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(54) Title: IN-USE REPAIRABLE ARTIFICIAL HEART

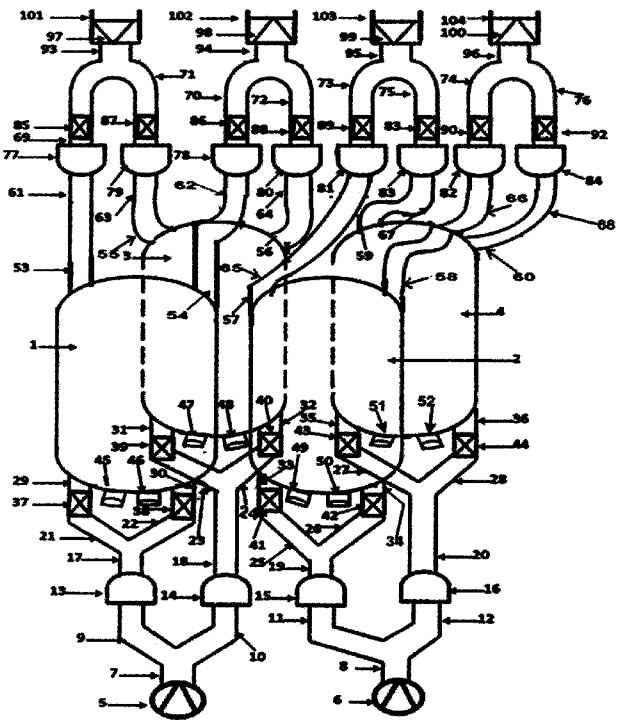

Figure 1

(57) Abstract: An in-use repairable artificial heart for self sealing a small leaks during use having real time estimation of the magnitude of the leak is presented. Further in the event of larger leaks which fail to self seal the system automatically deactivates the failed subunit of the artificial heart and switches on to a stand-by subunit of the artificial heart. The deactivated subunit is convertible to a flaccid form and removable by keyhole surgery while the blood circulation is maintained by the activated stand-by unit. The removed subunit is replaceable by keyhole surgical manipulation with a new subunit. The self repair and the interventional repair while the artificial heart is functioning gives the artificial heart a perpetual operational character.

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TITLE: "IN-USE REPAIRABLE ARTIFICIAL HEART"

BACKGROUND ART

The world over there is high incidence of physical debility and mortality due to failure of the heart to performs, its blood pumping action. There is very limited availability of biologically matching heart from persons whose hearts are normal and death was due accident or ailments with no cardiac pathology link and therefore there is a high need for alternatives to heart transplantation. Artificial hearts have been developed with this objective and have been used in patients. The number of artificial heart implantations is very small compared to the incidence of cardiac failure. A major factor limiting the usage of artificial hearts is that all models have limited functional lifetime.

Numerous artificial hearts and blood pumps have been devised to replace a defective or diseased heart and closely simulate the functioning of a healthy, natural heart. In contrast to heart transplantation, which requires a donor and involves serious rejection problems, a total artificial heart may be mass-produced and is potentially more compatible with the host's immune system. However, an artificial heart must be compact enough to fit in the chest cavity, and must consistently maintain proper blood flow based on the host's level of activity. The input and output flow characteristics of the artificial heart must be sufficient to protect the blood cells from hemolysis [dissolution] and thrombosis [clotting]. The artificial heart mechanism must also be extremely reliable and durable.

The natural heart contracts and expands over one hundred thousand times per day. The cumulative contraction/expansion cycle over a period of a few years is very high. Each contraction/expansion cycle imposes mechanical stresses on the structures of the heart producing material fatigue and micro damage. Sequential micro damage adds up and tends to breakdown the materials of the heart wall and also reduce the pumping action. The walls of the natural heart are muscles having on-going repair and rejuvenating processes. Therefore in spite of the cumulative micro damage the continuing cellular repair function maintains the heart muscles in normal functional state for long. On the other hand the materials of the artificial heart, mostly plastics and metals, do not have repair properties although research in that direction is underway. Therefore fatigue, functionality lowering permanent deformations and mechanical failure of materials making up the artificial heart is a commonly encountered phenomena. The usage of artificial heart gets limited.

Since the early stages of Artificial Heart development with the implantation of the total artificial heart (TAH) which was a replacement of both the ventricles and atria of the natural heart (Robert K. Jarvik US 4173796) there have been many developments. Mechanical Failure is a major issue . John Holfert and Don Olsen (Modified elliptical artificial heart – US4981484) used diaphragm structure of ellipsoidal configuration. The curvature of the medial section reduce occurrence of bi-axial folding and enhanced random folding. Thereby sections had reduced identical stress reversal pattern and longevity of the material increased. Yet failure did take place with no repair capability. More recently the artificial heart by Alain Carpentier (US 5135539) had a floating membrane for reducing wear. Further the membranes, electromechanical members and valves which are the elements most sensitive to wear, were removably mounted to allow rapid standard replacement. However there was no "self repair" and most of the stressed entities could not be replaced through keyhole surgery. Still another approach to address the mechanical failure issue was by Daniel Timms (US 8636638) wherein stress reversal of structures was minimized by having a continuous flow system with magnetically levitated units. Reduction of stress reversal prolongs structure life but provides no self repair or easy replaceability of failed/failing components.. Moreover such a pumping system with continuous non pulsatile flow provided circulation in a non physiological manner. Still another approach by Sujoy K. Guha, Prabal K. Guha and Ratul K. Guha "(Replaceable artificial heart implantable by keyhole surgery" (GB2483422) addressed the issue by having a flexible artificial heart which could be removed and replaced by keyhole surgery on prophylactic basis before actual failure. This design too did not have any "self repair" and onset of failure at the early stages could not be detected. Further only replacement of the heart as a whole instead of failed/failing components was possible with the patient requiring support on cardio-pulmonary bypass during the replacement procedure.

These known arrangements are generally deficient in meeting one or more of the requisites discussed above, and a need remains for a compact, self-repairable reliable artificial heart with added provision of interventional repair which thereby enables proper circulation of blood in the body on long term basis.

