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DEVICE AND ASSEMBLY TO REPAIR A HEART VALVE

Abstract

An assembly for reshaping a cardiac ventricle in a patient comprising an implantable device for reshaping a ventricle comprising a tether, a non-implantable tool which is detachably connectable to said implantable device and has a proximal portion and a distal portion opposite to said proximal portion; the implantable device further comprises an active anchor adapted to be detachably connected to the distal portion of the tool; the active anchor comprises an abutment portion adapted to abut against a structure of the ventricle; the active anchor of the implantable device comprises an adjustment device adapted to adjust the tensional state of the tether; the distal portion of the tool comprises an adjustment key adapted to cooperate with the adjustment device of the active anchor; the proximal portion of the tool comprises a maneuvering interface which is operatively connectable to said adjustment key for adjusting the tensional state of the tether by acting on the maneuvering interface of the proximal portion of the tool.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] The present application is a continuation of U.S. patent application Ser. No. 18/365,907, filed Aug. 4, 2023, now U.S. Pat. No. 12,290,440, which is a continuation of U.S. patent application Ser. No. 17/992,834, filed Nov. 22, 2022, now U.S. Pat. No. 11,766,331, which is a continuation of PCT Patent Application No. PCT/IB2021/054150, internationally filed May 14, 2021, which claims priority to Italian Patent Application No. 102020000012562, filed May 27, 2020. All prior applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION
[0002] The present invention relates to the technical domain of heart valve repair systems.
[0003] In particular, the present invention relates to valve repair according to an approach which includes the relative bringing together of native ventricle structures.
[0004] The present invention relates to an assembly to repair a heart valve.
BACKGROUND
[0005] A native atrioventricular heart valve can become damaged and unable to close effectively. A typical type of damage is related to the structural alteration of the ventricle which is dilated; the muscular-fibrous ring forming the passage opening can also be dilated. These alterations cause the inability of the valve leaflets to arrange themselves in the coaptation position and necessarily cause a highly undesirable regurgitation flow from the ventricle towards the atrium which in turn severely limits the effectiveness of the heart pump.
[0006] Typically, for the repair of an atrioventricular valve, for example the mitral valve, a hoop ring is implanted to reinforce the annulus so as to return the annulus to the original shape thereof, thus allowing the free margin of the leaflets to be brought closer together with the valve closed.
[0007] Devices which are implantable via trans-catheter have also been proposed in the form of a clip for capturing and bringing the free edge of the valve leaflets closer together, resulting in the formation of a double orifice valve, following the example of the Alfieri suture.
[0008] A further known approach includes the implantation of devices for bringing the walls of the heart chambers (atria and ventricles) closer together or bringing the papillary muscles forming the anchoring structures of the tendon to the inner side of the ventricle closer together.
[0009] For example, US-2017-0086975 shows a solution which includes fixing a tether between two atrial walls near the valve to be repaired. A similar solution is also shown by US-2005-222488. US-2007-203391 shows a tether for bringing the ventricular walls closer together. For example, US-2019-380699 shows a device which is implantable in the left ventricle via trans-catheter having

a pair of rigid plates which are fixed on the outer side of the papillary muscles, i.e., the side facing the ventricular wall, and a thread-like structure, such as a suture filament, extending therebetween.
[0010] All the solutions of the types described above are intrinsically unsuitable for allowing a precise adjustment of the degree of bringing the ventricular walls together, particularly after implantation, and could involve the replacement of the implantable device.
[0011] US-2019-0365539 includes the implantation inside the right ventricle of an accordion element coupled to two opposing inner ventricular walls, the device being preloaded with a spring so as to influence the walls to which it is coupled, bringing them together. Although advantageous from some points of view, this solution risks excessively stressing the ventricular walls in the first moments after implantation due to the elastic action exerted by the spring, effectively squeezing the ventricular chamber. Furthermore, the coupling of the device to the inner wall of the heart can fail very early under the elastic action of the spring.
[0012] The need is therefore felt to provide a solution to repair an atrioventricular valve which is of improved efficacy in both the short and long term.

