



PROSTHETIC RING FOR CARDIAC SURGERY

The present invention relates to a prosthetic ring for cardiac surgery, in particular for mitral, tricuspid or aortic annuloplasty.

5 In normal mitral, tricuspid or aortic valves, the valvules overlap at the center of the fibromuscular ring which surrounds the valve and thereby ensure the imperviousness of the valve to regurgitation of blood from the ventricle toward the atrium or from the aorta
10 into the ventricle.

Various conditions can lead to deformations or dilations of these rings, which result in defective sealing of the valvules and, consequently, in a regurgitation of the blood.

15 As long as the deformation of the ring is not too great, it is preferable to perform reconstructive annuloplasty rather than a total replacement of the valve.

A prosthetic ring provided for this purpose comprises a core covered by a sheath of hemocompatible textile material, this core being intended to have a rigidity which is sufficient to allow the deformations or dilations of the natural ring to be reduced, without, insofar as this is possible, disturbing the natural opening and closing movement of the valve, and the sheath
20 permitting the suturing of the prosthesis to the cardiac or aortic wall.
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Several models of prosthetic rings have been developed over the last twenty or so years.

The first implants were rigid, annular, or
30 partially annular implants, for example those described in the document US-A-3 656 185 (CARPENTIER).

The rigidity of these rings makes it possible to reduce the dilation of the natural ring and to restore a satisfactory shape thereto, but it has, on the other
35 hand, the disadvantage of opposing the natural flexibility of the ring of the posterior mitral valve and of the tricuspid septal valve, which fact can lead to dysfunctioning of these valves. In addition, these



prostheses with rigid rings offer resistance to the natural movements of the cardiac wall, such that their sutures on the cardiac wall are stressed and, as a consequence, are subjected to wear and distension.

5 British Patent GB-1264472 also describes a ring of this type, comprising a monobloc core which is made of titanium and is covered by a sheath made of a textile material known under the trademark "Dacron". This core has a flat cross section which is of substantially
10 constant thickness along the periphery of the ring and of relatively great height, such that the ring has no flexibility at its circumference.

 By contrast, some designers have proposed extremely flexible prosthetic rings, such as, for
15 example, those described in the document US-A-4 290 151 (MASSANA) and in the works by DURAN published in the journal "The Annals of Thoracic Surgery, Volume 22, No. 5, 458-463, (1976)". The document US-A-4 042 979 (ANGELL) also proposes a flexible ring which can be
20 adjusted, during the surgical intervention, to the geometry of the ring in question.

 All these very flexible rings, which permit too much deformation of the fibromuscular ring, do not always succeed in restoring a satisfactory coaptation of the
25 valvules.

 Document US-A-4 489 446 (REED) describes a ring which consists of two rigid elements which fit together, the one sliding within the other upon each cardiac contraction in such a way as to permit a deformation of
30 the ring in its plane. This ring also has the disadvantage of being too rigid, opposing the cardiac movements which are exerted perpendicular to the plane of the ring.

 More recently, prosthetic rings have been
35 proposed which have portions of different degrees of rigidity on their circumference.

 Thus, document US-A-4 917 698 (CARPENTIER) describes a prosthetic ring which is formed by the assembly of two segments for a mitral valve, and of three



segments for a tricuspid valve, the segments being linked to one another and articulated with respect to one another by means of a flexible cord of textile material which runs through them. One of the segments of this ring is rigid and is made of titanium alloy, whereas the other segment or segments is/are flexible and made of a synthetic material known under the trademark "DELFIN". Several flexible segments of different dimensions can be assembled to a rigid segment in order to form a ring, in such a way as to make it possible to modulate the flexibility of the flexible part of the ring according to the requirements.

Document US-A-5 061 277 (CARPENTIER and LANE) describes another ring having a rigid part which is made of titanium alloy and which is formed by a C-shaped element, and a flexible part which is formed by a flexible cord joined to the ends of said element and by cylindrical segments of compressible material which are fitted on the cord and give it an arched shape. This join has the disadvantage that it can be subject to wear and can thus affect the strength of the implant over time. In addition, this ring has a relatively complex structure which makes it relatively difficult to manufacture.

Patent US-A-5 104 407 (LAM, NGUYEN and CARPENTIER) describes a ring whose inner part is formed by a spiral winding of fine fibers of a cobalt-nickel alloy known under the name "ELGILOY". The various strata of fibers overlap in the rigid part, whereas they are separated from one another by an elastomeric material in the more flexible part. The number of layers of fibers varies depending on the elasticity which is to be obtained.

This structure makes it possible to obtain a better distribution, about the periphery of the ring, of the stresses which are exerted by the cardiac muscle. However, because of its structure, this ring appears difficult to deform other than in its plane, whereas the natural ring is also subjected to deformations perpendicular to its plane. This rigidity in this

direction also interferes with some components of the natural cardiac movement. In addition, this ring seems complex and difficult to manufacture.