SUMMARY OF INVENTION

An in-use repairable artificial heart combining in-use self repair with interventional repair comprising: at least two pumping units [1, 2] positioned in the thoracic cavity; at least two pump drive units [5, 6] configured for ingress and egress of drive fluid in pre-assigned pumping units; an array of tubes, joints

and valve arrangement operably connected to said pumping units adapted for driving the drive fluid in and out of said pumping units; as well as sucking in and pumping out blood, wherein each of the pumping units comprises: a shell wall [105] comprises of an inner layer [107] and an outer layer [106] having spot joints [108] which are randomly distributed over the shell wall in such a manner that between the layers there is intercommunicating spaces leading to formation of the cavity; and wherein the inner layer forms a space [110] into which the blood inflows via an entry port [53] and outflows via an exit port [54] having a self-sealing valve; and the space [110] encloses two leak proof balloons [111,112], wherein each balloon [111, 112] has bidirectional entry port [29, 30] for pumping and drawing out drive fluid.

As per another embodiment there is provided an in-use self and interventional repairable, artificial heart with provision of in-use replacement of failing parts, having a structure which is soft, flexible, collapsible and compact at the time of its implantation and by injecting a hardening chemical is transformed to a rigid structure after being implanted in the thoracic region, and for interventional repair can be transformed back to a soft, flexible and collapsible compact structure by injecting softening chemicals for removal through a keyhole opening in the thoracic wall.

Description

Configuration

Brief description of the accompanying Figures:

Figure 1 Schematic of the total artificial heart. The pumping units are shown spaced apart for diagrammatic clarity only

Figure 2 Details of a representative pumping unit

Figure 3a Cross-sectional view of tube leading to a Coupling/uncoupling tube joint

Figure 3b Details of Coupling/uncoupling tube joint

The natural human heart has four chambers: the left atrium; left ventricle; right atrium; and right ventricle. Deoxygenated blood from the body is drawn into the right atrium and is pumped into the right ventricle. The right ventricle pumps the deoxygenated blood into the blood vessels of the lungs where the blood is oxygenated. The oxygenated blood flows back to the heart into the left atrium and thereon to the left ventricle. Strong contraction of the left ventricle pumps the blood into the blood vessels all

over the body other than that of the lungs. The artificial heart [Figure 1] comprises of multiple pumping units [1-4] positioned in the thoracic cavity , the preferred number of units being four but could be two or more. Each pumping unit serves as a combined atrium and ventricle and in following description is referred to as "ventricle". For the preferred embodiment of four pumping units Pumping Unit [1] and Pumping unit [3] serve as the right ventricle . Pumping unit [2] and Pumping unit [4] serve as the left ventricle. The Pumping units [1-4] are in close proximity retained by the force exerted by the connecting tubings. For diagrammatic clarity the Pumping units are shown apart in Figure 1.
All pumping units could be identical in design. Or, to withstand the higher left ventricular pressure, the pumping units serving as the left ventricle could have stronger materials than that for those serving as right ventricle – the right ventricle having lower pressure than the left ventricle.

For generating pressure to propel blood out from the ventricles a drive fluid is driven into and sucked out from the pumping units [1-4] by means of drive pumps. Drive pump [5] drives the drive fluid for the right ventricular pumping action. Drive pump [6] drives the drive fluid for the left ventricular pumping action. The drive pumps [5,6] are positioned in the abdominal region. From drive pump [5] drive fluid is transported by tube [7]. Tube [7] bifurcates into tube [9] and tube [10]. Tube [9] directs the drive fluid to Pumping unit [1] and tube [10] directs drive fluid to Pumping unit [3]. From Drive pump [6] drive fluid is transported by Tube [8]. Tube [8] bifurcates into Tube [11] and Tube [12]. Tube [11] Directs the drive fluid to Pumping unit [2] and tube [12] directs drive fluid to Pumping unit [4].

A Coupling/Uncoupling tube joint [13] is positioned to couple or uncouple Tube [9] with Tube [17]. Correspondingly Coupling/Uncoupling tube joint [14] couples or uncouples Tube [10] with Tube [18]. Another Coupling/Uncoupling tube joint [15] couples and uncouples tube [11] with tube [19]. Coupling/Uncoupling tube joint [16] couples and uncouples tube [12] with tube [20] . Tube[17] bifurcates into tube [21] and [22]. Tube [18] bifurcates into tube [23] and tube [24]. Tube [19] bifurcates into tube [25] and [26] and Tube [20] bifurcates into Tube [27] and Tube [28]. A Bidirectional flow control valves [37;38;39;40;41;42;43; and 44] are positioned in the lumen of Tubes [21;22;23;24;25;26;27; and 28] respectively.

The cavity formed in between the two layers of the outer shell of Pumping unit [1] has an "Inter outer shell layer entry port (right) [45] and an Inter outer shell layer entry port (left) [46]. Corresponding entry

[3] are: right [47]; left [48]; for Pumping unit 2 they are left [49]; right [50] ; and for Pumping unit 4 they are left[51]; right [52].

Pumping unit [1] has a Blood entry port [53] and a Blood exit port [54]. Corresponding ports for Pumping unit [3] are Blood entry port [55]; exit port [56]. For Pumping Unit [2] they are Blood entry port [57] and Blood exit port [58]. For Pumping unit [4] they are Blood entry port [59] and Blood exit port [60].

Tubing [61] links to port [53]; tubing 62 links to port 54; tubing 63 links to port [55]; tubing 64 links to port [56]; tubing [65] links to port[57]; tubing [66] links to port [58]; tubing [67] links to port [59]; and tubing [68] links to port [60].

Tube [61] is coupled/uncoupled with Tube [69] by means of a Coupling//uncoupling tube joint [77].

Tube [62] is coupled/uncoupled with Tube [70] by means of a Coupling/uncoupling tube joint [78]

Tube [63] is coupled/uncoupled with Tube [71] by means of a Coupling//uncoupling tube joint [79]

Tube [64] is coupled/uncoupled with Tube [72] by means of a Coupling//uncoupling tube joint [80]

Tube [65] is coupled/uncoupled with Tube [73] by means of a Coupling//uncoupling tube joint [81].

Tube [66] is coupled/uncoupled with Tube [74] by means of a Coupling//uncoupling tube joint [82].

Tube [67] is coupled/uncoupled with Tube [75] by means of a Coupling//uncoupling tube joint [83].