SUMMARY

[0013] In Example 1, an assembly for reshaping a cardiac ventricle in a patient comprises: an implantable device for reshaping a cardiac ventricle comprising a tether; a non-implantable tool which is detachably connectable to said implantable device and has a proximal portion and a distal portion opposite to said proximal portion; wherein: the implantable device further comprises an active anchor adapted to be detachably connected to the distal portion of the tool, and a second anchor opposite to said active anchor with respect to said tether. The active anchor comprises an abutment portion adapted to abut against a structure of the cardiac ventricle; the active anchor of the implantable device comprises an adjustment device adapted to adjust the tensional state of the tether, the adjustment of the tensional state of the tether is preferably obtained by varying the useful length of the tether, i.e., the working length of the tether between the two anchors; the distal portion of the tool comprises an adjustment key adapted to cooperate with the adjustment device of the active anchor; the proximal portion of the tool comprises a maneuvering interface which is operatively connectable to said adjustment key for adjusting the tensional state of the tether by acting on the maneuvering interface of the proximal portion of the tool.
[0014] Example 2 is the assembly according to Example 1, wherein the tool also acts as a delivery tool of the active anchor of the implantable device.
[0015] Example 3 is the assembly according to Examples 1 or 2, wherein the tool is a trans-thoracic tool.
[0016] Example 4 is the assembly according to any one of the preceding examples, wherein a proximal section of the tether comprises an enlarged part, for example a knot, to stop the adjustment of the tensional state of the tether.
[0017] Example 5 is the assembly according to any one of the preceding examples, wherein the adjustment device of the active anchor of the implantable device comprises two portions rotatably associated with each other.
[0018] Example 6 is the assembly according to Example 5, wherein the tool further comprises a shaft fitted onto said adjustment key, so that the adjustment key and the shaft are rotatably associated with each other, and wherein the adjustment key is integrally connectable to a first portion of the adjustment device of the active anchor, and wherein the shaft is integrally connectable to a second portion of the adjustment device of the active anchor.
[0019] Example 7 is the assembly according to Examples 5 or 6, wherein a portion of said two portions of the adjustment device is integrally connectable to the tether.
[0020] Example 8 is the assembly according to Examples 5, 6 or 7, wherein a portion of said two portions comprises a winding shaft for winding the tether.
[0021] Example 9 is the assembly according to any one of Examples 5 to 8, wherein said two portions are rotatably associated with each other by means of a threaded coupling.

[0022] Example 10 is the assembly according to any one of Examples 1 to 4, wherein the adjustment device of the active anchor of the implantable device comprises an expandable element, for example an inflatable balloon.
[0023] Example 11 is the assembly according to any one of the preceding claims, wherein the active anchor of the implantable device comprises an anchor back opposite to said abutment portion, wherein the distal portion of the tool is detachably connectable to said anchor back; and/or wherein the anchor back is adapted to remain outside the ventricle.
[0024] Example 12 is the assembly according to any one of the preceding claims, wherein the tool comprises an outer case slidingly associated with said shaft so that the distal portion of the tool can protrude at various distances distally from the outer case.
[0025] Example 13 is the assembly according to any one of the preceding examples, wherein the tool comprises a tether guiding device adapted to guide a proximal section of the tether to allow the pre-assembly of the active anchor of the implantable device on the tool.
[0026] Example 14 is the assembly according to any one of the preceding examples, further comprising a cardiac catheter for the adjustment of the tether, wherein the cardiac catheter preferably comprises at the distal end thereof an elastic clip so as to deliver it inside the cardiac ventricle in order to adjust the tensional state of the tether.
[0027] Example 15 is the assembly according to any one of the preceding examples, comprising a vascular catheter for the delivery of at least one portion of the implantable device.

Description

DRAWINGS
[0028] Further features and advantages of the invention will become apparent from the description provided below of preferred exemplary embodiments thereof, given by way of non-limiting example, with reference to the accompanying drawings, in which:
[0029] FIG. **1** diagrammatically shows an implantable device when implanted in a patient, according to an embodiment;
[0030] FIG. **2** diagrammatically shows an assembly comprising a tool and an implantable device when implanted in a patient, according to an embodiment;
[0031] FIG. **3** shows an axonometric view of an implantable device, according to an embodiment;
[0032] FIG. **4** shows an axonometric view of an assembly comprising a tool and an implantable device, according to an embodiment;
[0033] FIGS. **5**A and **5**B diagrammatically show some steps of the implantation of the implantable device, according to a possible operating method;
[0034] FIG. **6** diagrammatically shows a possible step of the implantation of the implantable device, according to a possible operating method;
[0035] FIGS. **7**A, B and **7**C diagrammatically show some steps of the implantation of the implantable device subsequent to the steps shown in FIGS. **5**-A and **5**-B or in FIG. **6**, according to a possible operating method;
[0036] FIG. **8** is an isometric view with separated parts of an anchoring element of an implantable device, according to an embodiment;
[0037] FIGS. **9**A-**9**F diagrammatically and sectionally show an adjustment sequence which is achievable by the anchoring element in FIG. **8**;
[0038] FIG. **10**A shows an axonometric view with separated parts of an anchoring element, according to an embodiment;
[0039] FIG. **10**B shows an axonometric view of the anchoring element in FIG. **10**A during a possible adjustment sequence;
[0040] FIG. **11** shows an axonometric view and with assembled parts of the anchoring element in

FIG. **10**A locked on the tether;
[0041] FIGS. **12**A and **12**B diagrammatically show an adjustment sequence, according to an embodiment;
[0042] FIGS. **13**A, **13** B, **13**C and **13**D diagrammatically show an adjustment sequence, according to an embodiment;
[0043] FIG. **14** shows an axonometric view of an assembly, according to an embodiment;
[0044] FIG. **15** shows an axonometric view and with separated parts of a portion of an assembly, according to an embodiment;
[0045] FIG. **16** shows an axonometric and sectional view of a portion of an assembly, according to an embodiment;
[0046] FIG. **17** shows an axonometric and sectional view of a portion of an assembly, according to an embodiment;
[0047] FIG. **18** shows an axonometric view of a portion of an assembly, according to an embodiment;
[0048] FIG. **19** shows an axonometric and sectional view of a portion of an assembly, according to an embodiment;
[0049] FIGS. **20**A, B and C show some configurations of an adjustment device in vertical elevation;
[0050] FIGS. **21**A-**21** E show some steps of an adjustment sequence.

