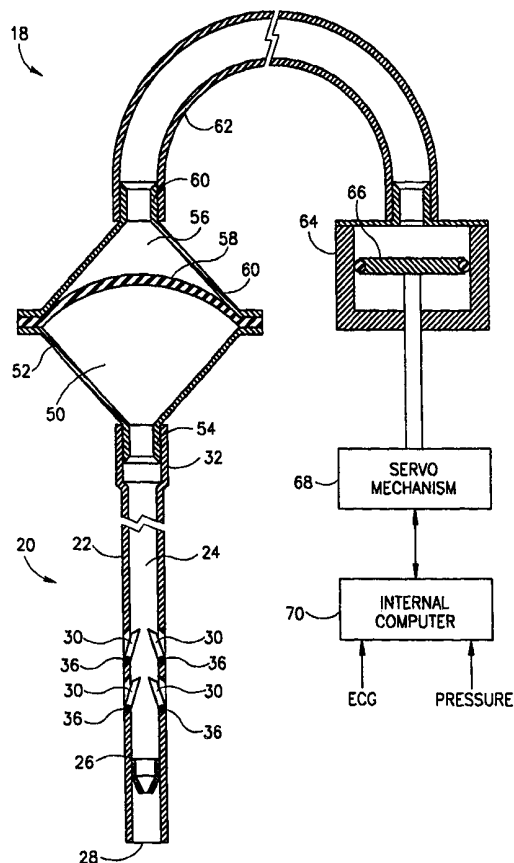
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61M 1/10</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/26676 (43) International Publication Date: 3 June 1999 (03.06.99)</p>
<p>(21) International Application Number: PCT/IL97/00386 (22) International Filing Date: 24 November 1997 (24.11.97) (71) Applicant (for all designated States except US): MEDICARD LTD. [IL/IL]; P.O. Box 250, 20692 Upper Yoqneam (IL). (72) Inventor; and (75) Inventor/Applicant (for US only): ROTTENBERG, Dan [IL/IL]; Einstein Street 117, 34601 Haifa (IL). (74) Agents: FENSTER, Paul et al.; Fenster & Company, P.O. Box 2741, 49127 Petach Tikva (IL).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>

(54) Title: HEART ASSIST SYSTEM WITH APEX CANNULA PUMP

(57) Abstract

This invention is a method of augmenting the blood flow from a ventricle of a heart to an artery exiting the ventricle, the method comprising inserting a cannula having a distal end and a proximal end into the heart and the artery, such that the distal end of the cannula is in the artery, a more proximal portion of the cannula is in the ventricle, and transferring blood from the ventricle to the artery via a lumen of the cannula. Also a heart assistance pump comprising a cannula (20) having a distal end (28), an outlet valve (26) communicating with an opening at or adjacent to the distal end of the cannula, and an intake valve (30) communicating with an opening proximate to the opening with which the outlet valve communicates.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakistan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

HEART ASSIST SYSTEM WITH APEX CANNULA PUMP**FIELD OF THE INVENTION**

The present invention relates generally to devices and systems for augmenting cardiac output, and specifically to intra-ventricular cardiac assist pumps.

BACKGROUND OF THE INVENTION

Intra-aortic and intra-ventricular cardiac assist devices are well known in the art. These devices are generally used to reduce the heart's work load after insult or surgery. They may also be used to increase blood flow from the left ventricle of the heart into the aorta in cases of insufficient cardiac output due, for example, to acute or chronic heart ailments or to interference with normal cardiac function during surgery.

One of the best-known and most widely-used intra-aortic pump systems is the Intra-Aortic Balloon Pump (IABP), comprising a catheter, having an inflatable balloon at its distal end, which is inserted through an artery into the aorta. The balloon is then alternately inflated and deflated by an external pump drive, so as to alternately block and unblock blood flow through the aorta, in synchrony with the beating of the heart, in order to assist the left ventricle in propelling blood into the arterial system. The IABP, however, provides only limited augmentation of the heart's natural, unassisted output, and is not adequate for overcoming heart failure.

U.S. patent 4,014,317, which is incorporated herein by reference, describes a cardiocirculatory assist cannula with a balloon pump and cardiac pacing electrode. The cannula is inserted percutaneously via the aorta so that its distal end is inside the left ventricle of the heart. During systole, inlet valves on the cannula inside the left ventricle open, and the contraction of the ventricle forces blood to flow into the cannula. Then, during diastole, the blood flows out, into the aorta, through one or more outlet valves along the cannula downstream from the inlet valve. A gas-filled balloon, similar in function to the IABP described above, is connected to the cannula downstream of the outlet valves. The balloon is typically inflated during diastole and deflated during systole, to assist in perfusion of the coronary arteries. The cannula has a small stroke volume, however, and relies on the contractile force of the heart to pump the blood. It is therefore of limited usefulness in augmenting the blood output of a weakened or failing heart.

PCT publication WO97/02850, the disclosure of which is incorporated herein by reference, describes a heart assist system based on a catheter system in which the distal end of the catheter is inserted into the left ventricle via the aorta. An intake valve draws blood from the ventricle and an outlet valve delivers blood to the aorta. A hydraulic pump mechanism external to the body, at the proximal end of the catheter, acts as a pump and reservoir for blood drawn from the ventricle. However, this system, while it is useful for the alleviation of heart insufficiency in a wide range of problems, suffers from the limitation that the diameter of the catheter is limited by the arterial path the catheter must travel on its way to the ventricle. Furthermore, the catheter is inserted against the direction of the leaves in the aortic valve, which may sometimes be problematical.

In PCT application PCT/IL97/00201, the disclosure of which is incorporated by reference, a cannula valve was described in which the inlet and output valves are formed in a unit which is situated between two tubular sections of a cannula.

In the Hemopump Cardiac Assist System, distributed by Johnson & Johnson Interventional Systems, a cannula containing a special, miniature rotor pump mechanism is inserted into the aorta. The pump is driven by a drive unit outside the body, to pump blood continuously from the aorta into the rest of the arterial system, thereby supplementing the heart's natural output rate. A system of this type is similarly described in U.S. patent 5,092,844, which is incorporated herein by reference. While continuous-flow devices are useful for short-term augmentation of cardiac output, however, it is medically known that pulsatile pumps provide more effective long-term support, since they approximate more closely the natural pump action of the heart.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an intraventricular cardiac assist pump having a sufficiently large internal volume and improved valve structure, so that adequate pulsatile perfusion of the body may be dependably maintained.

In a first aspect of the invention, a heart assist system is provided in which the cannula is inserted into the aorta from the left ventricle (preferably entering the ventricle via a puncture or incision in the apex of the ventricle). Such systems are especially useful where heart function is especially poor, as for example for patients awaiting a heart transplant. The

advantages, both short and long term, of such insertion, outweigh the disadvantages of puncturing of the ventricle.

In a second aspect of the present invention, wherein the pump comprises a cannula, one-way valve structures are provided in the sides of the cannula so as to reliably control the
5 alternate inflow and outflow of blood therefrom.

