



G00001

1

1 ATRIO-VENTRICULAR VALVULAR DEVICE

2 BACKGROUND OF THE INVENTION

3 1. Field of the Invention

4 The present invention is in the field of heart valve prostheses. More
5 specifically, the present invention is directed to the replacement of the
6 atrioventricular valves with an anatomically designed mitral valve. The
7 present invention is also directed to obturators and sizers to measure the
8 host's valve annulus diameter and select the appropriate size of the
9 prosthesis, to a holder to maintain the prosthesis during implantation, and
10 to a measuring instrument to determine the locations for suturing parts of
11 the prosthesis to the papillary muscles of the patient.

12 Brief Description of Background Art

13 Replacement of the diseased heart valves is a frequent operation in
14 cardiac surgery. As is known, heart valves (aortic, pulmonary, mitral and
15 tricuspid) function essentially as check valves operating hemodynamically
16 in synchronization with the pumping action of the heart, allowing blood to
17 flow in a downstream direction and blocking flow in the opposite or
18 upstream direction. In disease, this function is impaired either through
19 narrowing of the valve or regurgitation. The natural heart valves are of two
20 distinct basic configurations. The sigmoid valves (aortic and pulmonary
21 valves) are situated on the outflow of the left and right ventricles and are
22 made of three small and similar cusps inserted into the base of the aorta or
23 pulmonary trunk. The atrioventricular valves (mitral and tricuspid valves)
24 consist of several large leaflets of different size attached at their base to the
25 valve annulus and held at their free edge with a complex variety of tendons
26 called *chordae tendinae* that are inserted into the papillary muscles of the
27 ventricles.

28 The *chordae tendinae* are of two main types: those extending from
29 the papillary muscles to the free edge or margin of the leaflets are called



1 "marginal chords" and those extending from the papillary muscles to the
2 undersurface or ventricular surface of the leaflets are called "basal chords."
3 Among these basal chords, two thicker chords are attached to each
4 papillary muscle and to the undersurface of the anterior mitral leaflet close
5 to its base in the mitral annulus. These chords have been labeled
6 "principal," "strut," or "stay" chords. The marginal and basal cords serve
7 different functions. The marginal chords are essential for the competence of
8 the atrioventricular valves. During diastole the valve is open to allow for
9 the passage of blood, the leaflets are separated and the marginal chords are
10 slack. During systole, the pressure in the ventricle closes the valve by
11 bringing the leaflets together. The marginal chords become taut to
12 maintain the leaflets in contact. In a diseased heart rupture or elongation of
13 the marginal chords results in prolapse of the leaflets towards the atrium
14 and consequently, valve insufficiency. The basal chords hold the body of
15 the leaflets during systole, and the strut chords remain taut during the
16 whole cardiac cycle and fulfill the function of maintaining the overall
17 geometry of the ventricles.

18 The above-described functions of the *chordae tendinae* were ignored
19 until recently as far as atrioventricular valve replacement was concerned.
20 In surgery, when a diseased atrioventricular valve needed replacement, the
21 whole mitral apparatus was excised including the leaflets and marginal and
22 basal chords. However, recent experimental and clinical observations have
23 shown that maintaining the continuity or attachment between the papillary
24 muscles and the mitral annulus is essential to preserving the pumping
25 action of the ventricles (*Miki et al. Mitral Valve Replacement with*
26 *Preservation of Chordae Tendinae and Papillary Muscles. Annals Thoracic*
27 *Surgery* 1998;45:28-34). Therefore, relatively recently the art has
28 recognized the need to maintain annulo-papillary continuity when replacing
29 an atrioventricular valve, but attempts to do so have met less than full
30 success.

1 Proximally, the valve leaflets are attached to the annulus. This
2 structure is not rigid and changes in shape continuously during the cardiac
3 cycle. During diastole the atrio-ventricular annulus becomes circular and
4 therefore of the largest possible diameter to allow maximum blood flow.
5 During systole, the annulus area is significantly reduced, becoming smaller
6 and "D" shaped, and facilitating the apposition of the valve leaflets. In this
7 description of the prior art and ensuing description of the invention the
8 terms "proximal", "distal" "anterior" and "posterior" are used in the
9 anatomical sense. "Proximal" means "upstream" as far as blood flow is
10 concerned, "distal" means downstream; "anterior" means closer to the
11 sternum, and "posterior" means closer to the spine.

12 Restoration to normal function while maintaining whole the
13 atrioventricular valves is sometimes possible with specific repair
14 techniques (*Duran Perspectives in Reparative Surgery for Acquired*
15 *Valvular Disease. Advances in Cardiac Surgery, 1993;4:1-23*). Although
16 the results of this surgery have been shown to be superior to valve
17 replacement, the distortion of the valve often makes its replacement
18 imperative. The standard replacement of the mitral and tricuspid valves is
19 with either mechanical or bioprosthesis. All these prior art prostheses are
20 not anatomical, *i.e.* they do not reproduce the normal atrioventricular
21 valves. Usually, a single design is used for all positions, be it sigmoid or
22 atrioventricular. The mechanical valves used for replacement resemble
23 neither the sigmoid nor the atrio-ventricular valves.

24 The commercially available bio-prostheses are porcine or pericardial
25 aortic valves. The prostheses used for mitral or tricuspid replacement are
26 in fact aortic prostheses differing only in their sewing ring, not in the actual
27 valve mechanism. Furthermore, both the mechanical and the bio-prosthesis
28 are mounted on a rigid casing that does not allow for the normal changes in
29 shape and size of the atrioventricular annulus. This rigidity of the annulus
30 of the replacement valves of the prior art has been shown to reduce the

1 efficiency of ventricular function. Because the mitral valve is subjected to
2 much higher pressure and stress and has a lower flow velocity than the
3 other heart valves, its prosthetic replacement carries the worst clinical
4 results and prognosis in terms of durability and thromboembolism.

5 The only anatomically designed mitral valve used clinically is the
6 mitral homograft. In this case, the whole mitral valve apparatus from a
7 cadaver is transplanted into the recipient (*Doty, et al.* Mitral Valve
8 Replacement with Homograft. *Annals Thoracic Surgery* 1998;66:2127-31
9 and *Duran*, Mitral Valve Allografts. An opportunity. *J Heart Valve*
10 *Disease*;1995:4:29-30). This procedure is technically difficult, and its
11 results are still controversial. Probably, there are not more than 200 cases
12 worldwide.

13 More closely anatomically designed mitral valves made of
14 pericardium have also been designed and tested, mostly experimentally, in
15 the prior art. In 1964 *Van der Spuy* (Completely Anatomical Autogenous
16 Whole Mitral Valve. *Thorax* 1964;19:526-29) described a mitral valve
17 prosthesis made of two pairs of pieces of pericardium shaped as two large
18 anterior and two smaller posterior leaflets. Several strips of ilio-tibial
19 ligament were sutured to the leaflets (sandwiched between each pair of
20 leaflets) and the other extremities tied together into two bundles which
21 were anchored to the papillary muscles. A semicircular length of thick
22 nylon thread was sutured around the upper margin of the anterior and
23 posterior leaflets to provide stability to the valve. The author implanted
24 this valve in two patients; one died 10 hours after surgery and the other was
25 reported alive 6 weeks after implantation. No further information on this
26 technique is available.

27 In 1968 *Holdefer, et al.* described two designs of a mitral valve
28 made of autologous pericardium. (An Experimental Approach to Mitral
29 Valve Replacement with Autologous Pericardium. *Journal of Thoracic &*
30 *Cardiovascular Surgery* 1968;55:873-81) In the first design, two separate

1 pieces of pericardium were trimmed to reproduce the anterior and posterior
2 mitral leaflets with their base to be sutured to the mitral annulus. The free
3 edges of the two leaflets were trimmed into two strips for each leaflet to
4 represent the chords. These chords were attached to the contralateral
5 papillary muscle in an X configuration. In the second design, preferred by
6 the authors, two similar crescent shaped leaflets were supported by the two
7 pericardial chords attached to a long suture that was passed through the
8 papillary muscles and left ventricular wall and brought into the left atrium
9 close to the mitral annulus. The idea was to control the correct length of
10 the chords from the atrium by observing the leaflet closure. The authors
11 reported a maximum survival of 28 days in one out of 34 calves.