DETAILED DESCRIPTION

[0051] In accordance with a general embodiment, an implantable device **10** is included for reshaping a ventricle **11**, **21** in a patient. The implantable device **10** comprises at least one tether **16** and an active anchor **12** or first anchor **12**. Preferably, the implantable device **10** is designed to reshape the right ventricle **11** of a patient's heart **5** for the treatment of the tricuspid valve **15**.
[0052] The active anchor **12** comprises an abutment portion **13** adapted to abut against a structure of the ventricle **11**, **21**. Preferably, the terminology “ventricle structure” means a wall of the heart which delimits or is located inside the ventricle, such as an outer wall **4** of the patient's heart **5** delimiting the ventricular chamber or a papillary muscle **6** or an interventricular septum **7** of the heart **5**. For example, the structure of the ventricle **11** is an outer wall **4** of the patient's heart **5** delimiting the ventricular chamber **11** so that the abutment portion **13** of the active anchor **12** of the implantable device **10** is adapted to abut against the outer wall **4** of the heart **5**.
[0053] In accordance with an embodiment, when in the conditions of implantable device **10** implanted in the patient's heart **5**, the active anchor **12** forms a crossing gate of the outer wall **4** of the heart **5**, the abutment portion **13** of the active anchor **12** is outside the right ventricle **11** and abuts against the outer wall **4** of the heart **5**, the tether **16** crosses the right ventricle **11** to connect to a second structure of the right ventricle **11**, for example a wall of the interventricular septum **7** or a wall of a papillary muscle **6** of the right ventricle **11**.
[0054] Those skilled in the art will appreciate that the implantable device **10** can also be implanted in a left ventricle **21** to reshape the left ventricle **21** for the treatment of the mitral valve.
[0055] In accordance with a preferred embodiment, the implantable device **10** comprises a second further anchor **22**, opposite to the active anchor **12** with respect to the body of the tether **16**. Preferably, the tether **16** is fixed to said second further anchor **22**. In accordance with an embodiment, the second anchor **22** also comprises a second abutment portion **23** adapted to abut against a second structure of the ventricle **11**, opposite to the first structure of the ventricle **11** where the active anchor **12** abuts, so that the active anchor **12** and the second anchor **22** have respective abutment portions **13**, **23** opposite to each other and so that the tether **16** can exert a traction action between the two anchors **12**, **22**, consequently causing the reshaping of the ventricle **11**, **21**. In accordance with an embodiment, the second anchor **22** comprises a portion, for example a hook, for coupling to a second ventricle structure. For example, the abutment portion **23** of the second anchor **22** is intended to abut against a wall facing the left ventricle **21** of the

interventricular septum **7** so that the second anchor **22** is in the left ventricle **21**, the first anchor **12** is on the wall **4** of the heart **5** and the tether **16** extends from said first anchor **12** to said second anchor **22**. In accordance with an embodiment, the second anchor **22** is different from the first anchor **12**. The second further anchor **22** is preferably a passive anchor, and preferably does not comprise any device for adjusting the tensional state of the tether **16**.

[0056] Advantageously, the active anchor **12** of the implantable device **10** comprises an adjustment device adapted to adjust the tensional state of the tether **16**. The adjustment of the tensional state of the tether **16** is preferably obtained by varying the useful length of the tether **16**, i.e., the working length of the tether **16** between the two anchors **12**, **22**. Adjusting the tensional state of the tether **16** can lead to a change in the useful length of the tether. Adjusting the tensional state of the tether **16** allows to adjust the traction force between the two anchors **12**, **22**. Adjusting the tensional state of the tether **16** allows to adjust the relative position of the two anchors **12**, **22**.

[0057] The tether **16** can comprise an elastic element, to provide an elastic influence action aimed at bringing the two anchors **12**, **22** closer together or aimed at distancing the two anchors **12**, **22** away from each other.

[0058] The tether **16** can comprise at least one section made of shape-memory material.

[0059] At least one anchor **12** or **22** of said two anchors **12**, **22** can comprise at least one portion made of shape-memory material.

[0060] In accordance with a general embodiment, an assembly **1** is included for reshaping a ventricle in a patient comprising at least one implantable device **10** according to any of the previously described embodiments.