In preferred embodiments of the present invention, an intraventricular cardiac assist pump comprises a cannula, whose distal end is inserted preferably through the apex through the left ventricle and into the aorta and a pulsatile drive unit, coupled to the cannula at the proximal end thereof. The cannula comprises an outer sheath, defining and enclosing an
10 internal lumen, having at least one output valve, adjacent to and preferably communicating with the cannula's distal end, and one or more intake valves, disposed radially along the length of the cannula, downstream from the intake valve. The pulsatile drive unit alternately reduces and increases blood pressure in the cannula. When the pressure is reduced, the at least one intake valve opens, while the one or more outlet valves are closed, and blood flows through
15 the intake valve into the lumen of the cannula. The pressure in the cannula is then increased, causing the intake valves to close and the outlet valve to open, so that blood flows out of the lumen into the aorta.

Since the cannula is inserted into the aorta from the left ventricle, the cannula may be very large in comparison with prior art heart assist devices. The assist pump differs from prior
20 art cannula pumps in that the outlet valve is at or communicates with the distal end of the cannula and the intake valve is proximal to the outlet valve. Furthermore, the output valve may be (and preferably is) coaxial with the cannula such that the output from the valve is unobstructed by the walls of the aorta. This allows for higher pressure and flow to be applied to the vascular system than in assist devices of the prior art. Furthermore, while the intake
25 valves are generally on the sides of the cannula, the valve is in the ventricle and the intake valves are substantially unobstructed. Furthermore, since the ventricular portion of the pump does not have to pass through blood vessels, the cannula may have a different diameter at the intake and outlet.

In some preferred embodiments of the present invention, the pulsatile drive unit
30 includes a fluid reservoir, comprising first and second chambers, separated by a flexible diaphragm, each chamber having a fluid port. The fluid port of the first chamber is connected

to the proximal end of the cannula, so that blood may flow between the chamber and the cannula. The fluid port of the second chamber is connected to a hydraulic mechanism, which alternately increases and decreases the pressure, and hence the volume, of a control fluid in the second chamber. The flexible diaphragm couples pressure changes from the second to the first
5 chamber, without direct contact between the fluid in the second chamber and the blood in the first chamber, thereby controlling the flow of blood into and out of the lumen of the cannula, as described above. Such pumps are described, for example, in the aforementioned PCT publication. The use of the hydraulic mechanism enables substantially greater volumes of blood to be pumped, with greater efficiency, than pneumatic pump drive mechanisms that are
10 commonly used in other cardiac assist pumps known in the art. However, the invention is not limited to such pumps and other pumping systems, as known in the art, may be advantageously be a utilized in the present invention.

It will be appreciated that in preferred embodiments of the present invention, as described above, the blood being pumped remains entirely inside the cannula and in the first
15 chamber of the fluid reservoir connected thereto, without circulating substantially outside the body. Preferably, the cannula and fluid reservoir are disposable, intended for a single use, so as to reduce the likelihood of infection.

In preferred embodiments of the present invention, the cannula is capable of pumping at least 50 cc, and preferably up to 80 cc of blood, in each stroke of the pulsatile drive unit. It
20 will be appreciated, however, that depending on clinical requirements, the cardiac assist pump may be adjusted to pump a smaller volume in each stroke, for example 20 cc. The pulsatile drive unit is preferably operated substantially at the rate of the human heart beat, and the rate and volume are adjusted so that adequate perfusion of the arterial system is maintained. The drive is preferably synchronized with the heart beat, so as to draw blood into the lumen of the
25 cannula during systole and eject the blood into the aorta during diastole.

Alternatively, the drive may be counter-synchronized, so as to draw blood into the lumen during diastole and eject it during systole, or the drive may be operated asynchronously, independent of the heart beat.

In preferred embodiments of the present invention, the cannula comprises a flexible,
30 resilient tube having a diameter in the range of 15-45 French (5-15 mm) or even larger. It is preferably inserted through the left ventricle Apex into the left ventricle and then through the

aortic valve into the ascending aorta. This is compared to a lower limitation on sizes utilized in prior art devices which are inserted via the aorta into the ventricle

In some preferred embodiments of the present invention, the intake valve and outlet valve are comprised in a valve unit constructed of a rigid external tube with radial holes and a flexible internal structure. The internal flexible structure includes flexible leaflet type outlet valve and a cone sleeve which covers the holes from inside the tube forming an intake valve.

In another preferred embodiment of the invention, the cannula contains a sliding element, held inside the lumen, adjacent to the distal end thereof, in such a manner that the sliding element can slide axially along the lumen but preferably does not rotate. The sliding element includes radial and axial openings through which blood can flow. The cannula further includes an axial flexible leaflet valve serving as an outlet valve from the lumen, adjacent to the camera's distal end and one or more radial openings, serving as intake valves along the length of the cannula proximal to the output valve.

When the pressure inside the lumen is increased, the sliding element slides in the distal direction, thereby engaging and substantially closing the radial (intake) opening. When the sliding element is in this position, the radial openings of the sliding element are not aligned with the radial openings in the cannula, so that blood may not flow into or out of the lumen.

When the pressure inside the lumen is reversed, i.e., reduced to a negative pressure relative to the blood pressure outside the lumen, the sliding element moves proximally, away from the distal end of the cannula, so that blood may flow into the lumen through the radial openings of the cannula and the sliding element. When the slider is in the proximal position, the outlet leaflet valve is closed.

Preferably, a fluid reservoir, having a variable fluid volume, is connected to the proximal end of the cannula, such that blood may flow between the lumen and the reservoir and a pump drive coupled to the fluid reservoir and controlling the fluid volume in said reservoir is provided such that the pump mechanism alternately increases and decreases the fluid volume in the reservoir to produce a pulsatile pumping action of blood through the cannula.

There is thus provided, in accordance with a preferred embodiment of the invention, a method of augmenting the blood flow from a ventricle of a heart to an artery exiting the ventricle, the method comprising inserting a cannula having a distal end and a proximal end,

into the heart and the artery such that the distal end of the cannula is in the artery and a more proximal portion of the cannula is in the ventricle; and transferring blood from the ventricle to the artery via a lumen of the cannula.

Preferably, the method includes providing an intake valve communicating with an opening in the cannula proximate to the distal end of the cannula.

Preferably, the method includes providing an outlet valve, more preferably an axial valve communicating with an opening at the distal end of the cannula.

Preferably the outlet valve communicates with an opening in the cannula distal to the opening with which the intake valve communicates.

In a preferred embodiment of the invention, transferring blood comprises drawing blood from the ventricle, through the intake valve by reducing the pressure within the cannula; and ejecting blood from the cannula through the outlet valve into the artery by increasing the pressure in the cannula.

In a preferred embodiment of the invention, inserting a cannula into the heart and artery comprises inserting the cannula from the ventricle via a valve into the artery. Preferably, inserting a cannula into the heart and artery comprises inserting the cannula into the ventricle via the wall of the heart. In a preferred embodiment of the invention, the ventricle is the left ventricle, the artery is the aorta and the valve is the aortic valve.

Preferably the ventricle is the left ventricle and the artery is the aorta.

There is further provided, in accordance with a preferred embodiment of the invention, a heart assistance pump comprising a cannula having a distal end; an outlet valve communicating with an opening at or adjacent to the distal end of the cannula; and an intake valve communicating with an opening proximate to the opening with which the outlet valve communicates.

