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(54) **POST-IMPLANTATION TENSION
ADJUSTMENT IN CARDIAC IMPLANTS**

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(57) **ABSTRACT**

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A method of treating a heart of a patient is provided, including implanting a first tissue anchor in cardiac tissue of the patient, the first tissue anchor attached to one or more tethers that are fixed to a coupling element. A second tissue anchor is implanted in the patient. The coupling element is coupled to a first coupling site of the second tissue anchor, thereby coupling the first tissue anchor to the second tissue anchor via the one or more tethers. Thereafter, after allowing at least 24 hours for tissue growth on the first tissue anchor to strengthen anchoring of the first tissue anchor in the cardiac tissue, tension is increased between the first and the second tissue anchors by decoupling the coupling element from the first coupling site and coupling the coupling element to a second coupling site of the second tissue anchor. Other embodiments are also described.

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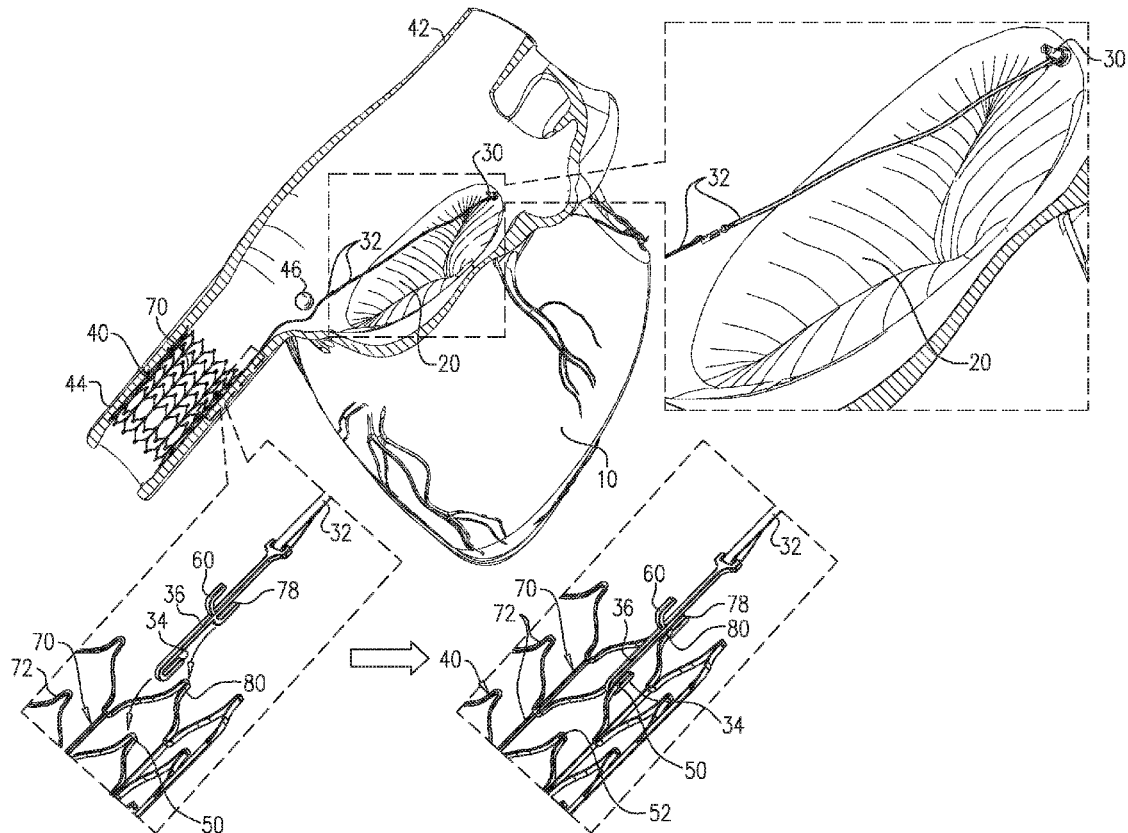
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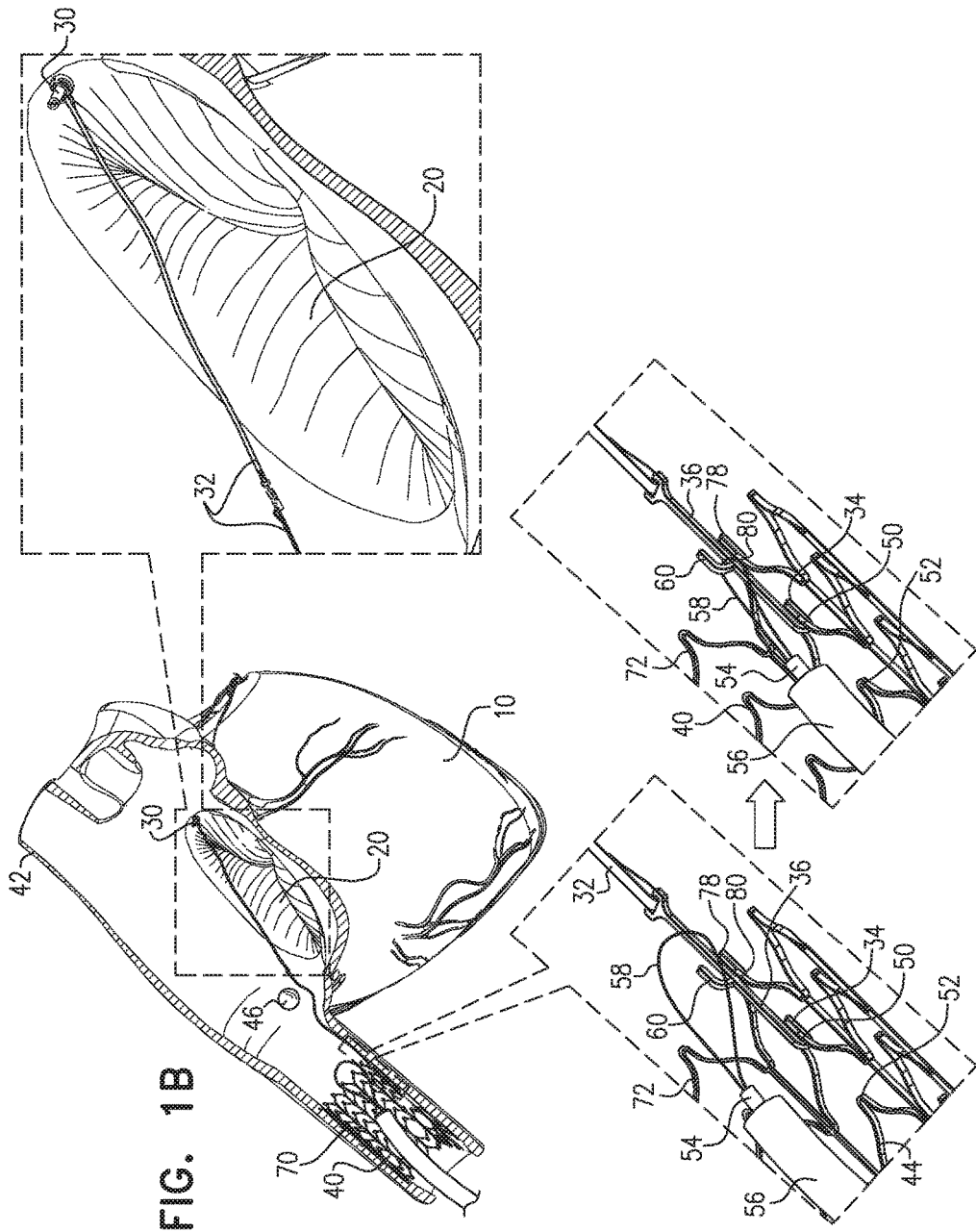