Tube [68] is coupled/uncoupled with Tube [76] by means of a Coupling//uncoupling tube joint [84]

Tube [69] has a Bidirectional flow control valve [85]

Tube [70] has a Bidirectional flow control valve [86]

Tube [71] has a Bidirectional flow control valve [87]

Tube [72] has a Bidirectional flow control valve [88]

Tube [73] has a Bidirectional flow control valve [89]

Tube [74] has a Bidirectional flow control valve [90]

Tube [75] has a Bidirectional flow control valve [91]

Tube [76] has a Bidirectional flow control valve [92]

Tubes [69 and 71] merge to form tube [93]

Tubes [70 and 72] merge to form tube [94]

Tubes [73 and 75] merge to form tube [95]

Tubes [74 and 76] merge to for Tube [96]

Tube [93] is provided with an unidirectional flow valve [97]which allows flow of blood into Pumping units [1 and 3].

Tube [94] is provided with an unidirectional flow valve [98] which allows flow of blood out of Pumping units [1 and 3].
Tube [95] is provided with an unidirectional flow valve [99] which allows flow of blood into Pumping units [2 and 4]
Tube [96] is provided with an unidirectional flow valve [100] which allows flow of blood out of Pumping units [2 and 4].

In use, the blood vessel Vena cava [101] bringing deoxygenated blood from the body parts other than the lungs is connected to the Tube [93]. Thereby the deoxygenated blood can enter into the Pumping units [1 and 3]. The Pulmonary artery [102] which transports blood from the right ventricle (represented in the Artificial Heart by Pumping units 1 and 3) to the lungs is connected to Tube [94]. Blood from the right ventricle (represented in the Artificial Heart by Pumping units 1 and 3) can flow out along the unidirectional valve [98] to flow into the lungs. The pulmonary vein [103] which transports oxygenated blood from the lungs is connected to Tube [95]. The oxygenated blood from the lungs can then flow into the left ventricle (represented in the Artificial Heart by Pumping units 2 and 4) via the unidirectional valve [99]. The Aorta [104] which transports blood from the left ventricle to body parts other than the lungs is connected to Tube [96]. Blood from the left ventricle (represented in the Artificial Heart by Pumping units 2 and 4) can flow out of the left ventricle (represented by Pumping units 2 and 4) via the unidirectional valve [100] into the Aorta [104].

Figure 2 shows Pumping unit [1] in detail. The outer shell has a Shell wall [105] which comprises of two layers [106, 107]. Fabric material used for the layers [106, 107] is thin, flexible non-stretchable and non porous to blood fabric. One suitable material is Polyethylene terephthalate (trade name Dacron). The two layers have Spot joints [108] which are randomly distributed over the Shell wall [105] in such a manner that between the layers [106, 107] there is intercommunicating spaces leading to the formation of a Cavity [109] between the layer [106, 107]. The Cavity [109] has two ports [45, 46]. Both the ports may be used as inlet/outlet to the Cavity [109].. The ports [45, 46] have a self sealing valve such that a large diameter needle can be inserted into the port to inject or suck out hardening chemical ~~fluid~~ from the cavity [109] and on removal of the large diameter needle the port seals automatically. The inner layer [107] forms a Space [110]. This Space [110] is the zone into which blood flows into via the Blood entry port [53] and flows out via the Blood exit port [54]. Within the zone enclosed by the

inner layer [107] there are two Balloons [111, 112]. The balloons are made of thin, highly flexible and large cyclic bending stress reversal withstanding material such as medical grade polyurethanes. It is a layered composite with the inside surface of the balloon material having a layer of material as for example styrene maleic anhydride grafted onto the balloon material, which in contact with blood forms a coagulum for sealing any leak that may occur in the balloon. The shape and relative orientation of the shell wall[105]; Balloon [111, 112] and the various ports may vary.

The open end of the balloon [111] is joined with the Entry port (right side balloon) [29] in such a manner that fluid pumped via the Entry port (right side balloon) [29] flows into the balloon [111]. The open end of the balloon [112] is joined with the Entry port (right side balloon) [30] in such a manner that fluid pumped via the Entry port (right side balloon) [30] flows into the balloon [112]. From the outer surface of Balloon [111] to the inside surface of layer [107] there is a short Anchor [113] in the form of a chord made of some material such as Nylon. The Anchor [113] prevents sagging of the Balloon [111]. From the outer surface of Balloon [112] to the inside surface of layer [107] there is a short Anchor [114] in the form of a chord made of some material such as Nylon. The Anchor [114] prevents sagging of the Balloon [112].

Figure 3a shows the cross section of tube [7]. Within the wall of the Tube [7] there are Tubular spaces [115-122]. The Tubular spaces run along the length of the tube. The Tubular spaces [115 – 118]] continue into Tube [9] and Tubular spaces [119-122] continue into tube [10]. Figure 3b shows the Coupling/Uncoupling tube joint [13]. Via Male tube member [133] the Tubular spaces [115-118] continue into Tube [17]. Beyond the bifurcation of Tube [17] the Tubular spaces [115, 116] continue into Tubular space within the wall of Tube [21]. Tubular space in Tube [21] reach up to Bidirectional flow control valve [37]. Beyond the bifurcation of Tube [17] the Tubular spaces [117, 118] continue into Tubular space within the wall of Tube [22]. Tubular space in Tube [22] reach up to Bidirectional flow control valve [38]. In a similar pattern Tubular spaces [119, 120] extend into Tubular spaces in the wall of Tube [23] reaching up to Bidirectional flow control valve [39]. Also Tubular spaces [121, 122] extend into Tubular spaces in the wall of Tube [24] reaching up to Bidirectional flow control valve [40]. The Tube [7] has a central Tube lumen [123] which distal to the Coupling/Uncoupling tube joint continues as the lumen of Tube [17]. The lumen of Tube [17] bifurcates to merge with the lumen of Tubes [21,22].

Embedded in the wall of Tube [7] there are light transmitting Optical fibres [124 -127]. Embedded in the wall of Tube [7] there are Electrical wire pairs [128-131] The Coupling/Uncoupling Tube joint [13] also incorporates coupling/uncoupling for optical fibres and electrical wire pairs.

The Optical fibre [124] reaches the end of Tube 21 just distal to Bidirectional flow control valve [37] to transilluminate Tube [21].

The Optical fibre [125] reaches the end of Tube [22] just distal to Bidirectional flow control valve [38] to transilluminate Tube [22].

The Optical fibre [126] reaches the end of Tube [23] just distal to Bidirectional flow control valve [39] to transilluminate Tube [23].