12 In 1989 *Mickleborough et al.* described a mitral valve made of a
13 rectangle of bovine pericardium wrapped around a rod and sutured to form
14 a cylinder. (A Simplified Concept for a Bileaflet Atrioventricular Valve
15 that Maintains Annular-Papillary Muscle Continuity. *Journal Cardiac*
16 *Surgery* 1989;4:58-68.) In this device two triangular portions of the
17 pericardium are removed leaving two wide strips of pericardium to be
18 sutured to the papillary muscles. To the present inventor's knowledge, this
19 valve has never been implanted in patients.

20 US Patent 5,344,442 and an article by *Deac et al.* described in 1995,
21 a design very similar to that of *Mickleborough et al.* (New Evolution in
22 Mitral Physiology and Surgery: Mitral Stentless Pericardial Valve. *Annals*
23 *Thoracic Surgery* 1995;60:S433-8.) Two trapezoidal pieces of pericardium
24 are sutured together to form an inverted cone with an upper or proximal
25 circumference to be sutured to the patient's mitral orifice. At the other
26 extremity of the cone, two semicircular portions of the pericardium are
27 excised resulting in extensions that are to be sutured to the two papillary
28 muscles. Three different valve sizes are described in this design to
29 accommodate the varying diameters of the mitral orifices of the different
30 patients. The author has reported favorable results in about 30 patients

1 operated in Rumania.

2 US Patent 5,415,667 and *Liao et al.* describe a quadricuspid mitral
3 prosthesis made of bovine pericardium (Intraoperative Epicardial
4 Echo/Doppler Evaluation of a Stentless, Chordally Supported Quadricuspid
5 Mitral Bioprosthesis. ASAIO Journal 1993;39:M634-8). A large anterior, a
6 smaller posterior and two even smaller "commissural" leaflets are sutured
7 together to form a square-shaped proximal orifice to be sutured to the
8 patient's mitral annulus. The distal extremities of the four leaflets are slit
9 and fashioned into six bands of the same material that are sutured together
10 into two strips that serve as chords and are anchored to both papillary
11 muscles. The valve is mounted on a temporary stent to simplify its
12 insertion. This bioprosthesis is under clinical trials.

13 The foregoing review of the previous art shows that the design of
14 mitral valve prostheses has lagged behind the large number of aortic valve
15 prostheses designed in the last three decades. This is perhaps because the
16 geometry of the natural mitral valve is far more complex than the geometry
17 of the sigmoid valves. The above-described five known mitral valve
18 designs of the prior art have the common feature that they are stentless.
19 Also, all of them have a proximal circular orifice that is sutured to the
20 patient's mitral orifice.

21 However, these known prior art designs have significant differences
22 in the distal or chordal apparatus that should correspond to the natural
23 chordal system to be attached to the papillary muscles. Mickleborough's
24 and Deac's models are basically a cylinder or a cone having its lower or
25 distal part slightly trimmed down. Primarily designed for construction at
26 the time of surgery, these two models are simple but they are far from
27 resembling the natural valve. Holdefer and Frater's designs have
28 pericardial chords in continuity with the leaflets and are therefore
29 structurally stronger than the separate tissue chords of Van der Spuy's
30 model. Holdefer's and Van der Spuy's models are rather complex and in

1 Holdefer's design, the chordal implantation technique is difficult and
2 unreliable. Frater's design is a quadrilateral valve. It represents an attempt
3 at being as close as possible to the normal valve, which in fact has six
4 scallops (one anterior, two commissural and three posterior). However,
5 none of the above described valves have basal chords, which as noted
6 above, are a constitutive part of the natural mitral apparatus and are
7 essential for the systolic function and proper geometry of the ventricle.

8 SUMMARY OF THE INVENTION

9 In accordance with the present invention, a mitral valve prosthesis
10 comprises a single unitary member that forms two leaflets. The prosthesis
11 is made of a flexible membrane of biocompatible synthetic or autologous,
12 homologous or heterologous tissue. To form the prosthesis a rectangle of
13 this membrane is trimmed so that two substantially trapezoidal flaps of
14 different size and shape result. The membrane flaps are configured for the
15 larger flap to form an anterior leaflet and for the smaller flap to form a
16 posterior leaflet of the mitral valve. In the prosthesis the two lateral sides
17 of the above formed membrane are joined together with a suture to form
18 substantially an inverted truncated cone having a circular non-supported
19 larger base that is to be sutured to the patient's valve annulus, and a smaller
20 base consisting of two narrow bands that undertake the function of the
21 marginal *chordae tendinae* of the mitral valve. The suture of the lateral
22 sides of the membrane can correspond to the junction of the anterior and
23 posterior leaflets or to the center of the posterior leaflet. The extremity of
24 the two tissue chords is reinforced with a Teflon, Dacron or like synthetic
25 pledget or by folding the extremity of the membrane on itself. Two strut
26 chords made of biological or non-absorbable synthetic suture-like material
27 extend between the base of the prosthesis and the extremity of both chordal
28 bands. The length of these strut chords is inferior to the maximum length
29 of the membrane between the prosthesis base or annulus and the extremity

1 of the membrane chords. For this reason the total height of the truncated
2 cone cannot be stretched completely because it is limited by the shorter
3 length of the strut chords.

4 A set or series of obturators are also provided for use during
5 implantation of the mitral valve prosthesis of the invention. The obturators
6 are plastics rods of varying diameters, and have a rounded end (to avoid
7 damage to the patient's tissues) and a flat end. Conspicuous marking
8 identifies the diameter of each obturator.

9 During implantation an obturator one size below the size of the
10 prosthesis (as determined by the sizer) is introduced through the prosthesis
11 after the prosthesis is in place, and the membrane chords have been sutured
12 to the papillary muscles and the prosthesis annulus has been sutured to the
13 mitral annulus but not tied. These sutures are then tied with the obturator
14 in place. This avoids constricting the annulus of the patient and of the
15 prosthesis which are not fixed by any rigid structure.

16 A holder for the mitral prosthesis of the present invention is also
17 provided to maintain the prosthesis in place during its implantation. The
18 holder is essentially a plastic cylinder of a diameter slightly smaller than
19 the diameter of the mitral prosthesis. One end of the cylinder is tapered
20 into a smaller diameter to serve as handle for the surgeon and the other end
21 of the cylinder is flat. The mitral prosthesis is introduced through the
22 holder and placed so that the extremities of the chordal bands protrude
23 beyond the end of the holder. The mitral prosthesis is held to the holder by
24 a band or bands to be removed when the holder is removed.

25 An instrument comprising a convoluted loop of wire, or a body of
26 like configuration, is provided to determine the proper points of attachment
27 by sutures of the strut cords to the chordal strips, and of the chordal strips
28 to the papillary muscles.

29 The relative sizes of all the components of the prosthesis are related
30 to each other so that a series of different size prostheses are available. The

1 appropriate prosthesis size is determined by the patient's mitral annulus.
2 The anatomically correct mitral prosthesis of the present invention is
3 stentless, and is bileaflet in appearance, but when closed under ventricular
4 pressure, it takes the appearance of one anterior and three posterior
5 scallops. The chords are in continuity with the leaflets and readily sutured
6 to the homolateral papillary muscle because of their thick extremity. The
7 invention overcomes a major surgical problem in mitral repair, mitral
8 homograft replacement and anatomic mitral valve prosthesis implantation
9 which is to determine the location in the papillary muscle where the chords
10 are to be sutured for correct tension. In accordance with the present
11 invention, the basal chords stretch between the extremity of the two chords
12 and the base of the leaflets. This distance is shorter than the length
13 between the leaflet bases and the extremity of the chords. At implantation,
14 once the basal chords are taut, they do not allow the marginal chords to be
15 sutured beyond their correct distance.