Preferably the outlet valve is an axial valve communicating with an opening at the distal end of the cannula.

Preferably, the inlet valve comprises a valve through which blood enters the cannula via orifices in a wall of the cannula. Preferably, said orifices are formed in a portion of the cannula which has a conical shaped inner wall and wherein said inlet valve comprises an inner flexible conical tube. Preferably, the inner flexible conical tube closes the orifices in the

absence of a pressure differential. Preferably, the inner flexible conical tube is moved away from the orifices by pressure external to the cannula, uncovering the orifices.

In a preferred embodiment of the invention, the inner flexible conical tube is integrally formed with the outlet valve. Preferably, the outlet valve is an axial valve communicating with an opening at the distal end of the cannula. Preferably, the outlet valve is a leaflet valve having a plurality of leaves.

There is further provided, in accordance with a preferred embodiment of the invention a cannula valve system including an inlet valve comprising a portion of the cannula having a conical shaped inner wall with orifices formed therein; and an flexible conical tube situated in the conical portion.

Preferably, the inner flexible conical tube closes the orifices in the absence of a pressure differential. Preferably, the inner flexible conical tube is moved away from the orifices by pressure external to the cannula, uncovering the orifices.

In a preferred embodiment of the invention the valve system further comprises an outlet valve integrally formed with the inner flexible conical tube. Preferably, the outlet valve is a valve communicating with an opening at the distal end of the cannula. Preferably, the outlet valve is an axial valve. Preferably the outlet valve is a leaflet valve having a plurality of leaves.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood with reference to the following detailed description of non-limiting preferred embodiments of the invention in which:

Fig. 1 is a schematic, sectional representation of a cardiac assist pump, in accordance with a preferred embodiment of the present invention;

Fig. 2 is a schematic representation of a cannula in accordance with a preferred embodiment of the present invention, illustrating the insertion of the cannula into the heart;

Fig. 3A is a sectional representation of a valve assembly in accordance with a preferred embodiment of the present invention, including intake and outlet valves, shown in a first configuration in which the intake valves are closed and the outlet valve is open;

Fig. 3B is a sectional representation of the valve assembly of Fig. 3A shown in a second configuration in which the intake valves are open and the outlet valve is closed;

Fig. 4A is a sectional representation of a valve assembly in accordance with another preferred embodiment of the present invention, including intake and outlet valves, shown in a first configuration in which the intake valves are closed and the outlet valve is open;

Fig. 4B is a sectional representation of the valve assembly of Fig. 4A shown in a second configuration in which the intake valves are open and the outlet valve is closed;

Fig. 5A is a representation of a standard configuration of an aortic insertion type pump in accordance with a preferred embodiment of the invention;

Fig. 5B shows an alternate preferred configuration in which the cannula is provided in two pieces and in which the inlet and outlet valves are provided as a unit inserted between the two pieces; and

Fig. 5C shows the configuration of Fig. 5B in assembled form.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic, sectional representation of a cardiac assist pump system 18, in accordance with a preferred embodiment of the present invention. The system comprises an intra-aortic cannula 20, having an outer sheath 22, which defines and encloses an inner lumen 24. Preferably cannula 20 has a diameter in the range of 15-45 French (5-15 mm) and is made of flexible, resilient material, for example, polyurethane reinforced with stainless steel wire, so that it may be inserted into and passed through major arteries of the human body. Cannula 20 further includes an outlet valve 26, preferably a leaflet valve and preferably axially disposed, connected to an outlet at or near its distal end 28, and one or more intake valves 30, radially disposed along sheath 22 of the cannula.

Outlet valve 26 and intake valves 30 are preferably one-way valves, so that blood may flow into and out of cannula 20 substantially only in a single direction: entering through intake valve 30 and exiting through outlet valve 26 (corresponding to the direction of blood flow in the body, as will be described below). In the preferred embodiment of the present invention shown in Fig. 1, the intake valves comprise mechanical flap valves, which rotate about hinges 36 to open and shut as desired.

Preferably, outlet valve 26 comprises a leaflet valve. However, in other preferred embodiments of the invention, it may comprise other types of valves such as valves similar to valves 30, which open outwardly. Such leaflet valves are known in the art for use in heart-assist devices, as described, for example, in a PCT patent application number

PCT/IL96/00044, entitled, "Method for Producing Heart Valves and Heart Valves Produced by the Method," filed on July 8, 1996 whose disclosure is incorporated herein by reference.

In other preferred embodiments of the present invention as, for example, will be described below, other types of intake valves may similarly be used.

5 Fig. 2 shows, schematically, the use of cannula 20 in a human heart 40. Preferably the cannula is inserted through an incision in the apex of a left ventricle 41 and passed downstream through aortic valve 42 into aorta 44. The length of cannula 20 is preferably approximately 30 cm, which is generally sufficient so that when distal tip 28 is positioned in aorta 44, proximal end 32 remains outside the body, adjacent to an incision in the chest or
10 abdominal wall.

Once cannula 20 is in place, intake valves 30 are opened, and blood flows from ventricle 46 into lumen 24. Preferably outlet valve 26 is kept closed while the blood fills the lumen. Proximal end 32 may be temporarily opened, to vent out air or fluid that was inside cannula 20 before its insertion. Then intake valve 30 is closed and outlet valve 26 is opened, so
15 that the blood may flow out of the lumen and into aorta 44.

In the preferred embodiment of the invention illustrated in Fig. 1, intake valves 30 and outlet valve 26 preferably open and shut in response to pressure exerted through pump system 18 to cannula 20, in the following manner. Proximal end 32 of cannula 20 is connected to a first chamber 50 of a fluid reservoir 52 through a first fluid port 54. Fluid reservoir 52 further
20 includes a second chamber 56, which is separated from first chamber 50 by a flexible diaphragm 58. Diaphragm 58, which is preferably made of flexible polyurethane, deforms to alter the respective volumes of chambers 50 and 56, so as to substantially equalize the fluid pressures in the two chambers, but prevents mingling of the fluids in the first and second chambers.

25 Second chamber 56 preferably contains a substantially incompressible liquid, such as water or, alternatively, any other suitable fluid, such as normal saline solution. Chamber 56 is coupled via a second fluid port 60 through a tube 62 to a pump drive 64. A piston 66 in pump drive 64 moves alternately up and down to correspondingly increase and decrease the fluid pressure in reservoir 52, thereby pumping blood out of and into lumen 24.

30 It will be appreciated that the maximum volume of blood that may be pumped in a single stroke of piston 66 is roughly determined by the volume of reservoir 50. Preferably this

maximum single stroke pumping volume is at least 50 cc, and more preferably up to 80 cc, although piston 66 may also be operated with a shorter stroke to pump a smaller volume of blood if desired. Preferably, the stroke is adjusted so that when pump drive 64 is operated at or about the heart's natural rate, sufficient blood can be pumped to perfuse substantially all of the person's body.

It will further be appreciated that blood may enter cannula 20 and flow into first chamber 50 only up to diaphragm 58. No blood flows through tubing 62 or into pump drive 64. Preferably, cannula 20 and reservoir 52 are disposable and made for single use only, to prevent transfer of infections and contamination.