The Optical fibre [127] reaches the end of Tube [24] just distal to Bidirectional flow control valve [40] to transilluminate Tube [24].

The Electrical wire pair [128] ends in miniature Photoelectric light sensor (not shown in the Figures) to be positioned transversely across the Tube [21] at the termination point of the optical fibre.

The Electrical wire pair [129] ends in miniature Photoelectric light sensor (not shown in the Figures) to be positioned transversely across the Tube [22] at the termination point of the optical fibre.

The Electrical wire pair [130] ends in miniature Photoelectric light sensor (not shown in the Figures) to be positioned transversely across the Tube [23] at the termination point of the optical fibre.

The Electrical wire pair [131] ends in miniature Photoelectric light sensor [not shown in the Figures] to be positioned transversely across the Tube [24] at the termination point of the optical fibre

Figure 3b shows Coupling/uncoupling tube joint [13] positioned in between Tubes [9] and [17]. By means of the Male tube member [132] the lumen of Tube [9] is placed in continuity of the lumen of Tube[17].

The Male tube member [133] is shown in respect of continuity of Tubular spaces [115-118]. The Male member [134] is shown in respect of continuity of Tubular spaces [119-122]
Similar arrangements are incorporated for Pumping units [2-4].

All parts of the artificial heart are bar coded with embossing of radio opaque material such as barium sulfate so that they can be identified under Xray imaging.

System operation

The Pumping units [1-4] are placed in the thoracic cavity in a state with the cavities corresponding to Cavity [109] of Pumping unit [1] unfilled. The wall of all pumping units corresponding to the Shell wall [105] of Pumping unit [1] will be soft and in a collapsed state. A hardening chemical which is a mixture of chemicals which are light in weight mixed with bubbles of carbon dioxide gas and which becomes semi solid is - pumped into the Cavity [109[. Via ports [45-52]. An example of such a mixture is gelatine mixed with hydroxyapatite in which bubbles of carbon dioxide gas is dispersed. The Shell wall thereby becomes semi solid and in cylindrical form. The Pumps [5, 6] have reservoir of drive fluid. One form of drive fluid is degraded gelatin mixed with water. For Pumping unit [1] the Bidirectional flow control valve [37] is opened for a short while by applying drive fluid pressure via Tubular space [115, 116]. Applying drive fluid pressure to Tubular space [115] opens the Bidirectional flow control valve [37] and applying drive fluid pressure to Tubular space [116] closes the Bidirectional fluid control valve [37]. In similar manner the right side balloons of all the pumping units are partially filled so as to occupy 10-20 % of the volume of the cavity [110] of Pumping unit [1] and similar cavities of all the other pumping units.

Next the Bidirectional flow control valve [38] of Tube [22] is opened by suitably applying drive fluid pressure to Tubular space [117, 118]. The same steps are done for the other three pumping units. All the manipulations performed by magnetically opening and closing valves placed with the Pumps [5] and [6].

The volume of filling of the right side balloons of all pumping units is assessed by Xray imaging. The Drive Pumps are run so that the drive fluid is pumped into and out of the left side balloons of all the pumping units. Drawing out drive fluid from the left side balloons lowers pressure in the cavities within the pumping units and draws in blood. Pumping in drive fluid into the left side balloon generates pressure inside the cavities of the pumping units thereby forcing out blood via the connected blood vessel. The sum of the blood volume expelled by Pumping units [2 and 4] is the Stroke volume. The Stroke volume multiplied by the number of pumps given by the Drive pumps per minute is the Cardiac Output per minute.

There is no bending of the Shell walls of the Pumping units. Since there is no stress reversal the mechanical failure of the shell walls will not occur. The right side balloon of all the pumping units are in static state. Consequently material stress is negligible. The left side balloon of all the pumping units do have cyclic bending. However none of the balloons are filled to its maximum and the balloons material is not stretched. Therefore the stress on the right side balloons are low. Further at all times the differential of pressure between the inside of the left side balloon and the outside of the left side balloon is low because as the inside the left side balloon rises the balloon expands and blood is forced out of the cavity inside the pumping units. The low pressure differential reduces stresses on the balloon material further. Additionally there is minimal longitudinal deformation of the balloons [111,112] and therefore stress is minimized.

Leak can develop in the left side balloon but there will be no sudden rupture on account of the stress reducing mechanisms mentioned earlier. If a leak occurs then during the balloon filling phase the fluid inside the balloon will in small amount leak out and mix with blood. Since the drive fluid used in the drive pumps [5,6] and for the filling of the balloons is a fluid used clinically for blood volume expansion there is no risk in the mixing of a small amount of the fluid with the blood.

During the phase in which fluid is being drawn out of the left side balloon a small amount of blood will enter the balloon via the leak. The balloon material on the inside has a layer of material, as for example styrene maleic anhydride, which will react with blood forming a fibrin clot. The clot will seal the leak. Thus while the operation of the artificial heart is underway self repair takes place.

The blood leaking into the balloon mixes with the drive fluid altering the optical transmission properties of the drive fluid in a light frequency dependent manner. The transmission of light between the optical fibre and the photoelectric sensor will change. An electronic system with computational facility placed with the Drive pumps estimates the extent of the leak by analyzing the change in optical transmission through the drive fluid at different light frequencies which are given as input to the optical fibres. A logic system assesses the progress of the leak and self repair. If repair takes place adequately the system is allowed to run without intervention. If the leak is substantial and increasing in magnitude the system program will effect suitable action which may be any one or combination of the following:

i) For the pumping unit in which a leak has occurred the left side balloon will be brought to a static state in partially filled mode. The pumping action to be transferred to the right side balloon. The transfer to be achieved by the automatic operation of the Bidirectional flow control valve in the line of the left side balloon closing and the Bidirectional flow control valve in line with the right side balloon opening. The shift in the state of the Bidirectional control valves will be automatically mediated by control of pressure in the corresponding tubular spaces.

ii) The pumping then occurs by the filling and drainage of the right side balloon. The left side balloon remains in static condition. In static condition the possibility of the self repair by formation of the small clot is greater than when in the dynamic state because the margins of the leak zone remain stationary when the balloon as a whole is in the stationary state.