16 Brief Description of the Drawing Figures

17 **Figure 1** is a schematic diagram, partly in cross-section, of the left
18 heart cavities of a mammal showing the natural mitral valve, the valve
19 annulus, leaflets and *chordae tendinae*.

20 **Figure 2** is a schematic diagram, partly in cross-section, of the left
21 heart cavities of the heart after excision of the mitral valve apparatus
22 showing the mitral annulus and papillary muscles.

23 **Figure 3** is a schematic diagram, partly in cross-section, of the left
24 heart cavities with a view of the mitral valve replaced with a stentless
25 mitral valve similar to the valve of the present invention but without strut
26 chords.

27 **Figure 4** is a schematic diagram, partly in cross-section, of the left
28 heart cavities showing the mitral valve of the invention including strut
29 chords.

1 **Figure 5** is a schematic diagram, partly in cross-section, of the left
2 ventricle showing with dotted lines the loss of geometry when a mitral
3 prosthesis without strut chords is implanted.

4 **Figure 6** is a schematic diagram, partly in cross-section, of an
5 opened left ventricle showing the mitral valve prosthesis of the present
6 invention implanted in place.

7 **Figure 7** is a top view of the first preferred embodiment of the
8 template used to construct the mitral prosthesis of the present invention
9 from biocompatible synthetic or biological membrane.

10 **Figure 8** is a top view of the second preferred embodiment of the
11 template

12 **Figure 9** is a perspective view of the first preferred embodiment of
13 the mitral valve prosthesis of the present invention.

14 **Figure 9A** is a plan view showing the suture points on a Teflon or
15 like predget;

16 **Figure 9B** is a perspective view of the first preferred embodiment,
17 showing it in a closed position during systole.

18 **Figure 10** is a perspective view of the second embodiment of the
19 mitral valve prosthesis of the present invention.

20 **Figure 10A** is a plan view showing the suture points on a Teflon or
21 like predget in accordance with the second preferred embodiment.

22 **Figure 10B** is a perspective view of the second preferred
23 embodiment showing it in a closed position during systole.

24 **Figure 11** is a perspective view of a holder in accordance with the
25 present invention, the holder having the mitral valve prosthesis attached to
26 it by bands.

27 **Figure 12** is a schematic diagram, partly in cross-section, of the left
28 ventricle showing a mitral valve sizer used to determine the diameter of the
29 patient's mitral orifice.

30 **Figure 13** is a plan view of an instrument designed to assist the

1 surgeon to determine the location in the patient's papillary muscles where
2 the chordal strips should be sutured.

3 **Figure 13A** is a perspective view of the instrument of **Figure 13**.

4 **Figure 14** is a schematic diagram, partly in cross-section, of the left
5 ventricle, of the prosthesis of the invention and an obturator or mitral valve
6 sizer of **Figure 12**, used for avoiding constricting the mitral annulus when
7 tying the sutures along the base of the prosthesis and the patient's annulus.

8 **Figure 15** is a schematic diagram showing the implanted mitral
9 valve prosthesis during systole.

10 DESCRIPTION OF THE PREFERRED EMBODIMENTS

11 The following specification, taken in conjunction with the drawings,
12 sets forth the preferred embodiments of the present invention. The
13 embodiments of the invention disclosed herein are the best modes
14 contemplated by the inventor for carrying out his invention in a commercial
15 environment, although it should be understood that various modifications
16 can be accomplished within the parameters of the present invention.

17 Referring now to the drawing figures, **Figure 1** is a schematic
18 diagram of a longitudinal section of the normal heart showing the aorta **1**,
19 aortic valve **2**, left ventricle **3**, mitral valve **4** and left atrium **5**. The mitral
20 valve **4** permits the unidirectional flow of the oxygenated blood from the
21 left atrium **5** into the left ventricle **3**. The aortic valve **2** permits the
22 unidirectional flow of blood from the left ventricle **3** to the aorta **1**. The
23 natural mitral valve **4** has two main leaflets; a larger anterior mitral leaflet **6**
24 and a smaller posterior leaflet **7**. The bases of the leaflets **6** and **7** are
25 attached to the mitral annulus **8** while the leaflet's free edge is held by the
26 *chordae tendinae*, which are attached to the papillary muscles **10**. The
27 *chordae tendinae* include the marginal chords **11** which are attached to the
28 free edges of the leaflets **6** and **7** and are taut during systole, maintaining
29 the leaflets in contact. The *chordae tendinae* include the basal chords **12**

1 which extend from the papillary muscles 10 to the ventricular surface of the
2 anterior and posterior leaflets 6 and 7. The basal cords include the strut or
3 stay chords 13 which are two particularly thick basal chords that stretch
4 from the papillary muscles 10 to the undersurface of the anterior leaflet 6
5 but also reach the annulus 8. These strut chords are taut during the whole
6 cardiac cycle, playing an essential role in maintaining the normal geometry
7 of the left ventricle 3. With respect to the drawing figures it should be
8 noted that their purpose is to illustrate the valve prosthesis of the present
9 invention and the manner of using it. It is not their purpose to provide
10 absolutely accurate anatomical depiction of the heart. This is indicated by
11 the frequent reference to the fact that the drawings are "schematic" or
12 diagrams only.

13 **Figure 2** is a schematic diagram of the left heart cavities after
14 surgical excision of the whole mitral apparatus. After this operation only
15 the mitral annulus 8 and the papillary muscles 10 remain and are shown in
16 this figure. The leaflets and *chordae tendinae* have been resected. A mitral
17 valve replacement with a mitral prosthesis is required.

18 **Figure 3** is a schematic diagram showing the left heart cavities 3
19 and 5 after replacement of the natural mitral valve 4 with a pericardial
20 stentless prosthesis. This prosthesis may be somewhat similar in
21 configuration to the prosthesis of the invention and has an anterior 6 and a
22 posterior 7 leaflet anchored to the mitral annulus 8 with a suture 14 and two
23 strips or chordal bands 15 and 16 of the same material (pericardium)
24 sutured to the papillary muscles 10. An important difference from the
25 present invention is that this design ignores the importance of the basal
26 chords, and has no replacement or equivalent to the natural strut cords that
27 are shown as 13 in **Figure 1**. Therefore, the left ventricle 3 is left
28 unsupported.

29 **Figure 4** is a schematic view, similar to **Figures 1, 2 and 3**,
30 showing the mitral valve 4 of the present invention in place. The bases of

1 the anterior 6 and posterior 7 leaflets have been sutured 14 to the host's
2 mitral annulus 8, and the two chordal bands 15 and 16 have been attached
3 by suture 17 to the papillary muscles 10. One of two strut chords 13 is
4 shown stretching from the extremity of one of the two chords 16 to the
5 anterior portion of the annulus or base 18 of the prosthesis.

6 The schematic view of **Figure 5** shows the aorta 1 and the aortic
7 valve 2 open and the natural mitral valve 4 closed during systole. In a
8 normal mitral valve 4, because of the presence of the strut chords 13, the
9 left ventricular wall 19 is supported, maintaining the normal geometry of
10 the ventricle 3, as shown in solid lines and by the direction of the apico-
11 basal arrow 20. In a diseased state without functioning strut cords 13, or in
12 case of a mitral valve prosthesis that lacks strut cords, the left ventricular
13 wall 19 is not supported and is displaced laterally as shown by the
14 direction of the apico-basal arrow 20a. The unsupported left ventricular
15 wall is shown by dotted lines.