Pump drive 64 is preferably driven by a servo mechanism 68, under the control of an internal computer 70, which regulates the rate and stroke volume of piston 66. Preferably, computer 70 receives physiological signal inputs, such as ECG and blood pressure signals, and uses these signals in optimally controlling pump drive 64, preferably to drive piston 66 at the rate of the heart beat.

Preferably, computer 70 further adjusts the delay of the piston stroke relative to the systolic stroke of the heart. This delay may be adjusted so that cannula 20 pumps blood out synchronously with the heart's systole; countersynchronously, during diastole; or at any suitable phase therebetween. Alternatively, the rate of piston 66 may be set to be independent of the heart rate, for example in order to maintain steady perfusion during arrhythmia or fibrillation.

It is noted that in the preferred embodiment of the invention described above, the cannula is inserted via the left ventricle (generally via a puncture in the apex of the aorta). Such systems are especially useful where heart function is especially poor, as for example for patients awaiting a heart transplant. The advantages, both short and long term, of such insertion, outweigh the disadvantages, under some circumstances, of puncturing of the ventricle. The cannula is preferably secured to the heart wall which is preferably sewn to form a closure around the cannula.

The assist pump of this aspect of the invention thus differs from prior art pumps in that the outlet valve is at the distal end of the cannula and the intake valve is proximal to the distal end. Since the cannula is inserted into the aorta from the left ventricle, the cannula may be very large in comparison with prior art heart assist devices. Furthermore, the output valve may

be coaxial with the cannula such that the output from the valve is unobstructed by the walls of the aorta. This allows for higher pressure and flow to be applied to the vascular system than in assist devices of the prior art. Furthermore, while the intake valves are generally on the sides of the cannula, the valve is in the ventricle and the intake valves are substantially unobstructed.

5 The cannula may be stiffer than cannula which must be used when it is inserted via the arteries. Finally, the diameter of the cannula need not be constant and a larger diameter may be used in the ventricle than in the aorta.

Fig. 3A and 3B illustrate schematically construction of a combined intake and outlet valve 80, in accordance with a preferred embodiment of the invention. Valve unit 80
10 comprises a preferably rigid tube 82 made of a bio-compatible plastic material such as, for example, polycarbonate (Lexan) or metal (such as stainless steel) or other suitable bio-compatible material. Holes 86 are formed on sleeve 82.

An insert or inner part 81 is preferably formed of a flexible bio-compatible material such as, for example, polyurethane or silicone rubber of other suitable material. It preferably
15 comprises an axial outlet leaflet valve 83 such as a bi- or tri-leaflet and a conical intake valve section 84. The two valve sections are preferably connected by a sleeve 85.

Section 84 is aligned with holes 86 such that section 84 and holes 86 comprise an intake valve. Attachment of inner part 81 to tube 82 is preferably by gluing sleeve 85 to tube
20 81 or by other means such as crimping.

Fig. 3A illustrates the valve configuration when pressure is applied to the valve unit such that blood is injected from the pump into the aorta. Leaflet valve 83 is open and section
25 84 is pressed against holes 86 closing them, such that no blood enters the pump from the ventricle. This pressure is preferably aided by the unstressed shape of section 84 which acts to close holes 86.

Fig. 3B illustrates valve unit 80 during a suction period, in which blood is sucked from the left ventricle. In this configuration valve 83 is closed and segment 84 is forced by the
30 suction into the lumen, such that blood can enter the ventricle through holes 86 from the ventricle.

Preferably, as described in PCT application PCT/IL96/00044, the disclosure of which
30 is incorporated herein by reference, valve 83 is partially open in the absence of differential pressure and the closure of the valve as illustrated in Fig. 3B is the result of the suction of the

pump. The cone shape of section 84 is preferred to assure that that, in the absence of a pressure differential, holes 86 are closed. This may prevent folding of the segment inside the lumen of the sleeve 82.

Figs. 4A and 4B illustrate schematically another construction of a combined intake and outlet valve unit 90, in accordance with a preferred embodiment of the invention. Valve unit 5 90 comprises a flexible leaflet outlet valve 91, similar in construction to valve 83 in the valve unit shown in Figs. 3A and 3B. Valve 91 is situated and held within a preferably rigid sleeve 92. Valve unit 90 also comprises a sliding intake valve comprised of a sliding inner sleeve 93 formed with holes 95. Holes 95 are aligned with holes 94 formed in sleeve 92 when the intake 10 valve is open. Sleeve 93 blocks holes 95 to close the intake valve.

As illustrated in Fig. 4A, during blood injection into the aorta, outlet valve 91 is open and inner sleeve 93 is pushed, by pressure applied on a protrusion 96 formed on sleeve 93, such that holes 94 are blocked by sleeve 93 closing the intake valve.

As illustrated in Fig. 4B, during blood suction from the left ventricle, outlet valve 91 is 15 forced closed and inner sleeve 93 is pushed to the position shown at which holes 94 and 95 are aligned thus opening the intake valve.

It should be understood, that while the valves shown in Figs 1, 3 and 4 are preferred, other intake and outlet valves as known in the art may be used.

In a preferred embodiment of the invention, valve units may be connected to standard 20 aortic or venous medical cannula 120 (Fig. 5A), having a distal end 122 and a proximal end 121 by simply cutting the cannula into two pieces and connecting them back with a valve unit 128 according to the invention between a distal piece 26 and a proximal piece 124 (Figs. 5B and 5C). Such construction is shown in the abovementioned PCT application PCT/IL97/00201, the disclosure of which is incorporated herein by reference.

It should be understood that the present invention is described in conjunction with 25 preferred embodiments thereof. Various combinations of the elements shown in the various embodiments, alternatively or additionally with other elements as known in the art or combinations having only some of the features or elements shown in the preferred embodiments may be used in certain alternative forms of the invention. It should be 30 understood that the scope of the invention is thus defined by the following claims and not by the preferred embodiments described above.

CLAIMS

1. A method of augmenting the blood flow from a ventricle of a heart to an artery exiting the ventricle, the method comprising:

inserting a cannula having a distal end and a proximal end, into the heart and the artery
5 such that the distal end of the cannula is in the artery and a more proximal portion of the cannula is in the ventricle; and

transferring blood from the ventricle to the artery via a lumen of the cannula.

2. A method according to claim 1 and including:

10 providing an intake valve communicating with an opening in the cannula proximate to the distal end of the cannula.

3. A method according to claim 1 and including providing an outlet valve communicating with an opening at the distal end of the cannula.

15 4. A method according to claim 1 and including providing an axial outlet valve communicating with an opening at the distal end of the cannula.

5. A method according to claim 2 and including providing an outlet valve communicating
20 with an opening in the cannula distal to the opening with which the intake valve communicates.

6. A method according to claim 2 and including providing an axial outlet valve communicating with an opening at the distal end of the cannula.

25 7. A method according to claim 5 wherein transferring blood comprises:

drawing blood from the ventricle, through the intake valve by reducing the pressure within the cannula; and

30 then ejecting blood from the cannula through the outlet valve into the artery by increasing the pressure in the cannula.

8. A method according to claim 6 wherein transferring blood comprises:
drawing blood from the ventricle, through the intake valve by reducing the pressure
within the cannula; and
ejecting blood from the cannula through the outlet valve into the artery by increasing
5 the pressure in the cannula.