[0061] The assembly **1** further comprises a tool **18**, which is non-implantable and detachably connectable to said implantable device **10**. The tool **18** comprises a proximal portion **2** and a distal portion **3** opposite to said proximal portion **2**. A longitudinal axis is defined between said proximal portion **2** and said distal portion **3** of the tool **18**.

[0062] The active anchor **12** of the implantable device **10** is adapted to detachably connect to the distal portion **3** of the tool **18**.

[0063] Advantageously, the distal portion **3** of the tool **18** comprises an adjustment key **48** adapted to cooperate with the adjustment device of the active anchor **12**. By operating the adjustment key **48**, it is possible to adjust the tensional state of the tether **16** by means of the operation of the adjustment device. The adjustment key **48** can have a distal head **35** with polygonal geometry adapted to engage a proximal portion of the active anchor **12** to perform the adjustment of the tensional state of the tether **16**.

[0064] With further advantage, the proximal portion **2** of the tool **18** comprises a maneuvering interface **42** which is operatively connectable to said adjustment key **48** for adjusting the tensional state of the tether by acting on the maneuvering interface of the proximal portion **2** of the tool **18**. Preferably, the maneuvering interface **42** is intended to remain outside the patient's body during the adjustment of the tensional state of the tether **16** while the distal portion **3** of the tool **18** is connected to the active anchor **12** inside the patient's body. The active anchor **12** can be placed on the outer wall **4** of the heart **5**, preventing the tool **18** from having to penetrate inside the patient's heart **5** to adjust the tensional state of the tether **16**.

[0065] In accordance with a preferred embodiment, the tool **18** also acts as a delivery tool at least for the active anchor **12** of the implantable device **10**. In other words, the same tool **18** has the dual function of delivering the active anchor **12** in the implantation site and allowing the adjustment of the tensional state of the tether **16** of the implantable device **10** by activating the adjustment device of the active anchor **12** from outside the heart **5**. As shown for example in FIG. **7**-B, the active anchor **12** can be delivered on the outer wall **4** of the heart **5** by the tool **18**, for example mounted on the distal end **3** of the tool **18**.

[0066] In accordance with an embodiment, the tool **18** also acts as a delivery tool for the tether **16**.

[0067] The inclusion of such a tool **18** allows to adjust the tensional state of the tether **16** both

during the implantation of the implantable device **10** and, if necessary, in a step subsequent to the implantation, while avoiding having to access inside the patient's heart **5**.
[0068] In accordance with an embodiment, the assembly **1** further comprises a delivery catheter **46** for delivering at least one portion of the implantable device **10**. As shown for example in FIGS. **5**-A and **5**-B, the delivery catheter **46** is intended to deliver the second further anchor **22** to the respective implantation site, for example the wall facing the right ventricle **21** of the atrial septum **7**, crossing the interventricular septum **7**.
[0069] In accordance with an embodiment, the assembly **1** further comprises a vascular catheter **45** for delivering at least one portion of the implantable device **10**. As shown for example in FIG. **6**, the vascular catheter **45** is intended to deliver the second further anchor **22** to the respective implantation site, for example the wall facing the right ventricle **21** of the atrial septum **7** crossing the patient's vascular system.
[0070] As shown for example in FIG. **7**-A, after the second anchor **22** has been delivered to the respective implantation site, the tether **16** can be extended through the ventricle **11**.
[0071] As shown for example in FIGS. **7**-B and **7**-C, the active anchor **12** is then delivered by means of the tool **18** and the tensional state of the tether **16** can be adjusted before the detachment of the active anchor **12** from the tool **18**.
[0072] The tensional state of the tether **16** can be adjusted in various manners.
[0073] In accordance with a preferred embodiment, the adjustment device of the active anchor **12** of the implantable device **10** comprises two portions **28**, **29** rotatably associated with each other. Thereby, by relatively rotating said two portions **28**, **29** of the active anchor **12** with each other, it is possible to adjust the tensional state of the tether **16**.
[0074] In accordance with a preferred embodiment, the tool **18** further comprises a shaft **49** fitted onto said adjustment key **48**, so that the adjustment key **48** and the shaft **49** are rotatably associated with each other. Preferably, the adjustment key **48** of the tool **18** is integrally connectable to a first portion **28** of the adjustment device of the active anchor **12**, and the shaft **49** of the tool **18** is integrally connectable to a second portion **29** of the adjustment device of the active anchor **12**. Thereby, it is possible to adjust the tension of the tether by means of rotation impressed on the adjustment key **48**, and preferably on the maneuvering interface **42**.
[0075] The inclusion of such a tool **18** allows to adjust the tensional state of the tether **16** by rotating the maneuvering interface **42** both during the implantation of the implantable device **10** and, if necessary, in a step subsequent to the implantation, while avoiding having to access inside the patient's heart **5**.
[0076] According to an embodiment, one portion **28** or **29** of said two portions **28**, **29** of the adjustment device of the active anchor **12** is integrally connectable to the tether **16**. Thereby, for example, it is possible to wind the tether **16** around a winding shaft **27** which can be included inside the active anchor **12**. In accordance with an embodiment shown for example in FIGS. **9**-A to **9**-F, a proximal section **31** of the tether **16** has an enlarged portion, for example a knot **41**, which acts as an end-of-stroke for integrally connecting the tether **16** to a first portion **28** of the adjustment device of the active anchor **12**, so that a relative rotation of the two portions **28**, **29** of the adjustment device causes the winding of a proximal portion of the tether **16** around a winding shaft **27**. By virtue of the inclusion of such a winding shaft **27** it is possible to obtain a winch system for adjusting the tensional state of the tether. The winding shaft **27** can be provided in a single piece or integral with the first portion **28**. The first portion **28** preferably comprises a termination site **17**, for example a through hole of a comparable gauge to that of the tether **16**, which is integrally connectable to a portion of the tether **16**. The second portion **29** can comprise a central channel **26** which receives the tether **16**. Preferably, the central channel **26** of the second portion **29** and the termination site **17** of the first portion **28** are offset from each other, i.e., they are not in axis, to cause the winding of the tether **16** around the winding shaft **27**.
[0077] As shown for example in FIGS. **9**-A and **9**-B, the tether **16** is secured to the termination