16 **Figure 6** is a schematic view showing the left ventricle 3 open with
17 its anterior wall laterally displaced to the right. The view shows both
18 papillary muscles 10. The mitral valve prosthesis of the present invention
19 is inserted into this left ventricle 3. The view discloses the anterior 6 and a
20 posterior 7 flaps, or leaflets of the prosthesis and the suture 14 that attaches
21 the base 18 of the prosthesis to the mitral annulus 8 of the patient. This
22 view also shows the leaflets 6 and 7 tapering into two chordal strips 15 and
23 16 and that these are sutured to the anterior and posterior papillary muscles
24 10. The hitherto described components or parts of the prosthesis comprise
25 one single, unitary piece made from a biologically acceptable membrane, as
26 described below. The view also shows two strut chords 13 extending from
27 the extremity of the chordal strips 15 and 16 to the base of the anterior
28 leaflet 6 close to the anterior portion of the mitral annulus 8. In this
29 fashion, the physical continuity between the papillary muscles 10 and the
30 mitral annulus 8 is maintained, ensuring the correct geometry of the left

1 ventricle 3.

2 The mitral valve prosthesis of the present invention can be
3 constructed from flexible biocompatible synthetic materials such as
4 polyurethane, or biological material such as pericardium, pleura,
5 peritoneum or gut submucosa. These biological membranes can be of
6 autologous, homologous or heterologous origin and treated with state-of-
7 the-art chemical or physical methods, or by such methods of tissue
8 treatment that may be developed in future. In the preferred embodiment,
9 the mitral valve prosthesis of the present invention is made from either
10 autologous or heterologous pericardium treated with glutaraldehyde, as
11 well known in the art. Alternatively the prosthesis can be made from
12 pericardium or other biological membrane treated with alcohol (or like
13 solvent) in the manner described in published PCT application WO
14 99/66967, published on December 29, 2000, incorporated herein by
15 reference.

16 **Figure 7** discloses a template **21** used to construct the first preferred
17 embodiment of the anatomical and stentless mitral prosthesis of the present
18 invention. A rectangular piece of synthetic or biological membrane is
19 placed over the template and the membrane, not shown in this figure, is
20 trimmed to the size and shape defined by the template **21**. A variety of
21 different template sizes are made in accordance with the invention to
22 conform the size of the prosthesis to the patient's mitral orifice. Although
23 the template **21** is one piece it can be conceptually divided into two main
24 flaps that correspond to the anterior **6** and posterior **7** mitral leaflets. The
25 overall base **22** of the template **21** corresponds to the base **18** of the anterior
26 **6** and posterior **7** leaflets of the prosthesis. Thus, this base **22** is divided
27 into two parts **23** and **24** corresponding to the bases of the anterior and
28 posterior leaflets. These two bases **23** and **24** are at an approximate angle
29 of 160° to one another. The height of the prosthesis corresponds to the two
30 equilateral sides **25** and **26** of the template **21**. The angle between the

1 lateral side **25** (corresponding to the anterior leaflet **6**) and the base **23** is
2 approximately 85°. The angle between the lateral side **26** (corresponding
3 to the posterior leaflet **7**) and the base **24** is approximately 75°. It should be
4 understood that purpose of the template **21** is to allow the shaping of a
5 biologically acceptable membrane to form the anatomically correct mitral
6 valves prosthesis of the invention. The herein described parameters in
7 terms of dimensions and angles are presently considered optimal to
8 accomplish this purpose. However, variations and modifications of these
9 parameters are possible and are within the scope of the invention as long as
10 the resulting mitral valve prosthesis is substantially anatomically correct.

11 After the membrane (not shown in **Figure 7**) has been trimmed, the
12 two sides **25** and **26** are sutured together. Suturing *per se* is well-known in
13 the art. In the preferred embodiment, 4/0 polypropylene sutures are used.
14 The joining of the lateral sides **25** and **26** with suture forms a truncated
15 cone with its wider base **18** defined by the base **22** of the template **21**, and
16 which corresponds to the mitral orifice of the patient. The lower or apical
17 portion of the template includes extensions **27** and **28** which can be best
18 described by visualizing two essentially semicircular cut-out portions **27a**
19 and **28a**. In the prosthesis the extensions **27** and **28** correspond to the free
20 edges of the anterior **6** and posterior **7** flaps or leaflets. Due to the shape of
21 the template **21** the heights of the leaflets **6** and **7** in the resulting valve
22 prosthesis are not equal. The height of anterior leaflet **6** is larger than the
23 height of the posterior leaflet **7**. Between the two cut out semicircular parts
24 **27a** and **28a**, there is a pillar-like extension **29** that in the trimmed
25 membrane corresponds to one chordal strip **15**. The two lateral sides **25**
26 and **26** of the template **21**, one corresponding to the anterior leaflet **6**, and
27 the other to the posterior leaflet **7**, form the second chordal strip **16**. The
28 ends **30** of the template material which correspond to the chordal strips **15**
29 and **16** are widened in order to form widenings in the membrane for
30 suturing to the patient's papillary muscles **10**. The two strut chords **13** used

1 in the mitral valve of the invention are not part of the template 21 but are
2 nevertheless shown in Figure 7, superimposed on the template 21.

3 In the preferred embodiment, the strut chords 13 are made of double
4 ended 3/0 polypropylene or PTFE (Gore-tex). These strut chords 13 extend
5 from points 31 at the origin of the chordal strips 15 and 16 to points 32 in
6 the mid-third of the base 23 of the anterior leaflet 6. These locations are
7 well demonstrated on Figure 7 that shows the template 21. In the mitral
8 valve the double-ended sutures are passed through the chordal bands 15
9 and 16 tied, passed through the base of the anterior leaflet 6, and tied. The
10 distance between the two points 32 where the strut chords 13 are attached,
11 respectively, to the base 23 corresponding to the anterior leaflet 6 is
12 approximately 0.4 mm times the diameter of the prosthesis ($0.4 \times D$). The
13 two strut chords 13 are of equal length and are approximately 1.08 mm
14 times the diameter of the prosthesis ($1.08 \times D$). The distance between a
15 mid-point 33 at the base of the prosthesis to a point 33a at the junction of
16 the anterior 6 and posterior 7 leaflets is called "commissural height",
17 indicated on the template by the arrow 33a. The length of each strut chord
18 13 is shorter than the "commissural height" 33a, and therefore in the
19 resulting valve prosthesis the strut cords 13 naturally curve the anterior
20 leaflet 6. The extremities of the two chordal strips 15 and 16 extend for a
21 distance of approximately 12mm beyond the point of attachment 31 of the
22 strut chords 15 and 16. Again, this is best illustrated in Figure 7, showing
23 the template. Distally from the points 31 the chordal strips 15 and 16
24 widen to form a square of approximately 10 mm per side. In the preferred
25 embodiment of the invention, a matching sized square of Teflon felt 34 is
26 attached to the square at the extremity of the chordal strips with several 5/0
27 polypropylene sutures. The template 21 described above is an essentially
28 flat surface in the preferred embodiment. Alternatively, the template 21
29 can be curved so as to impart curved surfaces to the flaps 6 and 7 of the
30 resulting mitral valve in their longitudinal, transverse or both directions.

1 The degree of curvature of the template **21** in the longitudinal dimension is
 2 preferably the same as the curvature of a sphere having a radius equal to the
 3 length of the strut cord **13**.

4 The actual relationships among the parameters of the first preferred
 5 embodiment, as reflected in the template **21** utilized to form the same are
 6 provided below.

7 Length of the base **23** of the anterior leaflet (33) = $0.50 \times \pi \times D$ (mm)

8 Length of the base **24** of the posterior leaflet (34) = $0.50 \times \pi \times D$ (mm)

9 Height of the Anterior Leaflet **25** = $0.51 \times d + 10$ (mm)

10 Height of the Posterior Leaflet **26** = $0.37 \times D + 10$ (mm)

11 Height of valve = $D + 17$ (mm)

12 Commissural height **33a** = $D + 5$ (mm)

13 Distance between strut chords at base **22** = $0.4 \times D$ (mm)

14 Length of strut chord **13** = $1.08 \times D$ (mm)

15 Where D = diameter (mm) of the mitral valve prosthesis at its base

16 **Figure 8** discloses another template **35** utilized to construct a second
 17 preferred embodiment of the mitral valve prosthesis of the present
 18 invention. This template **35** is similar in many aspects to the template **21**
 19 described above, and for this reason it needs to be described in lesser detail.