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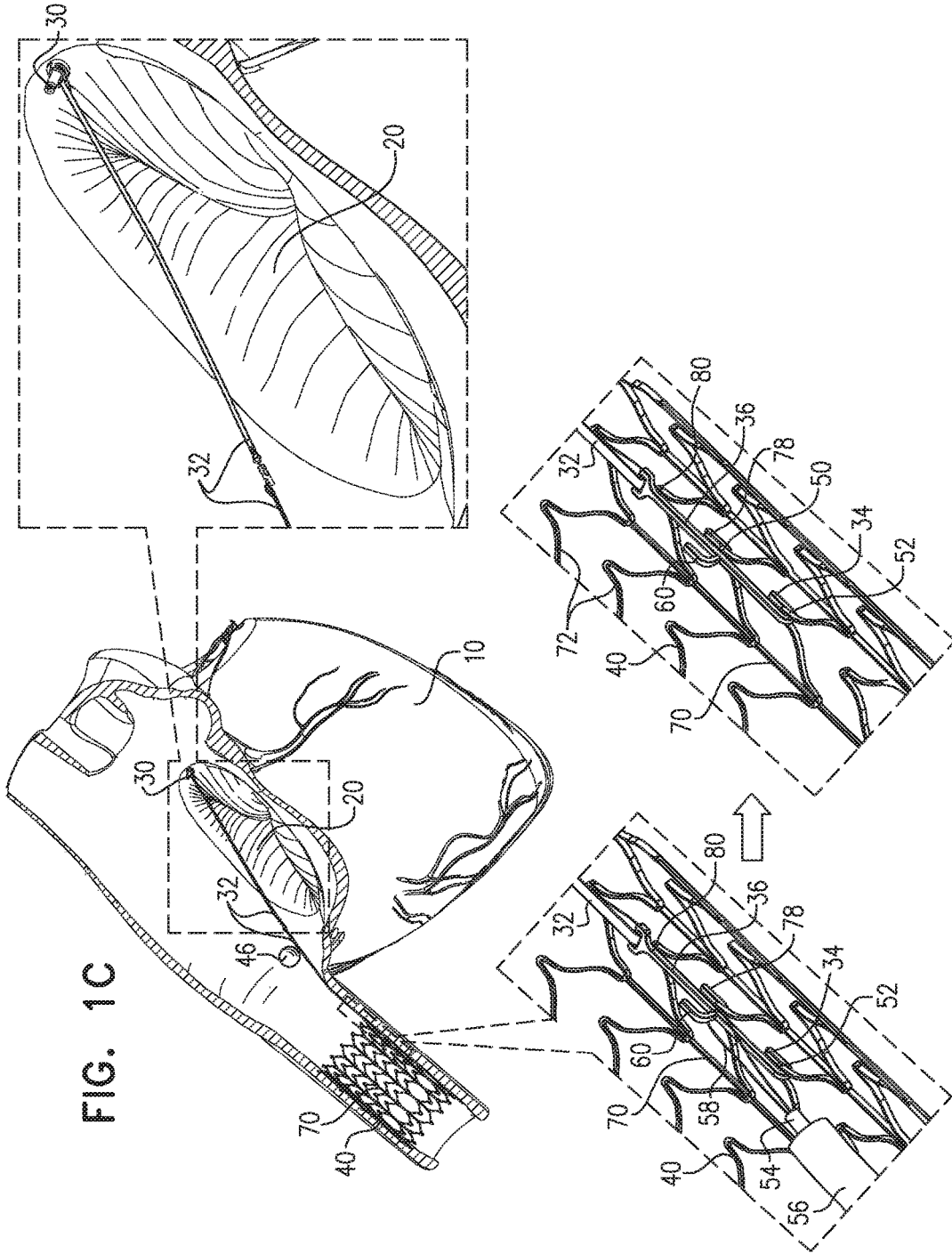
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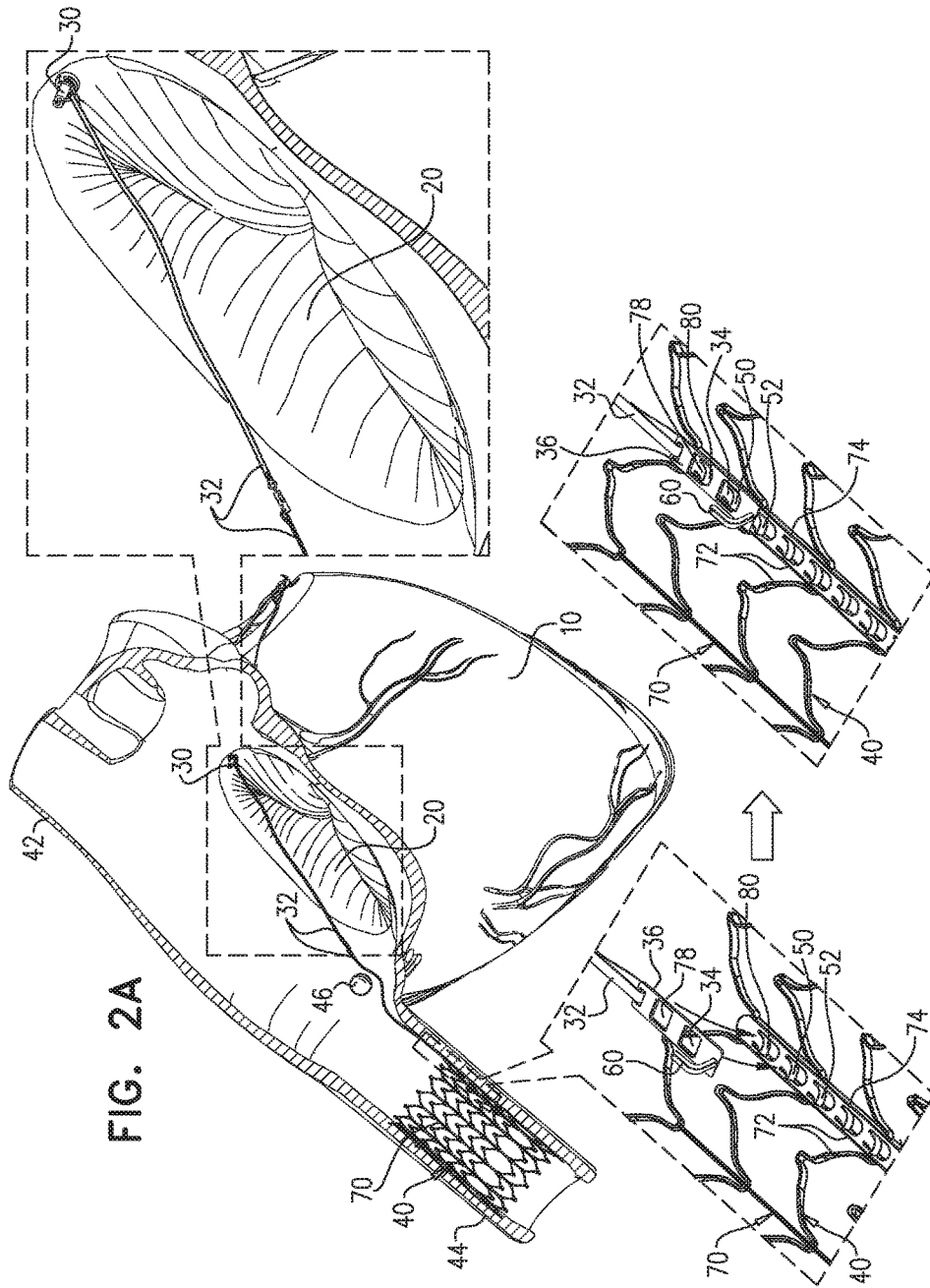
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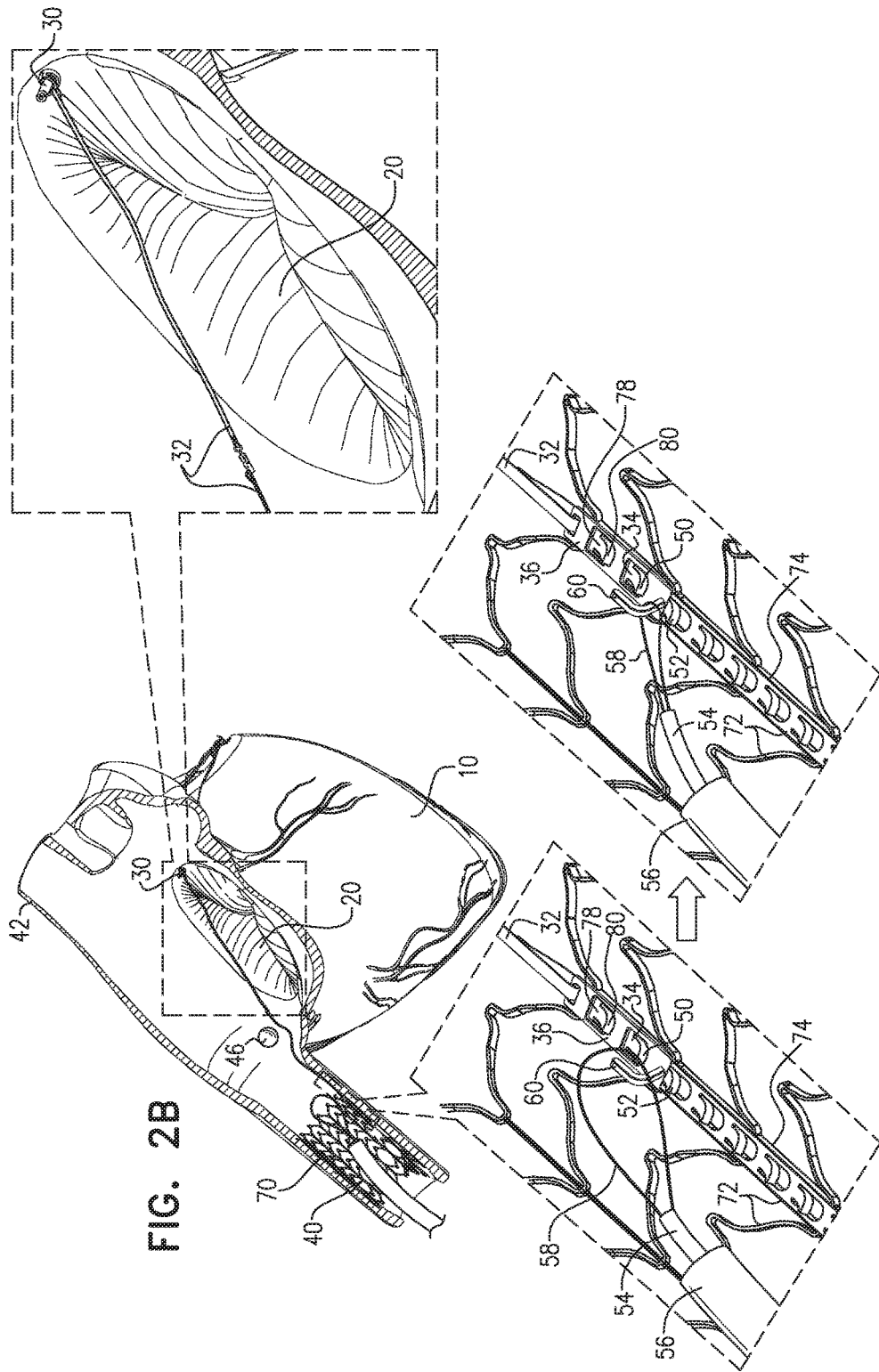
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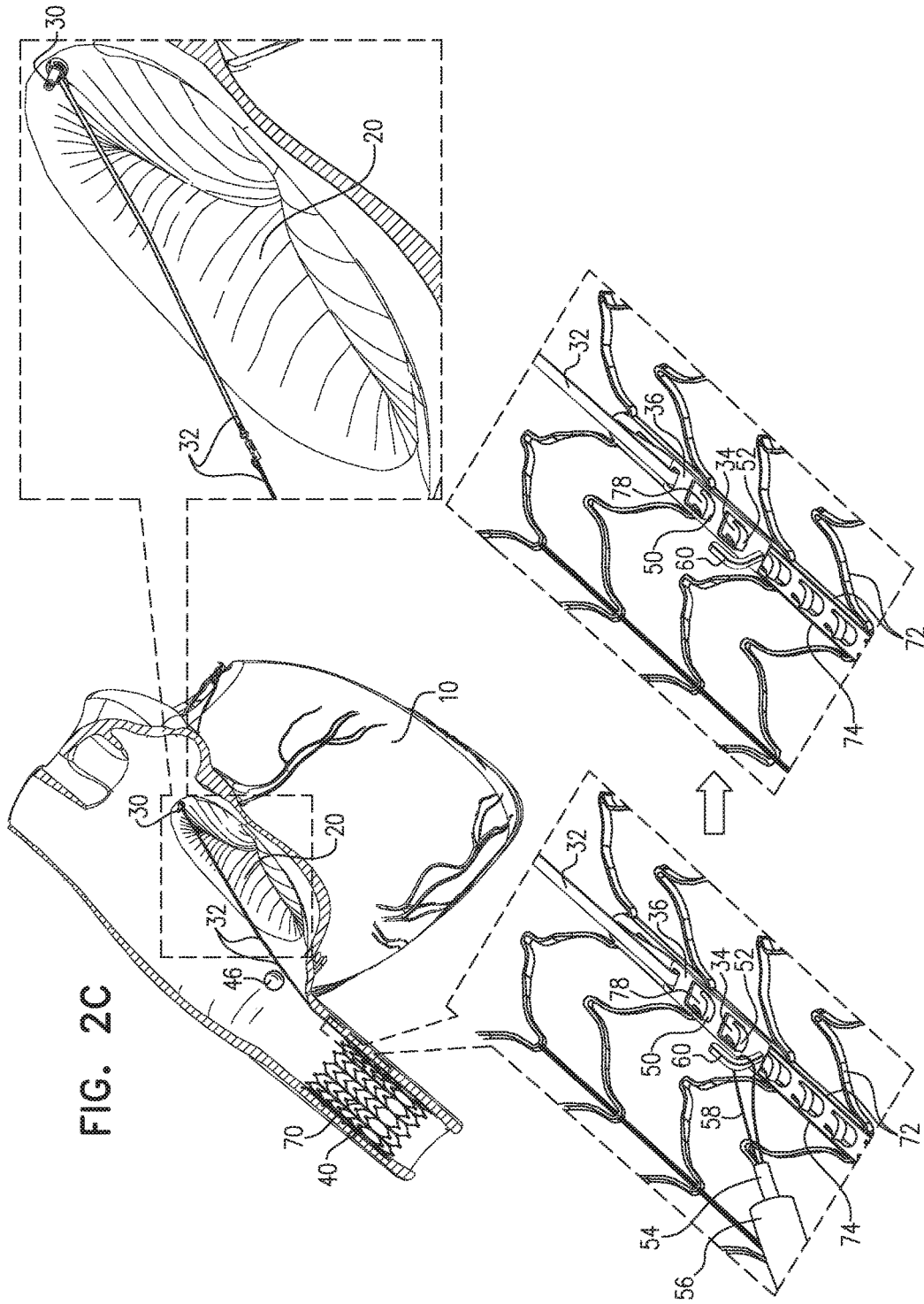