The system may be programmed to automatically switch to the right side static and left side balloon dynamic. If the sensing system indicates that there is no leak then the system can so function with the right side balloon static and left side balloon active. If repair has not taken place switch back can automatically be effected.

iii) The left side balloon may be emptied and brought to a static state. The right side balloon filling increased so that the right side balloon on full filling occupies the entire volume inside the Pumping unit. Thereby the entire pumping of that pumping unit is taken over by the right side balloon.

It is to be noted that the other pumping unit which pairs with the faulty pumping unit is continuing to work normally and the stroke volume continues to be the sum of the outputs of the pair.

iv) The output from the unaffected pumping unit of the pair can be increased and that of the defective pumping unit decreased to give partial rest to the defective pumping unit to help in self repair and/or reduce load on the defective pumping unit so as to check the increase of the leak.

Another possible mode of operation is that to begin with Pumping unit [1] acts as the sole Right Ventricle and Pumping unit [2] acts as the sole Left Ventricle. The Pumping unit [3] remains as a Stand by right ventricle and Pumping unit [4] remains as the stand by left ventricle. The Pumping unit performs the full right ventricle pumping action with one of the balloons collapsed and the other balloon filling to occupy the entire space [110] at the time of systole. In the same manner Pumping unit [2] performs the full left ventricle pumping action with one of the balloons inside collapsed and the other balloon filling to occupy the entire space [110] at the time of systole. When a leak is detected in Pumping unit [1] the Pumping unit [1] is automatically totally deactivated. Pumping unit [3] is automatically activated to serve as the functional right ventricle. If a leak is detected in Pumping unit [2] that pumping unit is deactivated and Pumping unit [4] is activated to serve as the left ventricle entirely.

In the event that the leak in a pumping unit is not self repairing then after a period of time steps may be taken to replace the faulty pumping unit. This feature of replacing one part of the artificial heart distinguishes the present invention from that of the Guha *et al.* (GB2483422). Also whereas the procedure of replacement of the artificial heart by the Guha *et al.* (GB2483422) required the patient to be put on a cardiac bypass system the replacement of one pumping unit by the present invention may be done with the artificial heart functioning. By inserting under xray imaging guidance a irrigation/suction probe having also an endoscope a solvent as for example ethanol for the hardening chemical gelatin and hydroxyapatite combination can be pumped into the space [109] of the faulty pumping unit via the Inter outer shell layer entry port of Pumping unit to dissolve the compound and suck it out. Thereby the outer shell [105] of the faulty pumping unit becomes flaccid. Thereafter the coupling//uncoupling tube joint corresponding to the faulty pumping unit is uncoupled by a special surgical instrument inserted through a keyhole opening in the chest wall. The faulty pumping unit can

then be extracted out of the keyhole opening in the chest wall. A new pumping unit is then inserted through the keyhole opening. At all times during the procedure the artificial heart continues to function.

By the above means an In-use repairable artificial heart is realized.

Legend to Figures

1. Pumping unit – Right ventricle analog [i]
2. Pumping unit – Left ventricle analog [i]
3. Pumping unit – Right ventricle analog [ii]
4. Pumping unit – Left ventricle analog [ii]
5. Drive pump for right ventricle
6. Drive pump for left ventricle

7-12 Tube

13-16 Coupling/Uncoupling tube joint

17-28 Tube

29. Entry port [right side balloon] into Pumping unit [1]
30. Entry port [left side balloon] into Pumping unit [1]
31. Entry port [right] into Pumping unit [3]
32. Entry port [left] into Pumping unit [3]
33. Entry port [right] into Pumping unit [2]
34. Entry port [left] into Pumping unit [2]
35. Entry port [right] into Pumping unit [4]
36. Entry port [left] into Pumping unit [4]

37-44 Bidirectional flow control valve

45. Inter outer shell layer entry port [right] Pumping unit [1]
46. Inter outer shell layer entry port [left] Pumping unit [1]
47. Inter outer shell layer entry port [right] Pumping unit [3]
48. Inter outer shell layer entry port [left] Pumping unit [3]
49. Inter outer shell layer entry port [right] Pumping unit [2]
50. Inter outer shell layer entry port [left] Pumping unit [2]
51. Inter outer shell layer entry port [right] Pumping unit [4]
52. Inter outer shell layer entry port [left] Pumping unit [4]
53. Blood entry port Pumping unit [1]
54. Blood exit port Pumping unit [1]
55. Blood entry port Pumping unit [3]
56. Blood exit port Pumping unit [3]
57. Blood entry port Pumping unit [2]
58. Blood exit port Pumping unit [2]
59. Blood entry port Pumping unit [4]
60. Blood exit port Pumping unit [4]

61.-76 Tube

77-84. Coupling/uncoupling tube joint

85-92. Bidirectional flow control valve
93-96. Tube
97-100. Unidirectional flow valve
101. Vena cava
102. Pulmonary artery
103. Pulmonary vein
104. Aorta
105. Shell wall
106. Layer [outer]
107. Layer [inner]
108. Spot joint
109. Cavity
110. Space
111. Balloon
112. Balloon
113. Anchor
114. Anchor
115-118 Tubular space
119-122 Tubular space
123. Tube lumen
124-127. Optical fibre
128-131 . Electrical wire pair
132. Male member
133-134. Male member

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

We Claim:

1. An in-use repairable artificial heart comprising: at least two pumping units [1, 2] positioned in the thoracic cavity; with drive units [5, 6] configured for ingress and egress drive fluid in pre-assigned pumping units; an array of tubes, joints and valve arrangement operably connected to said pumping units adapted for driving the drive fluid in and out of said pumping units and detachable for removal of pumping unit for replacement, having adapters for attachment of the replacement pumping unit wherein the pumping units contain a space [110]into which the blood is sucked in via an entry port [53] and forced out via an exit port [54]; and the space [110] encloses two leak proof balloons [111,112], wherein each balloon [111, 112] has bidirectional entry port [29, 30] for pumping in and drawing out drive fluid

2. The artificial heart as claimed in claim 1, wherein the artificial heart comprises preferably four pumping units [1-4] placed in close proximity and retained by the force exerted by the said array of tubes.

3. The artificial heart as claimed in claim 1, wherein the said pumping units have a shell wall [105] with an outer layer [106] and inner layer [107] sealed to each other by means of randomly distributed spot joints [108]with the layers of the shell wall made of thin, flexible non stretchable fabric material which is non-porous to blood.

