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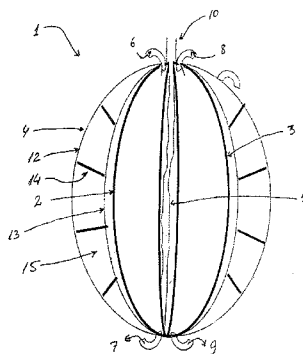


Figure 1

(57) Abstract: The present invention is related to a replaceable artificial heart comprising two heart like structures (2, 3) which are equivalent to right and left ventricles of the natural heart and are provided with an outer shell (4) surrounding the two heart like structures and an inner shell (5) provided in-between the two heart like structures, wherein it is capable of being implanted through keyhole surgery and transforming to an expanded rigid structure after having been implanted in the thoracic region, and re-transforming to a contracted soft structure within the thoracic region and vice versa, wherein the suction action around the ventricle like structures of the artificial heart is repeated in a continuous and uninterrupted manner so that it is capable of pumping the blood at a desired pressure in the entire body in a continuous and uninterrupted manner.

Replaceable artificial heart implantable by keyhole surgery.

Field of the Invention:-

The present invention relates to the field of implantable device capable of replacing the natural heart in animals and human body and serving to pump blood throughout the body. In particular, the present invention relates to a replaceable artificial heart implantable by keyhole surgery through a keyhole opening in the body.

Background of the Invention:-

The cardiovascular disease (CVD) is the leading cause of morbidity and mortality. An increasingly prevalent form of advanced CVD leads to heart failure (HF). At present, treatment of HF takes three forms – a) medical therapy, b) surgical therapy, and c) cardiac replacement. The need for the end stage cardiac replacement is quite high. Due to limited availability of matched cadaver donors, the heart transplant does not fulfill the need. To overcome this problem, the artificial heart models have been developed over the past decade.

The artificial heart models developed over the past decade have number of limitations, for example:-

Firstly, the presently known artificial hearts are rigid or semi-rigid in structure, and hence, require major surgery for their implantation means these cannot be implanted through keyhole surgery.

Secondly, the presently known artificial hearts are fairly large in size, and hence, not only require major surgery for their implantation, but also occupy a very large space in the thoracic cavity.

Thirdly, but not the least, the artificial hearts known in the art have inbuilt electrical motor drives which in-addition to occupying a very large space in the thoracic cavity are very cumbersome to implant in the thoracic cavity.

The above-described limitations of the known artificial heart models make the situation to deviate considerably from normal physiology.

Although the life span of the known artificial hearts is limited, the extensive surgical procedure, due to constructional and material limitations as described hereinabove, for their implantation and replacement in the body debars prophylactic replacement.

Need of the Invention:-

Therefore, there is a need for a replaceable artificial heart which is not only small in size, soft and flexible, and collapsible, but also capable of being implanted through keyhole surgery, that is, without extensive opening of the thorax.

Aims and Objects of the Invention:-

The present invention aims to provide a replaceable artificial heart which is capable of overcoming at least the above-described limitations of the prior art.

Accordingly, the main object of the present invention is to provide a replaceable artificial heart having soft and flexible structure, and capable of being implanted through keyhole surgery without requiring major surgery.

This is also an object of the present invention to provide a replaceable artificial heart having fairly small size, and collapsible, and therefore, not only being capable of implanted without requiring major surgery, but is also capable of occupying very small space in the thoracic cavity.

This is also an object of the present invention to provide a replaceable artificial heart having electrical motor drives which are capable of being fixed outside the thoracic region, and hence, the presently provided artificial heart not only occupies a very small space in the thoracic cavity, but is also very easy to be implanted in the thoracic cavity.

The additional object of the present invention is to provide a replaceable artificial heart having a structure which is soft, flexible, collapsible and compact at the time of its implantation through keyhole surgery and transforms to a rigid structure when implanted in the thoracic region, and thereafter, flushed with a fluid, and re-transforms to soft and flexible structure within the thoracic region when flushed fluid is withdrawn in such a manner that a suction action – a negative and positive pressure is generated within the artificial heart of the present invention so as to assist in filling the ventricles like structure with blood and pumping out of blood from the ventricles like structure for circulation in the body in a continuous and uninterrupted manner.

Other objects and advantages of the present invention will become more apparent when following description is read in conjunction with the accompanying figures, which are not intended to limit scope of the present invention.

Brief Description of the Accompanying Figures:-

Figure 1 illustrates schematic diagram of the replaceable artificial heart in accordance with one of the preferred embodiments of the present invention.

Figure 2 illustrates schematic diagram of the replaceable artificial heart having electrical motor drives which are being provided within the abdomen region in accordance with one of the preferred embodiments of the present invention.

Figure 3a and Figure 3b illustrate schematic diagram of functioning of the replaceable artificial heart having electrical motor drives being provided within the abdomen region in accordance with one of the preferred embodiments of the present invention.

Figure 4 illustrates schematic diagram of the replaceable artificial heart in accordance with another preferred embodiment of the present invention.

Figure 5 illustrates schematic diagram of the replaceable artificial heart having electrical motor drives which are being provided within the abdomen region in accordance with preferred embodiment of Figure 4 of the present invention.

Figure 6a and Figure 6b illustrate schematic diagram of functioning of the replaceable artificial heart having electrical motor drives being provided within the abdomen region in accordance with preferred embodiment of Figure 4 of the present invention.

Description and Preferred Embodiments of the Invention:-

It is now understood from the foregoing description that the artificial hearts as known in the art have main limitation of being large in size and having rigid structure, which makes them unsuitable for implantation through keyhole surgery, that is, without extensive opening of the thorax. If in order to overcome these limitations, an artificial heart being small in size and having soft structure is implanted in the thoracic region it will be easy to implant it, but it has been found that such an artificial heart will not be capable of circulating the blood at desired pressure in the entire body, because such a structure, firstly, will not be capable of withstanding the pressure at which a natural heart functions, and secondly, will not be capable of pumping the blood at desired pressure in the entire body.

Therefore, the need is not only to have a small and soft structured artificial heart, which can be implanted through keyhole surgery, but to have a small and soft structured artificial heart which is also capable of transforming to an expanded rigid structure after having been implanted in the thoracic region, and thereafter, is also capable of re-transforming to a contracted soft structure within the thoracic region and vice versa, in such a manner that it is capable of pumping the blood at a desired pressure in the entire body in a continuous and uninterrupted manner.

With above aim, the inventors have surprisingly found that if a suction action – a negative and positive pressure is generated around the heart like structure of the artificial heart which is equivalent to right and left ventricles of the natural heart in such a manner that a negative pressure is generated on outer side of the ventricle like structures and a positive pressure is generated in-between the two ventricle like structures, then the ventricle like structures expand and simultaneously draw in the blood upon formation of a negative pressure on their outer side, which is equivalent of Diastolic action of the heart, and the ventricle like structures contracts and simultaneously pump-out the blood therefrom for circulation in the body upon formation of a positive pressure in-between the two ventricle like structures, which is equivalent of Systolic action of the heart. Accordingly, if such a suction action – formation of negative and positive pressure around the ventricle like structures of the artificial heart can be repeated in a continuous and uninterrupted manner, the artificial heart will be capable of replacing the natural heart.

Accordingly, the present invention relates to a replaceable artificial heart comprising two heart like structures which are equivalent to right and left ventricles of the natural heart and are provided with an outer shell surrounding the two heart like structures and an inner shell provided in-between the two heart like structures, wherein it is capable of being implanted through keyhole surgery and transforming to an expanded rigid structure after having been implanted in the thoracic region, and re-transforming to a contracted soft structure within the thoracic region and vice versa, wherein the outer shell and inner shell are capable of generating a suction action – a negative and positive pressure around the heart like structures in such a manner that the outer shell generates a negative pressure on outer side of the ventricle like structures so as to cause the ventricle like structures to expand and simultaneously draw in the blood, which is equivalent of Diastolic action of the heart, and the inner shell generates a positive pressure in-between the two ventricle like structures so as to cause the ventricle like structures to contract and simultaneously pump-out the blood therefrom for circulation in the body, which is equivalent of Systolic action of the heart, wherein the suction action around the ventricle like structures of the artificial heart is repeated in a continuous and uninterrupted manner so that it is capable of pumping the blood at a desired pressure in the entire body in a continuous and uninterrupted manner.