Thus, the prior art reveals that the quest for
5 adequate flexibility of the ring leads to structures which are more and more complex to manufacture and whose strength over the course of time may be uncertain.

The present invention aims to remedy these disadvantages by making available a prosthetic ring which
10 is able to adapt perfectly to the natural ring, without interfering with the natural cardiac movement, and which at the same time remains simple to manufacture.

This ring is of the type comprising a core which is fitted in a textile sheath constituting a suturing
15 means, the core forming a ring, which may be complete or incomplete, which comprises at least one relatively rigid portion and a portion which is relatively flexible in relation to the latter.

According to the invention, the cross section of
20 the core varies along the circumference of the ring, that is to say decreases in the direction of that portion which is to be more flexible, in such a way as to permit a deformation of the ring in all planes.

The invention departs from the developments of
25 the prior art in order to make available a ring in which the required flexibility is obtained in a much simpler manner than in the rings of the prior art.

The compromise between rigidity and flexibility at the appropriate locations on this ring has been shown
30 to be entirely satisfactory in practice. This is because it has a rigidity which is sufficient to reduce the dilation of the natural ring and to restore a satisfactory geometry to the latter, while at the same time having, at the appropriate location, the flexibility
35 allowing it not to impede the natural cardiac movement.

In addition, it is perfectly robust over the course of time, both in terms of its actual structure and in the area of the sutures securing it to the cardiac or aortic wall.



The cross section of the ring can decrease in at least one transverse direction, in particular along the thickness and/or the height of the core, symmetrically or asymmetrically in relation to its center.

5 The core may be formed by assembling two segments made of suitable material, for example one segment made of titanium alloy to form its rigid part, and one segment made of synthetic material to form its flexible part. However, it is advantageously of monobloc structure, that
10 is to say, made in a single piece. In addition to increased ease of manufacture, such a core does not present any risk of wear or of rupturing where the segments are joined together under the effects of the repeated stresses to which it is subjected, as can be the
15 case when it is formed, in accordance with the prior art, by assembling several segments of different materials.

The reduction in the cross section is preferably gradual, either regular or irregular, in order to achieve a progressive change in the flexibility of the core and
20 for a uniform distribution, about its circumference, of the stresses which are exerted by the cardiac or aortic wall.

According to a first possibility, the core is formed by molding a synthetic material, in particular the
25 one known under the trademark "DELRIN".

According to another possibility, the core is made of titanium alloy known under the designation TA6V.

The flexible part can be covered by an insert of elastomeric material reinforcing the core, in order to
30 compensate for the reduction in the cross section thereof, if necessary.

If need be, the ring can additionally include a radiopaque element allowing it to be visualized during radiography.

35 For the invention to be fully understood, it will again be described hereinbelow with reference to the attached schematic drawing which represents, by way of a nonlimiting example, a preferred embodiment of the prosthetic ring to which the invention relates.





In this drawing:

Figure 1 is a plan view of a ring intended for mitral annuloplasty;

5 Figure 2 is a plan view of a ring intended for tricuspid annuloplasty;

Figure 3 is a side view of a ring intended for mitral annuloplasty, in an alternative embodiment;

10 Figure 4 is a plan view of a ring intended for mitral annuloplasty, partially sectioned in its plane, in another alternative embodiment;

Figure 5 is a sectional view thereof along the line V-V in Figure 4;

Figure 6 is a side view of a ring intended for aortic annuloplasty;

15 Figure 7 is a top view thereof, and

Figures 8, 9 and 10 are sectional views thereof along lines VIII-VIII, IX-IX and X-X, respectively, in Figures 6 and 7.

20 The prosthetic rings 2, 3 and 10 which are represented each have a general anatomical form, substantially of a D shape for the ring 2 intended for the reconstruction of the natural mitral ring, of a more or less ovoid shape for the ring 3 intended for the reconstruction of the natural tricuspid ring, and
25 comprising three curved portions which are connected to one another by commissures which are more or less perpendicular to the plane of the ring, for the ring 10 intended for the reconstruction of the natural aortic ring.

30 Each of these rings 2, 3 is formed by a core 4 fitted in a hemocompatible textile sheath 5 which constitutes a means of suturing to the cardiac wall.

Each core 4 has a relatively rigid portion 4a and a portion 4b which is relatively flexible in relation to
35 the portion 4a.

As has been indicated in Figures 1 and 2 by means of dot-and-dash lines, the cross section of the core 4 varies progressively along the circumference of the ring 2, 3, that is to say decreases progressively from its



most rigid portion 4a in the direction of its most flexible portion 4b, down to a minimum which is situated substantially opposite the median part of the most rigid portion 4a.

5 As is shown in Figure 5, the cross section of the core 4 is circular and decreases both as regards the thickness of the core 4, that is to say in the plane of the ring 2, 3, and as regards the height of the core 4, that is to say perpendicular to the plane of the ring 2,
10 3.

 In addition, each core 4 has a monobloc structure, that is to say is made in a single piece of material, in particular by molding a synthetic material, and especially the one known under the trademark
15 "DELRIN".