20 A substantial difference of template **35** from the template **21** is that
 21 instead of having flaps corresponding to the anterior **6** and posterior **7**
 22 leaflets in continuity, a flap or surface corresponding to the anterior leaflet
 23 **6** is situated in the middle of the template **35** and two flaps or surfaces that
 24 jointly correspond to the posterior leaflet **7** are located adjacent to the first
 25 flap. In the resulting mitral valve a suture **36** joining the two lateral sides
 26 of the membrane (corresponding to the two sides **25** and **26** of the template
 27 **35**) is shorter than in the first embodiment and is located in the middle of
 28 the posterior leaflet **7**. The suture **36** is shown in the perspective views of
 29 **Figures 9** and **10** for both embodiments. The angles between the base **23**
 30 of the flap for the anterior leaflet **6** and the bases **24** of both halves of the

1 flap for the posterior leaflet 7 are 160° , while the angles between the bases
 2 24 of flaps for the posterior leaflet and the lateral sides 25 and 26,
 3 respectively, of the template 35 are approximately 90° . The relative sizes
 4 of the flaps for leaflets 6 and 7 of the extensions 27 and 28 corresponding
 5 to the chordal strips 15 and 16 and of the strut chords 13 are similar to the
 6 previously described embodiment and are provided below. The extremities
 7 of the extensions 27 and 28 for the chordal strips 15 and 16 are different
 8 than in the first preferred embodiment. In this embodiment they are formed
 9 of a straight strip approximately 22mm in length and 10mm in width with a
 10 slight widening at their ends. Again the shape of the chordal strips 15 and
 11 16 of the second preferred embodiment is best illustrated by the template
 12 36 that is used to form the membrane from which the prosthesis is made.
 13 In this embodiment the strips are folded approximately 10mm from the
 14 points 31 of attachment of the strut chords 13 and sutured so that the end of
 15 the chordal strip has a double layer of pericardium. The areas
 16 corresponding to the sewing areas on the membrane are delineated by
 17 dotted lines on the template 21 and 35 of **Figures 7 and 8**.

18 The relationships among the parameters of the second preferred
 19 embodiment, as reflected in the template 35 utilized to form the same are
 20 provided below:

21 Length of the base 23 of the anterior leaflet 6 = $0.50 \times \pi \times D$ (mm)

22 Length of the base 24 of the posterior leaflet 7 = $0.50 \times \pi \times D$ (mm)

23 Height of anterior leaflet 25 = $0.51 \times D + 10$ (mm)

24 Height of posterior leaflet 26 = $0.37 \times D + 10$ (mm)

25 Height of valve = $D + 15$ (mm)

26 Commissural height 33a = $D + 5$ (mm)

27 Distance between strut chords 13 at base (33) = $0.4 \times D$ (mm)

28 Length of strut chords 13 = $1.15 \times D$ (mm)

29 Where D = diameter (mm) of mitral valve prosthesis at its base or
 30 prosthesis size.

1 **Figure 9** is a perspective view of the first preferred embodiment of
2 the mitral valve prosthesis **4A** of the present invention. As it can be seen
3 the lateral sides of the trimmed membrane have been joined together with a
4 surgical suture **36** resulting in a two leaflet valve having a larger anterior **6**
5 and a smaller posterior **7** leaflet. The diameter of the prosthesis is defined
6 by the based **23** and **24** of the template **21**. **Figure 9** also discloses the two
7 chordal strips **15** and **16** of the valve. These are sutured to the anterior and
8 posterior papillary muscles **10** and to one of the two strut chords **13**. **Figure**
9 **9A** discloses a preferred mode of placing sutures in the extremities of the
10 chordal strips **15** and **16**, affixing them to the anterior and posterior
11 papillary muscles **10**.

12 The perspective view of **Figure 9B** discloses and depicts the mitral
13 valve prosthesis of the present invention as seen from the left atrium **5**.
14 The valve has been sutured in position with running sutures **14** between the
15 base of the anterior leaflet **6** and the patient's mitral annulus **8** and the base
16 of the posterior leaflet **7** to the patient's mitral annulus **8**. The suture **36**
17 between the two sides of the membrane to form a cone is shown. The valve
18 is in the closed position showing a large anterior leaflet **6** and a posterior
19 leaflet **7** with an appearance of three scallops **37**, **38** and **39** similar to the
20 appearance of a native mitral valve.

21 **Figure 10** is a perspective view of the second preferred embodiment
22 of the mitral valve prosthesis of the present invention. As described above,
23 this embodiment has been constructed with template **35**. A principal
24 difference from the first embodiment shown in **Figure 9** is that the suture
25 **36** between the two lateral sides of the membrane corresponds to the
26 midpoint of the posterior leaflet **7**. **Figure 10A** discloses a second
27 preferred mode for placing sutures in the extremities of the chordal strips
28 **15** and **16**, affixing them to the anterior and posterior papillary muscles **10**.
29 Because the second preferred embodiment has a shorter suture **36** than the
30 first, it is less likely to suffer dehiscence and is presently preferred.

1 The perspective view of **Figure 10B** is similar to **Figure 9B** and
2 discloses the second preferred embodiment in a closed position, as it is
3 situated in systole. The suture **36** joining the two sides of the posterior
4 leaflet **7** and three scallops **37**, **38** and **39** of the posterior leaflet **7** which
5 form when the mitral prosthesis of the present invention closes under
6 pressure are visible in the figure.

7 **Figure 11** discloses a holder **40** to maintain the geometry of the
8 mitral valve prosthesis of the present invention during its surgical insertion.
9 Because the prosthesis is stentless, a rigid instrument is useful to hold the
10 prosthesis while suturing its base **18** to the patient's mitral annulus **8** and
11 the chordal strips **15** and **16** to the papillary muscles. The holder **40** is a
12 rod of the appropriate diameter corresponding to the annulus or base **18** of
13 the mitral prosthesis of the present invention. Each size of mitral valve
14 prosthesis requires a specific sized holder. One end of the holder rod **40**
15 terminates in a handle **41** to maintain the mitral valve prosthesis while the
16 surgeon (not shown) sutures it to the patient. The other end **42** is rounded
17 to avoid damage to the prosthesis. The holder **40** is introduced through the
18 orifice of the mitral prosthesis so that the distal end of the prosthesis,
19 corresponding to the extremity of the chordal strips **15** and **16**, protrudes
20 beyond the end **42** of the holder **40** and the base or upper end **18** of the
21 mitral prosthesis is closer to the handle end **41** of the holder **40**. In the
22 preferred embodiment the mitral prosthesis is temporarily attached to the
23 holder **40** with bands **43** situated close to the base **18** and close to the
24 chordal strips **15** and **16**. The bands **43**, temporarily affixing the prosthesis
25 to the holder **40** are made of materials well known in the art, such as
26 polytetrafluorethylene (TEFLON®). In this fashion, the whole mitral valve
27 of the present invention is held in position while the surgeon sutures the
28 chordal strips **15** and **16** to the patient's papillary muscles **10**. The bands
29 **43** and the holder **40** are removed after the suturing is done, but before the
30 suture **14** to the patient's mitral annulus is tied.

1 **Figure 12** discloses an obturator and sizer **44** used to determine the
2 diameter of the mitral orifice of the patient after his/her diseased mitral
3 valve has been excised. The obturator **44** is also a rod similar to the mitral
4 prosthesis holder **40** described in **Figure 11**, but has no holding bands **43**.
5 A set of obturators **44** of varying diameters are constructed corresponding
6 to the different diameters of the different patient's mitral orifices.
7 Presently, obturators **44** of 25, 27, 29, and 31mm diameter are
8 contemplated as adequate for a wide range of patients. The obturator and
9 sizer **44** is introduced through the open left atrium **5** then introduced
10 through the mitral orifice of the patient to determine the diameter of the
11 mitral orifice **8**. Once the actual diameter of the patient's mitral orifice **8**
12 has been determined, the appropriately sized mitral prosthesis of the
13 present invention is selected. The obturator and sizer **44** is also used for
14 another purpose, which is described below.