During simulation method, it has been observed that when fluid is pumped into inner shell, the inner shell causes expansion and compression of the heart like structures

being equivalent of right and left ventricles. It has been found that due to low pressure in right ventricular circulation than the left ventricular circulation, the inner shell expands more on the right side than the left side. Consequently, for some time the outflow from the right ventricle is more than that from the left ventricle. Accordingly, for a very short period of time, which presently could not be evaluated, there is a mismatch of outflow from right and left ventricles. However, when the inner shell expands fully, the right and left ventricles get fully compressed and the total outflow from both the ventricles become equal. Therefore, it has been observed that mismatch of outflow had been there, but only for a very short period of time. The present invention also provides solution to this problem. It has been found that if inner shell is made of two chambers separated by a partition, the problem of mismatch of outflow is surprisingly solved.

Accordingly, in one embodiment, the present invention relates to a replaceable artificial heart comprising two heart like structures which are equivalent to right and left ventricles of the natural heart and are provided with an outer shell surrounding the two heart like structures and an inner shell consisting of two chambers separated by a partition sheet and the inner shell together with the partition sheet is provided in-between the two heart like structures, wherein it is capable of being implanted through keyhole surgery and transforming to an expanded rigid structure after having been implanted in the thoracic region, and re-transforming to a contracted soft structure within the thoracic region and vice versa, wherein the outer shell and said inner shell are capable of generating a suction action – a negative and positive pressure around the heart like structures in such a manner that the outer shell generates a negative pressure on outer side of the ventricle like structures so as to cause the ventricle like structures to expand and simultaneously draw in the blood, which is equivalent of Diastolic action of the heart, and said inner shell generates a positive pressure in-between the two ventricle like structures so as to cause the ventricle like structures to contract and simultaneously pump-out the blood therefrom for circulation in the body, which is equivalent of Systolic action of the heart, wherein the suction action around the ventricle like structures of the artificial heart is repeated in a continuous and uninterrupted manner so that it is capable of pumping the blood at a desired pressure in the entire body in a continuous and uninterrupted manner.

In accordance with preferred embodiment of the present invention, the replaceable artificial heart is made of soft and flexible biocompatible polymeric sheets,

for example polyurethane, silicone rubber, which is capable of withstanding pressure equivalent of pressure generated in natural heart and capable of expanding and contracting to pump-out the blood therefrom.

In accordance with present invention, in the deflated state, the artificial heart is collapsible into a cylinder of elliptical cross-section in such a manner that it is capable of being implanted through a "keyhole" created in the thoracic wall in between two adjoining ribs.

In accordance with present invention, the artificial heart is soft and flexible when deflated for the ease of implantation, and is capable of transforming to a rigid structure when inflated within the thoracic region after having been implanted and upon flushing the fluid in the outer shell of the artificial heart. Accordingly, in accordance with preferred embodiment of the present invention, the outer shell is capable of transforming from the soft, flexible and collapsed state to an inflated and rigid state. In accordance with further embodiment of the present invention, when the fluid is withdrawn from the outer shell of the artificial heart, the outer shell is capable of transforming from the inflated and rigid state to the soft, flexible and collapsed state. Accordingly, in accordance with present invention, by pumping the fluid in the outer shell and by withdrawing the fluid from the outer shell the transformation from the soft, flexible and collapsed state to an inflated and rigid state, and vice versa can be achieved in a continuous and uninterrupted manner.

In accordance with preferred embodiment of the present invention, the fluid is pumped within the space formed in the outer shell of the presently disclosed artificial heart so as to form a rigid structure and is withdrawn therefrom so as to form a soft and flexible structure.

In accordance with one of the preferred embodiments of the present invention, the pumping means for pumping the fluid in the space within the outer shell and for withdrawing the fluid therefrom can be provided internally, but outside the thoracic region. In accordance with one of the preferred embodiments of the present invention, the pumping means can be provided in the abdominal space and is connectable to the outer shell via tubing means. In accordance with another preferred embodiment of the present invention, the pumping means for pumping the fluid in the space within the outer shell and for withdrawing the fluid therefrom can be provided externally on any part of the body and is connectable to the outer shell via tubing means.

In accordance with present invention, the pumping action of the heart is completed by means of a second pumping means which is capable of pumping the fluid into and withdrawing from the inner shell provided in-between the ventricle like structures.

In accordance with one of the preferred embodiments of the present invention, when inner shell consists of two chambers separated by a partition sheet, there may be provided two pumping means which are, individually, capable of pumping the fluid into and withdrawing from respective chamber of the inner shell provided in-between the ventricle like structures.

In accordance with one of the preferred embodiments of the present invention, the pumping means for pumping the fluid in and withdrawing from the inner shell can be provided internally, but essentially out side the thoracic region. In accordance with one of the preferred embodiments of the present invention, this (these) pumping means can be provided in the abdominal space and is (are) connectable to the inner shell via tubing means.

In accordance with another preferred embodiment of the present invention, this (these) pumping means for pumping the fluid in and withdrawing from the inner shell consisting of single chamber or dual chambers can be provided externally on any part of the body and is (are) connectable to the inner shell via tubing means.

Now the present invention is described with the help of accompanying figures, which are not intended to limit scope of this invention, but have been incorporated to elaborate the constructional features of the replaceable artificial heart of present invention.

In accordance with one of preferred embodiments of the present invention, the accompanying Figure 1 and Figure 4 illustrate schematic diagram of the replaceable artificial heart which are capable of being placed in the thoracic cage of the patient by keyhole surgery.

In accordance with present invention, the replaceable artificial heart (1), comprises two, soft and flexible, heart like structures (2 and 3) one of which is equivalent of the right ventricle of the natural heart (2) and another is equivalent of the left ventricle of the natural heart (3), and are provided with an outer shell (4) surrounding the two heart like structures (2 and 3) and an inner shell (5) provided in-between the two heart like structures (2 and 3), wherein the outer shell (4) is provided in such a manner that it encapsulates the two heart like structures (2 and 3), and the

inner shell (5) is provided in such a manner that the two heart like structures (2 and 3) encircle it (5).

It may be noted that in Figure 1 the inner shell consists of single chamber 5, and in Figure 4 the inner shell consists of two chambers (5a and 5b) separated by a partition sheet (5c). The inner shell of Figure 4 demonstrates additional advantages as described herein above. In accordance with one of the preferred embodiments of the present invention, the heart like structures may be referred to as left ventricle or right ventricle, as the case may be, or as pouches, or by any other name, and the inner shell, which may be consisting of single chamber or dual chambers may be referred to as central inflatable compressible bag or any other name, and the outer shell may be referred to as outer covering or by any other name. Accordingly, the identification of various constructional parts of the replaceable artificial heart by the names as used herein are not intended to limit scope of the present invention.

