

5 disclosed in US 2011/2008297 A1 where the height of the anterior stent side may be longer than the height of the posterior side.

Providing a stent anterior side of the same height of the posterior side when collapsed into a catheter, but ultimately having a shorter height than the posterior
10 side, after being released from the catheter, has already been proposed by the inventors, as disclosed in international patent application WO 2013/160439 A1.

This prior art also discloses an anterior native leaflet locking mechanism. Initially the stent is symmetric and is made of a memory shape material. The anterior side is thermally everted (pre-shaped in everted position and distended when the stent
15 is in collapsed state) and forms an engagement member for the anterior native leaflet.

Although innovative this latest solution is however not entirely satisfactory. Everting the complete stent anterior side may negatively affect the stent properties in this region. The stent may be too rigid and/or too thick. This
20 inconvenient also occurs at any symmetric or asymmetric segment of any stent, anterior, posterior or lateral.

As explained previously, there are many issues related to the stent shape and length, as well as the best anchoring system that take into account the
25 morphology and the physiology of the mitral valve.

There is, therefore, a need to improve the existing atrio-ventricular valve stents.

General description of the invention

30

Embodiments of the present invention seek to provide an atrio-ventricular valve stent.

The stent according to embodiments of the invention may be advantageously
35 used, but not exclusively, for replacement of the mitral valve.

5 According to an aspect of the present invention, there is provided an atrio-ventricular valve stent having a tubular shape, with a sub annular anterior side, a sub annular posterior side and sub annular lateral sides, the sub annular anterior side comprising a self-folding native leaflet engagement member that forms a straight extension of said sub annular anterior side when the stent is collapsed
10 and that is folded on itself when the stent is in an expanded state; said engagement member forming an integral part of the stent and wherein each sub annular lateral side is longer than said sub annular anterior side when the stent is in an expanded state.

In the present document the expression “anterior side” or “stent anterior side”
15 refers to the stent side that is directly facing the aortic valve when the stent is oriented in its definitive position within the native valve complex. The “posterior side” refers to the stent side that is opposite to the anterior side.

The expression “sub annular” refers to a stent region that is below the annulus
20 and within the ventricle, when the stent is located in its definitive position.

The valve stent, when deployed according to embodiments of the invention, is preferably shorter at the sub annular anterior side in order to reduce the risk of obstruction of the LVOT.
25

The valve stent, when deployed, may be longer at the posterior side in order to obtain a better anchoring of the valve during systole.

The stent according to embodiments of the invention may also be shorter at the
30 sub annular posterior side to reduce the contact between the stent and the posterior ventricular wall, therefore reducing the risk of stent fracture overtime.

In a preferred embodiment, in the collapsed state, the sub annular anterior side height added to the engagement member length may be equivalent, shorter or
35 longer than the sub annular height of the posterior side (in case the posterior side were shorter than the total stent length). The presence of the engagement member however, does not increase the total stent length in the collapsed state

5 because it comes from inside the stent structure. This embodiment offers two
important advantages. First, by not increasing the length of the stent and
consequently the length of the delivery system necessary to release the valve, it
may facilitate a transcatheter approach through an antegrade (e.g. from the left
atrium) access where the path to reach the mitral position is not straight. Longer is
10 the stent and consequently longer is the valve cover of the delivery system, less is
the possibility to reach the mitral valve through a trans-femoral approach. The
second main advantage is that having the same ventricular length, in a collapsed
state, may allow retaining the valve inside the valve cover of the delivery system
when the implant access is retrograde (e.g. from the left ventricle).
15 In another embodiment, in the collapsed state, the sub annular anterior side
height added to the engagement member length may be equivalent to the height
of the posterior side in case an engagement member is present also in the
posterior side to catch the posterior leaflet.
20 When the stent is released, the engagement (s) member bends, at least 90°
(preferably 160-180°). This creates an empty space at the anterior side and
consequently it does not obstruct the ventricular flow and at the same time the
anterior leaflet is grasped and taken away from the ventricular outflow tract. As far
as the posterior engagement member is concerned, the posterior empty space
25 created by the rotation of the posterior engagement member may reduce the
contrast between the posterior left ventricle wall and the stent.

In another embodiment the engagement member(s) bends of 180°, or close to
that value, when the stent is released. The bending angle is predefined when the
30 stent is manufactured.

Preferably the engagement member(s) is/are made of a memory shape material.
In this case the bending angle is thermally shaped.