9. A method according to any of the preceding claims wherein inserting a cannula into the
heart and artery comprises:
inserting the cannula via a valve from the ventricle into the artery.

10

10. A method according to claim 9 wherein inserting a cannula into the heart and artery
comprises inserting the cannula into the ventricle via the wall of the heart.

11. A method according to claim 10 wherein the ventricle is the left ventricle.

15

12. A method according to claim 11 wherein the artery is the aorta.

13. A heart assistance pump comprising:

a cannula having a distal end;

20

an outlet valve communicating with an opening at or adjacent to the distal end of the
cannula; and

an intake valve communicating with an opening proximate to the opening with which
the outlet valve communicates.

25

14. A heart assist pump according to claim 13 wherein the outlet valve is an axial valve
communicating with an opening at the distal end of the cannula.

15. A heart assist pump according to claim 14 wherein the outlet valve is a leaflet valve
having a plurality of leaves.

30

16. A heart assist pump according to claim 15 wherein the inlet valve comprises a valve through which blood enters the cannula via orifices in a wall of the cannula.

17. A heart assist pump according to claim 13 wherein the inlet valve comprises a valve
5 through which blood enters the cannula via orifices in a wall of the cannula.

18. A heart assist pump according to claim 17 wherein said orifices are formed in a portion of the cannula which has a conical shaped inner wall and wherein said inlet valve comprises an inner flexible conical tube.

10

19. A heart assist pump according to claim 18 wherein the inner flexible conical tube closes the orifices in the absence of a pressure differential.

20. A heart assist pump according to claim 19 wherein the inner flexible conical tube is
15 moved away from the orifices by pressure external to the cannula, uncovering the orifices.

21. A heart assist pump according to any of claims 18-20 wherein the inner flexible conical tube is integrally formed with the outlet valve.

22. A heart assist pump according to claim 21 wherein the outlet valve is an axial valve
20 communicating with an opening at the distal end of the cannula.

23. A heart assist pump according to claim 22 wherein the outlet valve is a leaflet valve having a plurality of leaves.

25

24. A heart assist pump according to any of claims 18-20 wherein the cannula has a substantially greater diameter at the intake valves than at the distal end thereof.

25. A cannula valve system including an inlet valve comprising:

30 a portion of the cannula having a conical shaped inner wall with orifices formed therein; and

a flexible conical tube situated in the conical portion.

26. A valve system according to claim 25 wherein the inner flexible conical tube closes the orifices in the absence of a pressure differential.

5

27. A valve system according to claim 26 wherein the inner flexible conical tube is moved away from the orifices by pressure external to the cannula, uncovering the orifices.

28. A valve system according to any of claims 25-27 and comprising an outlet valve
10 integrally formed with the inner flexible conical tube.

29. A valve system according to claim 28 wherein the outlet valve is a valve communicating with an opening at the distal end of the cannula.

15 30. A valve system according to claim 29 wherein the outlet valve is an axial valve.

31. A valve system according to claim 30 wherein the outlet valve is a leaflet valve having a plurality of leaves.

1/7

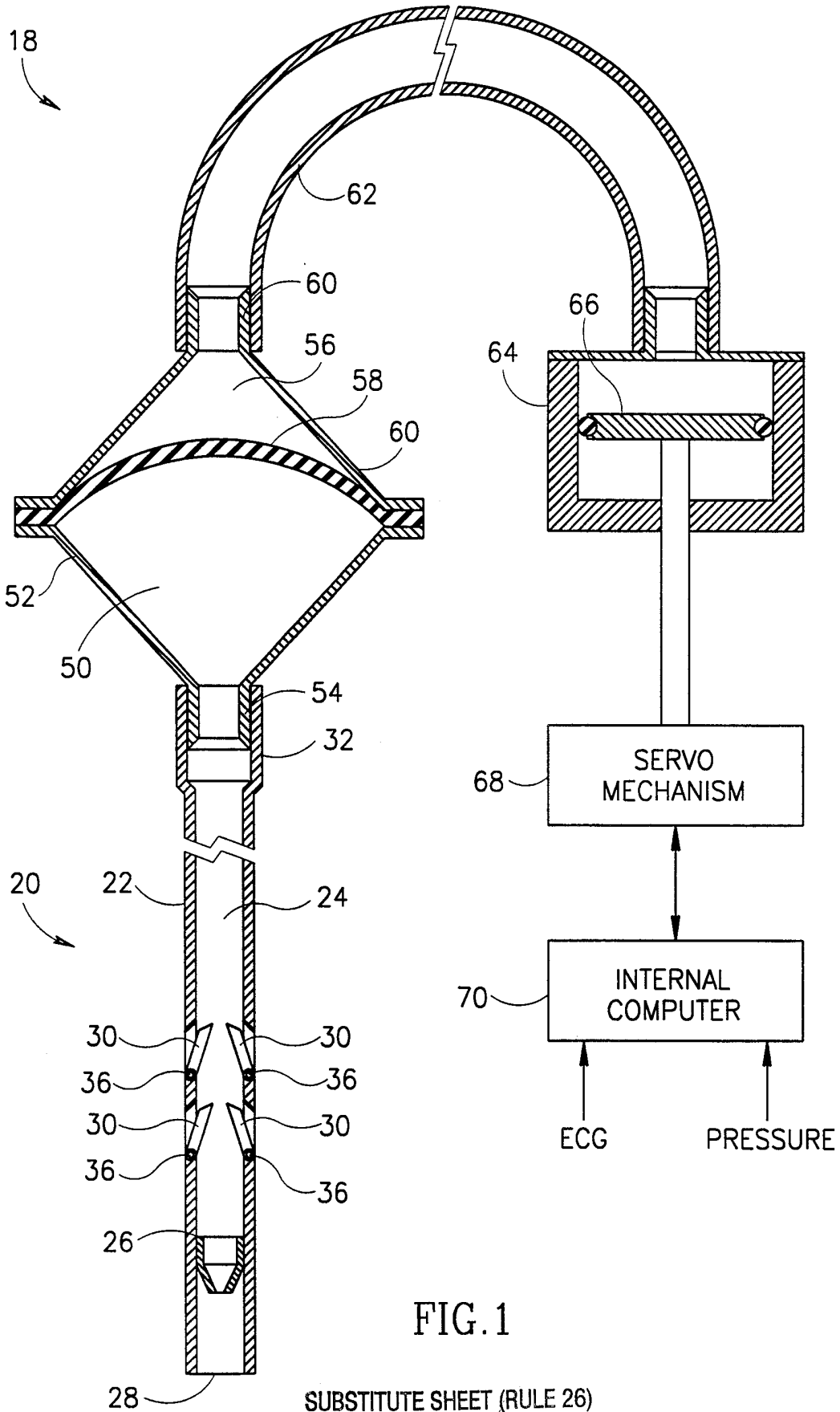
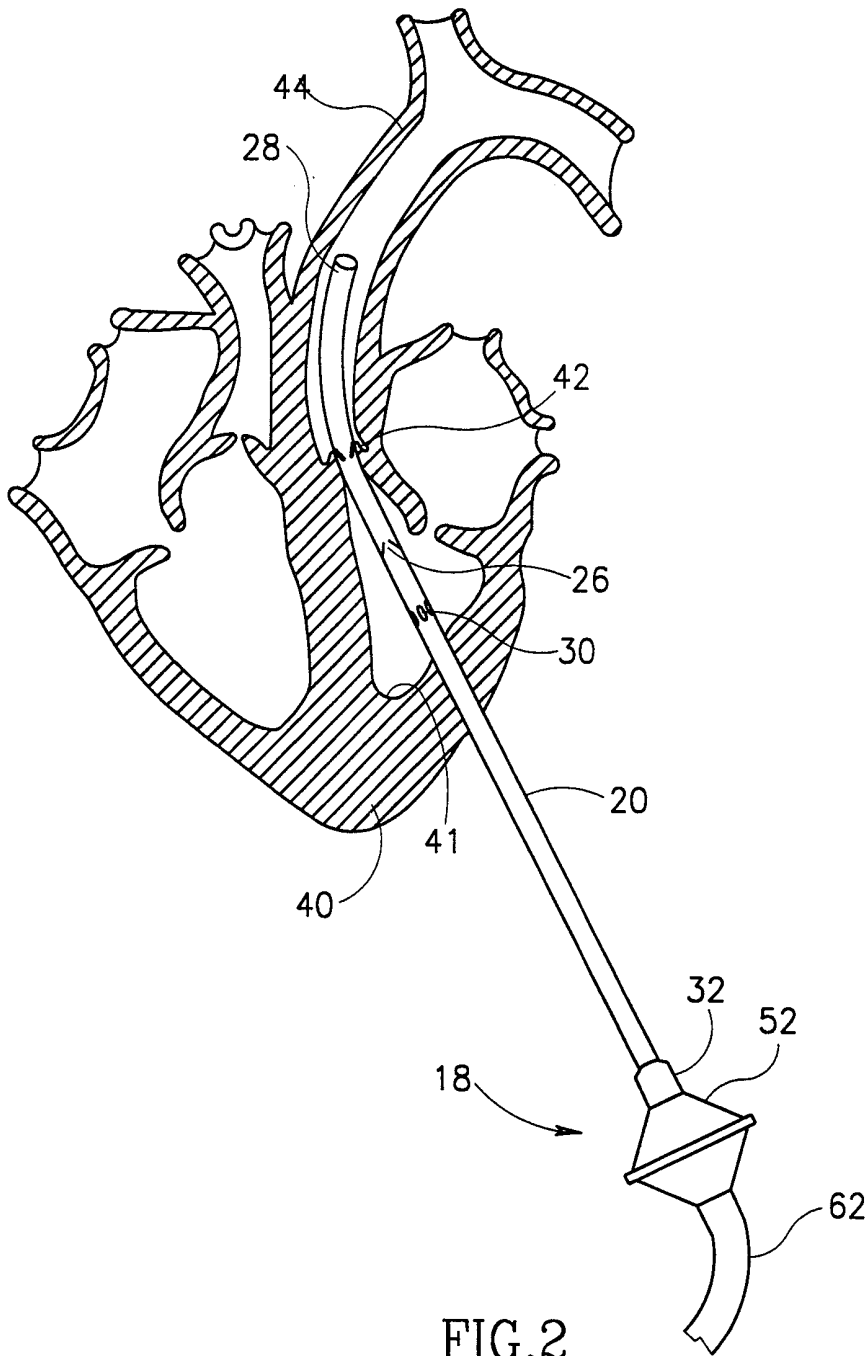