POST-IMPLANTATION TENSION ADJUSTMENT IN CARDIAC IMPLANTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Application 62/465,400, filed Mar. 1, 2017, which is assigned to the assignee of the present application and is incorporated herein by reference. The present application is related to an international application to Denti et al. filed on even date herewith, entitled, "Post-implantation tension adjustment in cardiac implants."

FIELD OF THE APPLICATION

[0002] The present invention relates generally to minimally-invasive valve repair, and more specifically to minimally-invasive methods for repairing the tricuspid valve.

BACKGROUND OF THE APPLICATION

[0003] Functional tricuspid regurgitation (FTR) is governed by several pathophysiologic abnormalities such as tricuspid valve annular dilatation, annular shape, pulmonary hypertension, left or right ventricle dysfunction, right ventricle geometry, and leaflet tethering. Treatment options for FTR are primarily surgical.

[0004] U.S. Pat. No. 8,475,525 to Maisano et al. describes a method that includes implanting at least a first tissue-engaging element in a first portion of tissue in a vicinity of a heart valve of a patient, implanting at least a second tissue-engaging element in a portion of a blood vessel that is in contact with an atrium of a heart of the patient, and drawing at least a first leaflet of the valve toward at least a second leaflet of the valve by adjusting a distance between the portion of the blood vessel and the first portion of tissue in the vicinity of the heart valve of the patient. In one configuration, a proximal end portion of a longitudinal member is shaped so as to define one or more engaging elements (e.g., hooks or barbs), which are coupleable with the struts of a stent member in order to maintain the tension applied to a longitudinal member for remodeling the tricuspid valve.

SUMMARY OF THE APPLICATION

[0005] Some applications of the present invention provide a method of treating a heart of a patient, such as to reduce tricuspid valve regurgitation. The method includes implanting a first tissue anchor in cardiac tissue of the patient, and a second tissue anchor in the patient. The first tissue anchor is attached to one or more tethers that are fixed to a coupling element. The coupling element is coupled to a first coupling site of the second tissue anchor, thereby coupling the first tissue anchor to the second tissue anchor via the one or more tethers. Thereafter, after allowing at least 24 hours for tissue growth on the first tissue anchor to strengthen anchoring of the first tissue anchor in the cardiac tissue, tension is increased between the first and the second tissue anchors by decoupling the coupling element from the first coupling site and coupling the coupling element to a second coupling site of the second tissue anchor.

[0006] There is therefore provided, in accordance with an application of the present invention, a method of treating a heart of a patient, including:

[0007] implanting a first tissue anchor in cardiac tissue of the patient, the first tissue anchor attached to one or more tethers that are fixed to a coupling element;

[0008] implanting a second tissue anchor in the patient;

[0009] coupling the coupling element to a first coupling site of the second tissue anchor, thereby coupling the first tissue anchor to the second tissue anchor via the one or more tethers; and thereafter, after allowing at least 24 hours for tissue growth on the first tissue anchor to strengthen anchoring of the first tissue anchor in the cardiac tissue, increasing tension between the first and the second tissue anchors by decoupling the coupling element from the first coupling site and coupling the coupling element to a second coupling site of the second tissue anchor.

[0010] For some applications, the one or more tethers are slack before increasing the tension.

[0011] For some applications, the coupling element includes a hook.

[0012] For some applications, the coupling element is shaped so as to define an opening, and coupling the coupling element to the first coupling site includes coupling the opening to the first coupling site. For some applications, the coupling element includes a loop, which is shaped to define the opening.

[0013] For some applications, the second tissue anchor includes a stent that includes a plurality of struts, which define the first and the second coupling sites. For some applications, the first and the second coupling sites extend radially inward to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent. For some applications, one or more of the struts extend radially inward at the first and the second couplings sites to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent. For some applications, the second tissue anchor includes hooks at the first and the second coupling sites, respectively.

[0014] For some applications, at least one of the struts is oriented axially along the stent, and the axially-oriented strut defines the first and the second coupling sites. For some applications, the first and the second coupling sites extend radially inward to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent. For some applications, the axially-oriented strut is wider than others of the struts so as to serve as a backbone for the stent.