portion **17** of the anchoring element **12** by forming a knot **41** in the proximal section **31** of the tether **16**. As shown for example in FIGS. **9**-C and **9**-D, by opposing the action of the spring **30**, the two portions **28**, **29** of the anchoring element **12** are released so that they can rotate with respect to each other, causing the proximal portion **31** of the tether **16** to be wound, which consequently tensions the tether **16**. As shown for example in FIGS. **9**-E and **9**-F, the action of the spring **30** interlocks the two portions **28**, **29** of the anchoring element **12** with each other in a predefined mutual configuration. Preferably, the winch adjustment system comprises one or more radial teeth **32** extending from a first portion **28** to be received in an annular groove **33** of a second portion **29** of the anchoring element **12**, when the action of the spring **30** is opposed. When the action of the spring **30** is not opposed, said one or more radial teeth **32** abut against a circumferential abutment **34** which prevents the portions **28**, **29** from rotating with respect to each other.

[0078] As shown for example in FIG. **8**, a preload spring **30** can be included between the two portions **28**, **29** of the anchoring element **12**. Preferably, the spring **30** mutually distances the two portions **28**, **29** of the anchoring element **12**, interlocking them in a mutual configuration. By opposing the action of the spring **30**, it is possible to unlock the configuration and rotate one portion **28** or **29** of the two portions **28**, **29** with respect to the other **29** or **28**, causing the tether **16** to be wound around the winding shaft **27**. The winch adjustment system formed by said two portions **28**, **29** of the anchoring element **12** can comprise a ratchet mechanism adapted to allow the relative rotation of the two portions **28**, **29** in a single rotation direction.

[0079] The maneuvering interface **42** can comprise a ratchet mechanism adapted to allow the rotation of the maneuvering key **48** with respect to the shaft **49** in a single rotation direction.

[0080] In accordance with an embodiment, said two portions **28**, **29** are rotatably associated with each other by means of threaded coupling. As shown for example in FIGS. **10**-A, **10**-B and **11**, a portion **29** comprises a passage channel **26** adapted to receive with clearance the tether **16** arranged on a male threaded element **37** so that the tether can slide with respect to the portion **29**, and in which the other portion **28** comprises a tightening nut **36** which, when screwed onto the male threaded element **37**, causes a narrowing of the gauge of the passage channel **26**, stopping the sliding of the tether **16** with respect to the male threaded element **37** of the portion **29** by friction.

[0081] In accordance with a preferred embodiment, the active anchor **12** of the implantable device **10** comprises an anchor back **19** opposite to said abutment portion **13**, in which the distal portion **3** of the tool **18** is detachably connectable to said anchor back **19**. When in operating conditions, the anchor back **19** is adapted to remain outside the ventricle **11**. Thereby, the active anchor **12** forms a sort of adjustment gate for the tensional state of the tether **16** having the anchor back **19** placed on the outer wall **4** of the heart **5** so that it can be reached by the access device **18** even after the implantation of the implantable device **10**, to adjust the tensional state of the tether **16** post-implantation without requiring an access inside the heart **5**.

[0082] In accordance with a preferred embodiment, the tool **18** further comprises an outer case **51** slidingly associated with said shaft **49** so that the distal portion **3** of the tool **18** can protrude at various distances distally from the outer case **51**. When in operating conditions, once the outer case **51** of the access device **18** has been positioned so that the distal end thereof is near the outer wall **4** of the heart **5**, it is possible to advance the shaft **49** and the adjustment key **48** in the distal direction so that they can engage the active anchor **12**, to adjust the tensional state of the tether **16**.