15 **Figure 12** depicts an obturator and sizer **44** marked "27", indicating
16 for the surgeon that the diameter of this instrument is 27mm.

17 **Figures 13** and **13A** disclose an instrument **45** designed to
18 determine the appropriate location in the papillary muscles **10** of the patient
19 where the chordal bands, **15** and **16** of the mitral prosthesis should be
20 sutured. The instrument **45** is a convoluted endless wire loop that has a
21 curved upper part **46** that is placed against the mitral annulus **8** of the
22 patient at the level of the resected mid-scallop of the posterior leaflet. The
23 length of the curved upper part **46** is approximately 1.2 of the diameter of
24 the patient's mitral valve orifice ($1.2 \times D$). The curved portion **46** includes
25 a downward extension **47** which is at an angle of 75° to the curved portion
26 **46**. The length of the first part of the extension **47** is approximately the
27 measured diameter of the patient's mitral orifice. At that point, extension
28 **47** bends at an angle of approximately 135° and extends further for
29 approximately 10mm where it turns at an angle of 90° to close the wire
30 loop. The bend **48** of 135° angle indicates the most proximal location in

1 the papillary muscle where the strut cords **13** are to be sutured to the
2 chordal strips **15** and **16**. The distal or bottom end **49** of the instrument **45**
3 indicates to the surgeon (not shown) where the distal part of the chordal
4 strips **15** and **16** should be sutured to the papillary muscles **10**.

5 A set of instruments **45**, having the aforesaid dimensions relative to
6 differing annulus diameters (D) are provided within the scope of the
7 invention.

8 Instead of being made of a loop of wire, the instrument **45** can also
9 be made as a solid object, for example as a molded plastic object, that has
10 substantially the same overall shape as the above-described loop of wire.

11 **Figure 14**, similar to **Figure 4**, is a diagram of the left heart cavities
12 where the mitral prosthesis of the present invention has been placed within
13 the left ventricle **3**. The extremities of the chordal strips **15** and **16** of the
14 mitral prosthesis have been anchored to the papillary muscles **10**. The base
15 **18** of the mitral prosthesis has been sutured **14** but not tied to the mitral
16 orifice **8** of the patient, maintaining the strut chords **13** under tension.
17 Because the prosthesis of the present invention is stentless, there is a
18 danger of constricting the patient's mitral orifice **8** and the annulus or base
19 **18** of the prosthesis when tying the sutures **14**. This is avoided by using an
20 obturator or sizer **44** of one size smaller than the measured size of the
21 mitral prosthesis. This obturator **44** is introduced through the mitral orifice
22 **8** and held while the sutures **14** are tied, thus eliminating the possibility of
23 constricting the base **18** of the mitral prosthesis. The obturator and sizer **44**
24 shown in **Figure 14** is marked "25", indicating that it is of 25mm diameter,
25 that is "one size smaller" than the obturator and sizer shown in **Figure 12**.

26 **Figure 15** discloses the mitral valve prosthesis of the present
27 invention in place within the left ventricular cavity **3**. The prosthesis is
28 shown in the closed position and sutured at its base **18** to the mitral orifice
29 **8** and its chordal strips **15** and **16** are sutured to the patient's papillary
30 muscles **10**. The two strut chords **13** extending from the papillary muscles

1 10 to the base 18 of the anterior leaflet 6 are also shown. Although the
2 prosthesis only has one large anterior 6 and a smaller posterior 7 leaflet,
3 when subjected to the left ventricular 3 systolic pressure, it acquires the
4 shape of four leaflets: an anterior 6 and three scallops 37, 38 and 39, similar
5 to the normal configuration of the natural mitral valve.

6 TEST RESULTS

7 The mitral valve prosthesis of the present invention is stentless
8 because it does not incorporate any rigid structure and can therefore follow
9 all the natural movements of the left ventricle. Its orifice adapts to the
10 natural changes in size and shape of the patient's mitral orifice during the
11 cardiac cycle. During diastole, when blood flows from the left atrium to
12 the left ventricle, the mitral orifice and the prosthesis orifice both have a
13 circular configuration achieving the maximum possible orifice area.
14 During systole, the mitral orifice becomes smaller and "D" shaped,
15 considerably reducing the orifice that has to be closed by the prosthesis.

16 The mitral valve prosthesis of the present invention is also
17 anatomical because it imitates the general anatomical characteristics of the
18 natural mitral valve. It has a large anterior and smaller posterior leaflets of
19 trapezoidal shape made of a single flexible membrane that is anchored to
20 the mitral orifice and maintained in position by the chordal strips of the
21 same material which are anchored to the patient's papillary muscles. The
22 prosthesis of the present invention like the natural valve also has two strut
23 chords that maintain under constant tension the continuity between the
24 mitral annulus and the papillary muscles.

25 Although the valve prosthesis of the invention has been described
26 and is primarily used to replace a natural mitral valve, it could also be used,
27 with only such modifications which may become readily apparent to those
28 skilled in the art in light of the present disclosure, to replace a tricuspid
29 valve.

The cardiac valve of the present invention can be assembled by the surgeon using a biocompatible membrane or the patient's own tissues such as pericardium. The patient's own pericardium is usually most readily available and is of low cost. However, it is preferred that the prosthesis be prepared in a specialized processing laboratory to assure quality control over the preparation, assembly and mounting of the prosthesis in its holder.

For testing the mitral prosthesis of the present invention has been constructed with porcine, bovine and sheep pericardium as described above. It has been tested both *in vitro* and *in vivo*.

10 *In Vitro* Test

In 10 isolated porcine hearts, the natural mitral valve was excised and the mitral prosthesis of the present invention was sutured in place as described above. The porcine hearts were then placed in a rig that injected saline into the left ventricular cavity at incremental pressures of 50, 100 and 150 mmHg while the atrial aspect of the prosthesis was continuously observed and still photographs taken. The amount of mitral regurgitation was measured at each pressure level. The two leaflets came in contact under left ventricular pressures below 50 mmHg and soon the posterior leaflet acquired a three scallop appearance similar to the natural valve shown in Figure 15. The volume of mitral regurgitation measured was insignificant considering that the annular sutures were not yet healed. No regurgitant jets were observed, even at a left ventricular pressure of 200 mmHg.

24 *In Vivo* Tests

25 Mitral valve prosthesis of the present invention were tested *in vivo*
26 by implantation into 8 adult sheep. Under general anesthesia and
27 endotracheal anesthesia, a left thoracotomy of sheep through the fourth
28 intercostal space was performed. A rectangle of pericardium from the sheep
29 was resected and treated with 0.6% glutaraldehyde for ten minutes and then
30 rinsed three times in saline for ten minutes. This treated autologous

1 pericardium was then placed onto a template of the appropriate size (orifice
2 diameters between 25 and 29mm) and trimmed following the edges of the
3 template. The two extremities of the pericardium were joined with a
4 continuous 4/0 polypropylene suture. Two strut chords made of 3/0
5 polypropylene sutures were then anchored to the base of the prosthesis and
6 to the extremity of the chordal strips. The extremities of the chordal strips
7 were then sutured to 8 x 4 mm Teflon pledgets. The prosthesis so
8 constructed was then placed into the prosthesis holder 38 shown in **Figure**
9 **11**. During the time of construction of the mitral prosthesis, the sheep was
10 placed under total cardiopulmonary by-pass with single cannulation of the
11 right atrium and aorta. An apical left vent was placed into the left ventricle
12 under continuous suction. The aorta was cross-clamped and 800 ml of
13 crystalloid cardioplegia infused into the proximal ascending aorta. The left
14 atrium was opened through the left appendage and the mitral valve orifice
15 measured with the appropriate obturator and sizer 44, shown in **Figure 12**.
16 The sheep's mitral valve was completely excised. The mitral valve
17 prosthesis of the present invention was then sutured in place, the atriotomy
18 closed and the aortic clamp removed. The heart was defibrillated and the
19 sheep weaned off by-pass. Simultaneous pressures were recorded from the
20 left atrium and left ventricle. Epicardial echocardiograms were also
21 performed and recorded. The chest was then closed and the animal placed
22 in the recovery room under pain control medication. Four animals had a
23 transthoracic echocardiographic study performed one week after surgery.
24 All but one animal survived the surgery and were transported to the farm
25 awaiting long-term studies. The one mortality (ID 949) resulted from the
26 suture between the base of the prosthesis and the mitral annulus of the
27 sheep dehiscing and creating a massive mitral insufficiency. This animal
28 was the reason and origin for using an obturator in the mitral orifice before
29 tying the annular sutures as shown in **Figure 14**. The results of the
30 implantations are in Tables 1 - 4.