[0015] For some applications, increasing the tension includes increasing the tension after allowing at least one week for tissue growth on the first tissue anchor.

[0016] For some applications, increasing the tension includes increasing the tension within two months after implanting the first tissue anchor.

[0017] For some applications, the coupling element is a first coupling element, and the one or more tethers are additionally fixed to a second coupling element, and coupling the coupling element to the first coupling site includes coupling one or more of the first and the second coupling elements to a plurality of first coupling sites.

[0018] For some applications, coupling the coupling element to the first coupling site includes coupling the coupling element to the first coupling site after implanting the first and the second tissue anchors.

[0019] For some applications, coupling the coupling element to the first coupling site includes coupling the coupling

element to the first coupling site before implanting the first and the second tissue anchors.

[0020] For some applications, coupling the coupling element to the first coupling site includes coupling the coupling element to the first coupling site after implanting the first tissue anchor and before implanting the second tissue anchor.

[0021] For some applications, the coupling element is coated with a tissue-growth-inhibiting coating.

[0022] For some applications, the first and the second coupling sites are coated with a tissue-growth-inhibiting coating.

[0023] For some applications, the first tissue anchor includes a helical tissue-anchoring element.

[0024] For some applications, implanting the first tissue anchor includes implanting the first tissue anchor in the vicinity of the tricuspid valve of the patient.

[0025] For some applications, implanting the second tissue anchor includes implanting the second tissue anchor in a blood vessel selected from the group consisting of: a superior vena cava (SVC), an inferior vena cava (IVC), and a coronary sinus.

[0026] There is further provided, in accordance with an application of the present invention, a system for treating a heart of a patient, including:

[0027] a first tissue anchor, which is configured to be implanted in cardiac tissue of the patient;

[0028] a coupling element;

[0029] one or more tethers, which are attached to the first tissue anchor and are fixed to the coupling element; and

[0030] a second tissue anchor, which is configured to be implanted in the patient, and which includes a stent that includes a plurality of struts, which define first and second coupling sites to which the coupling element is configured to be coupled so as to couple the first tissue anchor to the second tissue anchor via the one or more tethers, wherein the first and the second coupling sites extend radially inward to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent, wherein the coupling element is coupleable to the first coupling site, and thereafter decoupleable from the first coupling site and coupleable to the second coupling site so as to increase tension between the first and the second tissue anchors.

[0031] For some applications, the coupling element is shaped so as to define an opening, which is configured to be coupled to the first and the second coupling sites.

[0032] For some applications, the coupling element includes a loop, which is shaped to define the opening.

[0033] For some applications, the second tissue anchor includes hooks at the first and the second coupling sites, respectively.

[0034] For some applications, at least one of the struts is oriented axially along the stent, and the axially-oriented strut defines the first and the second coupling sites. For some applications, the axially-oriented strut is wider than others of the struts so as to serve as a backbone for the stent.

[0035] For some applications, one or more of the struts extend radially inward at the first and the second couplings sites to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent.

[0036] For some applications, the coupling element is a first coupling element, and the system includes a second coupling element, which is fixed to the one or more tethers.

[0037] For some applications, the coupling element is coated with a tissue-growth-inhibiting coating.

[0038] For some applications, the first and the second coupling sites are coated with a tissue-growth-inhibiting coating.

[0039] For some applications, the first tissue anchor includes a helical tissue-anchoring element.

[0040] The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] FIGS. 1A-C are schematic illustrations of a method of treating a heart of a patient, in accordance with an application of the present invention; and

[0042] FIGS. 2A-C are schematic illustrations of a method of treating a heart of a patient, in accordance with an application of the present invention.

DETAILED DESCRIPTION OF APPLICATIONS

[0043] FIGS. 1A-C and 2A-C are schematic illustrations of methods of treating a heart **10** of a patient, in accordance with respective applications of the present invention. For some applications, the methods are performed to treat a tricuspid valve **20**, such as by reducing tricuspid valve regurgitation.

[0044] As shown in FIGS. 1A and 2A, during a first stage of an implantation procedure, a first tissue anchor **30** is implanted in cardiac tissue of the patient, such as in the vicinity of tricuspid valve **20**. First tissue anchor **30** is attached to one or more tethers **32** that are fixed to a coupling element **34**, such as a hook, as shown in FIG. 1A, or an opening, as shown in FIG. 1B. Optionally, coupling element **34** comprises a loop, which is shaped so as to define the opening (configuration not shown). Optionally, a coupling support structure **36** is provided, which comprises coupling element **34** and attaches coupling element **34** to the one or more tethers **32**. A second tissue anchor **40** is implanted in the patient, either before or after implanting first tissue anchor **30**, such as in a superior vena cava (SVC) **42**, an inferior vena cava (IVC) **44** (as shown), and a coronary sinus **46**. Typically, first and second tissue anchors **30** and **40** are implanted in a transcatheter procedure (typically endovascularly, such as percutaneously), via a catheter, such as described in the applications incorporated hereinbelow by reference. Optionally, the one or more tethers **32** comprise two tethers **32** that are coupled together in situ during the first stage of the implantation procedure, such as using techniques described in one or more of the applications incorporated by reference hereinbelow.

[0045] Also as shown in FIGS. 1A and 2A, coupling element **34** is coupled to a first coupling site **50** of second tissue anchor **40**, thereby coupling first tissue anchor **30** to second tissue anchor **40** via the one or more tethers **32**. Coupling element **34** may be coupled to first coupling site **50** either after or before implanting first and second tissue anchors **30** and **40**, or after implanting first tissue anchor **30** and before implanting second tissue anchor **40**. For some applications, at this first stage of the implantation procedure, the one or more tethers **32** are slack, i.e., do not apply tension between first and second tissue anchors **30** and **40**.