35 In another embodiment, the engagement member(s) is forming an integral part of
the stent.

5 Advantageously there is only one single point that links the engagement member to the stent anterior/posterior side.

In another embodiment the engagement member(s) is/are provided with a specific geometry containing at least one wavy line. Such a configuration may allow a bending with a minimal torsion that avoids the damage of the metal crystalline structure and preserves the superelastic characteristics of the memory shape material.

10

In another embodiment the stent comprises a native leaflet locking system. Advantageously this locking system is defined by at least one extensions body, preferably two, bent out of preferably 30° from the stent structure. The locking system works in grabbing and retaining the native leaflet impeding its interference with the LVOT and providing thereby an efficient anterior anchoring to the valve. The locking mechanism is based on the sequence of events occurring during the release of the stent from the catheter. Initially the extension bodies are released and open, e.g. at 30°. Then the engagement member is released and bends out to a predefined angle, usually between 160-180°, in a way that moving upward the rim of the anterior mitral leaflet it allows the extension bodies to retain the native leaflet. Finally the native leaflet is pinched and retained between the extension bodies and the engagement members.

15

20

25 In another embodiment according to the invention the stent comprises one anterior and one posterior engagement members, which respectively block the anterior and the posterior mitral leaflets, both engagement members being located on the stent sub annular edge. The length of the anterior and posterior mitral leaflets is different. The anatomic distance between the anterior mitral annulus and the free edge of the anterior leaflet (middle of A2) is around 28 mm. The distance between the posterior mitral annulus and the edge of the posterior leaflet (P2) is around 20 mm. In case two engagement members are used to block both leaflets, they may be released at different level in the sub-annular stent structure. The anterior engagement member may be released further down because it needs to grab a longer leaflet. Otherwise, the posterior engagement member may be released at a higher level because it needs to grab a shorter leaflet.

30

35

- 5 To prevent any traumatic damage of leaflet(s) tissue, sleeves can be used to cover the engagement member(s). For the same purpose to prevent damages to the cardiac tissue the distal end of the engagement members can be protected by protection caps.
- 10 In some embodiments in addition to the engagement member(s) and seeking to further increase the anchoring of the stent, at least two or more extension bodies fixed to the stent annular zone, i.e. not to the bottom of the ventricular part of the stent are placed below the mitral annulus to secure the stent in place. This type of anatomic anchoring can be perfectly and safely used in both retrograde and
- 15 antegrade approach because systematically capture mitral leaflets.

To prevent any traumatic damage of cardiac tissue, protection caps can be used to cover the distal end of extension bodies, which is in contact with the surrounding tissue, thus preventing tissue damage and also increasing the

20 contact surface area. Having a larger area of anchoring further may improve the stability of the stent and help to better distribute the expulsion forces during ventricular systole.

- 25 In other embodiments the anatomic anchoring is obtained with an extension body from the annular part that are designed to be placed at the trigones, together with an extension body coming from the bottom of the ventricular part of the stent. This extension body can be either non-traumatic or partially traumatic depending on the presence of protection caps.

30

- In other embodiments the anatomic anchoring is obtained with an extension body from the annular part that are designed to be placed at the trigones, together with two extension bodies coming from the annular part of posterior segment of the stent. This extension body/ies can be either non-traumatic or partially traumatic
- 35 depending on the presence of protection caps. Two engagement members, the

5 anterior that captures the anterior leaflet acting in both ways, anchoring and preventing LVOT obstruction in a similar way the posterior engagement member also has a double function, capture the posterior leaflet and in its final position is placed below the atrial groove as an additional anchor. These two engagement members can also be associated to the four extension bodies. This embodiment
10 has therefore seven points of anchoring.

Advantageously the extensions bodies are forming an integral part of the stent, i.e. they are directly obtained from the stent frame. This may avoid the additional anchoring structures placed below (beyond) the defined profile of the stent (the
15 distal end of the stent) and bent out of 100 to 180°, or external structures added by welding or mechanical grip that are overlapping the stent structure. Preferably the extension bodies according to embodiments of the invention come from the stent frame, therefore do not increase the stent length, and do not increase the stent thickness in collapsed configuration, both major features for a transcatheter valve.
20 valve.

Detailed description of the invention

The invention is discussed below in a more detailed way with examples illustrated by the following figures:

25

Figure 1 represents a native mitral valve.

Figure 2 shows an example of a mitral valve stent according to the invention.

Figure 3 better shows the anterior side of the stent of figure 2.

Figure 4 shows a portion of a stent according to the invention, in a flat
30 configuration.

Figure 5 represents native leaflet retained by a stent according to the invention.

Figure 6 represents the leaflet of figure 5 in a locked position.