1 As can be seen, the left atrial and left ventricular pressure were
2 normal in all animals except the one that had the suture dehiscence. The
3 mean trans-mitral gradients were very low. The echocardiographic studies
4 showed very low mean transvalvular gradients (1.7 mmHg) and a large
5 mitral effective orifice area (5.21 cm²). These data confirm the efficacy of
6 the mitral valve prosthesis of the present invention.

1 Table 1. Hemodynamic data

No.	ID	Weight (kg)	Sex	Valve Size	Heart Rate (beats/min)	Blood Pressure (mmHg)	LAP (mmHg)	LVP (mmHg)	Pressure gradient (mmHg)	
									Peak	Mean
1	3	854	52	F	29	133	95/40	12/0	103/5	4 0
2	4	855	45	M	29	106	80/60	13/5	79/2	3 0
3	5	944	37	F	27	116	62/22	9/3	70/-1	8 3
4	6	912	37	M	27	116	82/39	20/10	82/7	7 2
5	7	929	46	M	29	117	80/34	21/9	112/5	8 2
6	8	949	31	F	25	106	87/33	30/6	86/6	3 0
7	9	917	41	M	27	125	82/47	7/1	84/1	3 0
8	10	951	44	M	27	115	83/47	13/4	96/3	7 1
Mean	11		41.6		27.5	116.8	81.4/40.2	15.6/4.8	89.0/3.5	5.4 1.0

12 LAP: Left Atrial Pressure

13 LVP: Left Ventricular Pressure

Table 2. Echocardiographic data (at operation day)

No.	ID	Weight (kg)	Sex	Valve Size	Heart Rate (beats/min)	Blood Pressure (mmHg)	LVEDD (mm)	LVESD (mm)	EF (%)	Pressure Gradient (mmHg)	EOA (cm ²)	Grad M
										Peak	Mean	
1	854	52	F	29	123	80/40	38.0	26.5	58.38	2.69	1	4.89
2	855	45	M	29	90	100/70	38.9	25.7	71.17			
3	944	37	F	27	102	108/48	34.9	23.4	62.55	5.02	3	5.37
4	912	37	M	27	96	90/45	35.6	24.8	58.72	1.00	0	5.37
5	929	46	M	29	103	87/46	34.0	22.2	65.06	5.11	1	5.95
6	949	31	F	25	114	95/40	39.4	24.1	69.86	9.12	3	4.15
7	917	41	M	27	120	88/44	37.5	24.5	64.65	5.20	2	5.24
8	951	44	M	27	102	92/48	38.7	26.2	61.25	7.18	2	5.50
Mean		41.6		27.5	106.2	92.5/47.6	37.1	24.7	63.95	5.05	1.7	5.21
												0.

LVEDD: Left Ventricular End Diastolic Diameter

LVESD: Left ventricular End Systolic Diameter

EF: Ejection Fraction

EOA: Effective Orifice Area

Table 3. Echocardiographic data (1 week post implantation)

No.	ID	Sex	Valve	Heart Rate (beats/min)	Blood Pressure (mmHg)	LVEDD (mm)	LVESD (mm)	EF (%)	Pressure gradient (mm Hg)	EOA (cm ²)	Gra of
			Size						Peak	Mean	
2	855	M	29	120	80/60	35.5	24.2	68.33	1.54	5.12	0
3	944	F	27	120	Conscious	36.9	26.0	57.41	3.76	5.50	
4	912	M	27	114	Conscious	41.0	29.6	54.37	4.49	5.50	0
5	929	M	29	120	Conscious	38.2	22.9	71.44	9.36	5.95	0
7	917	M	27	94	Conscious	40.2	27.3	60.81	7.29	5.50	0
Mean			27.8	113.6		38.4	26.0	62.47	5.29	5.51	0

LVEDD: Left Ventricular End Diastolic Diameter

LVESD: Left Ventricular End Systolic Diameter

EF: Ejection Fraction

EOA: Effective Orifice Area

MR: Mitral Regurgitation

Table 4. Echocardiographic data (1 month post implantation)

No.	ID	Sex	Valve	Heart Rate (beats/min)	Blood Pressure (mmHg)	LVEDD (mm)	LVESD (mm)	EF (%)	Pressure Gradient (mmHg)	EOA (cm ²)	Grad of M
			Size						Peak	Mean	
4	912	M	27	102	Conscious	45.6	29.5	64.73	6.97	2	5.50
5	929	M	29	126	Conscious	37.7	22.6	71.48	4.75	2	5.79
Mean			28	114.0		41.7	26.1	68.10	5.86	2.0	5.64

LVEDD: Left Ventricular End Diastolic Diameter

LVESD: Left Ventricular End Systolic Diameter

EF: Ejection Fraction

EOA: Effective Orifice Area

MR: Mitral Regurgitation

1 WHAT IS CLAIMED IS:

2 1. A stentless heart valve prosthesis to be used for the replacement of a
3 diseased atrioventricular valve in the heart of a recipient mammal,
4 comprising:

5 a single unitary body of biologically acceptable non-absorbable
6 flexible membrane configured substantially in the shape of an
7 anatomically correct mitral valve, the membrane forming a hollow
8 inverted truncated cone having a substantially circular base forming an
9 annulus at its first end, said base forming annulus corresponding to the
10 mitral annulus of the heart of the recipient and configured and adapted
11 for suturing into the mitral annulus of the heart of the recipient, the
12 membrane further forming an anterior and posterior leaflet configured
13 substantially in the form of the anterior and posterior leaflets of the
14 natural mitral valve of the heart of the recipient, and the membrane still
15 further forming two narrow extensions at its second end opposite to the
16 annulus where the inverted cone is narrower than at its first end, the
17 extensions substantially configured as anatomically correct cords and
18 adapted to be sutured to the papillary muscle of the heart of the
19 recipient, and

20 two lines of biologically acceptable non-absorbable material, the
21 lines configured and positioned as substantially anatomically correct
22 strut cords of the natural mitral valve, each of said lines being affixed
23 at one end substantially to the base of the truncated cone and at a
24 second end substantially to the extremity of one of the extensions,
25 respectively, whereby after implantation into the heart of the recipient
26 the anterior and posterior leaflets of the prosthesis collapse during
27 systole and form a plurality of scallops in substantial simulation of a
28 natural mitral valve.

1 **2.** A heart valve prosthesis in accordance with Claim 1 wherein each
2 line configured as a strut cord is shorter than the total distance between the
3 base of the prosthesis and the extremity of the respective extension.

4 **3.** A heart valve prosthesis in accordance with Claim 1 wherein the
5 membrane forming the truncated cone includes one suture along its length in
6 the axial direction, the suture joining together the anterior and posterior
7 leaflets.

8 **4.** A heart valve prosthesis in accordance with Claim 3 wherein the
9 membrane consists essentially of biocompatible synthetic material.

10 **5.** A heart valve prosthesis in accordance with Claim 3 wherein the
11 membrane consists essentially of biocompatible biological material.