In accordance with present invention, the right ventricle (2) is provided with an inlet tube (6) with an inbuilt inflow valve [not shown] and an outlet tube (7) with an inbuilt outflow valve [not shown]. The inflow tube (6) is connectable to the blood vessel Vena Cava [not shown] which returns the deoxygenated blood from the body into the right ventricle (2) via the right Atrium [not shown]. The outflow tube (7) is connectable to the Pulmonary Artery [not shown] which carries the deoxygenated blood from the right ventricle (2) to the lungs. The left ventricle (3) is provided with an inflow tube (8) with an inbuilt inflow valve [not shown], and an outflow tube (9) with an inbuilt outflow valve [not shown]. The inflow tube (8) is connectable to the Pulmonary Vein [not shown] which brings the oxygenated blood from the lungs to the left ventricle (3) via the left Atrium [not shown]. The outflow tube (9) is connectable to the Aorta [not shown] which transports the oxygenated blood from the left ventricle (3) to the general circulation in the body. In the artificial heart the atria and ventricle are combined into an integrated space.

In accordance with one of the preferred embodiments of present invention, the two heart like structures are made of polymeric material, which is capable of withstanding the pressure at which the natural heart functions and capable of expanding and contracting to pump the blood to various parts of the body and is capable of lasting for sufficiently longer duration to avoid early replacement of the artificial heart.

In accordance with present invention, the inflatable compressible bag (5) provided in between the pouches (2 and 3), the equivalents of the right and left

ventricles is connectable by means of a connecting means (10) to one of the reciprocating pumping means (11) [Figure 2]. The pumping means (11) is capable of pumping a fluid to inflatable compressible bag (5) and is also capable of withdrawing the fluid from inflatable compressible bag (5) to, respectively, inflate and deflate the bag (5), which has been found to be capable of generating positive pressure on the heart like structures (2 and 3) for causing outflow of blood from the heart like structures.

In accordance with one of the preferred embodiments of the present invention, the inflatable compressible bag (5) consisting of two chambers (5a, 5b), provided in between the pouches (2 and 3), the equivalents of the right and left ventricles, is connectable by means of corresponding connecting means (10r, 10l) to corresponding reciprocating pumping means (11r, 11l) [Figure 5]. The pumping means (11r, 11l) are capable of pumping a fluid to corresponding chamber of inflatable compressible bag (5) and are also capable of withdrawing the fluid from corresponding chamber of inflatable compressible bag (5) to, respectively, inflate and deflate chambers of bag (5). Such action has been found to be capable of generating positive pressure on the heart like structures (2 and 3) for causing outflow of blood from the heart like structures and additionally avoiding mismatch of outflow of blood.

In accordance with present invention, when the filled right and left ventricles (2 and 3) are required to be compressed to eject the blood from ventricles of the artificial heart, the pumping means (11, or 11r and 11l) get activated to pump the fluid into the inflatable compressible bag (5) resulting in inflation of bag (5, or both chambers 5a and 5c of bag) thereby causing positive pressure on the ventricles (2 and 3). The positive pressure on the ventricles (2 and 3) has been found to result in outflow of blood therefrom. The blood from right ventricle (2) outflows via outflow means (7) through the Pulmonary Artery to the lungs. The blood from left ventricle (3) outflows via outflow means (9) through the Aorta for general circulation to body. This action is the analog of the "Systole" of the natural heart. At the time of the systolic pumping the outer shell (4) is maintained in a deflated and flaccid state.

In accordance with one of the preferred embodiments of present invention, the inner shell (5) consisting of single chamber or dual chambers is made of polymeric material, which is capable of withstanding and generating the pressure at which the natural heart functions and capable of expanding to cause positive pressure on the right and left ventricles of the artificial heart and is capable of lasting for sufficiently longer duration to avoid early replacement of the artificial heart.

In accordance with one of the preferred embodiments of the present invention, the fluid in the pumping means (11) can be any fluid capable of withstanding body temperature and compatible with the polymer material used to manufacture the inflatable compressible bag (5). For example, the fluid can be water or silicone oil.

In accordance with present invention, the outer shell (4) of the artificial heart comprises an outer layer (12) and an inner layer (13) connected to each other via connecting means (14). In accordance with present invention, the connecting means (14) preferably comprises a narrow flexible strip (14) capable of bridging the outer layer of the outer shell with inner layer of the outer shell, preferably capable of bridging inside surface of the outer layer of the outer shell with outside surface of the inner layer of the outer shell.

In accordance with present invention, when outer shell (4) is distended it comprises a space (15) between its outer and inner layers, and this space (15) is one continuous space in the entire outer shell (4) in such a manner that if a fluid is pumped into this space, it occupies the entire space.

In accordance with one of the preferred embodiments of the present invention, bridges (14) are made of narrow about 6 - 10 mm wide strips of the soft and flexible material as is used for the manufacture of layers (12 and 13) of the outer shell (4). The length and width of the bridges (14) are precisely selected to form one intercommunicating space (15) between the distended outer and inner layers at that point. In accordance with one of the preferred embodiments of this invention, the bridges (14) at different places in the outer shell have different lengths.

The advantage of above-described judiciously selected design of the outer shell (4) is that when the space (15) is filled by pumping in a fluid by means of the pumping means (16) via connecting means (17) [Figure 2 or Figure 5], the soft and flexible outer shell transforms to rigid form, which has been surprisingly found to cause negative pressure on the heart like structures (2 and 3) in a such a manner that the heart like structures (2 and 3) expand resulting in inflow of blood via inflow tubing means (6) through connectable blood vessel Vena Cava [not shown] in the right ventricle (2) thereby causing return of the deoxygenated blood from the body in the right ventricle (2) via the right Atrium [not shown], and inflow tubing means (8) connectable to the Pulmonary Vein [not shown] in the left ventricle (3) thereby causing inflow of oxygenated blood from the lungs to the left ventricle (3) via the left Atrium [not shown].

The additional advantage of above-described judiciously selected design of the outer shell (4) is that when fluid is withdrawn from the space (15) by means of the pumping means (16) via connecting means (17), the rigid outer shell transforms back to the soft and flexible outer shell (becomes flaccid), which has been surprisingly found to further enhance outflow of blood from the right and left ventricles, which takes place when positive pressure is generated by expansion bag (5).

In the diastolic filling phase of the ventricles of the artificial heart, a part of the filling action is on account of the pressure in the Vena Cava and the Pulmonary Vein. In addition pumping means (16) is activated to distend outer shell and transform it to a rigid structure. As described hereinabove, this distension with rigidity generates a negative pressure suction effect on the ventricles thereby assisting in drawing in blood into the ventricles in the diastolic phase. After filling of the ventricles the outer shell is deflated by drawing-out the fluid from space (15) by means of pumping means (16). Thereafter, the inflatable compressible bag (5) is inflated by another pumping means (11, or 11r and 11l) which is (are) capable of pumping the fluid into the bag or to corresponding chambers of bag thereby causing outflow of blood from the ventricles, and hence, completing the cycle. It is now understood that this entire process can be easily repeated by employing replaceable artificial heart of present invention in a continuous and uninterrupted manner, therefore, replaceable artificial heart of present invention is capable of replacing the natural heart in the animal and human.

In accordance with one of the preferred embodiments of present invention, the outer shell (4) of the artificial heart is made of soft and flexible polymeric material, which is capable of withstanding the pressure at which the natural heart functions and capable of expanding to cause negative pressure on the right and left ventricles of the artificial heart and is capable of lasting for sufficiently longer duration to avoid early replacement of the artificial heart.

In accordance with one of the preferred embodiments of the present invention, the fluid in the pumping means (16) can be any fluid capable of withstanding body temperature and compatible with the polymer material used to manufacture the outer shell (4). For example, the fluid can be water or silicone oil.

In accordance, with present invention, the artificial heart can be manufactured by any known means. In accordance with one of the preferred embodiments, method of manufacturing the replaceable artificial heart comprises steps of forming outer shell (4) comprising an outer layer (12) and an inner layer (13) connected to each other via

connecting means (14), inserting analogs of the ventricles (2 and 3) into the outer shell (4), and inserting inflatable compressible bag (5) consisting of single chamber (5) or dual chambers (5a and 5b) in between the analogs of the ventricles (2 and 3), and thereafter providing connecting means, and inflow and outflow means.