[0083] In accordance with a preferred embodiment, the tool **18** comprises said maneuvering key **48** rotatable inside said longitudinally hollow shaft **49** and adapted to engage a first portion **28** of the active anchor, the tool **18** comprising at the distal end of said shaft **49** one or more fingers **52** which extend distally like a crenellation in order to engage, for example in a snap-fit manner, the second portion **29** of the active anchor **12**. Preferably, the set of the maneuvering key **48** and shaft **49** are capable of moving forward and backward with respect to the case **51**. An advancement control **53** can be included in order to cause the relative moving forward and/or backward of the case **51** with respect to the set of the maneuvering key **48** and the shaft **49**, formed for example by a longitudinal

slot **54** placed on the case **51** which defines a plurality of seats **54**-*a*, **54**-*b*, **54**-*c* adapted to receive a radial pin **55** extending the shaft **51** so as to lock the set of the maneuvering key **48** and shaft **49** in a mutual position with respect to the case of the access device **18**. Said seats **54**-*a*, **54**-*b*, **54**-*c* are preferably aligned in the longitudinal direction of the tool **18**. An end-of-stroke pin **56** can be included which is integral with the shaft **49**, forming a proximal abutment for the case **51**.

[0084] The inclusion of such a pin **55** and such a slot **54** allows to mechanically visualize the relative position in which the set of the maneuvering key **48** and shaft **49** with respect to the case **51** is located.

[0085] As shown for example in FIGS. **20**-B and **20**-C, by distally advancing the maneuvering key **48** and the shaft **49** with respect to the case **51**, the pin **55** is moved from the seat **54**-*b* to the seat **54**-*c*.

[0086] In accordance with an embodiment, the tool **18** comprises a tether guiding device **57** adapted to guide a proximal portion **31** of the tether **16**. For example, the tether guiding device **57** comprises a perforated plate **58** arranged on the case **51**, in which the hole **59** of the perforated plate **58** of the tether guiding device **57** receives a proximal portion of the tether **16**. By virtue of the inclusion of said tether guiding device **57**, it is possible to temporarily lock a proximal section **31** of tether **16** having a predetermined length in order to obtain said knot **41** or said enlarged portion **41** on the proximal section **31** of the tether **16**. Furthermore, by virtue of the inclusion of said tether guiding device **57** it is possible to preassemble the active anchor **12** to the distal end **3** of the tool **18**, in other words, by virtue of the inclusion of said tether guiding device **57**, it is possible to provide an assembly **1** having the active anchor **12** of the implantable device **10** preassembled on the tool **18**, avoiding assembling the active anchor **12** on the tool **18** during the operation. For example, as shown in FIG. **21**-A, the proximal portion **31** of the tether **16** passes through the active anchor **12**, the tool **18** in a proximal direction and exits from the hole **59**. As shown in FIG. **21**-B, by activating the command **47**, the diameter of the hole **59** is reduced, locking the proximal portion **31** of the tether **16** in the hole **59** by friction. As shown in FIGS. **21**-C and **21**-D a knot **41** or an enlarged portion is made on the proximal portion **31** of the tether **16** and the section of the tether **16** proximal to the knot **41** is cut. As shown in FIG. **21**-E, the command **47** is deactivated and the section of the hole **59** passes through the tether **16** and the knot **41**, so that by distally advancing the knot **41** it abuts the termination portion **17** of the active anchor **12**. The inclusion of such a tether guiding device **57** also allows the tether **16** to be kept close to the case **51**.

[0087] In accordance with an embodiment, the adjustment device of the active anchor **12** of the implantable device **10** comprises an expandable element **38**, for example an inflatable balloon. By expanding the expandable balloon **38**, the termination portion **17** to which the tether **16** is secured is distanced from the abutment portion **13** of the active anchor **12**. The abutment portion **13** of the active anchor **12** can be included on the expandable element **38**. The expandable element **38** is integrally connectable to the termination portion **17** in a portion thereof. In this case, in order to adjust the tensional state of the tether **16** it is necessary to inflate the expandable element **38**, and the inflation of the expandable element **38** can be achieved by using a percutaneous port **18′** having a fluid communication duct with the expandable element **38**, to expand it, in which the fluid communication duct **48′** therefore acts as an adjustment key **48′**, the percutaneous port **18′** being provided with an inflation tank **39** having a maneuvering interface **42′**, for example a deformable pouch when pressed. By applying pressure to the deformable pouch, which acts as a maneuvering interface **42′**, the inflation fluid moves from the inflation tank **39** to the expandable element **38** which thereby distancing the tether termination portion **17** from the abutment portion **13** of the active anchor **12** allows to tension the tether **16**.

[0088] In accordance with a preferred embodiment, the active anchor **12** comprises two portions **28**, **29** slidingly coupled so that a relative distancing of the two portions allows to adjust the tensional state of the tether **16**, acting as an adjustment device. In accordance with a preferred embodiment, the two mutually slidingly coupled portions of the anchoring element **12** can be

interlocked with each other, acting as a locking device. The sliding coupling between the two portions **28**, **29** can be included in addition to or in place of the rotatable coupling between the two portions **28**, **29**.