4. The artificial heart as claimed in claim 1, wherein the drive pumps [5, 6] pump drive fluid into the two balloons [111,112] via bidirectional entry port [29,30] for pumping and drawing out of the drive fluid which generates cyclically a positive pressure forcing out blood from the space [110] and followed by a negative pressure generation inside the space [110] sucking blood into space [110].

5. The artificial heart as claimed in claim 1, wherein the cavity [109] has inlet / outlet ports [45, 46], include a self-sealing valve such that a large diameter needle can be inserted into the port to inject or draw out hardening chemical from the cavity.

6. The artificial heart as claimed in claim 1, wherein the balloons are made of thin, highly flexible and large cyclic bending stress reversal withstanding material.

7. The artificial heart as claimed in claim 1, wherein the balloons are layered by a material from inside which in contact with blood forms a coagulum for self sealing and consequent self repair of any leak that may occur in the balloon. claimed in claim 1, wherein the wall of the interconnecting tubes contains tubular spaces which run along the length of the tube and via the Coupling/Uncoupling tube joint maintains flow continuity with another tubing in the same flow line.

8. The artificial heart as claimed in claim 1, wherein the wall of said tubes are embedded with light transmitting optical fibres configured for trans-illumination of the tube and Electrical wire pairs [128-131] configured for connecting photoelectric sensors.

9. The artificial heart as claimed in claim 1, wherein the components of artificial heart are bar-coded by embossing with radio opaque material to facilitate identification on Xray imaging.

10. The artificial heart as claimed in claim 4, wherein right side balloon of all the pumping units are in static state and left side balloon of all the pumping units have cyclic bending wherein the balloons are not filled to their maximum capacity and differential of pressure caused during inflow and outflow of drive fluids through said balloons is kept low without causing any stretch on the balloon material.

11. The artificial heart as claimed in any of the preceding claims, wherein the pumps [5, 6] have reservoir of drive fluid which in routine clinical practice is used for increasing blood circulation volume.

12. The artificial heart as claimed in any of the preceding claims, wherein during operation the bidirectional flow control valves of the tube leading to the active space are opened for a short period by applying fluid pressure via Tubular space for all the different pumping units.

13. The artificial heart as claimed in any of the preceding claims, wherein in case of any leak, the blood leaking into the balloon mixes with the drive fluid altering the optical transmission properties of the drive fluid in light frequency dependent manner to such extent that change is recognized by an electronic computational system integrated with the optical system.

14. The artificial heart as claimed in claim 13, wherein the said computational system assesses the progress of the leak and self repair and under condition that the repair takes place adequately the said artificial heart is allowed to run without intervention.

15. The artificial heart as claimed in claim 13, wherein under condition that the leak is substantial following action is carried out as under :

i) for the pumping unit in which a leak has occurred the left side balloon is brought to a static state in partially filled mode and the pumping action is transferred to the right side balloon;

ii) the pumping then occurs by the filling and drainage of the right side balloon and the left side balloon remains in static condition;

iii) the left side balloon may be emptied and brought to a static state and the right side balloon filling increased so that the right side balloon on full filling occupies the entire volume inside the Pumping unit, thereby the entire pumping of that pumping unit is taken over by the right side balloon; and

iv) the output from the unaffected pumping unit of the pair is increased and that of defective pumping unit decreased to give partial rest to the defective pumping unit to help in self repair and/or reduce load on the defective pumping unit so as to check the increase of the leak.

16. The artificial heart as claimed in claim 15, wherein the transferring at step [i] is achieved by the automatic control of pressure in the tubular space corresponding to the Bidirectional flow control valve thereby closing the valve to the left side balloon and opening the valve to the right side balloon.

17. The artificial heart as claimed in claim 15, wherein at step (ii) during the static condition the possibility of the self repair by formation of the small clot is greater than when in the dynamic state since the margins of the leak zone remain stationary when the balloon as a whole is in the stationary state.

18. The artificial heart as claimed in claim 15 and 16, wherein the system is configured to automatically switch to the right side static and left side balloon dynamic and if the sensing system indicates that there is no leak then the system functions with the right side balloon static and left side balloon active and if the said repair has not taken place switch back can automatically be effected.

19. The artificial heart as claimed in claim 15 and 16, wherein the pumping unit which pairs with the faulty pumping unit is continued to work normally and the stroke volume continues to be the sum of the outputs of the pair.

20. An in-use repairable artificial heart for sealing a leak during use, the artificial heart comprises: two pumping units [1, 2] positioned in the thoracic cavity as sole right ventricle and sole left ventricle and further two pumping units [3, 4] positioned in the thoracic cavity as a standby for right ventricle and a standby for the left ventricle; at least two pump drive units [5, 6] configured for drive fluid in respective pumping units; an array of tube, joints and valve arrangement operably connected with the said pumping units adapted for pumping the drive fluid in and out of the said pumping units; wherein each of the pumping units comprises: a shell wall [105] further comprises of an inner layer [107] and an outer layer [106] having spot joints [108] which are randomly distributed over the shell wall in such a manner that between the layers there is intercommunicating spaces leading to formation of cavity [109] with inlet and outlet ports [45 -46]; and wherein the inner layer forms a space [110] into which the blood flows in via entry port [53] and out via exit port [54] having a self-sealing valve; and the space [110] encloses two leak proof balloons [111,112], wherein each balloon [111, 112] has bidirectional entry port [29, 30] for pumping and drawing out fluid; and wherein under condition a leak is detected in pumping unit [1] the pumping unit [1] is automatically totally deactivated and the pumping unit [3] is automatically activated to serve as the functional right ventricle and under condition a leak is detected in pumping unit [2] that pumping unit is deactivated and pumping unit [4] is activated to serve as the left ventricle entirely.