The functioning of the presently disclosed artificial heart is now described with the help of accompanying Figure 3 and Figure 6, which are also not intended to limit its scope, but have been incorporated to elaborate preferred mode and best mode of functioning of the replaceable artificial heart of present invention.

Figure 3 illustrates schematic diagram of functioning of the replaceable artificial heart having electrical motor drives being provided within the abdomen region in accordance with one of the preferred embodiments of the present invention, wherein states of the heart in five phases during a heart cycle are illustrated for understanding functioning of the presently disclosed artificial heart. In Phase I [Figure 3a(i)] which is just before diastolic filling of the heart, the heart outer shell (4); the inflatable compressible bag (5) consisting of single chamber; heart like structure being analog of the right ventricle (2); heart like structure being analog of the left ventricle (3) are all in the collapsed state. During the inter-phase between Phase I [Figure 3a(i)] and Phase II [Figure 3a(ii)], the blood flows into the right ventricle (2) [as shown by an arrow – 18 (Figure 3a(iii))] and also there is flow into the left ventricle (3) [as shown by an arrow – 19 (Figure 3a(iii))]. Concurrently from the reciprocating pumping means (16) fluid is pumped along the tubing means (17) from the pumping means (16) to the space (15) within the outer shell (4). The distension of the outer shell (4) creates a negative suction which helps to draw in blood into the two ventricles (2 and 3). Thus in the Phase II state (Figure 3a(ii)), the two ventricles are full and the outer shell is distended and somewhat rigid. Then reciprocating pumping means (11) pumps fluid via tubing means (10) into the inflatable compressible bag (5). The inflatable compressible bag (5) distends. The outer shell (4) is in a rigid state and cannot distend further. Therefore, the ventricles (2 and 3) which are sandwiched between the inflatable compressible bag (5) and the outer shell (4) are squeezed and blood flows out from the right ventricle (2) as shown by the arrow (20) and from the left ventricle (3) as shown by the arrow (21) [Figure 3b(iv)]. The transition from Phase III [Figure 3b(i)] to Phase IV [Figure 3b(ii)] is equivalent to the “Systole” of the heart. Ultimately in Phase IV [Figure 3b(ii)] the inflatable compressible bag (5) is almost fully distended; the ventricles (2 and 3) are collapsed; and the outer shell (4) still remaining distended. The flow from pumping

means (11) into the inflatable compressible bag (5) is gradually reduced with no flow immediately after Phase IV. Thereafter, pumping means (11) withdraws fluid from the inflatable compressible bag (5) via tubing means (10) and consequently the inflatable compressible bag (5) transforms to the collapsed state. Also via tubing means (17) the reciprocating pumping means (16) withdraws fluid from the outer shell (4) and as a result the outer shell (4) becomes flaccid and transforms to the collapsed state all of which takes the system to the Phase I state [Figure 3b(iii)]. It is now understood that the entire cycle can be repeated continuously and uninterruptedly, therefore, the artificial heart of present invention is capable of replacing the natural heart in the human and animals.

Figure 5 also illustrates schematic diagram of functioning of the replaceable artificial heart in the same manner as in Figure 3. The difference in these Figures is of inner shell, which in Figure 5 consists of two chambers (5a and 5b) separated by partition sheet (5c), and chamber 5a is connected to corresponding pumping means 11r via connecting means 10r, chamber 5b is connected to corresponding pumping means 11l via connecting means 10l.

In accordance with this embodiment, in Phase I [Figure 6a(i)] which is just before diastolic filling of the heart, the heart outer shell (4); both chambers of inflatable compressible bags (5a, 5b); heart like structure being analog of the right ventricle (2); heart like structure being analog of the left ventricle (3) are all in the collapsed state. During the inter-phase between Phase I [Figure 6a(i)] and Phase II [Figure 6a(ii)], the blood flows into the right ventricle (2) [as shown by an arrow – 18 (Figure 6a(iii))] and also there is flow into the left ventricle (3) [as shown by an arrow – 19 (Figure 6a(iii))]. Concurrently from the reciprocating pumping means (16) fluid is pumped along the tubing means (17) from the pumping means (16) to the space (15) within the outer shell (4). The distension of the outer shell (4) creates a negative suction which helps to draw in blood into the two ventricles (2 and 3). Thus in the Phase II state [Figure 6a(ii)], the two ventricles are full and the outer shell is distended and somewhat rigid. Then reciprocating pumping means (11r and 11l) pump fluid via corresponding tubing means (10r and 10l) into corresponding chambers of the inflatable compressible bag (5a and 5b) respectively. Concurrently the outer shell (4) is deflated by drawing fluid via tubing (17). The inflatable compressible bags (5a, 5b) distend. The outer shell (4) comes to a flaccid state and allows full squeezing of blood out of the ventricles (2, 3). Therefore, the ventricles (2 and 3) which are sandwiched between the inflatable compressible bag

(5a, 5b) and the outer shell (4) are squeezed and blood flows out from the right ventricle (2) as shown by the arrow (20) and from the left ventricle (3) as shown by the arrow (21) (Figure 6b(iv)). The transition from Phase III [Figure 6b(i)] to Phase IV [Figure 6b(ii)] is equivalent to the "Systole" of the heart. Ultimately in Phase IV [Figure 6b(ii)] the inflatable compressible bags (5a, 5b) are almost fully distended; the ventricles (2 and 3) are collapsed; and the outer shell (4) still remaining stretched by the internal pressure of the ventricles. The flow from pumping means (11r, 11l) into corresponding chambers of inflatable compressible bag (5a, 5b) is gradually reduced with no flow immediately after Phase IV [Figure 6b(ii)]. Thereafter, pumping means (11r, 11l) withdraw fluid from the corresponding chambers of inflatable compressible bags (5a, 5b) via corresponding tubing means (10r, 10l) and consequently the inflatable compressible bags (5a, 5b) transform to the collapsed state. The outer shell (4) having no fluid in the space (15) and also no internal pressure from the ventricles become totally flaccid and in the collapsed state. These steps take the system to the Phase I state [Figure 6b(iii)]. It is now understood that the entire cycle can be repeated continuously and uninterruptedly, and that's too without mismatch of outflow of blood, therefore, the artificial heart of present invention is capable of replacing the natural heart in the human and animals.

It may be noted that merely for the simplicity, the outflow and inflow of blood has been illustrated by arrows. However, it flows through respective valves and vessels as described hereinabove. Further, the electrical motor herein means a electrical pump driven by motor.

In accordance with one of the embodiments of the present invention, before the end of the estimated life span of the artificial heart, the artificial heart can be deflated, and endoscopically the connections to the blood vessels can be detached and the artificial heart can be easily extracted through a keyhole opening in the chest wall and can be replaced by a new artificial heart of present invention.

It may be noted that accompanying Figures are merely illustrations of preferred embodiments of the present invention and are not to the scale, and are not intended to limit scope of present invention. It will be obvious to the persons skilled in the art that various modifications are possible of the embodiments illustrated herein without deviating from the intended scope of the present invention. Accordingly, in one embodiment of the present invention, such modifications are inclusive.