12 **6.** A heart valve prosthesis in accordance with Claim 5 wherein the
13 biological material of the membrane is of autologous, homologous or
14 heterologous origin.

15 **7.** A heart valve prosthesis in accordance with Claim 1 wherein the
16 membrane forming the truncated cone includes one suture along its length in
17 the axial direction, the suture joining together two substantial halves of the
18 posterior leaflet.

19 **8.** A heart valve prosthesis in accordance with Claim 7 wherein the
20 membrane consists essentially of biocompatible synthetic material.

21 **9.** A heart valve prosthesis in accordance with Claim 7 wherein the
22 membrane consists essentially of biocompatible biological material.

23 **10.** A heart valve prosthesis in accordance with Claim 9 wherein the
24 biological material of the membrane is of autologous, homologous or
25 heterologous origin.

26 **11.** A heart valve prosthesis in accordance with Claim 1 wherein a
27 biologically acceptable reinforcing member is attached to the extremity of

1 each one of the extensions whereby sutures attaching the extensions to the
2 papillary muscle of the heart of the recipient have a reinforced base.

3 **12.** A stentless heart valve prosthesis to be used for the replacement
4 of a diseased atrioventricular valve in the heart of a recipient mammal,
5 comprising:

6 a single unitary body of biologically acceptable non-absorbable
7 flexible membrane configured substantially in the shape of an
8 anatomically correct mitral valve, the membrane forming a hollow
9 inverted truncated cone having a substantially circular base forming an
10 annulus at its first end, said base forming annulus corresponding to the
11 mitral annulus of the heart of the recipient and configured and adapted
12 for suturing into the mitral annulus of the heart of the recipient, the
13 membrane further forming an anterior and posterior leaflet configured
14 substantially in the form of the anterior and posterior leaflets of the
15 natural mitral valve of the heart of the recipient, and the membrane still
16 further forming two narrow extensions at its second end opposite to the
17 annulus where the inverted cone is narrower than at its first end, the
18 extensions substantially configured as anatomically correct cords and
19 adapted to be sutured to the papillary muscle of the heart of the
20 recipient, and

21 two lines of biologically acceptable non-absorbable material, the
22 lines configured and positioned as substantially anatomically correct
23 strut cords of the natural mitral valve, each of said lines being affixed
24 at one end substantially to the base of the truncated cone and at a
25 second end substantially to the extremity of one of the extensions,
26 respectively, and each line being shorter than the total distance between
27 the base of the prosthesis and the extremity of the respective extension

1 whereby after implantation into the heart of the recipient the anterior
2 and posterior leaflets of the prosthesis collapse during systole and form
3 a plurality of scallops in substantial simulation of a natural mitral
4 valve.

5 **13.** A heart valve prosthesis in accordance with Claim 12 wherein the
6 membrane forming the truncated cone includes one suture along its length in
7 the axial direction, the suture joining together the anterior and posterior
8 leaflets.

9 **14.** A heart valve prosthesis in accordance with Claim 13 wherein the
10 membrane consists essentially of biocompatible biological material of
11 autologous, homologous or heterologous origin.

12 **15.** A heart valve prosthesis in accordance with Claim 14 wherein a
13 biologically acceptable reinforcing member is attached to the extremity of
14 each one of the extensions whereby sutures attaching the extensions to the
15 papillary muscle of the heart of the recipient have a reinforced base.

16 **16.** A heart valve prosthesis in accordance with Claim 12 wherein the
17 membrane forming the truncated cone includes one suture along its length in
18 the axial direction, the suture joining together two substantial halves of the
19 posterior leaflet.

20 **17.** A heart valve prosthesis in accordance with Claim 16 wherein the
21 membrane consists essentially of biocompatible biological material of
22 autologous, homologous or heterologous origin.

23 **18.** A heart valve prosthesis in accordance with Claim 17 wherein the
24 extremity of each of the extensions comprises a double layer of biological
25 membrane whereby sutures attaching the extensions to the papillary muscle of
26 the heart of the recipient have a reinforced base.

27 **19.** A template configured and adapted to serve for directing the

1 trimming of a flexible membrane in the shape of the template, to construct an
2 anatomically substantially correct atrioventricular heart valve prosthesis to be
3 implanted into the heart of a recipient mammal, the template comprising:

4 a surface formed of two substantially trapezoidal bodies laterally
5 joined to one another and forming a unitary body, each trapezoidal
6 body having a wider and a narrower base, the surface further having
7 three prolongations extending from the narrower bases of the
8 trapezoids, one of said trapezoids configured to provide in the trimmed
9 flexible membrane an anterior leaflet of the valve prosthesis, the other
10 of said trapezoids configured to provide in the trimmed flexible
11 membrane a posterior leaflet of the valve prosthesis, and said
12 extensions configured to provide in the trimmed flexible membrane
13 cords to be sutured to the papillary muscle of the heart of the recipient.

14 **20.** A template in accordance with Claim 19 wherein the wider bases
15 of the two trapezoids are joined in angle of approximately 170 °.

16 **21.** A template in accordance with Claim 20 having a substantially flat
17 surface.

18 **22.** A template in accordance with Claim 20 having a curved surface.

19 **23.** A template configured and adapted to serve for directing the
20 trimming of a flexible membrane in the shape of the template to construct an
21 anatomically substantially correct atrioventricular heart valve prosthesis to be
22 implanted into the heart of a recipient mammal, the template comprising:

23 a surface formed of a larger and two smaller substantially
24 trapezoidal bodies, each of the smaller bodies joined to a respective
25 lateral side of the larger trapezoidal body, the surface having two
26 prolongations respectively extending substantially from areas in the
27 narrower base of the larger trapezoid where it is joined to the smaller

1 trapezoids, the larger of said trapezoids configured to provide in the
2 trimmed flexible membrane an anterior leaflet of the valve prosthesis,
3 the two smaller trapezoids configured to provide in the trimmed flexible
4 membrane a posterior leaflet of the valve prosthesis, and said
5 extensions configured to provide in the trimmed flexible membrane
6 cords to be sutured to the papillary muscle of the heart of the recipient.

7 **24.** A template in accordance with Claim 20 having a substantially flat
8 surface.

9 **25.** A template in accordance with Claim 20 having a curved surface.

10 **26.** A set of obturators and sizers comprising:

11 a series of rods, each rod comprising a cylinder having a blunt
12 end, and a second end from which a handle extends, the diameters of
13 the respective cylinders of the rods being of different dimensions and
14 adapted for measuring the diameter of the mitral annulus of the heart of
15 a mammal, each rod having conspicuous marking to indicate the
16 diameter of the cylinder.

17 **27.** A set of holders for holding an atrioventricular valve during
18 operation of implantation into the heart of a mammal, each holder comprising
19 a cylinder having a blunt end, and a second end from which a handle extends,
20 the diameters of the respective cylinders of the rods being of different
21 dimensions, and adapted for having an atrioventricular valve of corresponding
22 dimension temporarily attached to it.

23 **28.** A set of instruments for determining locations in the heart of a
24 mammal receiving a mitral valve prosthesis where chordal bands and base of
25 the prosthesis is to be sutured, each instrument comprising:

26 a body having a curved upper portion having a length of approximately
27 1.2 X D, an elongated portion extending from the curved upper portion, the

1 elongated portion having a length of approximately 1 D, said elongated
2 portion being joined to the curved upper portion at an angle of approximately
3 75 °, and an extension, extending in a bend from the elongated portion at an
4 angle of approximately 135 ° thereto, and having a length of approximately
5 10 mm, where D represents the diameter of the mitral annulus of the heart of
6 the mammal to receive the valve prosthesis; during open heart surgery the
7 curved upper portion determining the location for suturing the base of the
8 valve prosthesis, the bend determining the location for suturing replacement
9 strut cords to extensions of the valve prosthesis, and the end of the
10 approximately 10 mm long portion determining the location where chordal
11 bands of the valve prosthesis are to be sutured to the papillary muscles of the
12 heart of the recipient mammal.