[0089] According to an embodiment, as shown for example in the FIGS. **13**-A to **13**-D, the adjustment of the tensional state of the tether **16** can occur by means of a cardiac catheter **45**′ with vascular access which delivers a forceps **60**, for example an elastic clip **60**, inside the ventricle **11** in order to adjust the tensional state of the tether **16**. Thereby the adjustment of the tensional state of the tether **16** can occur either by acting on the active anchor **12** by means of the tool **18** or by means of a trans-catheter action performed with a cardiac catheter **45**′. Preferably, the cardiac catheter **45**′ comprises at the distal end thereof an elastic clip **60**, preferably detachably connected to the cardiac catheter **45**, so as to deliver it inside the ventricle **11** in order to adjust the tensional state of the tether **16**.

[0090] The adjustment of the tensional state of the tether **16** carried out by means of a trans-catheter approach can be included in place of the adjustment of the tensional state of the tether **16** obtained by means of the active anchor **12**.

[0091] According to a general embodiment, an assembly **1** for reshaping a ventricle in a patient comprises an implantable device **10** for reshaping a ventricle comprising a tether **16**, and a cardiac catheter **45**′ for adjusting the tensional state of the tether **16**. The cardiac catheter **45**′ is preferably a vascular access catheter adapted to reach the ventricle **11**, **21**, for example the right ventricle **11**, of the patient's heart **5** with a distal portion thereof. The cardiac catheter **45**′ preferably comprises at the distal end thereof forceps **60** or a clip **60** for adjusting the tensional state of the tether **16** of the implantable device **10**, as shown for example in FIGS. **13**-A to **13**-D. The implantable device **10** preferably comprises two opposite anchors at opposite ends of the tether **16**. For example, the implantable device **10** is adapted to reshape a ventricle to repair a heart valve, for example to repair the tricuspid valve **15**.

[0092] By virtue of the features described above provided separately or jointly with each other in particular embodiments, it is possible to obtain a device as well as an assembly which at the same time satisfies the above described requirements, contrasting each other, and the aforementioned desired advantages, and in particular: [0093] it allows to adjust the tensional state of the tether of an implantable device for reshaping a ventricle, in order to repair a heart valve; [0094] the adjustment can occur with a trans-thoracic tool; [0095] it allows to adjust the tension of the tether by maneuvering a maneuvering interface placed outside the patient's body, at the proximal end of the trans-thoracic tool; [0096] the trans-thoracic tool can also act as a device for delivering the active anchor of the implantable device; [0097] it allows to adjust the tensional state of the tether after implantation, without requiring direct access to the ventricle; [0098] the active anchor forms an adjustment gate for the tether placed on the outer wall of the heart; [0099] the active anchor acts as a device for adjusting the tensional state of the tether; [0100] it allows to repair a heart valve by approximating, i.e., by bringing closer together, the structures of the ventricle such as the ventricular walls, the interventricular septum, the papillary muscles, a combination of the above.

[0101] Those skilled in the art may make many changes and adaptations to the embodiments described above or may replace elements with others, which are functionally equivalent, in order to meet contingent needs without however departing from the scope of the appended claims.

LIST OF REFERENCE NUMERALS

[0102] **1** Assembly [0103] **2** Proximal portion of the tool [0104] **3** Distal portion of the tool [0105] **4** Outer wall of the heart [0106] **5** Heart [0107] **6** Papillary muscle [0108] **7** Interventricular septum [0109] **10** Implantable device [0110] **11** Right ventricle [0111] **12** Active anchor or first anchor [0112] **13** Abutment portion [0113] **15** Tricuspid valve [0114] **16** Tether [0115] **17** Termination portion [0116] **18**, **18**′ Tool [0117] **19** Anchor back [0118] **21** Left ventricle [0119] **22** Second anchor [0120] **23** Second abutment portion [0121] **26** Channel [0122] **27** Winding shaft [0123] **28** First portion of the active anchor [0124] **29** Second portion of the active anchor [0125] **30** Spring

[0126] **31** Proximal section of the tether [0127] **32** Radial teeth [0128] **33** Annular groove [0129] **34** Circumferential abutment [0130] **35** Distal head of the adjustment key [0131] **36** Nut [0132] **37** Male threaded element [0133] **38** Expandable element [0134] **39** Inflation tank [0135] **41** Knot, or enlarged portion, of the tether [0136] **42**, **42′** Adjustment key maneuvering interface [0137] **45**, **45′** Vascular catheter [0138] **46** Delivery catheter [0139] **48**, **48′** Adjustment key [0140] **49** Tool shaft [0141] **51** Tool case [0142] **52** Distal fingers of the shaft [0143] **53** Advancement command [0144] **54** Slot [0145] **54***a-c* Seats [0146] **55** Radial pin [0147] **56** End-of-stroke [0148] **57** Tether guiding device [0149] **58** Perforated plate [0150] **59** Hole [0151] **60** Forceps or clip