 This reduction in cross section makes it possible to obtain the required flexibility of the core 4 at the appropriate location, and to do this in a way permitting very simple manufacture.

20 The prosthetic ring 2, 3 thus formed has a rigidity which is sufficient to reduce the dilation of the natural ring and to restore a satisfactory shape to the latter, while at the same time having, at the appropriate location, the flexibility which allows it not
25 to oppose the natural movements of the heart.

 The sutures with which the ring is fixed to the cardiac wall are therefore only slightly stressed.

 By virtue of the aforementioned reduction in the cross section of the core 4 both in thickness and in
30 height, a flexibility of the ring 2, 3 is obtained both in its plane and perpendicular to its plane. This dual possibility of deformation renders the ring 2, 3 according to the invention fully functional.

 Figure 3 represents a ring for mitral
35 annuloplasty having the same construction as the ring 2 represented in Figure 1, except for the fact that it has a deformation 6 outside its plane, situated at the level of the rigid part 4a of the core 4 intended to rest against the fibrous trigone. This deformation 6 is



symmetrical with respect to the anteroposterior axis of the ring.

The ring 2, thus deformed, has the advantage of being better adapted to the natural geometry of the ring.

5 Figure 4 represents another alternative embodiment of the mitral ring 2. Here, the elements which have previously been described and which figure again in this alternative are designated by the same reference labels.

10 In this mitral ring 2, the core 4 is made of titanium alloy known under the designation TA6V. In order to obtain sufficient flexibility, the reduction in the cross section of the core 4 in the area of its part 4b is considerable, as is shown by Figure 5. This reduction is
15 therefore compensated by an insert 7 of biocompatible elastomeric material, reinforcing the core 4 at this location. The internal section of the insert 7 evolves in a manner complementing that of the core 4, in such a way as to confer upon the ring 2 a substantially constant
20 external section.

Figures 6 to 10 show the ring 10 intended for aortic annuloplasty.

The ring 10 comprises three curved portions 10a which are connected to one another by commissures 10b
25 which are oriented substantially perpendicular to the plane of the ring 10, these commissures 10b being continued via bearing fingers 10c allowing it to be secured to the corresponding zone of the aortic ring and of the aortic wall, thus constituting a novel surgical
30 technique.

In the same way as described above, this ring 10 is formed by a core 4 which is fitted in a textile suturing sheath 5, the core 4 being formed by molding a thermoplastic synthetic material such as that known under
35 the trademark "DELIRIN".

As is shown in Figures 7 to 10, the cross section of the core 4 changes along the ring 10, within each curved portion 10a. It is minimum in the median part of each of these curved portions 10a and increases in the

direction of the commissures 10b.

In the same way as for the rings which have been described above, this ring 10 makes it possible to reduce the dilation of the natural aortic ring by giving it a shape which permits the covering of the valvules, while at the same time having the flexibility allowing it not to impede the cardiac movement. This ring 10 is therefore fully functional.

Of course, the invention is not limited to the two embodiments which have been described hereinabove by way of examples. Instead, it encompasses all the alternative embodiments thereof.

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CLAIMS



1. Prosthetic ring for mitral or, tricuspid or aortic annuloplasty, of the type comprising a core which is fitted in a textile sheath constituting a suturing means, the core forming a ring which may be complete or incomplete and comprising at least one relatively rigid portion and a portion which is relatively flexible in relation to the latter, characterized in that the cross section of the core (4) varies along the circumference of the ring (2, 3, 10), that is to say decreases in the direction of its portion (4b) which is to be more flexible, in such a way as to permit a deformation of the ring in all planes.
2. Prosthetic ring according to Claim 1, characterized in that the cross section of the core decreases in at least one transverse direction, in particular along the thickness and/or the height of the core (4), symmetrically or asymmetrically in relation to its center.
3. Prosthetic ring according to Claim 1 or Claim 2, characterized in that the reduction in the cross section of the core (4) is gradual, either regular or irregular.
4. Prosthetic ring according to one of Claims 1 to 3, characterized in that the core (4) is of monobloc structure, that is to say is made in a single piece.
5. Prosthetic ring according to Claim 4, characterized in that the core (4) is formed by molding a synthetic material, in particular the one known under the trademark "DELRIN".
6. Prosthetic ring according to Claim 4, characterized in that the core (4) is made of titanium alloy known under the designation TA6V.
7. Prosthetic ring according to one of Claims 1 to 3, characterized in that the core (4) is formed by assembling at least two segments made of suitable material, at least one of which allows its rigid part (4a) to be formed, and at least one other of which allows its flexible part (4b) to be formed.



8. Prosthetic ring according to one of Claims 4 to 6, characterized in that the flexible part (4b) of the core (4) is covered by an insert of elastomeric material reinforcing it.

- 5 9. Prosthetic ring according to one of Claims 1 to 8, characterized in that it comprises a radiopaque element.

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