[0046] As shown in FIGS. 1B-C and 2B-C, thereafter, during a second stage of the implantation procedure, typi-

cally after allowing at least 24 hours (e.g., at least one week, such as at least one month) for tissue growth (e.g., fibrous and/or endothelial tissue growth) on first tissue anchor **30** to strengthen anchoring of first tissue anchor **30** in the cardiac tissue, tension is increased between first and second tissue anchors **30** and **40** by decoupling coupling element **34** from first coupling site **50** and coupling coupling element **34** to a second coupling site **52** of second tissue anchor **40** (different from first coupling site **50**). For some applications, the tension is increased within two months after implanting first tissue anchor **30**. Typically, second coupling site **52** is farther from first tissue anchor **30** than first coupling site **50** is from first tissue anchor **30**. Typically, application of the tension remodels tricuspid valve **20**, by drawing two or three of the leaflets together to enhance coaptation. The procedure may optionally include subsequent stages (e.g., a third stage) after the second stage (e.g., at least 24 hours after the second stage), in which tension is further increased by decoupling coupling element from its current coupling site (e.g., coupling site **50**) and coupling coupling element **34** to yet another coupling site (e.g., a third coupling site).

[0047] Typically, in order to decouple coupling element **34** from first coupling site **50**, during the second stage of the implantation procedure a tool **54** is introduced through the vasculature via a catheter **56**, and used to recapture coupling element **34**. For example, tool **54** may comprise a lasso **58**, which is used to engage a hook **60** of coupling element **34**. The hook may extend radially inward into a lumen of second tissue anchor **40** in order to facilitate engagement by tool **54** (e.g., lasso **58**) when tool **54** has been introduced into the lumen of second tissue anchor **40**.

[0048] For some applications, as shown in the figures, second tissue anchor **40** comprises a stent **70** that comprises a plurality of struts **72**, which define first and second coupling sites **50** and **52**. For some applications, such as shown in FIGS. 1A-C and 2A-C, first and second coupling sites **50** and **52** extend radially inward (i.e., toward a central longitudinal axis of stent **70**) to facilitate the coupling of coupling element **34** to first and second coupling sites **50** and **52** from within stent **70**. For some of these applications, such as shown in FIGS. 1A-C, one or more of struts **72** extend radially inward at first and second couplings sites **50** and **52** to facilitate the coupling of coupling element **34** to first and second coupling sites **50** and **52** from within stent **70**. For others of these applications, such as shown in FIGS. 2A-C, second tissue anchor **40** comprises hooks (which are optionally shaped as tabs, as shown in FIGS. 2A-C) at first and second coupling sites **50** and **52**, respectively; the hooks, and thus first and second coupling sites **50** and **52**, extend radially inward (optionally, one or more of struts **72** (e.g., axially-oriented strut **74**, described immediately below) also extend radially inward).

[0049] For some applications, at least one 74 of struts **72** is oriented axially along the stent, and axially-oriented strut **74** defines first and second coupling sites **50** and **52**. Optionally, axially-oriented strut **74** is wider than others of struts **72** so as to serve as a backbone for the stent. (Although not illustrated, this backbone may also be provided for the configuration shown in FIGS. 1A-C.)

[0050] For some applications, first tissue anchor **30** comprises a helical tissue-anchoring element. For some applications, fibrous glue is applied to the tissue-coupling element to help secure the anchor in place and minimize

detachment. Optionally, tissue-growth-enhancing coating is also applied to the tissue-coupling element.

[0051] For some applications, coupling element **34** is a first coupling element **34**, and the one or more tethers **32** are additionally fixed to a second coupling element **78**, such as a hook, as shown in FIGS. 1A-C, or an opening, as shown in FIGS. 2A-C (or to more than two coupling elements, such as shown in FIGS. 2A-C); for example, coupling support structure **36**, if provided, may comprise second coupling element **78** in addition to first coupling element **34**. For these applications, coupling coupling element **34** to first coupling site **50** comprises coupling one or more of first and second coupling elements **34** and **78** to a plurality of first coupling sites **50**. Providing a plurality of coupling elements provides redundancy; in case one of the coupling elements does not catch on second tissue anchor **40**, another of the coupling elements may catch (or both may catch, as shown in the figures).

[0052] For some applications, first and second coupling elements **34** and **78** are arranged along coupling support structure **36**, optionally at a distance apart that is the same as a distance between first and second coupling sites **50** and **52**, such that when first coupling element **34** is repositioned from first coupling site **50** to second coupling site, as described hereinabove with reference to FIGS. 1B-C and 2B-C, second coupling element **78** is repositioned from a third coupling site **80** to first coupling site **50**, i.e., takes the coupling site vacated by first coupling element **34**.

[0053] For some applications, coupling element **34**, first coupling site **50**, and/or second coupling site **52** are coated with a tissue-growth-inhibiting coating (e.g., silicone). Such coating may facilitate the decoupling of coupling element **34** from first coupling site **50** and/or the coupling of coupling element **34** to second coupling site **52**, as described hereinabove with reference to FIGS. 1B-C and 2B-C.