FIG. 1



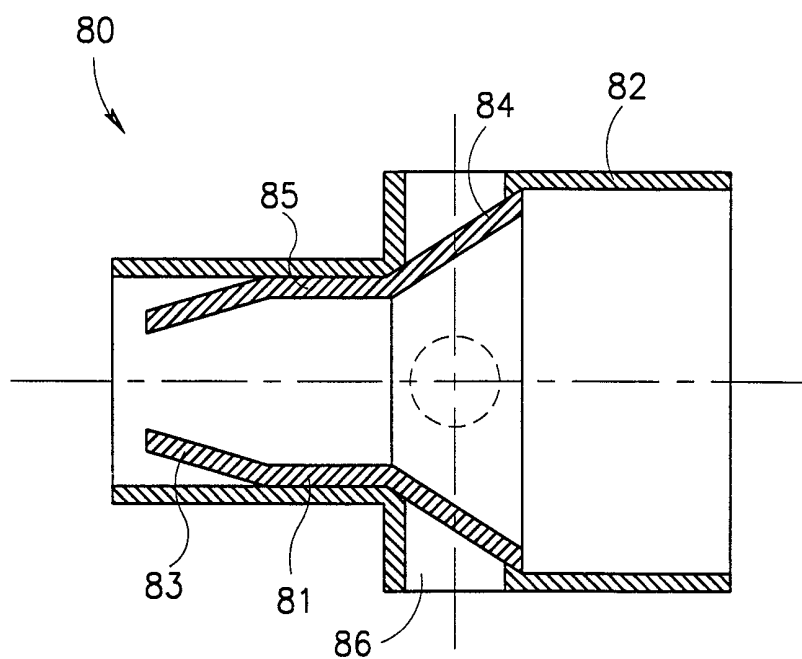


FIG.3A

4/7

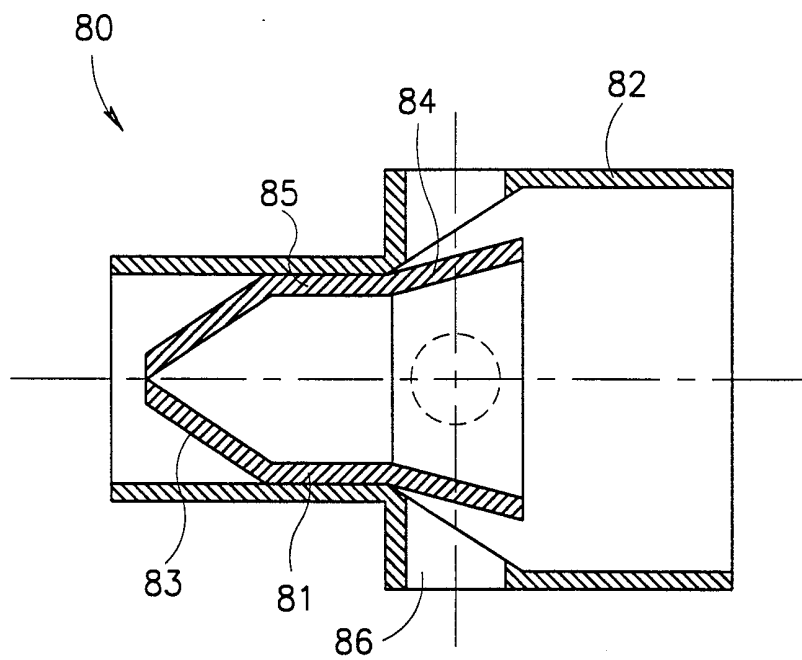


FIG.3B

5/7

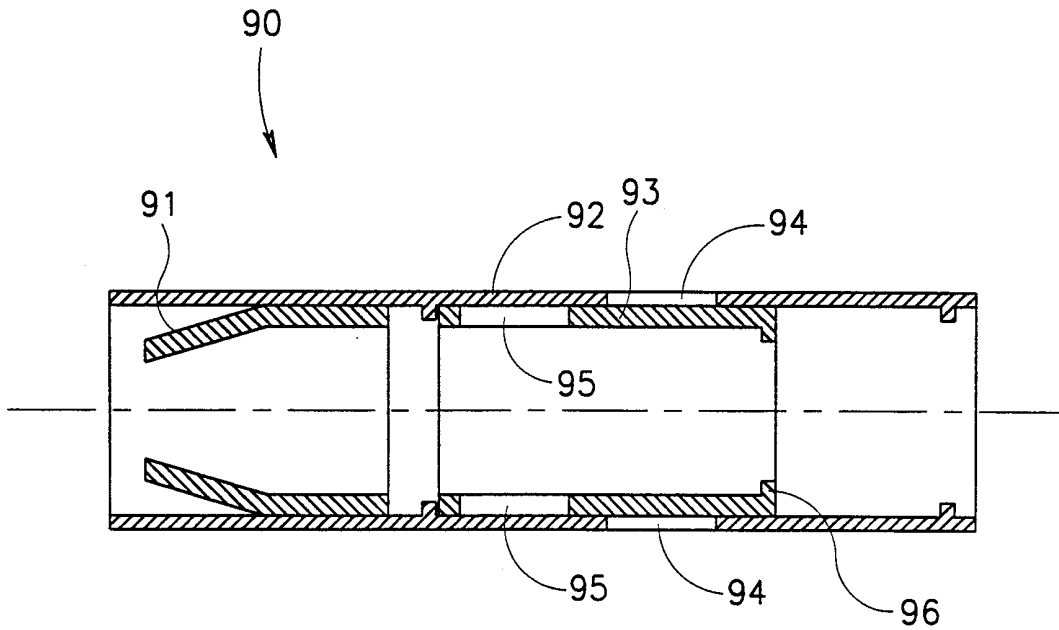


FIG. 4A

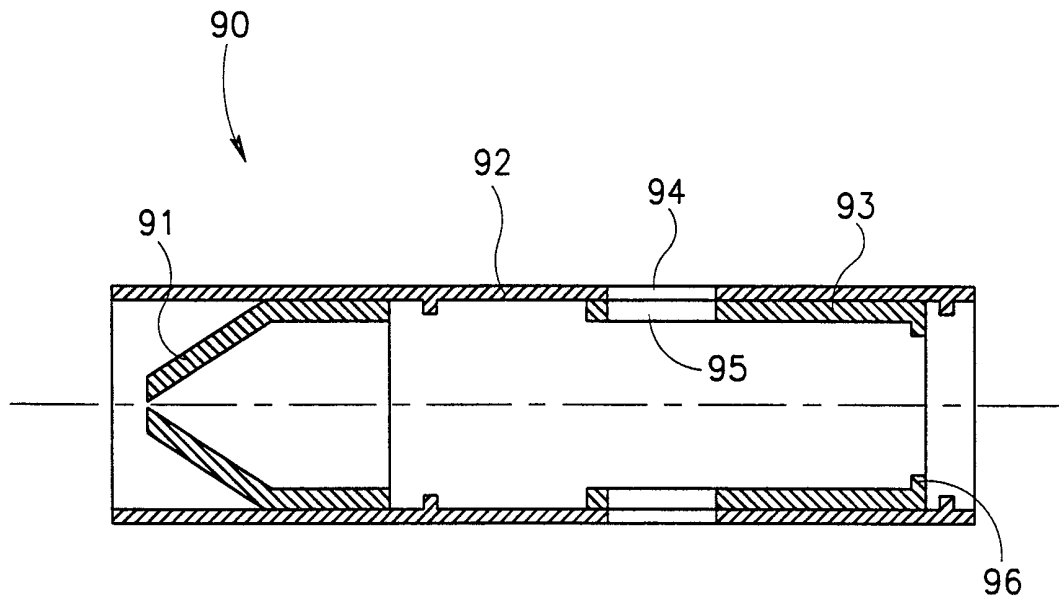


FIG. 4B

6/7

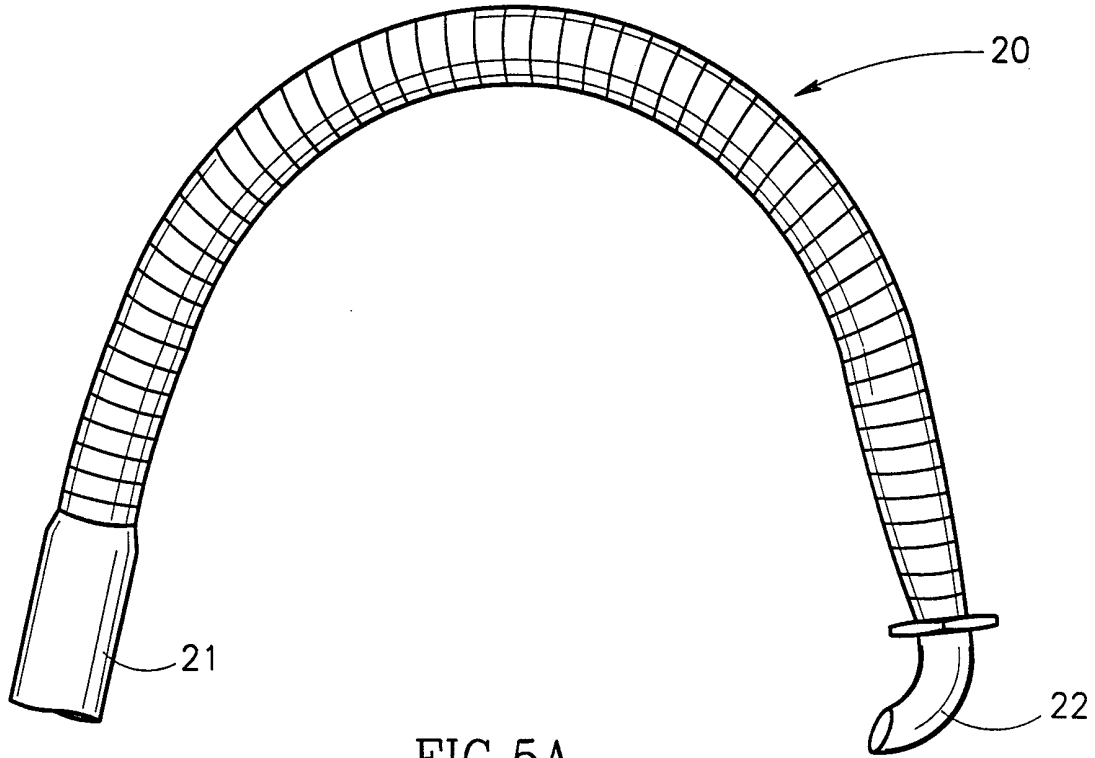


FIG. 5A

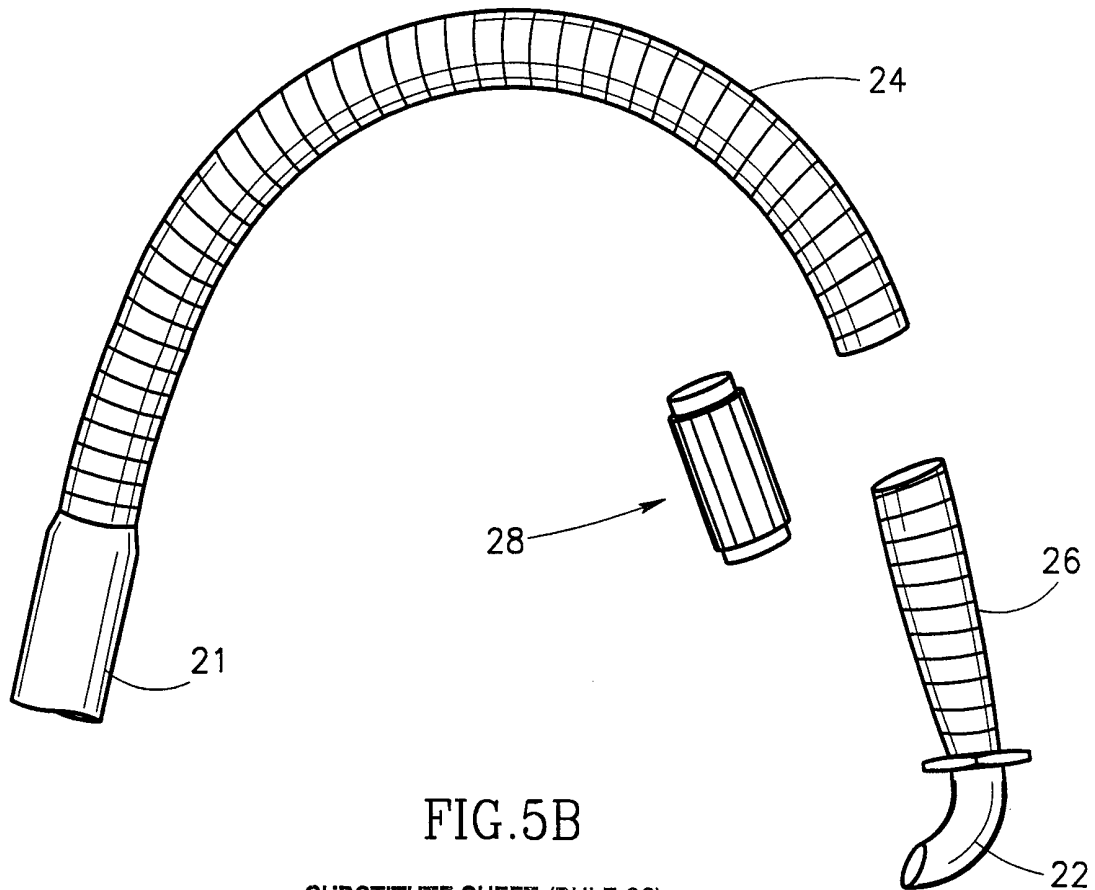


FIG. 5B

7/7

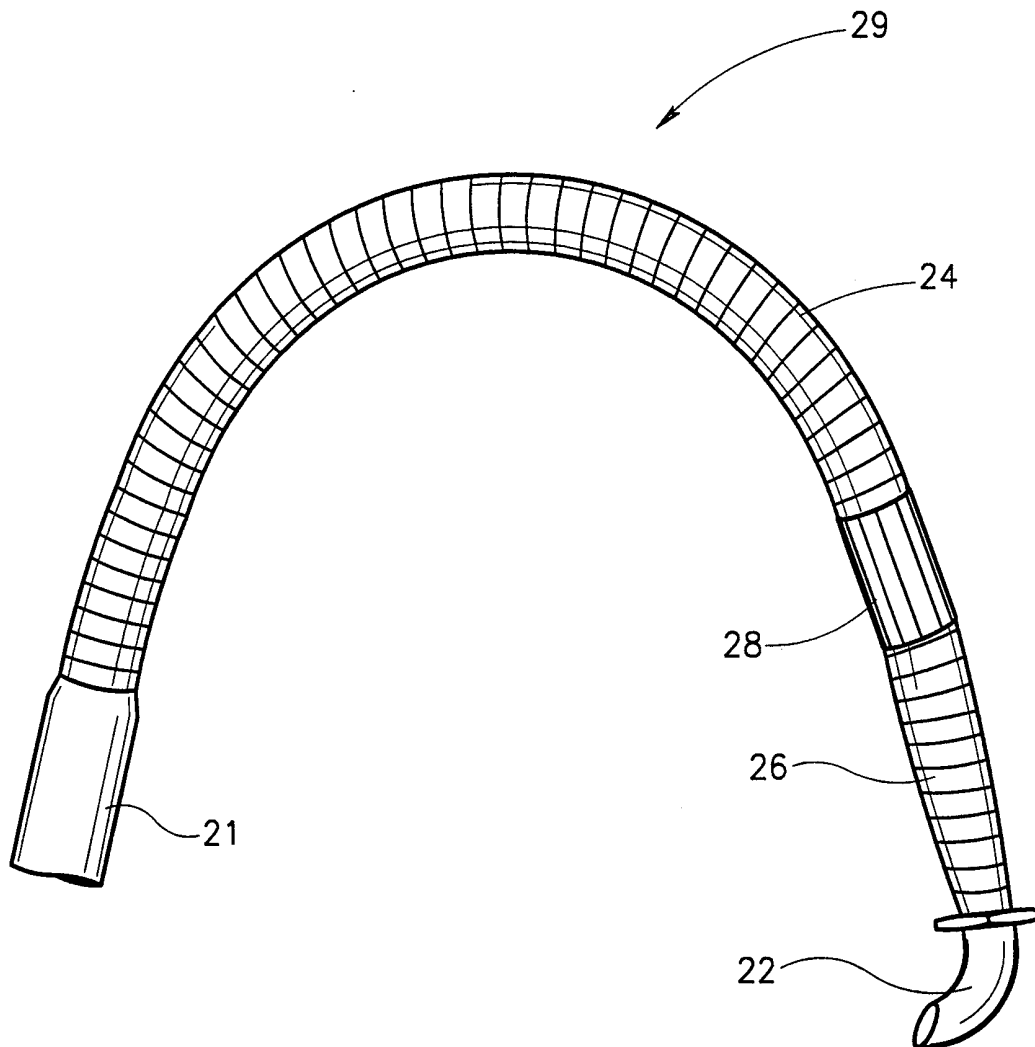


FIG.5C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00386

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/10
US CL :600/16

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)

U.S. : 600/16, 17; 623/3

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,376,114 A (JARVIK) 27 December 1994, entire document.	1, 9-12
X	US 5 129 789 A (THORTON et al) 14 July 1992, entire document.	13-15

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be of particular relevance	*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
B earlier document published on or after the international filing date	*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
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)	*G* document member of the same patent family
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	

Date of the actual completion of the international search 16 MARCH 1998	Date of mailing of the international search report 10 APR 1998
--	---

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer <i>A. Leon Meek</i> GEORGE EVANISKO Telephone No. (703) 308-2612
---	---