Claims

1. An assembly adapted to be implanted by a tool having a tool proximal portion and a tool distal portion, the assembly adapted for reshaping a chamber of a heart in a patient, the assembly comprising: an active anchor including an abutment portion adapted to abut against an exterior wall of the chamber of the heart and a tether portion rotatably coupled to the abutment portion, the abutment portion having a first outer diameter larger than a second outer diameter of the tether portion such that each of the abutment portion and the tether portion are configured to independently couple with the tool; a septal anchor for coupling to a septum of the heart, wherein the septum is located across the chamber from the exterior wall; and a tether coupled to the septal anchor and having a working length extending between the active anchor and the septal anchor, and a proximal length, extending through the abutment portion and coupled to the tether portion; wherein the abutment portion and the tether portion are configured such that a relative rotation of the tether portion with respect to the abutment portion adjusts the working length and the proximal length.

2. A system including the assembly of claim 1 further comprising a tool having a tool proximal portion and a distal portion, wherein the tool proximal portion includes an interface and the distal portion includes a hollow shaft and an adjustment component adapted to engage the tether portion of the active anchor.

3. The system of claim 2 wherein the tool proximal portion includes an interface operatively coupled to the adjustment component, the interface adapted to allow a user to impart relative rotation to the adjustment component.

4. The system of claim 2 wherein a distal end of the hollow shaft includes an engagement member configured to engage the first outer diameter of the abutment portion of the active anchor so as to resist rotation thereof.

5. The system of claim 4 wherein the engagement member includes one or more fingers extending from the distal end of the hollow shaft.

6. The assembly of claim 1 wherein the tether portion includes a winding shaft configured such that the relative rotation causes the proximal length of the tether to wind around the winding shaft.

7. The assembly of claim 1 wherein the abutment portion and the tether portion are rotatably coupled using a winch adjustment system.

8. The assembly of claim 1 wherein the abutment portion and the tether portion include a locked configuration and an adjustment configuration, the active anchor further comprising a biasing mechanism for biasing the abutment portion and the tether portion to the locked configuration.

9. The system of claim 8 wherein the active anchor is configured such that a force applied to the tether portion overcomes the biasing mechanism and transitions the active anchor into the adjustment configuration.

10. The system of claim 9 wherein in the adjustment configuration, the active anchor is configured to allow the relative rotation to occur in both directions.

11. The system of claim 3 wherein the interface includes a maneuvering element rotatable inside the shaft.

12. A method of treating regurgitation in a patient's heart having a heart chamber, a heart outer wall a septum disposed across the heart chamber from the heart outer wall, and an atrioventricular valve, the method comprising: providing an implantable assembly including an active anchor, a septal anchor coupled to a tether having a working length extending between the active anchor and the septal anchor and a proximal length associated with the active anchor; advancing a delivery catheter through the heart outer wall and through the septum; delivering the septal anchor through the delivery catheter to a position adjacent the septum; positioning the septal anchor against the septum; removing the delivery catheter such that the tether extend from the septal anchor, through the septum and through the outer wall of the heart chamber; advancing the active anchor over the tether to a position adjacent the outer wall of the heart chamber, the active anchor including an abutment portion adapted to abut against the wall and a tether portion rotatably coupled to the abutment portion; securing the tether to the tether portion of the active anchor; and applying a rotational force to the tether portion of the active anchor such that a relative rotation of the tether portion with respect to the abutment portion adjusts the working length and the proximal length of the tether; wherein decreasing the working length reshapes the heart chamber.

13. The method of claim 12 wherein the advancing step includes coupling the active anchor to a distal end of the adjustment tool and positioning the abutment portion of the active anchor adjacent the outer wall of the heart chamber using a proximal portion of the adjustment tool.

14. The method of claim 12 wherein the positioning step includes advancing a catheter through the septum and using the catheter to dispose the septal anchor adjacent the septum.

15. The method of claim 12 wherein the locating step includes coupling the active anchor to a distal end of a delivery tool and positioning the abutment portion of the active anchor adjacent the outer wall of the heart chamber using a proximal portion of the delivery tool.

16. The method of claim 15 further including coupling a hollow shaft of the adjustment tool to the abutment portion of the active anchor and coupling an adjustment component of the adjustment tool to the tether portion of the active anchor and wherein rotation of the adjustment component causes the relative rotation of the portions of the active anchor.

17. The method of claim 12 further comprising coupling the proximal portion of the tether to the tether portion of the active anchor.

18. The method of claim 17 wherein the coupling step includes forming an enlarged portion in the proximal portion of the tether.

19. The method of claim 18 wherein the enlarged portion is a knot and further wherein a portion of the tether proximal to the knot is removed.