[0054] The scope of the present invention includes embodiments described in the following applications, which are assigned to the assignee of the present application and are incorporated herein by reference. In an embodiment, techniques and apparatus described in one or more of the following applications are combined with techniques and apparatus described herein:

- [0055]** U.S. Pat. No. 8,475,525 to Maisano et al.;
- [0056]** U.S. Pat. No. 8,961,596 to Maisano et al.;
- [0057]** U.S. Pat. No. 8,961,594 to Maisano et al.;
- [0058]** PCT Publication WO 2011/089601;
- [0059]** U.S. Pat. No. 9,241,702 to Maisano et al.;
- [0060]** PCT Publication WO 2013/011502;
- [0061]** U.S. Provisional Application 61/750,427, filed Jan. 9, 2013;
- [0062]** U.S. Provisional Application 61/783,224, filed Mar. 14, 2013;
- [0063]** PCT Publication WO 2013/179295;
- [0064]** U.S. Provisional Application 61/897,491, filed Oct. 30, 2013;
- [0065]** U.S. Provisional Application 61/897,509, filed Oct. 30, 2013;
- [0066]** U.S. Pat. No. 9,307,980 to Gilmore et al.;
- [0067]** PCT Publication WO 2014/108903;
- [0068]** PCT Publication WO 2014/141239;
- [0069]** U.S. Provisional Application 62/014,397, filed Jun. 19, 2014;
- [0070]** PCT Publication WO 2015/063580;

[0071] US Patent Application Publication 2015/0119936;

[0072] U.S. Provisional Application 62/086,269, filed Dec. 2, 2014;

[0073] U.S. Provisional Application 62/131,636, filed Mar. 11, 2015;

[0074] U.S. Provisional Application 62/167,660, filed May 28, 2015;

[0075] PCT Publication WO 2015/193728;

[0076] PCT Publication WO 2016/087934;

[0077] US Patent Application Publication 2016/0242762;

[0078] PCT Publication WO 2016/189391;

[0079] US Patent Application Publication 2016/0262741; and

[0080] U.S. Provisional Application 62/376,685, filed Aug. 18, 2016.

[0081] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

1. A method of treating a heart of a patient, comprising: implanting a first tissue anchor in cardiac tissue of the patient, the first tissue anchor attached to one or more tethers that are fixed to a coupling element; implanting a second tissue anchor in the patient; coupling the coupling element to a first coupling site of the second tissue anchor, thereby coupling the first tissue anchor to the second tissue anchor via the one or more tethers; and

thereafter, after allowing at least 24 hours for tissue growth on the first tissue anchor to strengthen anchoring of the first tissue anchor in the cardiac tissue, increasing tension between the first and the second tissue anchors by decoupling the coupling element from the first coupling site and coupling the coupling element to a second coupling site of the second tissue anchor.

2. The method according to claim 1, wherein the one or more tethers are slack before increasing the tension.

3. The method according to claim 1, wherein the coupling element comprises a hook.

4. The method according to claim 1, wherein the coupling element is shaped so as to define an opening, and wherein coupling the coupling element to the first coupling site comprises coupling the opening to the first coupling site.

5. The method according to claim 4, wherein the coupling element comprises a loop, which is shaped to define the opening.

6. The method according to claim 1, wherein the second tissue anchor comprises a stent that comprises a plurality of struts, which define the first and the second coupling sites.

7. The method according to claim 6, wherein the first and the second coupling sites extend radially inward to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent.

8. The method according to claim 7, wherein one or more of the struts extend radially inward at the first and the second

couplings sites to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent.

9. The method according to claim 7, wherein the second tissue anchor comprises hooks at the first and the second coupling sites, respectively.

10. The method according to claim 6, wherein at least one of the struts is oriented axially along the stent, and the axially-oriented strut defines the first and the second coupling sites.

11. The method according to claim 10, wherein the first and the second coupling sites extend radially inward to facilitate the coupling of the coupling element to the first and the second coupling sites from within the stent.

12. The method according to claim 10, wherein the axially-oriented strut is wider than others of the struts so as to serve as a backbone for the stent.

13. The method according to claim 1, wherein increasing the tension comprises increasing the tension after allowing at least one week for tissue growth on the first tissue anchor.

14. The method according to claim 1, wherein increasing the tension comprises increasing the tension within two months after implanting the first tissue anchor.

15. The method according to claim 1, wherein the coupling element is a first coupling element, and the one or more tethers are additionally fixed to a second coupling element, and wherein coupling the coupling element to the first coupling site comprises coupling one or more of the first and the second coupling elements to a plurality of first coupling sites.

16. The method according to claim 1, wherein coupling the coupling element to the first coupling site comprises coupling the coupling element to the first coupling site after implanting the first and the second tissue anchors.

17. The method according to claim 1, wherein coupling the coupling element to the first coupling site comprises coupling the coupling element to the first coupling site before implanting the first and the second tissue anchors.

18. The method according to claim 1, wherein coupling the coupling element to the first coupling site comprises coupling the coupling element to the first coupling site after implanting the first tissue anchor and before implanting the second tissue anchor.

19. The method according to claim 1, wherein the coupling element is coated with a tissue-growth-inhibiting coating.

20. The method according to claim 1, wherein the first and the second coupling sites are coated with a tissue-growth-inhibiting coating.

21. The method according to claim 1, wherein the first tissue anchor comprises a helical tissue-anchoring element.

22. The method according to claim 1, wherein implanting the first tissue anchor comprises implanting the first tissue anchor in the vicinity of the tricuspid valve of the patient.

23. The method according to claim 1, wherein implanting the second tissue anchor comprises implanting the second tissue anchor in a blood vessel selected from the group consisting of: a superior vena cava (SVC), an inferior vena cava (IVC), and a coronary sinus.

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