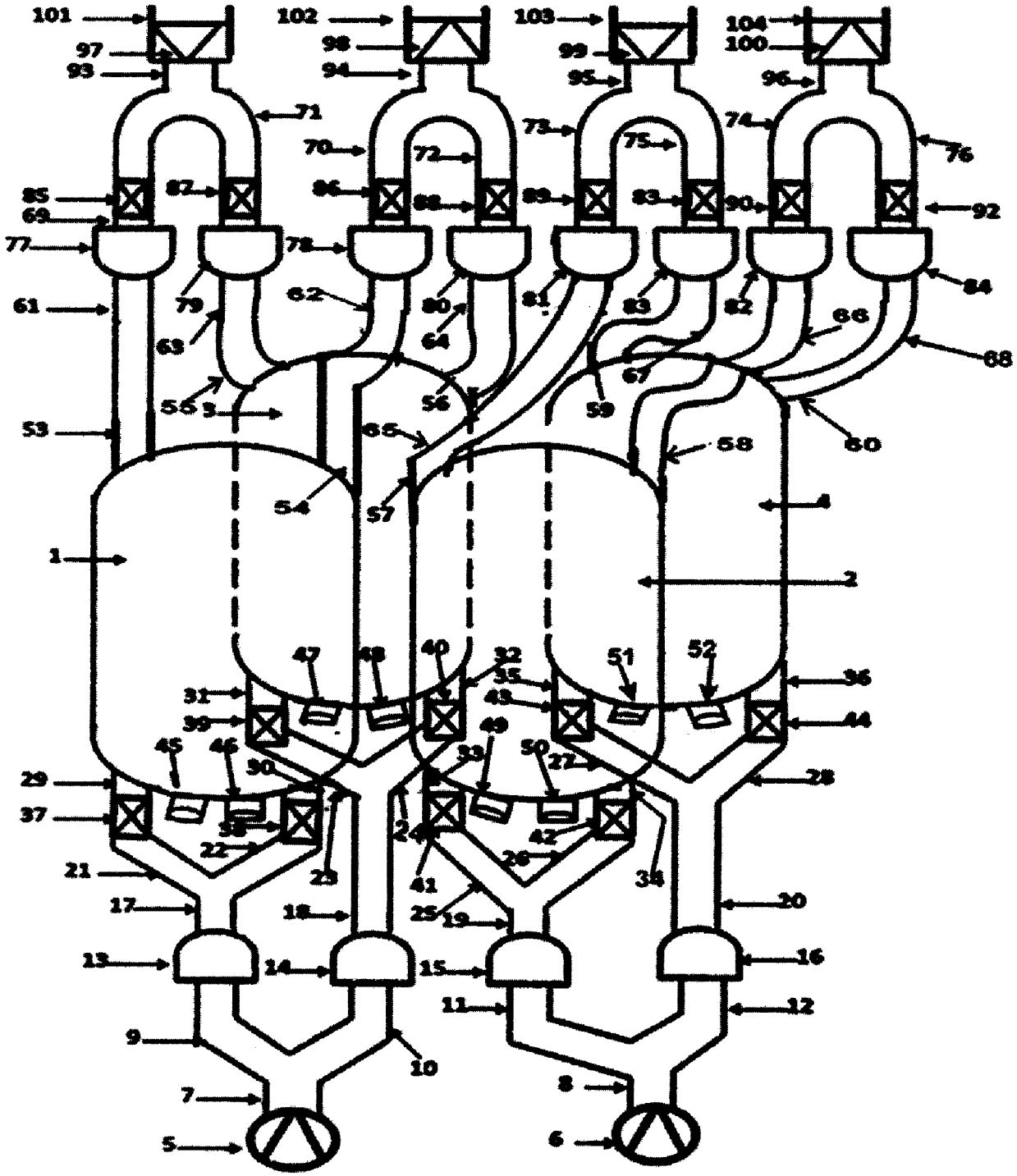
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Figure 1