Claims

1. The replaceable artificial heart (1), comprising two heart like structures (2 and 3) one of which is equivalent of right ventricle of natural heart (2) and another is equivalent of left ventricle of natural heart (3), an outer shell (4) surrounding said two heart like structures (2 and 3), and an inner shell (5) provided in-between said two heart like structures (2 and 3), wherein said outer shell (4) is provided in such a manner that it encapsulates said two heart like structures (2 and 3), and said inner shell (5) is provided in such a manner that said two heart like structures (2 and 3) encircle it (5).
2. A replaceable artificial heart as claimed in claim 1, wherein said inner shell consists of single chamber (5).
3. A replaceable artificial heart as claimed in claim 1, wherein said inner shell consists of two chambers (5a and 5b) separated by a partition sheet (5c).
4. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said right ventricle (2) is provided with an inlet means (6) with an inbuilt inflow valve and connectable to blood vessel Vena Cava, and an outlet means (7) with an inbuilt outflow valve and connectable to Pulmonary Artery.
5. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said left ventricle (3) is provided with an inflow means (8) with an inbuilt inflow valve and connectable to the Pulmonary Vein, and an outflow means (9) with an inbuilt outflow valve and connectable to the Aorta.
6. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said inflatable compressible bag (5) is connected to reciprocating pumping means (11) by connecting means (10).
7. A replaceable artificial heart as claimed in claim 3, wherein said chambers of said inflatable compressible bag (5) are connected by corresponding connecting means (10r, 10l) to corresponding reciprocating pumping means (11r, 11l).
8. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said outer shell (4) is connected to reciprocating pumping means (16) by a connecting means (17).
9. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said outer shell (4) comprises an outer layer (12) and an inner layer (13) connected to each other via connecting means (14).

10. A replaceable artificial heart as claimed in claim 9, wherein said connecting means (14) comprises a narrow flexible strip (14) capable of bridging said outer layer of said outer shell with said inner layer of said outer shell.
11. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said outer shell (4) in distended state comprises a space (15) between its said outer and said inner layers.
12. A replaceable artificial heart as claimed in claim 11, wherein said space (15) is one continuous and intercommunicating space in entire outer shell (4) in such a manner that if a fluid is pumped into this space, it occupies the entire space.
13. A replaceable artificial heart as claimed in claim 9 or 10, wherein said bridges (14) are made of narrow about 6 - 10 mm wide strips of soft and flexible material.
14. A replaceable artificial heart as claimed in claim 9 or 10, wherein said bridges (14) at different places in said outer shell have different lengths.
15. A replaceable artificial heart as claimed in any one of the preceding claims, wherein said two heart like structures, said inner shell and said outer shell are made of polymeric material.
16. A method of manufacturing replaceable artificial heart of any one of claims 1-15, comprising steps of forming outer shell (4) comprising an outer layer (12) and an inner layer (13) connected to each other via connecting means (14), inserting analogs of the ventricles (2 and 3) into said outer shell (4) and inserting inflatable compressible bag (5) consisting of single chamber (5) or dual chambers (5a and 5b) in between the analogs of said ventricles (2 and 3), and thereafter providing connecting means, and inflow and outflow means.
17. The replaceable artificial heart substantially as herein described with the help of foregoing examples and as illustrated in the accompanying figures.
18. The method of manufacturing replaceable artificial heart substantially as herein described with the help of foregoing examples and as illustrated in the accompanying figures.