Figure 7 shows different orientations of an engagement member according to the invention.

35 Figure 8 illustrates another example showing the fixation of an engagement member to the stent body.

Claims

1. Atrio-ventricular valve stent having a tubular shape, with a sub annular anterior side, a sub annular posterior side and sub annular lateral sides, the sub annular anterior side comprising a self-folding native leaflet engagement member that forms a straight extension of said sub annular anterior side when the stent is collapsed and that is folded on itself when the stent is in an expanded state; said engagement member forming an integral part of the stent and wherein each sub annular lateral side is longer than said sub annular anterior side when the stent is in an expanded state.
2. Atrio-ventricular valve stent according to claim 1 wherein each sub annular lateral side is longer than said sub annular posterior side when the stent is in an expanded state.
3. Atrio-ventricular valve stent according to claim 1 or 2 wherein said sub annular posterior side is longer than said sub annular anterior side when the stent is in an expanded state.
4. Atrio-ventricular valve stent according to claim 1 or 2 wherein said sub annular posterior side is shorter than said sub annular anterior side when the stent is in an expanded state.
5. Atrio-ventricular valve stent according to claim 1 or 2 wherein said sub annular posterior side and said sub annular anterior side have the same length when the stent is in an expanded state.
6. Atrio-ventricular valve stent according to anyone of the previous claims having a D-shape cross section.

- 5 7. Atrio-ventricular valve stent according to anyone of the previous claims
 wherein said engagement member and said anterior side are through at
 least a single point.
- 10 8. Atrio-ventricular valve stent according to anyone of the previous claims
 wherein said engagement member comprises a foldable portion that is
 made of at least one wavy line.
- 15 9. Atrio-ventricular valve stent according to claim 8 comprising two symetric
 wavy lines wherein at least one wave of the first line is linked to one wave
 of the second line.
10. Atrio-ventricular valve stent according to anyone of the previous claims
 wherein said engagement member comprises a free end that is flared.
- 20 11. Atrio-ventricular valve stent according to anyone of the previous claims
 comprising an anterior native valve locking system made of at least one
 self-orienting extension body that forms an integral part of the stent and
 that is located within said sub annular anterior side, said extension body
 being coincident with said sub annular anterior side when the stent is
25 collapsed and which is oriented in another direction when the stent is in an
 expanded state.
- 30 12. Atrio-ventricular valve stent according to claim 11 wherein said extension
 body is oriented at approximately 30° towards proximal end of said sub
 annular anterior side when the stent is in an expanded state.
13. Atrio-ventricular valve stent according to anyone of the previous claims
 comprising several engagement members.

- 5 14. Atrio-ventricular valve stent according to anyone of the previous claims comprising one native posterior leaflet engagement member that is located on the stent posterior side.
- 10 15. Atrio-ventricular valve stent according to claim 12 comprising a posterior native valve locking system made of at least one self-orienting extension body that forms an integral part of the stent and that is located within said posterior side, said extension body being coincident with said sub annular posterior side when the stent is collapsed and which is oriented in another direction when the stent is in an expanded state.
- 15 16. Atrio-ventricular valve stent according to anyone of claims 11 to 15 wherein at least one extension body is surrounded by a window frame and wherein one end of said extension body is fixed to one side of said frame.
- 20 17. Atrio-ventricular valve stent according to claim 16 wherein said window frame fully coincides with the stent wall when the stent is in a collapsed state and which does not coincide with the stent wall when the stent is in an expanded state.
- 25 18. Atrio-ventricular valve stent according to claim 16 or 17 wherein said extension body being fixed to the frame upper side.
- 30 19. Atrio-ventricular valve stent according to claim 16 or 17 wherein said extension body being fixed to the frame lower side.
- 35 20. Atrio-ventricular valve stent according to anyone of claims 11 to 15 wherein said extension body forms an angle between 60° and 120° with the frame when the stent is in an expanded state.
21. Atrio-ventricular valve stent according to anyone of claims 11 to 15 wherein said angle is between 5° and 30°.

- 5 22. Atrio-ventricular valve stent according to anyone of claims 11 to 15 wherein
 said extension body forms an angle between 150° and 180° with the stent
 wall when the stent is in an expanded state.
23. Atrio-ventricular valve stent according to anyone of claims 11 to 15 wherein
10 said extension body is entirely made of a flat blade.
24. Atrio-ventricular valve stent according to anyone of claims 11 to 23 wherein
 said wavy-line bridge is covered by a sleeve.
- 15 25. Atrio-ventricular valve stent according to claim 23 or 24 wherein said flat
 blade is covered at its end by a cap.