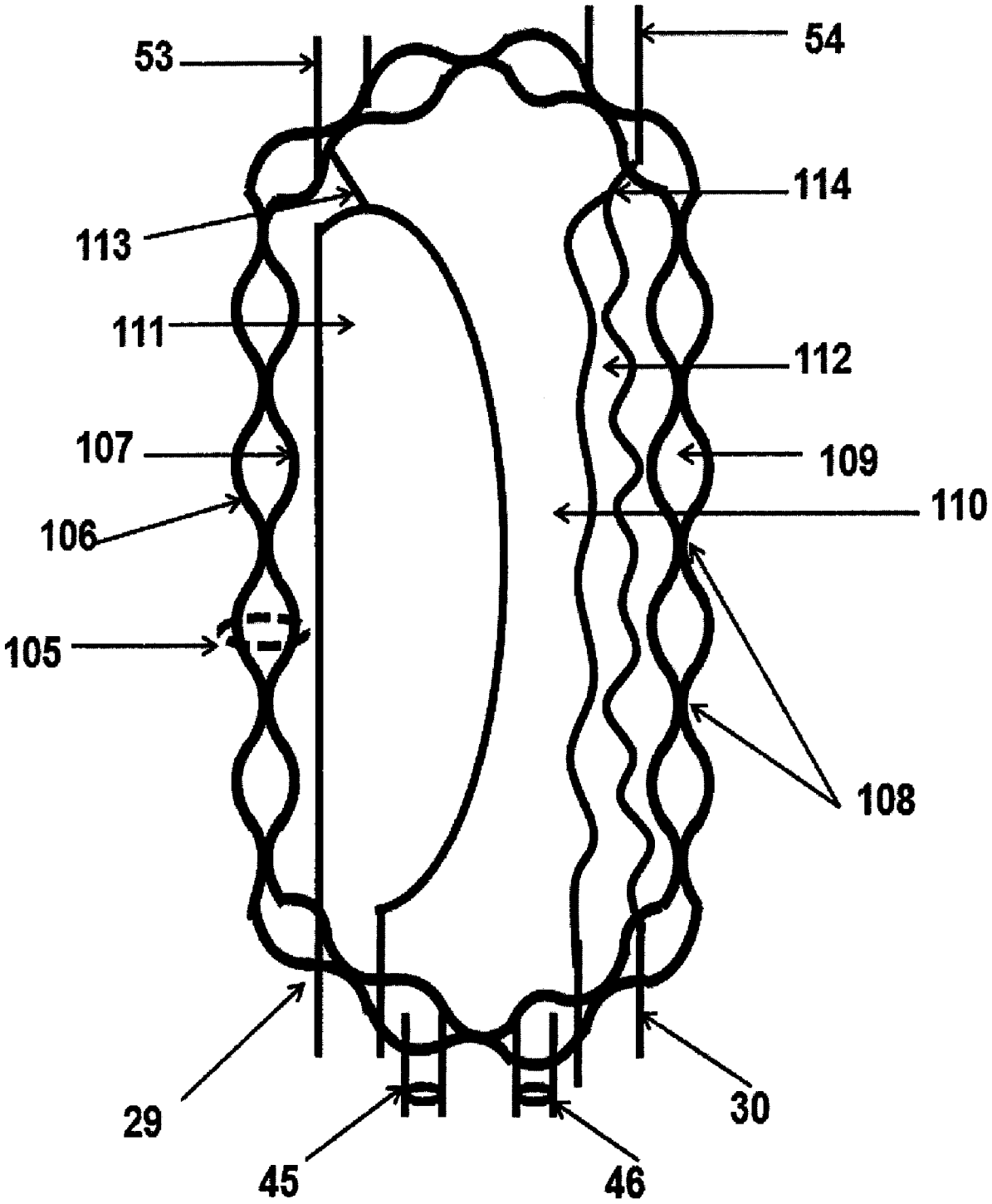

Figure 2

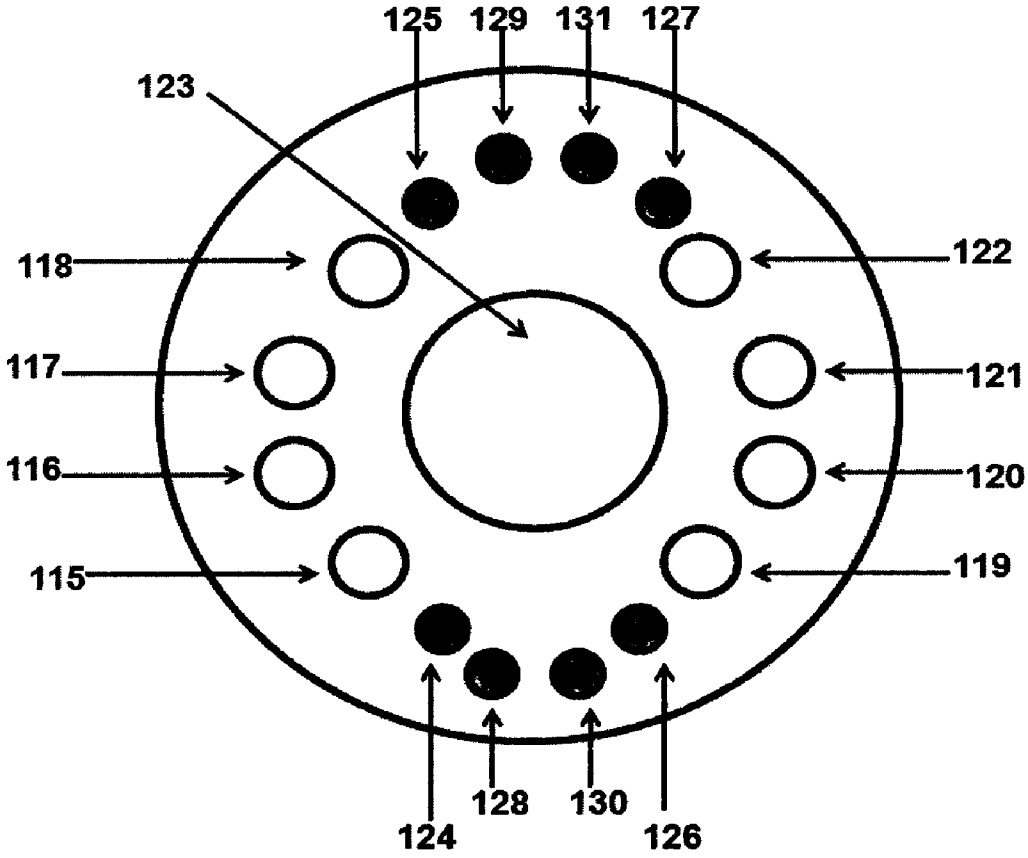

Figure 3a

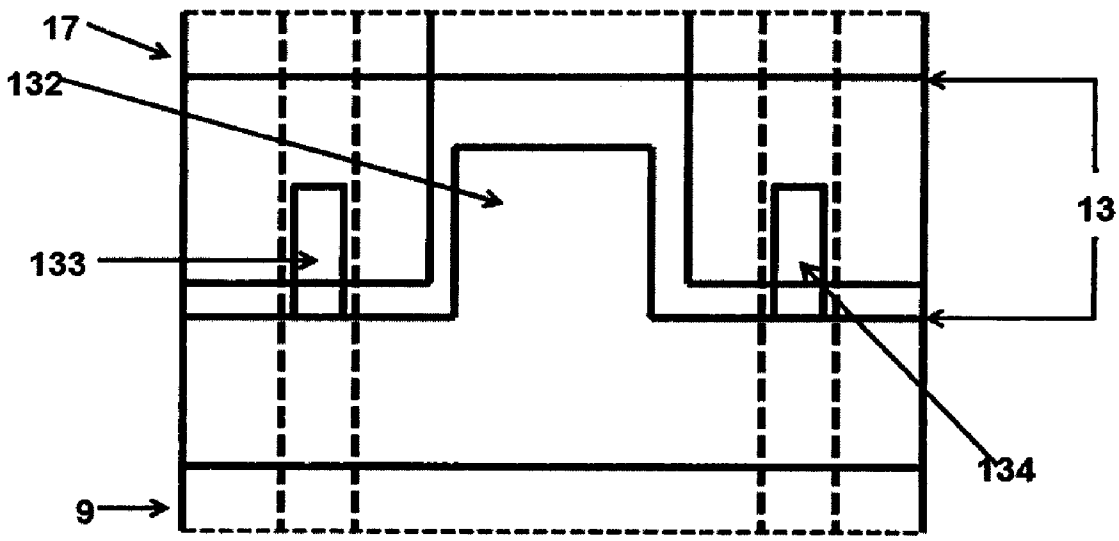

Figure 3b

Figure 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2016/000100

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/10 A61M1/12
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 practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/054251 A1 (LIOTTA DOMINGO SANTO [AR]) 18 March 2004 (2004-03-18)	1,2
A	abstract; figures paragraphs [0090] - [0092] paragraphs [0097], [0099] paragraphs [0079], [0080]	3-20
A	GB 1 307 135 A (CUTTER LAB) 14 February 1973 (1973-02-14) figures	1,20
A	FR 2 585 249 A1 (BIOMASYS SA [FR]) 30 January 1987 (1987-01-30) abstract; figures	1,20

☐ 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

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2016	18/08/2016

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IN2016/000100

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