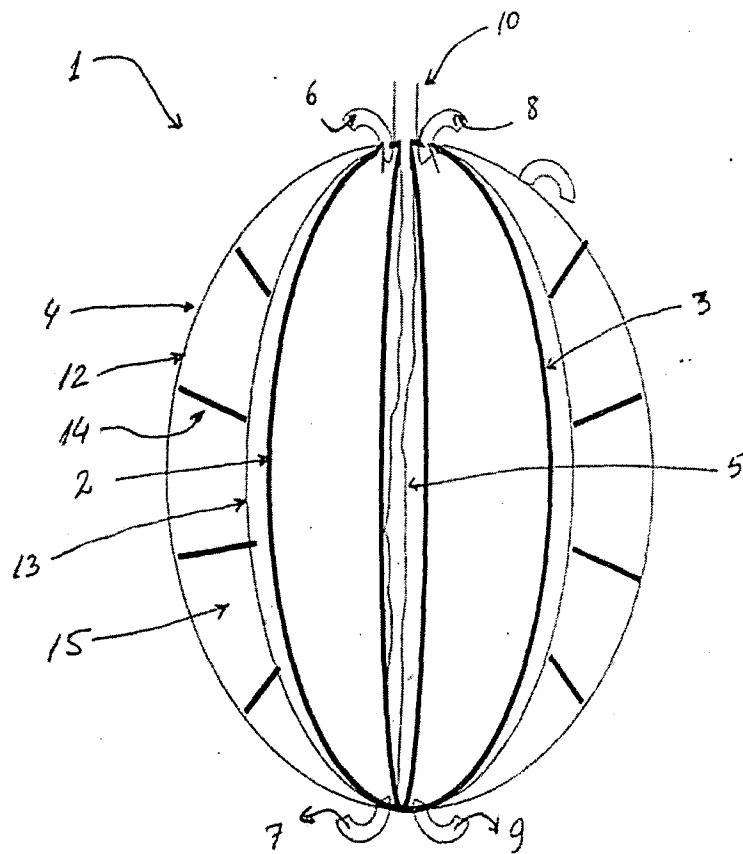


Figure 1

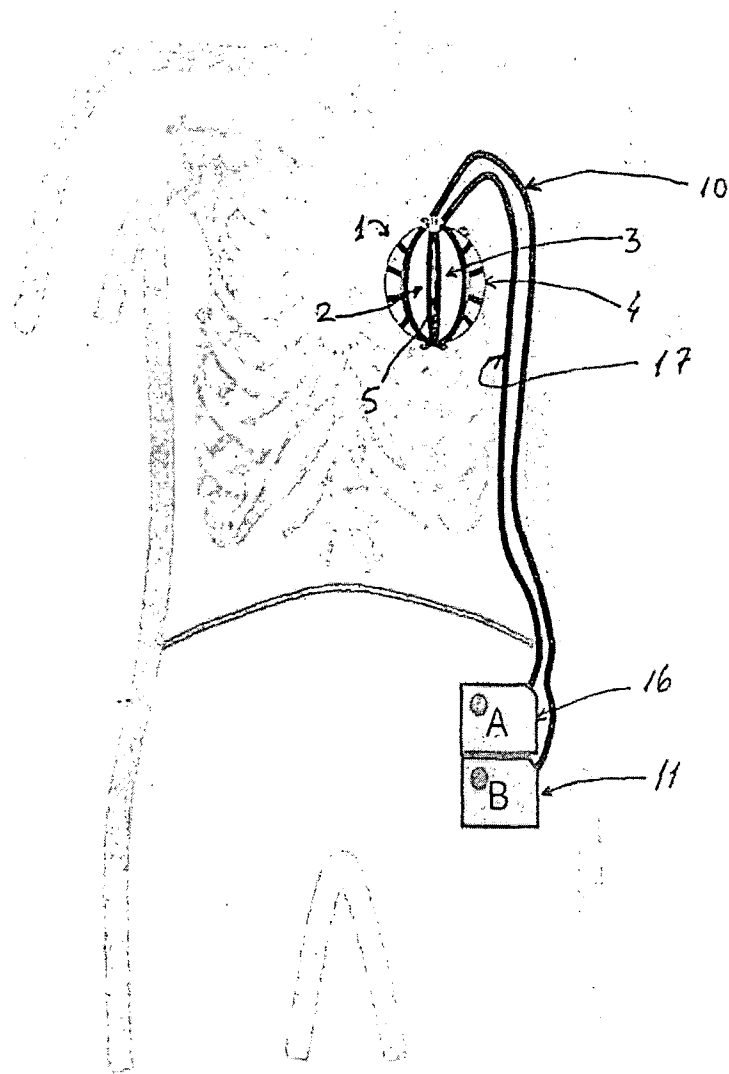


Figure 2

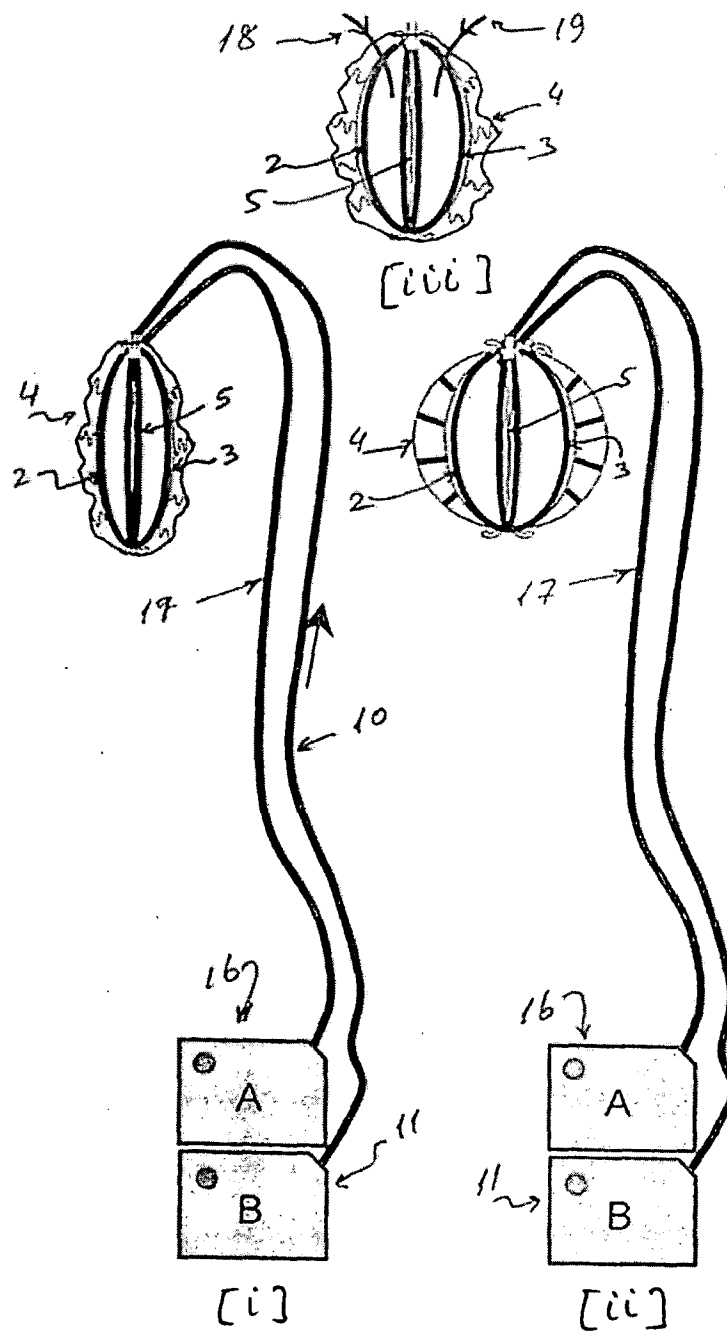


Figure 3a

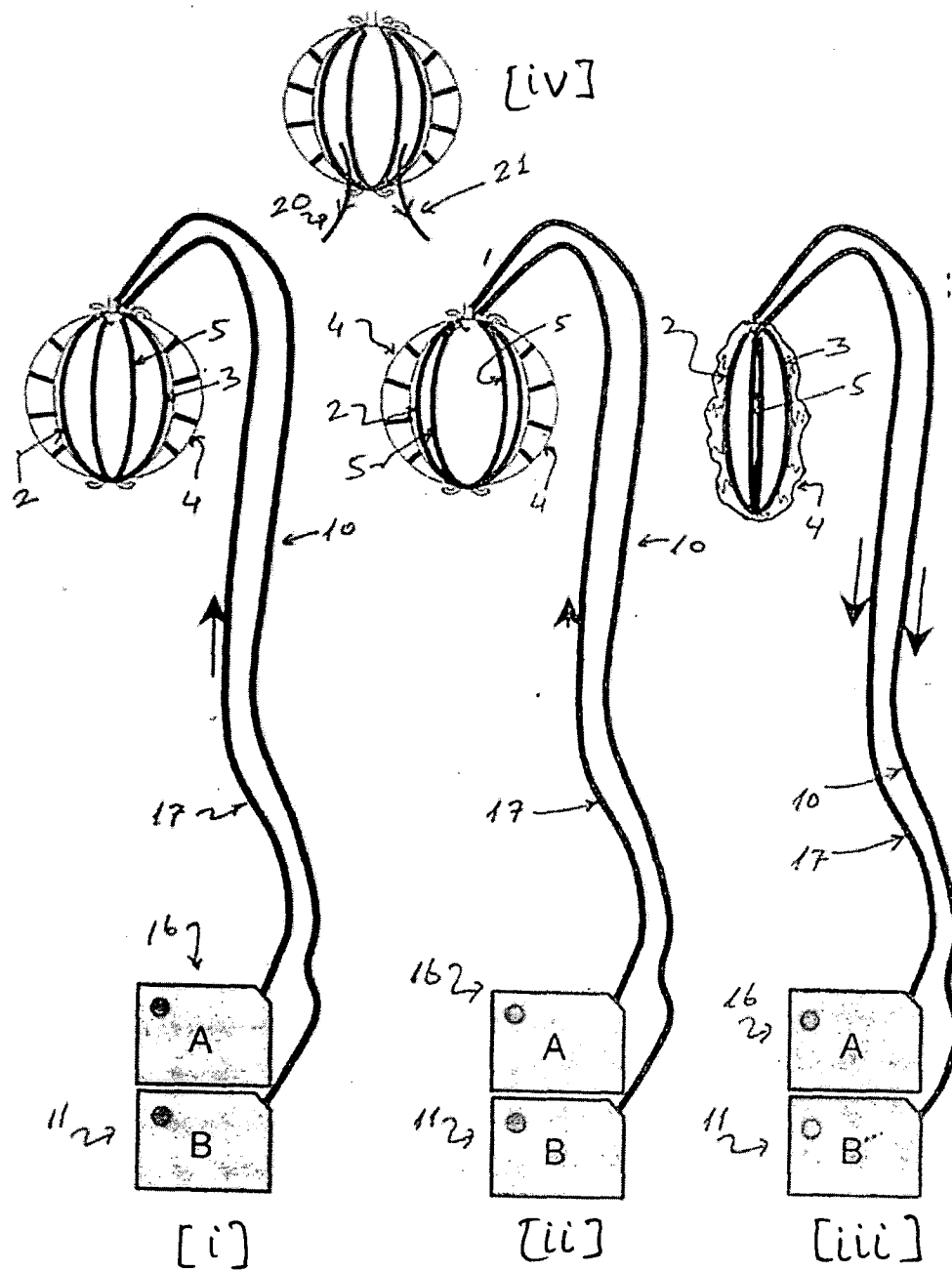


Figure 3b

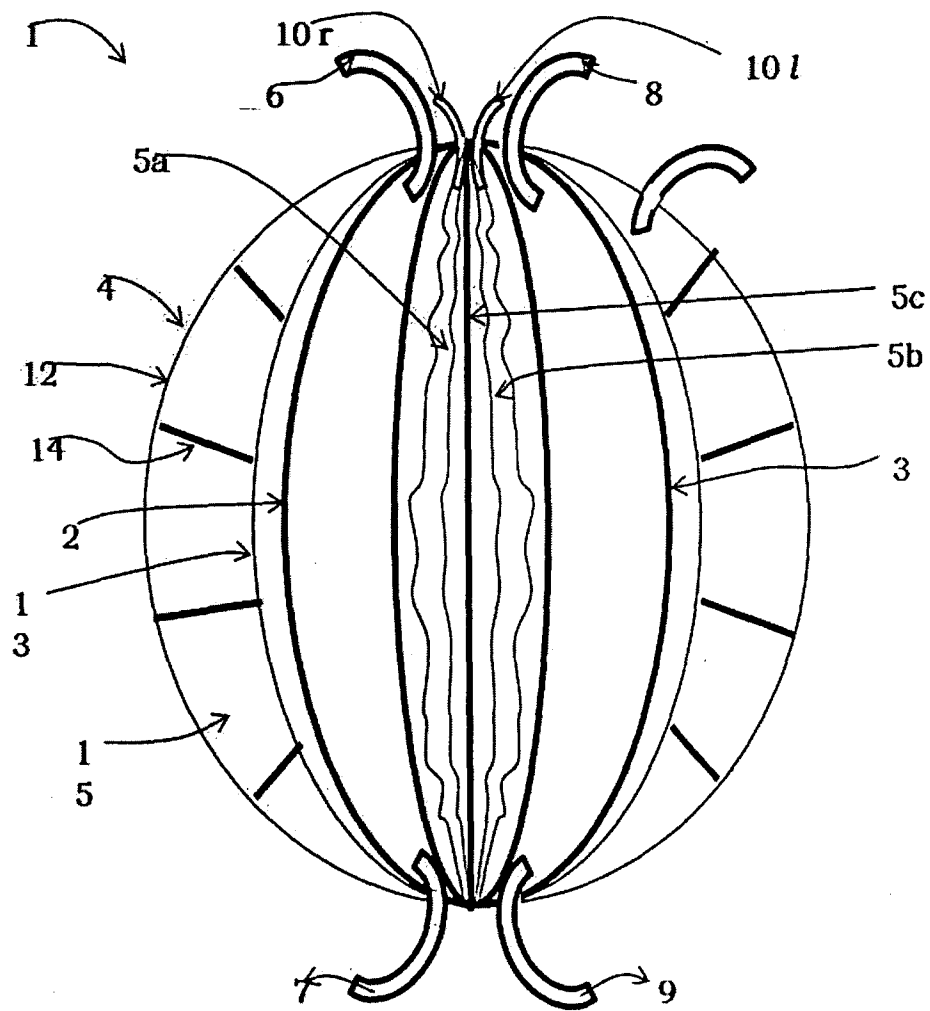


Figure 4

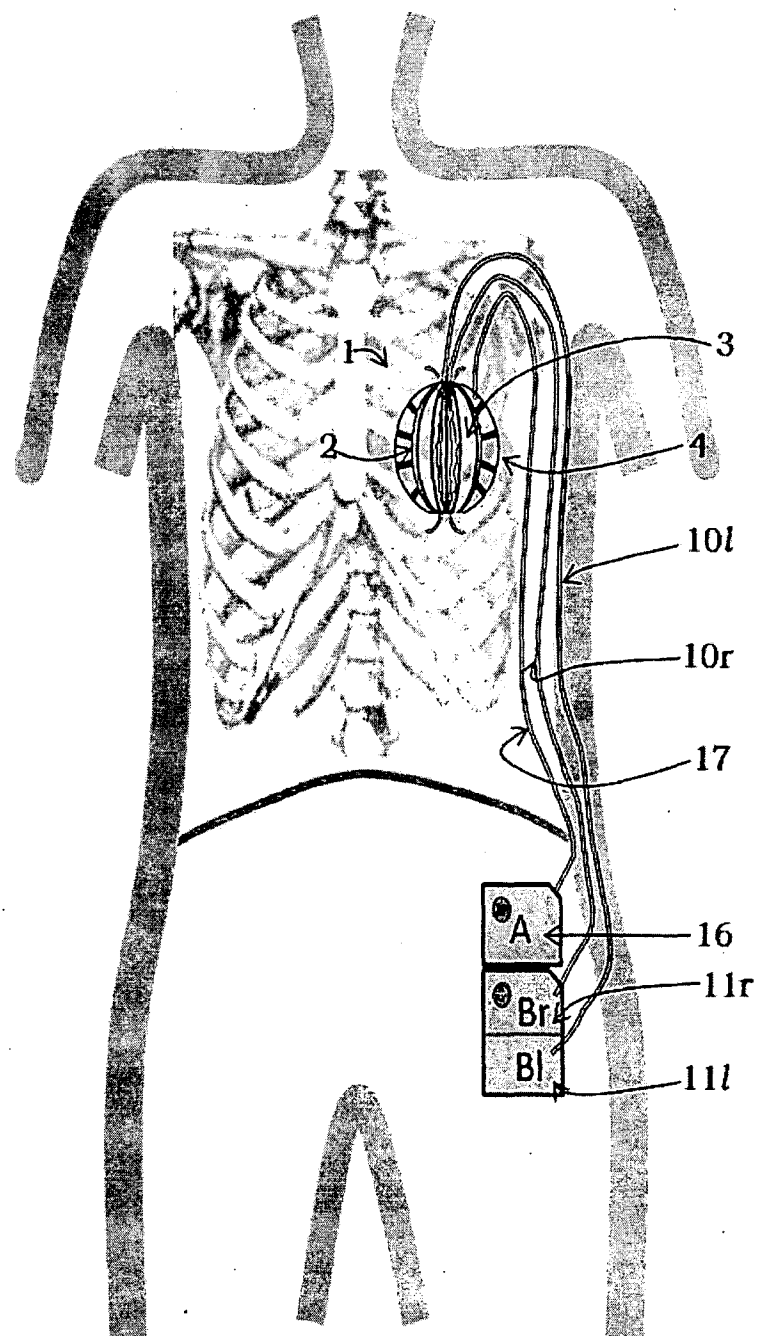


Figure 5

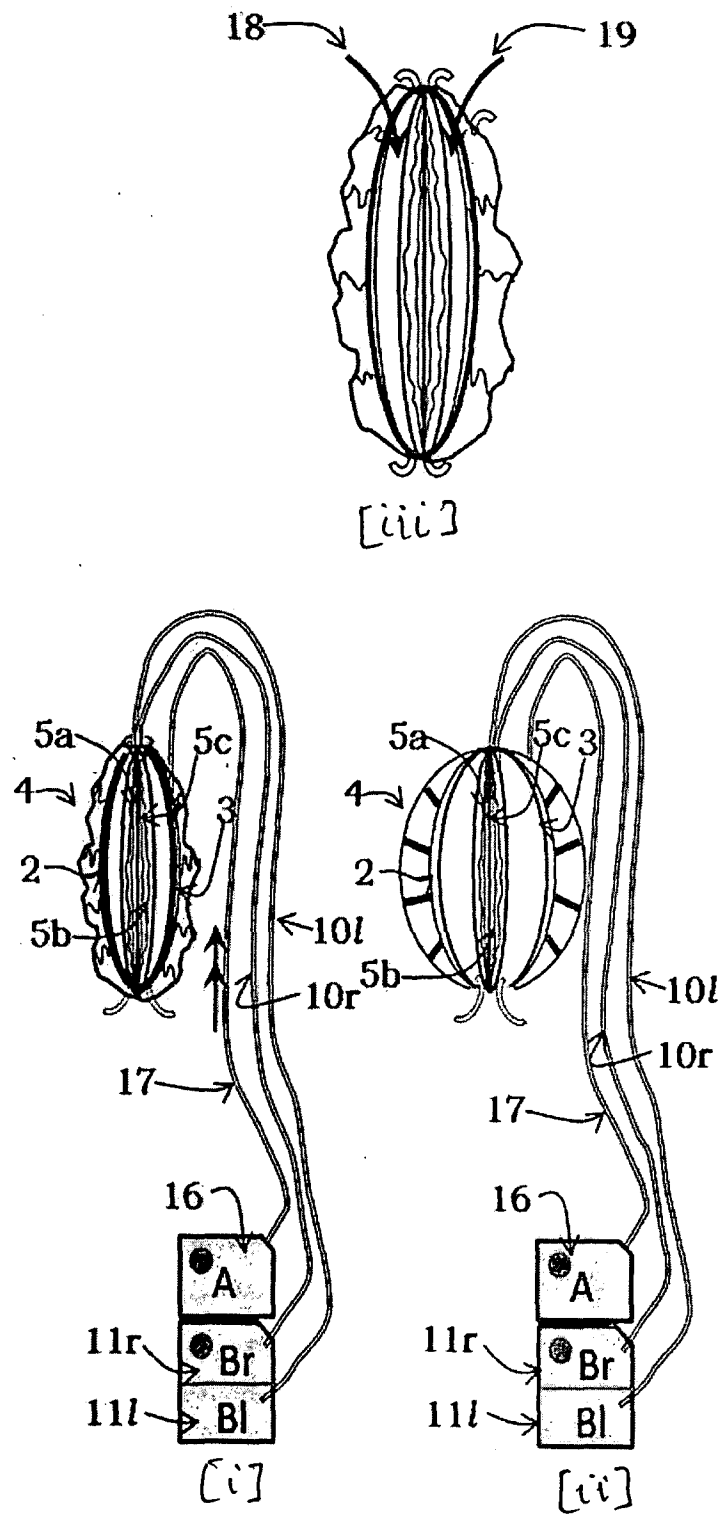


Figure 6a

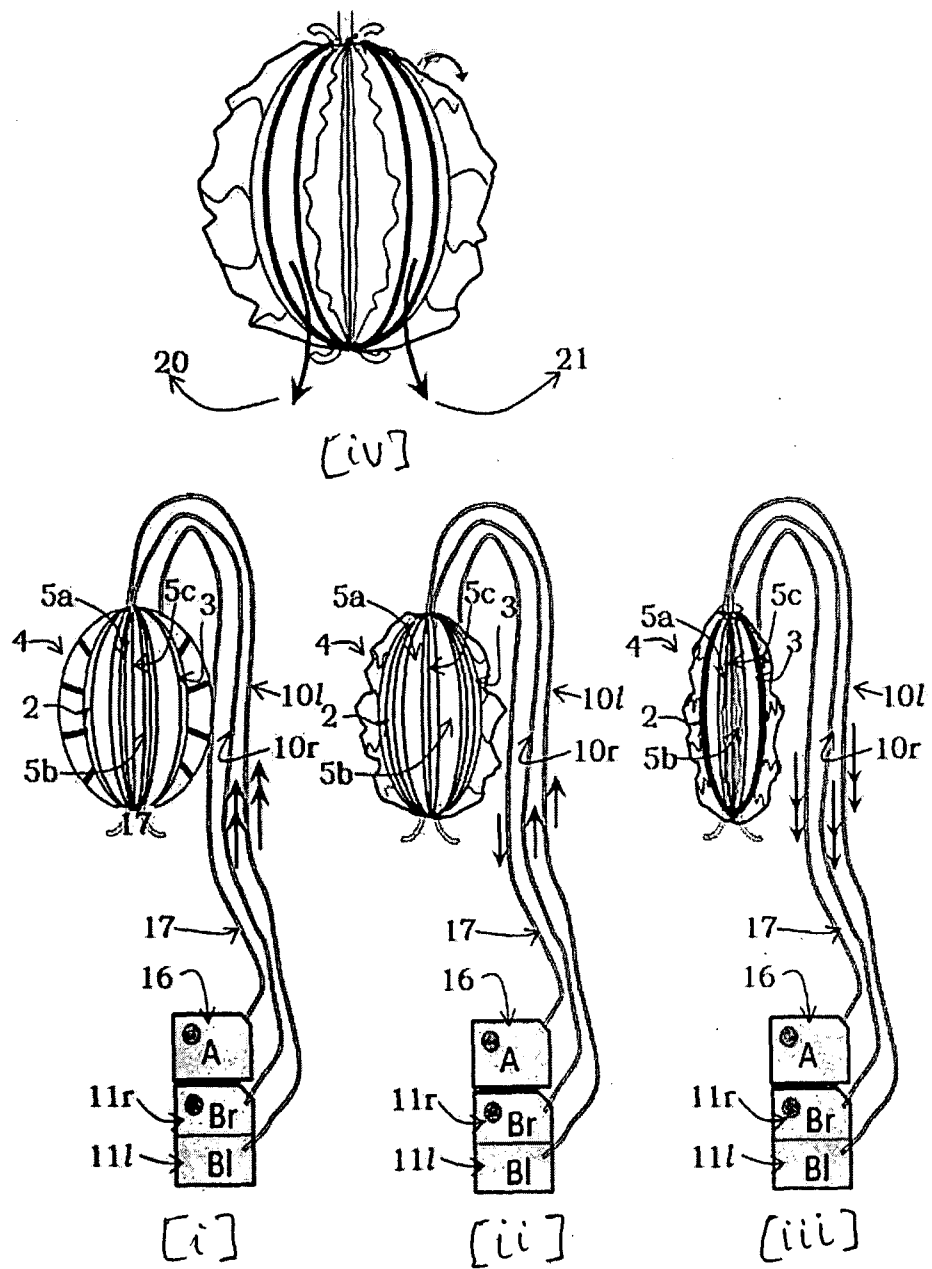


Figure 6b

INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2010/000461

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M1/10
ADD.

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)

A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 668 708 A (TINDAL JAMES A) 13 June 1972 (1972-06-13)	1,2,4-6, 8-15
Y	* abstract; figures 10-11 column 1, line 64 - column 2, line 45 column 10, line 9 - column 11, line 15 -----	16
X	US 2002/147495 A1 (PETROFF CHRISTOPHER [US]) 10 October 2002 (2002-10-10) * abstract; figure 2 paragraphs [0009] - [0015], [0036] - [0037] -----	1,2,4-6, 8-15
X	US 5 306 295 A (KOLFF WILLEM J [US] ET AL) 26 April 1994 (1994-04-26) * abstract; figure 1 column 2, line 25 - column 3, line 43 column 4, line 18 - column 5, line 27 ----- -/--	1,3,5-8, 15

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

☒ See patent family annex.

* 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 document 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

11 November 2010

Date of mailing of the international search report

23/11/2010

Name and mailing address of the ISA/

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Authorized officer

Kaden, Malte

INTERNATIONAL SEARCH REPORT

International application No

PCT/IN2010/000461

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 139 516 A (MOGENDOVICH EUGENE [US]) 18 August 1992 (1992-08-18)	1,2,4-6, 8,15
Y	* abstract; figure 1 column 1, line 55 - column 2, line 7 column 2, lines 51-68 -----	16
X,P	EP 2 078 533 A1 (CARMAT [FR]) 15 July 2009 (2009-07-15) * abstract; figures 1-5 paragraphs [0019] - [0029] -----	1,3-8
A	US 3 641 591 A (KOLFF WILLEM J) 15 February 1972 (1972-02-15) * abstract; claims; figures column 1, line 45 - column 2, line 8 -----	1,16
A	US 4 902 291 A (KOLFF WILLEM J [US]) 20 February 1990 (1990-02-20) * abstract; figures 8-10 column 8, lines 8-61 -----	1,16

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 17, 18

No search report has been established for claims 17 and 18 in view of Articles 17(2)(a)(ii) and 17(2)(b) PCT. These claims merely refer to the drawings and fail to comply with the requirements of Rule 6.2(a) PCT to such an extent that a meaningful search cannot be carried out.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2010/000461

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.: 17, 18
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:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
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 an 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IN2010/000461

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3668708	A	13-06-1972	NONE	
US 2002147495	A1	10-10-2002	NONE	
US 5306295	A	26-04-1994	NONE	
US 5139516	A	18-08-1992	NONE	
EP 2078533	A1	15-07-2009	AU 2009224517 A1 CA 2711921 A1 FR 2926223 A1 WO 2009112662 A2	17-09-2009 17-09-2009 17-07-2009 17-09-2009
US 3641591	A	15-02-1972	NONE	
US 4902291	A	20-02-1990	NONE	